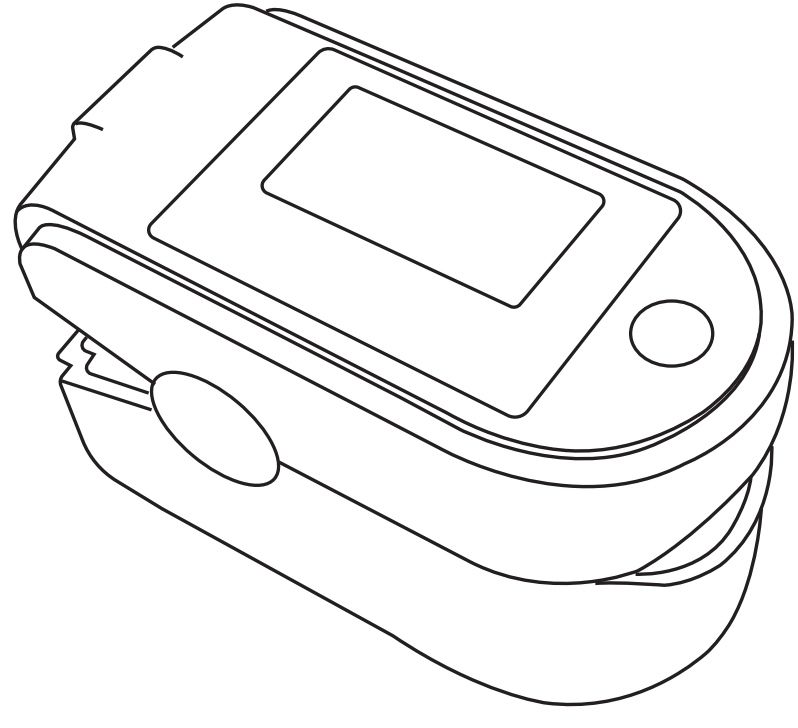
A&D Medical

FINGERTIP PULSE OXIMETER

UP-200BLE



INSTRUCTIONS TO USER

Dear Users, thank you for purchasing the UP-200BLE Pulse Oximeter.

The manual describes the Pulse Oximeter's requirements, features, functions, specifications, and the safety procedures to protect both the user and the oximeter. It also states the correct methods for transportation, use, repair, maintenance and storage.

Please read the manual carefully before using this oximeter. These instructions describe the operating procedures to be followed strictly; failure to follow these instructions can cause measuring abnormality, oximeter damage and personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, personal injury and oximeter damage due to user's negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

Due to product updates, the specific products you received may not be in accordance with the description of this User Manual.

If you have any questions regarding to the use of this product, please call us at one of the numbers listed at the end of this manual.

Indication for Use

The Pulse Oximeter is a non-invasive device intended for the spot-check of saturation of arterial hemoglobin(SpO2) and the pulse rate of adult in home use environments.This oximeter is not intended for continuous monitoring.The oximeter can be multi-used. The pulse oximeter is intended for wellness use.

WARNING:

- **An uncomfortable or painful feeling may appear if using the oximeter continuously, especially for the microcirculation barrier users. It is recommended that the sensor should not be applied to the same finger for over 2 hours.**
- **Don’t place the oximeter on the edema or tender tissue.**
- **Do not stare at the red and infrared light emitter (the infrared light is invisible) after turning on the oximeter, as it may be harmful to the eyes.**
- **Results may be influenced by external coloring agents (such as nail polish or color skin care products), don’t use the oximeter on surfaces with coloring agents.**
- **Results may be influenced by fingers that are too cold, too thin, or if fingernails are too long. You can use a larger finger such as thumb or middle finger and place deeply into the probe, while also ensuring fingers are moderate tempearture and nails are not too long.**
- **Please review the relative content about the clinical restrictions and caution.**

1. SAFETY

1.1 Instructions for Safe Operations

- Inspect the main unit and all accessories periodically to make sure that there is no visible damage that may affect user's safety and monitoring performance. It is recommended that the oximeter should be inspected weekly at least. When there is obvious damage, stop using it.
- The maintenance to this oximeter can only be performed by qualified service personnel specified by manufacturer. Users are not permitted to maintain the oximeter by themselves.
- The oximeter cannot be used with equipment not specified in this Manual. Only the accessories recommended by the manufacturer can be used, otherwise it may cause injury to the user or damage to the oximeter.
- This product is calibrated before leaving factory.

1.2 Warnings

- Explosive hazard—DO NOT use the oximeter in environment with inflammable gas such as anesthetic.
- When using the oximeter, please keep it away from equipment which can generate strong electric field or strong magnetic field. Using the oximeter in an inappropriate environment may cause interference to the surrounding radio equipment or affect its working.
- DO NOT use the oximeter while examining by MRI or CT, as the induced current may cause burn.

