AULISA

Guardian Angel® Rx

Infant Oximeter Module

Instructions For Use

7MN00057-00

Disclaimer

At the time of publication, this manual is believed to be accurate and up-to-date. In the interest of continued product development, Taiwan Aulisa Medical Devices Technologies, Inc. reserves the right to make changes and improvements to this manual and the products described within at any time, without notice or obligation.

References to “Aulisa” in this manual shall imply Taiwan Aulisa Medical Devices Technologies, Inc.

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CAUTION!!! Read this entire manual carefully before using Guardian Angel® Rx Infant Oximeter.

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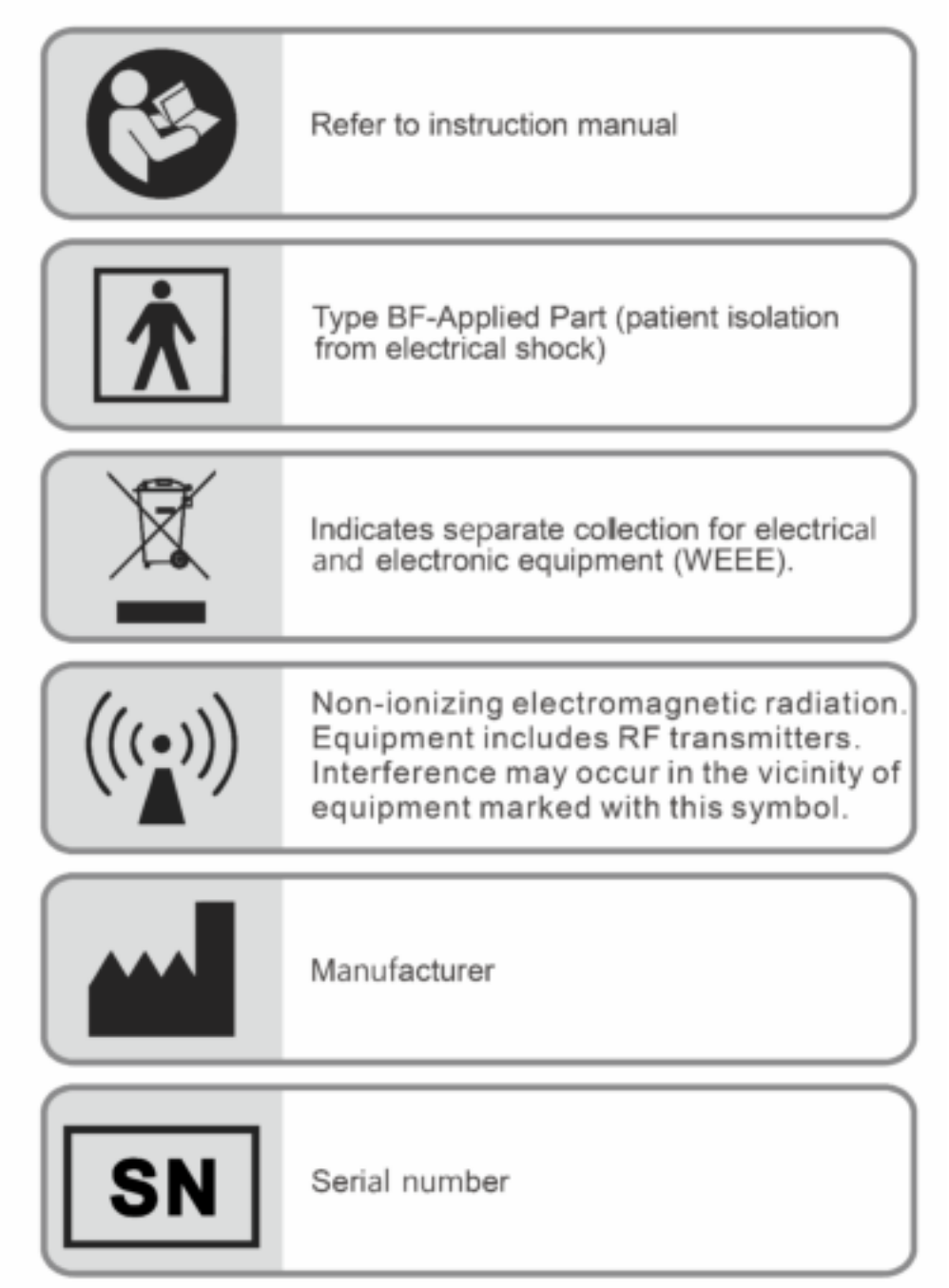
Guide to Symbols



