AULISA®

Guardian Angel® Rx

Guardian Angel® Rx Lite

Aulisa Infant Oximeter Module 2nd Gen.

Instructions For Use

GA-OM0018

Version 6.0
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7MN00069-05

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.

CAUTION !

- Read this entire manual carefully before using Infant Oximeter Module 2nd Gen. of Aulisa-developed software application.

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Guide to Symbols

	Refer to instruction manual
	Indicates separate colection for electrical and electronic equipment (WEEE)
	Non-ionizing electromagnetic radiation. Equipment includes RF transmitters Interference may occur in the vicinity of equipment marked with this symbol
	Manufacturer
	Serial number
	Lot number
	Federal law (USA) restricts this device to sale by or on the order of a licensed health care professional only.
	Temperature limit The condition of -20°C or 60°C back to use should stand for 3 hours at room temperature.
	Non-sterile
	Type BF applied part

IP23	Ingress Protection / 2: Protected against a solid object greater than 12.5mm such as finger / 3: Protected against sprays of water up to 60 degrees from the vertical. Limited ingress permitted for three minutes.
	Date of Manufacture
	Humidity limitation
MR	MR Unsafe: must not be used in an MRI environment.
QR	QR code (quick-response code)
	Do not reuse
	Do not use if package is damaged
	warning
FC	Federal Communications Commission (FCC)
	National Communications Commission (NCC)

Welcome

This manual will help you get started with monitoring using the Infant Oximeter Module 2nd Gen. of Aulisa-developed software application. The Infant Oximeter Module 2nd Gen. is intended for use with Aulisa-developed software application. 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 intended to replace a caregiver.

Warnings

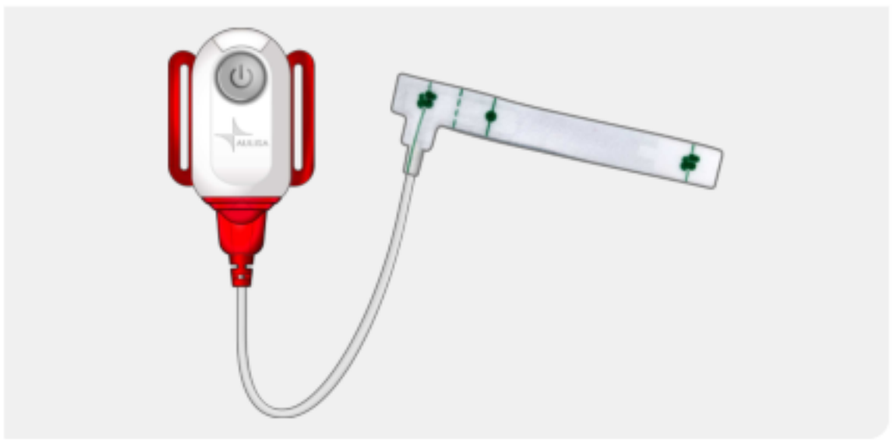
1. This device is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
2. The oximeter is calibrated in the factory before sale, there is no need to calibrate it during use.
3. This device readings may be affected by the use of an electrosurgical unit.
4. Anemia may affect the accuracy of the measurement.
5. As with all medical equipment, carefully route all cables to reduce the possibility of entanglement, strangulation or injury to the patient.
6. Be careful with small parts that can be removed from the device and swallowed. They are hazardous to children.
7. Excessive pressure to the sensor application site for prolonged periods may cause damage to the skin beneath the sensor.
8. Do not use this device if it is damaged in any way. Discontinue using it immediately and replace with a new one.
9. Do not use in or around water or any other liquid when AC power adaptor is used.
10. Only use this device with charging adaptors provided by Aulisa.
11. 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.
12. Use this device only when it is within the specified distances, approximately 32.8 feet (10 meters) spherical radius to the Aulisa-developed software application. Moving outside this range may cause missing, lost, and/or inaccurate data.
13. 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.
14. This device is not a substitution for physical supervision.
15. Always refer to Instructions For Use for full warnings and instructions.
16. Failure to follow instructions and warnings may result in serious injury or death.
17. Operator needs to verify the compatibility of the monitor, probe, and cable before use, otherwise patient injury can result and incompatible components can result in degraded performance.
18. A functional tester cannot be used to assess the accuracy of this device. This device does not require calibration.
19. 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.