- DO NOT swing the lanyard to avoid damaging the oximeter. Do not use the lanyard if you are allergic to lanyard material. Do not wrap the lanyard around neck to avoid an accident.
- DO NOT use the measured values as the sole basis for clinical diagnosis. Please consult with your physician.
- The oximeter contains silicone, PVC, TPU, TPE and ABS materials and has passed biocompatibility testing in accordance to ISO 10993-1. An individual who is allergic to silicone, PVC, TPU, TPE or ABS cannot use this oximeter.
- The disposal of this oximeter, its accessories and packaging should follow the local laws and regulations, to avoid polluting the local environment. The packaging materials must be placed out of reach of children.
- Please inspect the packing before use to ensure the oximeter and accessories are in accordance with the packing list. Otherwise, the oximeter may not work properly.
- Functional testers cannot be used to assess the accuracy of the SpO2 probe and Pulse Oximeter.
- It is NOT recommended to use multiple pulse oximeters on the same user, simultaneously, as danger may occur due to overlap of leakage current.
- This oximeter is not intended for treatment.

1.3 Cautions

- DO NOT place the oximeter in places exposed to direct sunlight, high temperature, humidity, dust, cotton wool or near water, to avoid affecting its performance. If the oximeter gets wet, please stop using it.
- When the oximeter is carried from cold environment to warm or humid environment, please wait 4 hours before using.
- DO NOT operate buttons on front panel with sharp materials.
- The update period of data is less than 30 seconds, which is dependent on pulse rate value.
- If the plethysmographic waveform is not normalized or not smooth and stable, then the accuracy of the measured value may be degraded. The optimal accuracy of the measured value is when the waveform is smooth and stable.
- If an abnormal condition appears on the screen during measurement, please pull out your finger and reinsert it to measure again.
- The oximeter has 5-year service life.
- The oximeter may not work for all users. If you are unable to achieve stable readings, discontinue use.
- A flexible circuit connects the two parts of the oximeter. Do not twist or pull on the connection.
- Before using the oximeter, ensure it is in a normal working state and the operating conditions are met.

- To get the most accurate measurement, the oximeter should be used in a quiet and comfortable environment.
- Standard pulse oximetry (SpO2) cannot screen for CO exposure.

If you are suffering from toxicosis, which is caused by monoxide, the oximeter is not recommended to be used.

2. OVERVIEW

The Pulse Oximeter features a compact design, low power consumption, and convenient operation. It is only necessary for user to put one finger into a fingertip photoelectric sensor for measurement, and a display screen will directly show measured value of Hemoglobin Saturation.

2.1 Features

- Displays: SpO2, pulse rate, bar graph, pulse waveform
- Easy to use
- Easy to view with a display that changes direction automatically
- Small, lightweight design with convenient carrying case
- Low power consumption
- Oximeter will enter standby mode after 60 seconds of inactivity
- Low-battery indication: appears before oximeter stops working properly
- Can transmit data to the A&D Heart Track app via Bluetooth®

- Can transmit data to gateway equipment or third party apps via Bluetooth®, if integrated

2.2 Major Applications and Scope of Application

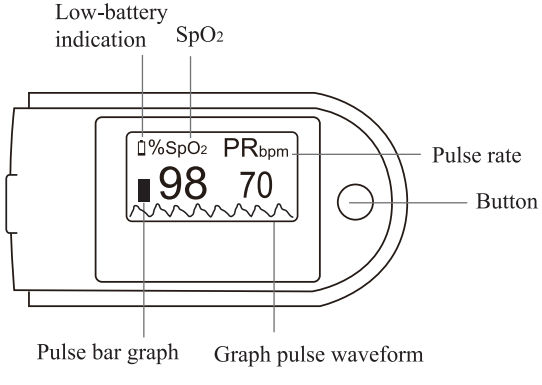
The Pulse Oximeter can be used in measuring pulse oxygen saturation and pulse rate through finger. The product is suitable for family use. The oximeter can be used before or after doing sports, but it is not recommended to be used during sports activity.