LOT	Lot number
Rx Only	Prescription use only
	Temperature limit
	Non-sterile
IP22	Classification for water ingress and particulate matter
	Date of Manufacturer
	MR Unsafe: must not be used in an MRI environment.

Welcome

This manual will help you get started with monitoring using the Infant Oximeter Module of Guardian Angel® Rx Digital Vital Sign Monitoring System. The Infant Oximeter Module is intended for use with Guardian Angel® Rx Digital Vital Sign Monitoring System . Refer to the system Instructions for Use for detailed instructions.

Precautions for Use

Contraindications

1. Do not use any part of this device in an MRI environment.
2. Explosion Hazard: Do not use this device in an explosive atmosphere or in the presence of flammable anesthetics or gases.
3. This device is not a replacement for a caregiver.

Warnings

1. This device is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
2. A functional tester cannot be used to assess the accuracy of this device. This device does not require calibration.
3. This device readings may be affected by the use of an electrosurgical unit.
4. Anemia may affect the accuracy of the measurement.
5. Only use the accessories manufactured by Aulisa. These accessories are manufactured to meet the accuracy specifications for this device. Using other manufacturers' components can result in improper device performance and injury may occur.
6. The operator must verify the compatibility of the accessories before use, otherwise injury can result.
7. As with all medical equipment, carefully route all cables to reduce the possibility of entanglement, strangulation or injury to the patient.
8. Be careful with small parts that can be removed from the device and swallowed. They are hazardous to children.
9. Excessive pressure to the sensor application site for prolonged periods may cause damage to the skin beneath the sensor probe.

10. Do not use this device if it is damaged in any way. Discontinue using it immediately and replace a new one.
11. Do not use in or around water or any other liquid when AC power adaptor is used.
12. Only use this device with charging adaptors provided by Aulisa.
13. This device is designed to determine functional oxygen saturation, the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin, such as methemoglobin, might affect the accuracy of the measurement.
14. Use this device only when it is within the specified distances, approximately 32.8 feet (10 meters) spherical radius to Guardian Angel® Rx Digital Vital Sign Monitoring System. Moving outside this range may cause missing, lost, and/or inaccurate data.
15. Loss of monitoring can result if any objects hinder the pulse measurement. Ensure that no blood flow restrictors (e.g. blood pressure cuff) hinder pulse measurements.
16. This device is not a substitution for physician supervision.
17. Always refer to Instructions For Use for full warnings and instructions.
18. Failure to follow instructions and warnings may result in serious injury or death.

Cautions

1. This device complies with International Standard IEC 60601-1-2: 2014 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of interference due to close proximity or strength of a source might disrupt the device's performance.
2. Radios and cell phones or similar devices can affect the wireless connection of this device and must be kept at least 6.5 feet (2 meters) away from it.
3. If this device fails to respond as described, discontinue use until the situation is corrected by qualified personnel.
4. Cardiogreen and other intravascular dyes may affect the accuracy of SpO_2 measurements.
5. This device might not work on cold extremities due to reduced circulation. Warm or rub the foot to increase circulation or reposition the sensor.
6. This device might misinterpret motion as good pulse quality. Minimize motion

of the monitored site.