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. If this device fails to respond as described, discontinue use until the situation is corrected by qualified personnel.
3. Cardiogreen and other intravascular dyes may affect the accuracy of SpO_2 measurements.
4. This device might not work on cold extremities due to reduced circulation. Warm or rub the foot to increase circulation or reposition the sensor.
5. This device might misinterpret motion as good pulse quality. Minimize motion of the monitored site.
6. Excessive ambient light may affect the accuracy of the measurement.
7. 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.
8. Do not place liquids on top of the device.
9. Do not immerse the device or any of the components in any liquids.
10. Do not use caustic or abrasive cleaning agents on the device.
11. Do not gas sterilize or autoclave this device.
12. Batteries might leak or explode if used or disposed of improperly.
13. Follow local governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
14. Do not subject the device to extreme hot or cold temperatures, humidity, or direct sunlight.
15. Do not fasten this device too tightly around the foot. Inaccurate readings and discomfort could result.
16. System connection failure (Bluetooth connection) may result in loss of data transfer.
17. This equipment complies with International Standard EN 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.
18. Some nail polish colors or artificial nails can reduce light transmission and affect SpO_2 accuracy.
19. Tattooed skin can impact light transmission and affect SpO_2 accuracy.
20. Only connected the sensor module to a trusted device installed with Aulisa-developed software application.
21. Only use official app stores to download the Aulisa-developed software application. If in doubt, contact Aulisa by going online at www.aulisa.com.

Device Overview

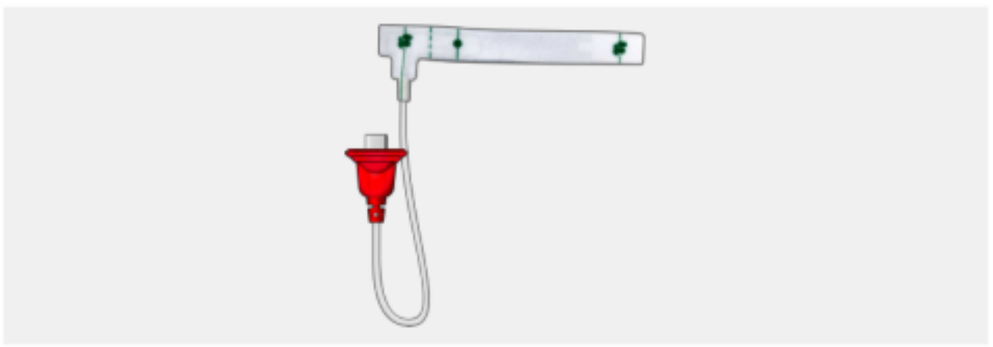
GA-OM0018



Device Components

Infant Oximeter Box

Infant Reusable Transmissive Oximeter Sensor



Charging Adaptor

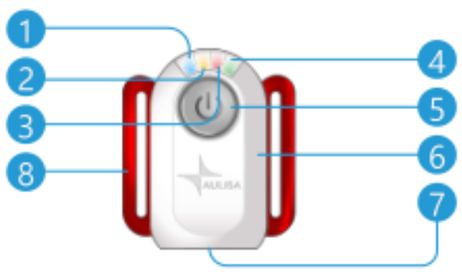
Leg Band

Device Description

The Infant Oximeter Module 2nd Gen. is a component of the Aulisa-developed software application. The Infant Oximeter Module 2nd Gen. is comprised of the Infant Oximeter Box and a sensor i.e.Infant Transmissive Oximeter Sensor.
The device is worn on the thigh to continuously record SpO_2 and pulse rate of infant patients. The vital sign data gets transmitted to the Aulisa-developed software application via Bluetooth technology. The data provided by Infant Oximeter Module 2nd Gen. is intended to aid caregivers in making diagnoses by providing additional information to standard of care patient monitors.