2.3 Accessories

- 1 Lanyard
- 2 Batteries
- 1 User Manual
- 1 Carrying Case

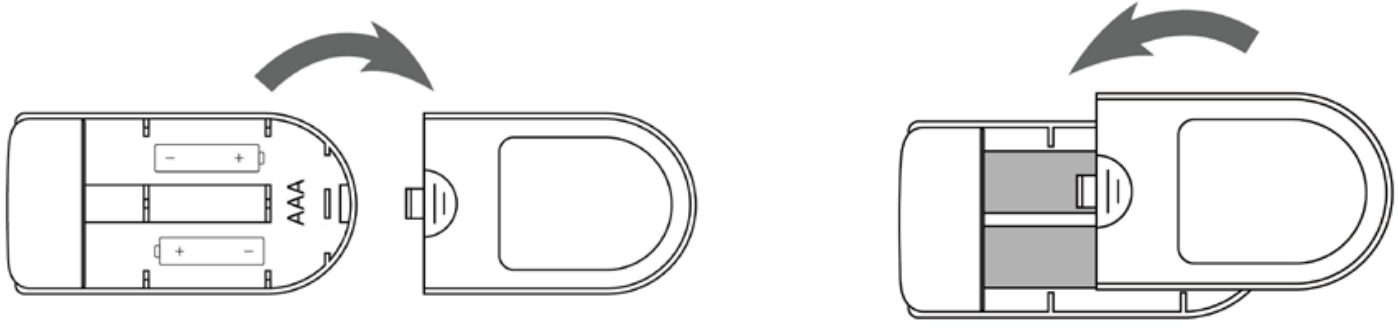
3. SET UP

3.1 View of the Front Panel



3.2 Battery

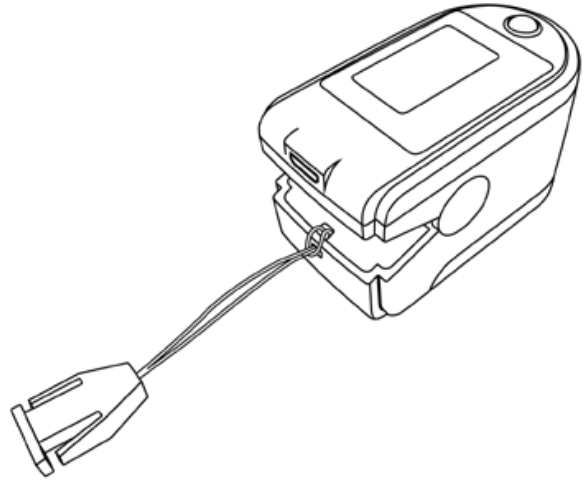
Step 1. Insert two AAA size batteries in the proper direction.
Step 2. Put the cover back on.



Please take care when you insert the batteries for the improper insertion may damage the oximeter.

3.3 Attaching the lanyard

Step 1. Put the thin loop through the hole on the oximeter.
Step 2. Put the lanyard strap through the thin loop and tighten.



4. OPERATING GUIDE CAUTIONS

4.1 Download the “A&D Heart Track” application

4.2 Pairing

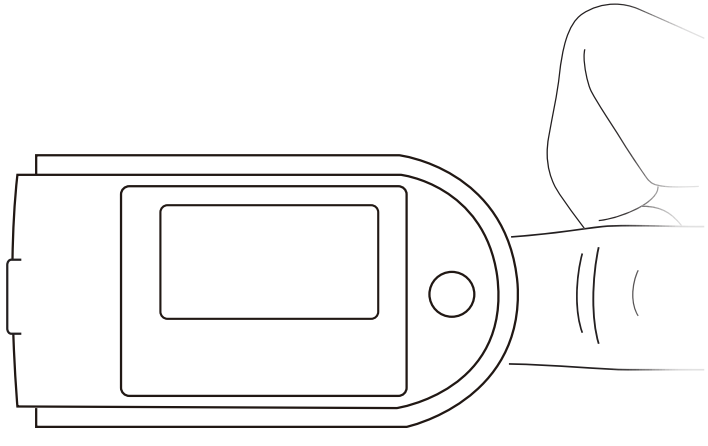
1. In the A&D Heart Track application, click on the “Menu” icon in the upper left.
2. Choose “Add Bluetooth Devices.”
3. Click on the “+” icon in the lower right corner. Choose “Pulse Oximeter.”
4. Choose UP-200BLE.
5. Follow the onscreen instructions to complete the pairing.