7. Excessive ambient light may affect the accuracy of the measurement.
8. Inspect and relocate the sensor application site at least every 6 hours to ensure correct sensor alignment and skin integrity. Personal sensitivity to a sensor may vary due to medical status or skin condition.
9. Do not place liquids on top of the device.
10. Do not immerse the device or any of the components in any liquids.
11. Do not use caustic or abrasive cleaning agents on the device.
12. Do not gas sterilize or autoclave this device.
13. Batteries might leak or explode if used or disposed of improperly.
14. Follow local governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
15. Do not subject the device to extreme hot or cold temperatures, humidity, or direct sunlight.
16. Do not fasten the Leg Band too tightly around the leg. Inaccurate readings and discomfort could result.
17. System connection failure (Bluetooth/Wi-Fi wireless connection) may result in loss of data transfer.

Device Overview

Device Components

Infant Oximeter Box	Infant Oximeter Disposable Sensor Cable
	
Infant Oximeter Reusable Sensor Cable	**Adhesive Patch**
	
Leg Band	Charging Adaptor
	

Device Description

Infant Oximeter Box

The Infant Oximeter Box worn on the leg includes a Bluetooth transmitter and a sensor chip along with electronics for vital sign measuring and analyzing. It must be used within 32.8 feet (10 meters) to Guardian Angel® Rx Digital Vital Sign Monitoring System.

Infant Oximeter Disposable Sensor Cable

The Infant Oximeter Disposable Sensor Cable is intended to be attached to the Infant Oximeter Box on one end and to the toe on the other end. Discard the sensor cable after each use. It can be purchased separately.

Infant Oximeter Reusable Sensor Cable

The Infant Oximeter Reusable Sensor Cable is intended to be attached to the Infant Oximeter Box on one end and to the toe on the other end using the Adhesive Patch. The sensor cable is reusable. Discard the Adhesive Patch after each use.

Device Intended Use

The Aulisa Infant Oximeter Module is intended to measure SpO2 and pulse rate of infant patients during non-motion and under well-perfused conditions in hospitals, medical facilities, home care, and subacute environments. The parameters derived by Aulisa Infant Oximeter Module are transmitted to Aulisa's Digital Vital Sign Monitoring System for display.

Device Principle of Operation

This device measures SpO_2 and pulse rate based on non-invasive light-emitting diode (LED) reflectance technology, measuring the absorbance of red and infrared light passed through the perfused tissue during each pulse.

Device Set Up

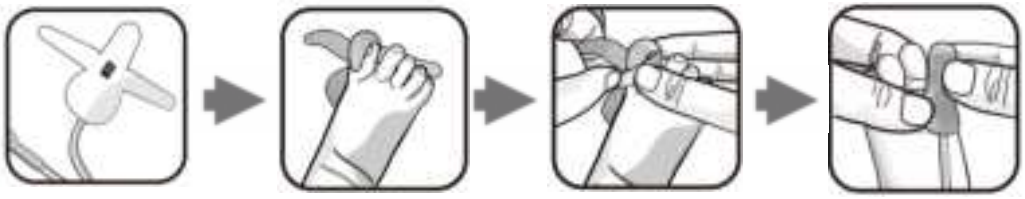
Before you begin your monitoring session, unpack the device and become familiar with its parts. It is recommended to fully charge the Infant Oximeter Box prior to setting up. It takes approximately 1 hour to fully charge. Refer to "Device Charging" section for detailed instructions.

Step 1: Assemble the device.

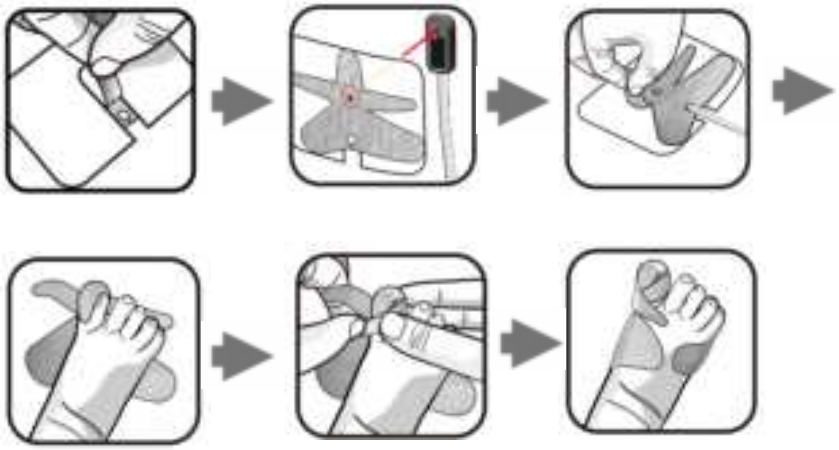
Insert the Leg Band through the holder of the Infant Oximeter Box. The fluffy side of the Leg Band should face upward. And then plug in the sensor cable.