Infant Oximeter Box

The Infant Oximeter Box is secured on the thigh by the Aulisa-provided leg band. The Infant Oximeter Box is embedded with a Bluetooth transmitter and a sensor chip along with electronics for vital sign measuring and analyzing. The Infant Oximeter Box must be used within 32.8 feet (10 meters) spherical radius to the Aulisa-developed software application.



1 Charging LED
2 Medium-Priority Alarm LED
3 High -Priority Alarm
4 Power On/Off LED
5 Power On/Off Button
6 Oximeter Box
7 Charging Port / Senser Port
8 Holder

Light Signal

Color \ State	Blinking Status	Light On Status	Light Off Status
Blue	NA	Charging	Fully charged
Orange	NA	Foot off、Low battery	NA
Red	NA	Abnormal signal values	NA
Green	Bluetooth Connecting	Power On	Power Off

Infant Transmissive Oximeter Sensor

The Infant Transmissive Oximeter Sensor is intended to connect to the Infant Oximeter on one end and wrapped around the infant's foot on the other end. (GA-RS0011)

Leg band

The reusable leg band is intended to secure the Infant Oximeter Box on the thigh.

Device Indications for Use

The Aulisa Infant Oximeter Module (2nd Gen.) is indicated for spot-checking and/or continuous monitoring SpO_2 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 the Aulisa Oximeter Module (2nd Gen.) are transmitted to a commercially available mobile device that runs an Aulisa-developed application for display and review.

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. When used with the Infant Transmissive Oximeter Sensor, the device measures SpO_2 and pulse rate based on non-invasive light-emitting diode (LED) transmittance technology.

Device Set Up

Before you begin your monitoring session, unpack the Infant Oximeter Module 2nd Gen. and become familiar with its parts. It is recommended to fully charge the battery of the Infant Oximeter Module 2nd Gen. prior to set up. It takes approximately 40 minutes to fully charge. Refer to "Device Charging" section for detailed instructions.

Step 1： Charge the Infant Oximeter Box

Before first use (around 2 hours). Plug the Type-C end of the charging adaptor into the charging port on the Infant Oximeter Box. The charging LED will turn off when fully charged.

Please Note: The battery will last up to 24 hours after full charge.

Status	LED Color
Charging	Blue
Fully charged	Off

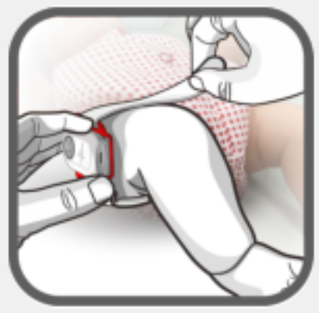
Step 2： This product is intended to be used with Aulisa-developed software application. Refer to the System Interface Quick Start Guide to set up the system connection.

Step 3： Wearing steps

1

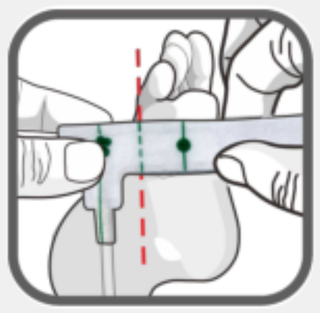
Insert the strap (hair side up) into the bracket hole.

2



Fix the strap on the leg.

3



Align the dotted line symbol ⋮ on the probe with the side bone extending next to the little thumb, and make sure the wire is facing the heel.

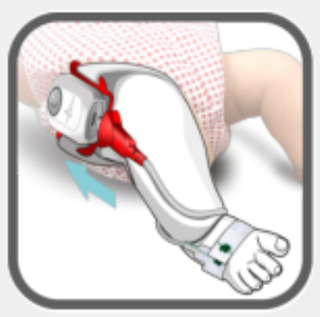
4

Press the Oximeter Sensor position and wrap it properly to fit the sole of the foot.

5

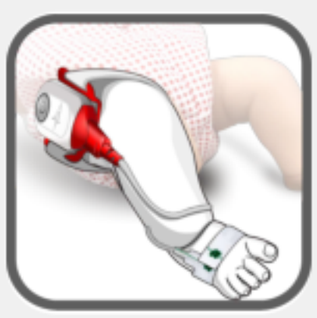
Finish wearing the Oximeter Sensor.

6



Wrap the Oximeter Sensor wire to the main unit behind the thigh, and plug it into the main unit.