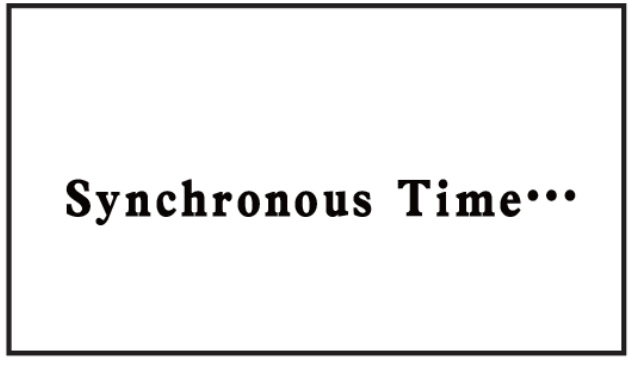
4.3 Taking Measurement

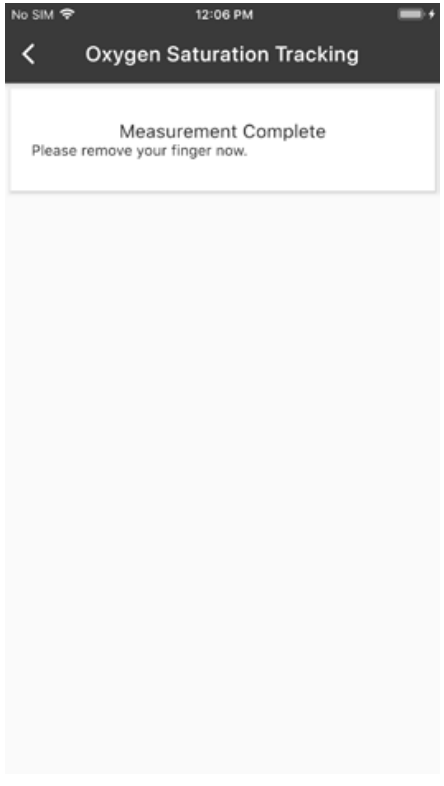
1. Open the “A&D Heart Track” application.
2. On the home screen, click on the “O2” icon in the upper right corner.
3. Click “+ Measure.”
4. Follow the on screen instructions to complete measurement.
5. Open the oximeter.

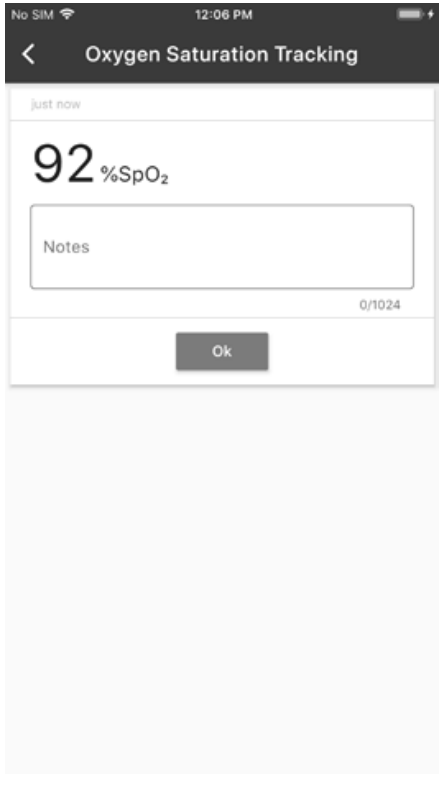
6. Place finger into the rubber cushions (make sure the finger is in the right position), then clip the finger.
7. Do not shake the finger and keep the user in a stable state during the process.
8. Press “Button” to exit from the standby mode.
9. “Synchronous Time” appears on the display. (Figure 6).
10. At the end of the measurement, the app will instruct you to remove your finger. The measurement value will transmit to the app.

Fingernails and the luminescent tube should be on the same side.









After replacing the batteries, take a measurement in the app to synchronize the date and time.

5. CLEANING, MAINTENANCE, TRANSPORTATION AND STORAGE

5.1 Cleaning and disinfection

- The oximeter must be turned off before cleaning - do not submerge into liquid.
- Remove the batteries before cleaning.
- To clean, use 75% isopropanol alcohol dampened on a soft cloth. Then, wipe the oximeter for disinfection. Let air dry or dry with a soft cloth.
- DO NOT spray liquid directly on the oximeter to avoid liquid from penetrating into the oximeter.

High-pressure sterilization cannot be used on the oximeter. Do not immerse the oximeter in liquid. It is recommended that the oximeter should be kept in a dry

5.2 Maintenance

- There is no need to calibrate the oximeter.
- Clean and disinfect the oximeter before/after using it according to the User Manual.
- Replace the batteries when low-battery appears.
- Remove the batteries if the oximeter is not used for a long time.
- When storing the oximeter, keep it away from children, pets and insects.