Step 2: Attach the sensor to the toe.

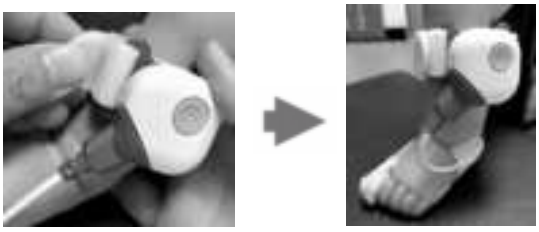
If you go with Infant Oximeter **Disposable** Sensor Cable, peel off the release paper on the sensor first and wrap the adhesive patch around the toe.



If you go with Infant Oximeter **Reusable** Sensor Cable, peel off the arch-shaped section of the release paper of the Adhesive Patch, followed by placing the back of the sensor probe over the hole on the center of the patch, and peel off the whole release paper and wrap the patch around the toe.



Step 3: Secure the Leg Band around the leg.



Step 4: Press the Power button to turn on the Infant Oximeter Box.

NOTE: The power LED will light green when the power is ON.

Step 5: Set up Guardian Angel® Rx Digital Vital Sign Monitoring System.

NOTE: Refer to the Instructions for Use of Guardian Angel® Rx Digital Vital Sign Monitoring System for set up instructions and verifying system operation.

Step 6: Wait for the wireless connection of the system to be established. Once connected, the vital signs and the device status information will appear on the MAIN screen.

NOTE: Refer to "Device Pairing" section below for more information.
NOTE: The device must be used within 32.8 feet (10 meters) spherical radius to Guardian Angel® Rx Digital Vital Sign Monitoring System.
NOTE: The power LED on the Infant Oximeter Box will blink green when pairing succeeds, and data transmission starts.

Device Pairing

Automatic Pairing

The system automatically scans and pairs to the Aulisa sensor module(s) from the same starter kit.

NOTE: The device must be placed within 32.8 feet (10 meters) to the Guardian Angel® Rx Digital Vital Sign Monitoring System.
NOTE: The Bluetooth connection status icon will turn blue once the pairing succeeds.
NOTE: The power LED on the Infant Oximeter Box will blink green when pairing succeeds, and data transmission starts.

Manual Pairing

Follow the below instructions to manually setup pairing of a new Infant Oximeter Module.

NOTE: Up to four (4) Infant Oximeter can be stored in the system.

Step 1: Turn on the Infant Oximeter.
Step 2: In the Setting menu, select “PAIRING”→“SENSOR MODULE”.
Step 3: Scan the QR Code or key in the serial number located on the back of the Infant Oximeter Box.
Step 4: Press “CONFIRM” if the serial number (SN) displayed matches with the one on the Infant Oximeter Box.
Step 5: To confirm that the process was successful, ensure that the Bluetooth connection status icon on the MAIN screen is lit blue.

NOTE: The device remains paired with the system until the serial number is deleted from the list.

NOTE: The device must be placed within 32.8 feet (10 meters) to Guardian Angel® Rx Digital Vital Sign Monitoring System.

NOTE: The Power On/Off LED indicator lights green when the power is ON.

Device Power Off

The device will be turned off by either:

1. press the Power button on the Infant Oximeter Box, or
2. when the device detects no signal for 3 minutes.

NOTE: The power LED goes off when power off.

Device Charging

The Guardian Angel® Rx Digital Vital Sign Monitoring System will alert the user when the device is on low power. Follow the instructions below to charge the device.

Step 1: Unplug the sensor cable from the Infant Oximeter Box.

Step 2: Plug the Type-C end of the charging adaptor into the Infant Oximeter Box.