7



Wearing is complete! Press the power button to turn on the device.

Step 4： Secure the Infant Oximeter Module 2nd Gen. around the thigh.

NOTE：

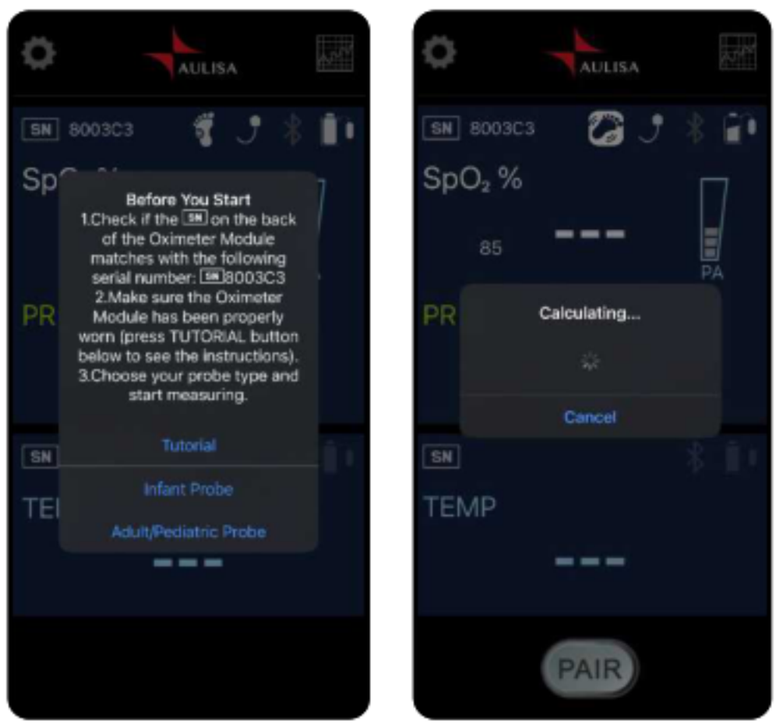
- The Leg Band is suitable for patient's weight < 10Kg or leg circumference ≤ 18 cm.
- The Leg Band can be cut shortened for adjust the length to fit the leg circumference.
- If the Leg Band is too short to be placed on the thigh, you can place the Leg Band on the calf.

Step 5： Press the Power On/Off button to turn on the Infant Oximeter Module 2nd Gen..

NOTE：

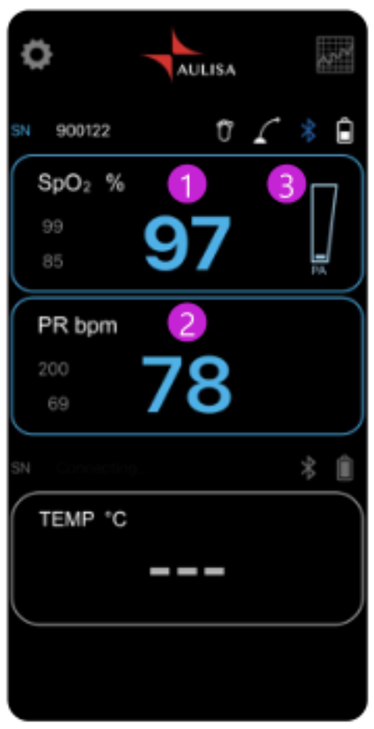
- The power LED will light green when the power is ON.

Step 6： **Connect Infant Oximeter Module 2nd Gen. to the system.**



Select “Infant Probe” and wait for your infant’ vitals to calculate (Please note: Calculating may take a few minutes). If vitals do not successfully calculate please ensure module pairing was completed successfully by repairing your Infant Oximeter Box.

Wait for the wireless connection of the system to be established. Once connected, the vital signs of the Infant Oximeter Module 2nd Gen. status information will appear on the MAIN screen.



1. SpO_2 reading
2. Pulse rate reading
3. Pulse Amplitude indicator

The Pulse Amplitude indicator is used to indicate the signal quality for the vital signs reading, it has the quality level defined in the table below.