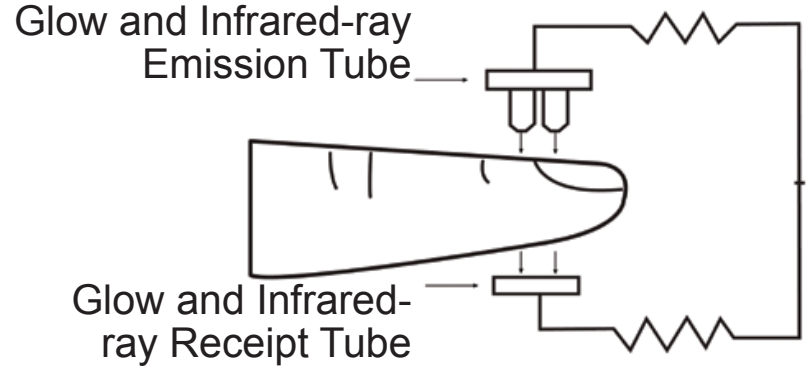
5.3 Transport and Storage

- The packed oximeter can be transported by ordinary conveyance or according to transport contract. During transportation, avoid strong shock, vibration and getting wet. It can not be transported mixed with toxic, harmful, corrosive material.
- The packed oximeter should be stored in room with no corrosive gases and good ventilation.

6. PRINCIPLE AND CAUTION

6.1 Principle of Measurement

Principle of the Oximeter is as follows: An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO_2) in glow & near-infrared zones. Operation principle of the instrument is: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning & Recording Technology, so that two beams of different wavelength of lights 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 screen through treatment in electronic circuits and microprocessor.



Operating Principle

6.2 Cautions

1. The finger should be placed properly, or else it may cause inaccurate measurement.
2. The SpO_2 sensor and photoelectric receiving tube should be arranged in a way with the subject's arteriole in a position there between.
3. The SpO_2 sensor should not be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection.
4. Make sure the optical path is free from any optical obstacles like rubberized fabric.
5. Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight etc.
6. Extreme electrosurgical interference may also affect the accuracy.
7. Frequent movement (active or passive) of the user or intense activity may affect the measured accuracy.

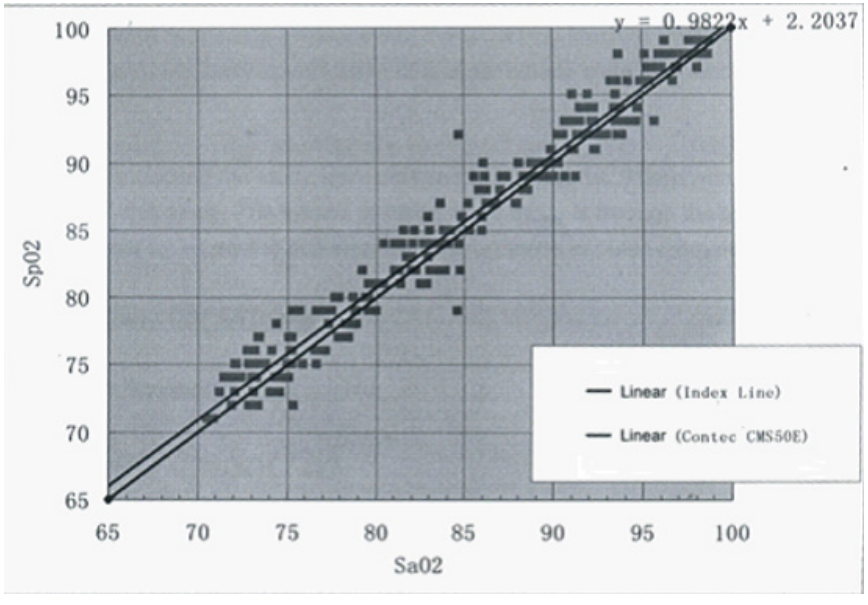
8. Defibrillation and the short period after defibrillation may affect the measured accuracy as it does not have a defibrillation function.