Step 3: Attach the wall adaptor to a power outlet .

NOTE: The device works for up to extra 2 hours in the low power status.

NOTE: It takes approximately 1 hour to fully charge the device.

NOTE: The Power On/Off LED indicator lights blue during charging and goes off when fully charged.

NOTE: The device powers off while charging.

CAUTION!!! Only use charging adaptor supplied or manufactured by Taiwan Aulisa Medical Devices Technologies, Inc.

Alarms

The Infant Oximeter Box is equipped with an LED indicator that will blink red when a high priority alarm occurs and blink yellow for medium priority alarm.

For more information about the alarm system, refer to the Instructions for Use of Guardian Angel® Rx Digital Vital Sign Monitoring System.

Care and Maintenance

The advanced digital circuitry within the device requires no calibration or periodic maintenance. Field service or repair of this system is not possible. Do not attempt to open the case of the device for that will cause damage and void the warranty. If the device is not functioning properly, see “Troubleshooting” section for more information.

Cleaning and Disinfection

The device is expected to be cleaned and disinfected before use, i.e., once per day. It has been tested to withstand 300 times of cleaning within 1.5 years of re-use life. Do not use the device that has exceeded its re-use life.

We recommend you clean and disinfect the device with the instructions below.

First, lightly wipe the surface of the device with a soft cloth dampened with rubbing alcohol for cleaning. Secondly, disinfect the surface of the device with a soft cloth saturated with a solution of 10% chlorine bleach in tap water. Lastly, allow the device to dry thoroughly. Visual inspection is necessary at the end of cleaning and disinfecting cycle. Repeat the previous cycles to remove visible residual soil on the device. Do not use a visibly soiled device again.

Reuse Life

This device is reusable with an expected life of 1.5 years. However, if you notice any signs of deterioration from below, stop using it and replace it with a new one or contact Aulisa Customer Support by going online at www.aulisa.com:

- button malfunctions;
- cracks appear on external case;
- edge of the gel covering the sensor probe window starts curling up;

- the strap frays or breaks and the wires inside become exposed.

Using deteriorated component(s) may cause the device performance to degrade and do harm to the user.

CAUTION!!! Do not pour or spray any liquids onto this device, and do not allow any liquids to enter any openings in the device.

CAUTION!!! Do not immerse the device in liquid and do not use caustic or abrasive cleaning agents on the device.

CAUTION!!! The Infant Oximeter Disposable Sensor Cable is for single use.

Troubleshooting

Problem	Possible Solution
Cannot turn on the device	1. Make sure the device is kept away from any magnetic devices while using. 2. Fully charge the device until the LED blue light on the Infant Oximeter Box goes off.
Unable to obtain a valid SpO_2 or pulse rate reading **NOTE: In some instances, perfusion of person being monitored may be inadequate for pulse detection**.	1. Reposition the sensor cable and keep it motionless for at least 10 seconds. 2. Relocate the sensor cable to a different site. 3. Make sure the device is assembled firmly and attached to the toe securely. 4. Check the accessories for any visible signs of deterioration. 5. Warm the application site by rubbing or covering with a blanket. 6. Allow the foot to rest comfortably without squeezing or pressing the sensor probe on a hard surface. 7. Make sure the device is within 32.8 feet (10 meters) spherical radius to the Guardian Angel® Rx Digital Vital Sign Monitoring System. 8. Reduce or eliminate any interference. Make sure the device is NOT placed on the same leg being used for other medical therapies or diagnostics (e.g. blood pressure cuff). 9. Check the Guardian Angel® Rx Digital Vital Sign Monitoring System for any alarms or error messages. 10. Check if the device is in low power. 11. Verify the system's wireless connection. 12. Make sure that the system is not in proximity with other RF radiating devices (such as diathermy, electrocautery, RFID, and security systems).
Unstable or constant SpO_2 and Pulse Rate readings	1. Shield the sensor probe from any light source. 2. Relocate the sensor cable to a different site. 3. Make sure the device is assembled firmly and attached to the toe securely.