6.3 Clinical Restrictions

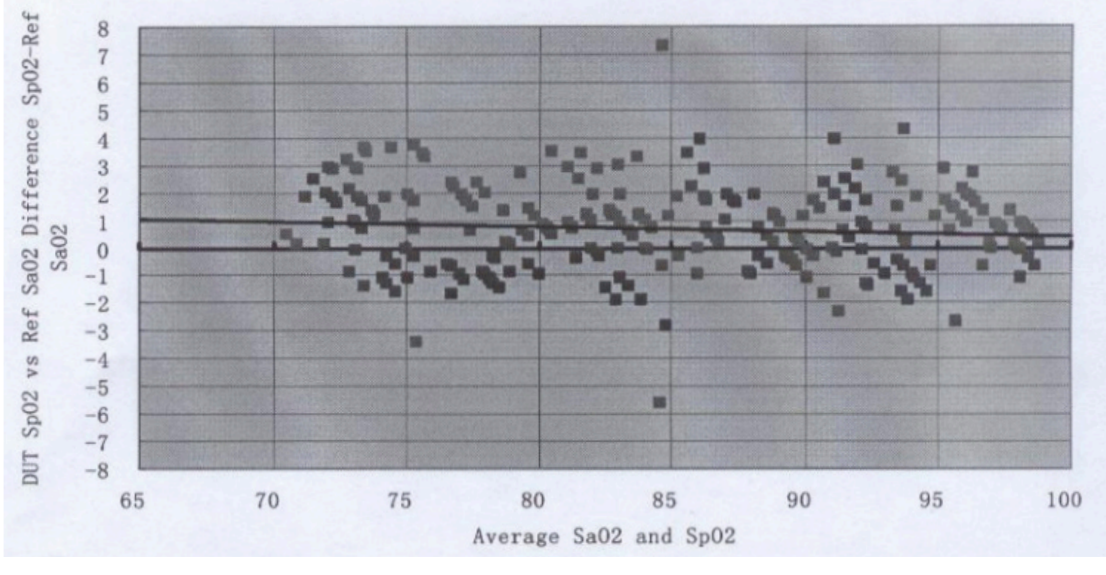
1. Since the measurement is taken on the basis of arteriole pulse, substantial pulsating blood flow of subject is required. For a subject with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.
2. For those with a substantial amount of staining dilution drug (such as methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO2 determination by this monitor may be inaccurate.
3. Drugs such as dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor for serious error of SpO2 measure.
4. As the SpO2 value serves as a reference value for judgement of anemic anoxia and toxic anoxia, some users with serious anemia may also report good SpO2 measurement.

7. TECHNICAL SPECIFICATIONS

1. **Power Requirements:** 2 × 1.5 V AAA alkaline battery (or rechargeable battery), battery voltage:DC 3.0V.
2. **Power Consumption:** Less than 100 mA.
3. **Measurement Performance in Weak Filling Condition:** SpO2 and pulse rate can be shown correctly when pulse-filling ratio is 0.4%. SpO2 error is ±4%, pulse rate error is ±2 bpm or ±2% (select larger).
4. **Resistance to surrounding light:** The deviation between the value measured in the condition of man-made light, indoor natural light and darkroom is less than ±1%.
5. **It is equipped with a switch function:** The product will enter standby mode when no signal is in the product within 5 seconds.
6. **Optical Sensor**
   Red light (wavelength is 660 nm, 6.65 mW)
   Infrared (wavelength is 905 nm, 6.75 mW)



SpO_2 regression plot



Bland–Altman plot

7. ***Bluetooth*® specifications**
   ***Bluetooth*® protocol:** *Bluetooth*® Low Energy
   Operating frequency: 2.4 GHz ISM band
   Modulation: GFSK(Gaussian Frequency Shift Keying)
   Transmitting power: 0 dBm, -6 dBm, -23 dBm
   Sensitivity: ≤-84 dBm @ 0.1% BER
   Transfer rate: 1 Mbps
   Safety features: Authentication and encryption
   Support Services: *Bluetooth*® Data Transfer
8. **FCC ID:2ABOGCMS50D-BT**
9. **IC: 28491-MS50DBT**

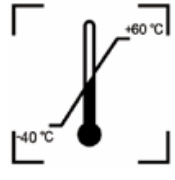
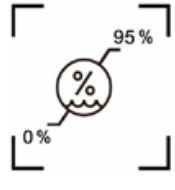
8. TROUBLESHOOTING

Trouble	Possible Reason	Solution
The SpO_2 and Pulse Rate values are not displayed normally	1. The finger is not properly positioned. 2. The user's SpO_2 is too low to be detected.	1. Place the finger properly and measure again. 2. Remain still while taking measurement. 3. If issue persist, consult with physician.

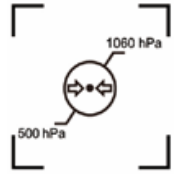
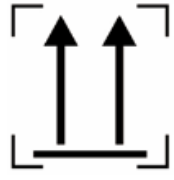
Trouble	Possible Reason	Solution
The $Sp0_2$ and Pulse Rate are not displayed stably	1. The finger is not placed inside deep enough. 2. The finger is shaking or the user is moving	1. Place the finger properly and try again. 2. Remain still while taking the measurement
The oximeter cannot be turned on	1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. Malfunction of the oximeter.	1. Change batteries. 2. Reinstall batteries. 3. Please contact customer support.
The display is off suddenly	1. The product will enter standby mode when no signal is in the product within 60 seconds. 2. The batteries are almost drained.	1. The oximeter has entered standby mode (normal operation). 2. Change batteries.

9. KEY OF SYMBOLS

Symbol	Description
	Type BF
	Refer to instruction manual
%SpO_2	The pulse oxygen saturation (%)
PRbpm	Pulse rate (bpm)
	Alarm inhibit
	The battery voltage indication is deficient (change the battery in time avoiding the inexact measure)

Symbol	Description
	WEEE (2002/96/EC)
IP22	Ingress of liquids rank
	Manufacturer
	Manufacture Date
	Storage and Transport Temperature limitation
	Storage and Transport Humidity limitation

Symbol	Description
— — —	1. No finger inserted 2. An indicator of signal inadequacy 3. Probe error
+	Battery positive electrode
−	Battery negative electrode
®	*Bluetooth*® icon
SN	Serial number
	Exit Standby mode
	Use-by date

Symbol	Description
	Storage and Transport Atmospheric pressure limitation
	This side UP
	Fragile, handle with care
	Keep dry
	Recyclable
Finger Out	The finger is not inserted.
Synchronous Time···	Synchronous time interface (Bluetooth equipment)

10. FUNCTION SPECIFICATION

SpO_2 Parameter Specification (see note 1)	
Display range	0% ~ 99%
Measurement range	0% ~ 100%
Accuracy (see note 2)	*70%~100%: ±2%;* *0%~69%: unspecified.*
Resolution	1%
Pulse Parameter Specification	
Display range	30 bpm ~ 250 bpm
Measurement range	30 bpm ~ 250 bpm
Accuracy (see note 3)	±2 bpm or ±2%, whichever is greater.
Resolution	1 bpm
Accuracy under low perfusion (see note 4)	Low perfusion 0.4%: SpO2: ±4%; PR: ±2 bpm or ±2%, whichever is greater
Light interference	Under normal and ambient light conditions, the SpO2 deviation ≤ 1%

Pulse intensity	Continuous bar-graph display, the higher display indicate the stronger pulse.
Upper and lower limit of measured values	
Sp02	0% ~ 100%
Pulse Rate	0 bpm ~ 254 bpm
Optical sensor (see note 5)	
Red light	Wavelength: about 660 nm, optical output power: < 6.65 mW
Infrared light	Wavelength: about 905 nm, optical output power: < 6.75 mW
Safety Class	Internally powered equipment, type BF applied part
International protection	IP22
Working voltage	DC 3 V
Working current	≤ 100 mA
Battery Requirement	
1.5V (AAA size) alkaline batteries × 2 or rechargeable battery	
Battery Useful Life	
Two batteries can work continually for 24 hours	

Dimensions and Weight	
Dimensions	2.3 (L) x 1.3 (W) x 1.3 (H) inch / 58(L) × 32(W) × 34(H) mm
Weight	~ 2 oz / 52 g (with the batteries)
Environment Requirements	
Storage Environment	-40°C ~ +60°C/ ≤95% / 500hPa ~ 1060hPa
Operating Environment	10°C ~ 40°C / ≤75% / 700hPa ~ 1060hPa

NOTE 1: the claims of SpO2 accuracy shall be supported by clinical study measurements taken over the full range. By artificial inducing, get the stable oxygen level to the range of 70 % to 100 % SaO2, compare the SpO2 values collected by the secondary standard pulse oximeter equipment and the tested equipment at the same time, to form paired data, which are used for the accuracy analysis.
There are 12 healthy volunteers (male: 6. female: 6; age: 18~45; skin color: black: 2, light: 8, white: 2) data in the clinical report.

NOTE 2: because pulse oximeter equipment measurements are statistically distributed, only about two-thirds of pulse oximeter equipment measurements can be expected to fall within ±Arms of the value measured by a CO-OXIMETER.

NOTE 3: Patient simulator has been used to verify the pulse rate accuracy, it is stated as the root-mean-square difference between the PR measurement value and the value set by simulator.

NOTE 4: percentage modulation of infrared signal as the indication of pulsating signal strength, patient simulator has been used to verify its accuracy under conditions of low perfusion. SpO2 and PR values are different due to low signal conditions, compare them with the known SpO2 and PR values of input signal.

NOTE 5: optical sensors as the light-emitting components, will affect other medical devices applied the wavelength range. The information may be useful for the clinicians who carry out the optical treatment.For example, photodynamic therapy operated by clinician.