	4. Check the accessories for any visible signs of deterioration. 5. Reduce motion.
"---" appears on the vital sign displays	1. Make sure the device is assembled firmly and attached to the toe securely. 2. Reposition the sensor cable and keep it motionless for at least 10 seconds. 3. Relocate the sensor cable to a different site. 4. Make sure the device is within 32.8 feet (10 meters) spherical radius to the Guardian Angel® Rx Digital Vital Sign Monitoring System. 5. Verify the system's wireless connection.
Data update period has exceeded the limit	1. Reposition the sensor cable and keep it motionless for at least 10 seconds. 2. Relocate the sensor cable to a different site.
Cannot establish system connection	1. Make sure the device is within 32.8 feet (10 meters) spherical radius to the Guardian Angel® Rx Digital Vital Sign Monitoring System. 2. Turn off the system and retry.

For additional troubleshooting, refer to the Guardian Angel® Rx Digital Vital Sign Monitoring System Instructions for Use.

If these solutions do not correct the problem, please contact your distributor, or contact Aulisa by going online at www.aulisa.com under "Contact Us".

CAUTION!!! This system is a precision electronic instrument and must be repaired by knowledgeable and specially trained Aulisa personnel only. Do not attempt to open the case or repair the electronics.

Device Performance

SpO_2 Accuracy

SpO_2 accuracy testing is performed by in vivo accuracy testing under laboratory conditions on healthy subjects with varying skin pigmentation in an independent research laboratory through induced hypoxia studies. Analysis of bias* was performed vs. Hemoximeter data. The limits of agreement shown are calculated per: Bland JM, Altman D. (2007) Agreement between methods of measurement with multiple observations per individual. Journal of Biopharmaceutical Statistics 17, 571 – 582.

Root mean square error (RMS error) is calculated as follows:

$$\text{RMS Error} = \sqrt{\frac{\sum (SpO_2 - SaO_2)^2}{n}}$$

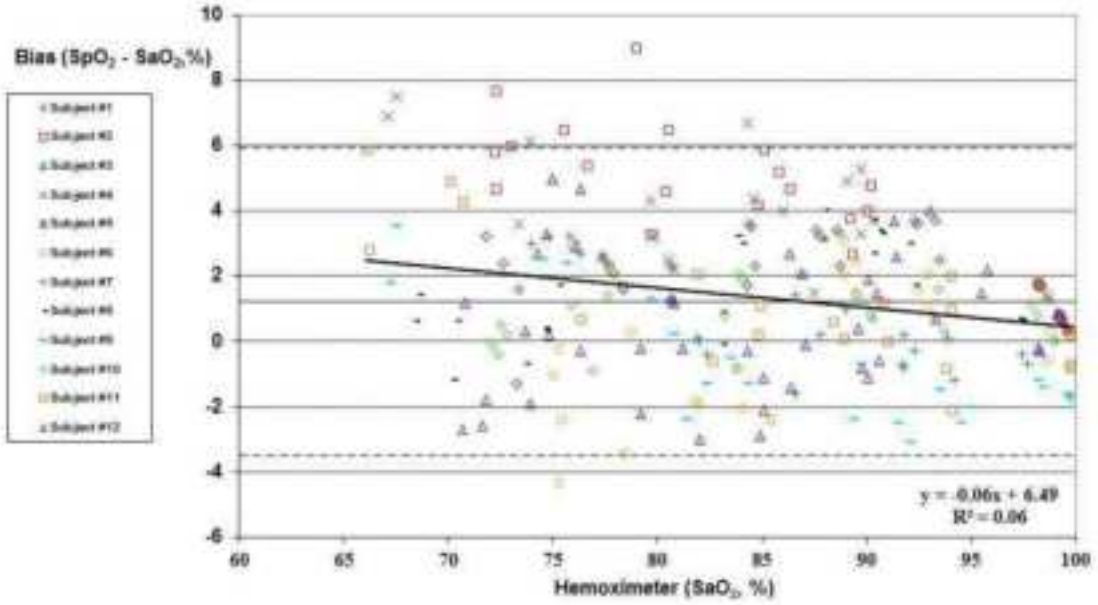
*Bias is defined as the monitor under test reading minus the hemoximeter reading.

NOTE: Because pulse oximeter equipment measurements are statistically distributed, only about two-thirds of this device measurements can be expected to fall within ±Arms of the value measured by a co-oximeter.

A_{rms} from the Clinical Study

Accuracy (A_{rms})	90%-100%	1.82
	80%-90%	2.66
	70%-80%	3.19

The graph below shows the error (SpO_2 – SaO_2) plots of each subject measured by this device with upper and lower 95% limits of agreement. Each sample data point is from a clinical study in healthy volunteers.



Pulse Rate Accuracy

Pulse rate accuracy has been functionally tested against an electronic pulse simulator from 30 to 300 bpm in 10bpm intervals, with combinations of Pulse Amplitude settings of 0.5, 1, 3, 5, 7, 10, 12, 15, 17 and 20, and SpO_2 settings of 100%, 95%, 90%, 85%, 80%, 75% and 70%. All 1960 combinations of testing points (=7 x 28 x 10) of Pulse Rate passed the ± 3 digits acceptance criteria.

Equipment Response Time

This device uses a moving average to determine the pulse rate and SpO_2. The following table shows the equipment response time of this device.

Equipment Delays (second)	
Data Averaging	≤ 4 seconds
Alarm Condition Delay	≤ 4 seconds
Alarm Signal Generation Delay	0 second
Data Update Period	1 second

Manufacturer’s Declaration

Refer to the following table for specific information regarding compliance to IEC 60601-1-2 for this device.

***For all EQUIPMENT and SYSTEMS**

Guidance and Manufacturer's Declaration - Electromagnetic Emission		
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	This device 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	This device is suitable for use in all establishments, including domestic 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	Complies	
Voltage fluctuations/ flicker Emissions IEC 61000-3-3	Complies	

***For all EQUIPMENT and SYSTEMS**

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment -guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical Fast Transient / Burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV Line to Line	±1 kV Line to Line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% UT in 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT in 1 cycle at 0° 70% UT in 25/30 cycles at 0° 0% UT in 250/300 cycles at 0° and 180°	0% UT in 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT in 1 cycle at 0° 70% UT in 25/30 cycles at 0° 0% UT in 250/300 cycles at 0° and 180°	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60 Hz)	30 A/m	30 A/m	Power frequency magnetic fields should be at levels

Magnetic Field IEC 61000-4-8			characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the AC mains voltage before application of the test level.			

***For EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING**

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment -guidance**
Conducted RF IEC 61000-4-6	3 V 150 kHz to 80 MHz 6 V ISM and amateur radio bands	3 V 150 kHz to 80 MHz 6 V ISM and amateur radio bands	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V 80MHz to 2.7 GHz	10 V 80MHz to 2.7 GHz	
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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating thedevice.

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

FCC Compliance

Declaration of Conformity with FCC for Electromagnetic Compatibility
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 undesignated operation.

Federal Communications Commission (FCC) Notice
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. If not installed and used in accordance with the instructions, it may 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:
(1) Reorient or relocate the receiving antenna.
(2) Increase the separation between the equipment and receiver.
(3) Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
(4) Consult the dealer or an experienced radio/TV technician for help.

The device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government. These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. The guidelines are based on the safety standards previously set by both U.S. and international standards bodies. This equipment has been shown to be capable of compliance for localized specific absorption rate (SAR) for uncontrolled environment/ general population exposure limits specified in ANSI/IEEE Std. C95.1-1992 and has been tested in accordance with the measurement procedures specified in IEEE Std. 1528-200X (Draft 6.5, January 2002).

FCC Radiation Exposure Statement
For body worn operation, to maintain compliance with FCC RF exposure guidelines, use only accessories that contain nonmetallic components. RF exposure separation distance is 5 mm. Use of other accessories may violate FCC RF exposure guidelines

and should be avoided.