11. APPENDIX I

State	Prompt Condition Delay	Prompt Signal Generation Delay
Low voltage prompt	1s	20ms
SpO2 prompt	330ms	20ms
Pulse rate prompt	330ms	20ms
Probe error prompt	16ms	20ms

12. APPENDIX II EMC GUIDANCE AND MANUFACTURER DECLARATIONS

Table 1: Guidance and manufacture's declaration – electromagnetic emissions for all EQUIPMENT and SYSTEMS

Guidance and Manufacture's Declaration – Electromagnetic Emission	
The *UP-200BLE Pulse Oximeter* is intended for use in the electromagnetic environment specified below. The customer or the user of the *UP-200BLE Pulse Oximeter* should assure that it is used in such and environment.	
Emission test	**Compliance**
RF emission CISPR 11	Group 1
RF emission CISPR 11	Class B

Table 2: Guidance and manufacture's declaration – electromagnetic immunity for all EQUIPMENT and SYSTEMS

Guidance and Manufacture's Declaration – Electromagnetic Immunity		
The *UP-200BLE Pulse Oximeter* is intended for use in the electromagnetic environment specified below. The customer or the user of *UP-200BLE Pulse Oximeter* should assure that it is used in such an environment.		
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air
Power frequency (50/60Hz) Magnetic field IEC-61000-4-8	30 A/m	30 A/m

Table 3: Guidance and manufacture's declaration – Electromagnetic Immunity

Guidance and manufacture's declaration – Electromagnetic Immunity		
The *UP-200BLE Pulse Oximeter* is intended for use in the electromagnetic environment specified below. The customer or the user of *UP-200BLE Pulse Oximeter* should assure that it is used in such an environment.		
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz
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.		

[a] 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 *UP-200BLE Pulse Oximeter* is used exceeds the applicable RF compliance level above, the *UP-200BLE 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 *UP-200BLE Pulse Oximeter*.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4: Guidance and manufacture's declaration – Electromagnetic Immunity

Guidance and manufacture's declaration – Electromagnetic Immunity
The *UP-200BLE Pulse Oximeter* intended for use in the electromagnetic environment specified below. The customer or the user of the *UP-200BLE Pulse Oximeter* should assure that it is used in such an environment.

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

	Test Frequency (MHz)	Band a) (MHz)	Service a)	Modula-tion b)	Modu-lation b) (W)	Dis-tance (m)	Immunity Test Level (V/m)
Radiated RF IEC61000-4-3 (Test specifica-tions for ENCLO-SURE PORT IMMUNITY to RF wireless commu-nications equiment)	385	380 - 390	TETRA 400	Pulse modu-lation b) 18 Hz	1.8	0.3	27
	450	380 - 390	GMRS 460, FRS 460	FM c) ± 5 kHz devia-tion 1 kHz sine	2	0.3	28
	710	704 - 787	LTE Band 13, 17	Pulse modu-lation b) 217 Hz	0.2	0.3	9
	745						
	780						

Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equiment)	Test Frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Modulation b) (W)	Distance (m)	Immunity Test Level (V/m)
	810	800 - 960	GSM 800/ 900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0.3	28
	870						
	930						

Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equiment)	Test Frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Modulation b) (W)	Distance (m)	Immunity Test Level (V/m)
	1720	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0.3	28
	1845						
	1970						

Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equiment)	Test Frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Modulation b) (W)	Distance (m)	Immunity Test Level (V/m)
	2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0.3	28
	5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0.2	0.3	9
	5500						
	5785						

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation:
Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.

WARNINGS:

1. Don’t use near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.
2. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
3. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.”
4. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the oximeter including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
5. Active oximeters are subject to special EMC precautions and they must be installed and used in accordance with these guidelines.

13. WARRANTY

Limited Warranty:
A&D Medical (“A&D”) warrants to the first purchaser (“You”) that the A&D product You purchased (the “Product”) will be free from defects in material, workmanship and design for the applicable Warranty Term stated above from the date You purchased the Product under normal use. This Limited Warranty is personal to You and is not transferable. If the Product is defective, then You return the Product to A&D in accordance with the procedure set forth below. A&D’s warranty obligation is limited to the repair or replacement, at A&D’s option, of the defective Product that has been returned by You within the warranty period. Such repair or replacement will be at no charge to You. The repaired or replacement Product is warranted here-under for the longer of the remainder of the original warranty period or 90 days from the date of shipment of the repaired or replacement Product. To obtain a warranty service, please contact us in **US at 1-888-726-9966 or in Canada at 1-800-461-0991** for return address, shipping and handling fee, and other instructions for processing warranty. Please ensure you have satisfactory proof of the date of Your purchase and a description of the defect.

Returns will not be accepted unless a Return Material Authorization (RMA) Number has been issued from A&D Customer Service Representative.

In Latin America: Please return to your local dealer.

CONTACT INFORMATION

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