The FCC requires the user to be notified that any changes or modifications to this device that are not expressly approved by Taiwan Aulisa Medical Devices Technologies, Inc. may void the user's authority to operate the equipment.

CAUTION!!! No modifications to this device are allowed that in any way affect or alter its antenna or antenna configuration.

Service, Support, and Warranty

Taiwan Aulisa Medical Devices Technologies, Inc. (“Aulisa”) warrants to the purchaser that each of Aulisa's product will be free from material defect for a period of one year from the date of purchase (the “Warranty Period”), and Aulisa will repair or replace at its discretion, free of charge, each Aulisa's product found to be materially defective during the Warranty Period and for which Aulisa has been notified during the Warranty Period (the “Warranty”). This Warranty shall be the sole and exclusive remedy by the purchaser for the Aulisa product delivered to the purchaser, irrespective whether such remedy is under contract, tort, or by law.

Aulisa's obligation under the Warranty is only if (i) Aulisa has received written notice of the warranty claim within the Warranty Period, (ii) purchaser has returned the product to Aulisa in accordance with instructions provided on Aulisa's support webpage, and (iii) Aulisa has verified that the product is defective. Aulisa warrants a replacement or repaired product only for products purchased from authorized resellers and only for the unexpired term of the Warranty Period for the defective product.

A return merchandise authorization (“RMA”) and its associated RMA number is required before any product can be returned to Aulisa. To obtain this return authorization number, please contact Aulisa Customer Support by going online at www.aulisa.com under "Contact Us".

Under this Warranty, the purchaser is responsible for the cost of delivery of the product to Aulisa's place of repair as designated by Aulisa, and Aulisa is responsible for the cost of delivery back to the purchaser. Aulisa reserves the right to charge a fee for a warranty repair request on an Aulisa product that is found to be within

Specifications

Dimensions	1.9" x 1.8" x 0.6" (47.5mm x 46.2mm x 15.9mm)
Weight	0.4 oz (12g)
Ingress Protection	IP23
Display Range	
Blood Oxygen Saturation (SpO_2)	1-100%
Pulse Rate	30-300 bpm
Accuracy	
Blood Oxygen Saturation (SpO_2)	70-100% ±3 digits
Pulse Rate	30-300 bpm ±3 digits
Measurement Wavelengths and Output Power	
Red	660 nanometers
Infrared	940 nanometers
Battery Type	3.7V battery
Battery Life	6 hours of continuous operation
Temperature	
Operating	+5°C to +40°C
Storage/Transportation	–25°C to +70°C
Humidity	
Operating	15% to 90% R.H. non-condensing
Storage/Transportation	10% to 93% R.H. non-condensing
Operating Altitude	altitude ≤ 3000 m
Atmospheric Pressure	700 hPa to 1013 hPa
Wireless Communication	
Frequency	2402-2480 MHz
Protocol	BT4.0
Power Output	0.0038W
Antenna Info	Chip, 2.5dBi
Security	AES-128
Range	32.8 feet (10 meters) spherical radius
Direction	Bi-direction
Data rate	Up to 100k Bps
Classifications per IEC 60601- 1	
Type of Protection	Class II, MOPP (on AC power)

	Internally powered (on battery power)
Type of Protection	Type BF-Applied Part
Mode of Operation	Continuous

Parts and Accessories

Parts and Accessories	Model Number
Infant Oximeter Box	GA-OB0004
Infant Oximeter Disposable Sensor Cable	GA-DS0004
Infant Oximeter Reusable Sensor Cable	GA-RS0007
Adhesive Patch	GA-AP0013
Leg Band	GA-LB0002
Charging Adaptor	GA-AD0001
Infant Oximeter Module (Box + Disposable Sensor Cable)	GA-OM0011
Infant Oximeter Module (Box + Reusable Sensor Cable)	GA-OM0009

You may also contact your distributor or contact Aulisa by going online at www.aulisa.com under "Contact Us".

CAUTION!!! Using accessories not by Taiwan Aulisa Medical Devices Technologies, Inc. may result in inaccurate measurements. Always use parts and accessories by Taiwan Aulisa Medical Devices Technologies, Inc.

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