PA Level							
PA Value	< 0.1	< 0.3	< 0.5	< 0.7	< 1.0	< 2.0	>= 2.0

NOTE：

- Refer to “Device Pairing” section below for more information.
- The device must be used within 32.8 feet (10 meters) spherical radius to Aulisa-developed software application.
- 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) spherical radius to Aulisa-developed software application.
- The Bluetooth connection status icon will turn blue once the pairing succeeds.
- The power LED on the Sensor 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 2nd Gen..

NOTE :

- Up to two (2) Infant Oximeter Module 2nd Gen. can be stored in the system.

Step 1 : Turn on the Aulisa-developed software application.

Step 2 : In the Setting menu, select “MODULE PAIRING”.

Step 3 : Scan the QR Code or key in the serial number located on the back of the Infant Oximeter Module 2nd Gen..

Step 4 : Press “CONFIRM” if the serial number (SN) displayed matches with the one on the Infant Oximeter Module 2nd Gen..

Step 5 : Assemble the Infant Oximeter Module 2nd Gen. and position on to the body to power on the device.

Step 6 : To confirm that the pairing is successful, ensure that the Bluetooth icon will change to blue .

NOTE :

- Make sure the battery is installed and fully charged before use.
- The device remains paired with the system until the serial number is deleted from the list.
- The device must be placed within 32.8 feet (10 meters) spherical radius to Aulisa-developed software application. If it moves outside the range, the bluetooth disconnected alarm will be triggered.
- The Power LED lights green when the power is ON.

Device Power Off and Removal

The device will be turned off by pressing the Power On/Off button and hold for 3 seconds on the Infant Oximeter Box.

NOTE :

- The power LED goes off when power off.

When removing the device, it is recommended to spray 75% alcohol on the probe to facilitate removal.

Device Charging

The Infant Oximeter Module 2nd Gen. is powered by a rechargeable battery. When the low battery alarm is displayed, the battery is exhausted and needs recharging. Follow the instructions below to recharge the battery.

Step 1： Plug the Type-C end of the charging adaptor into the charging port on the Infant Oximeter Box.

NOTE：

- The Infant Oximeter Module 2nd Gen. works for up to extra 30 minutes in the low power status.
- It takes approximately 40 minutes to fully charge the Infant Oximeter Box.
- The charging LED indicator lights blue during charging and goes off when fully charged.

Step 2： Attach the wall adaptor to a power outl

CAUTION !

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

Alarms and Limits

Alarm Features

NOTE：

- Some indicator lights only function if the device is paired with mobile application.

The Aulisa-developed software applications provides high and medium priority audible and visual alarms. The visual alarm is indicated by the alarm window on the screen. Audio alarms will sound from the device speaker.

High Priority Alarms

High priority alarms are those that require immediate attention to the person being monitored, including SpO_2 and Pulse rate alarms. On the screen, high priority alarms are indicated with rapid blinking vital sign readings in red color and with alarm notification when alarm limits are met or exceeded (see figure below). The alarm notification will be shown on the top of Aulisa-developed software applications.

NOTE :

- Alarm LED indicator on the Aulisa Infant Oximeter Module will blink red along with displays on the screen.

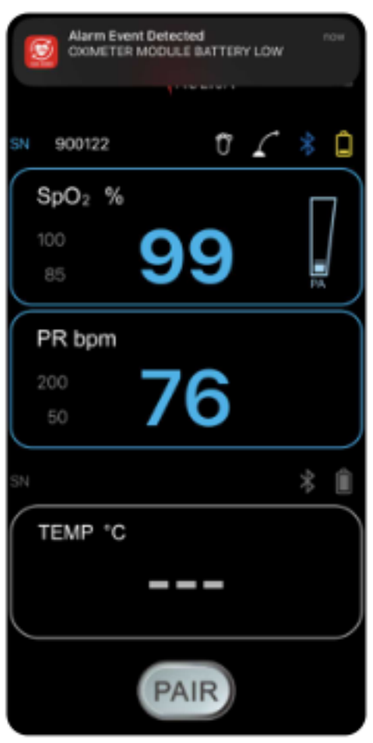
High priority audio alarms are: 3 beeps, short pause, 2 beeps, short pause, 3 beeps, short pause, 2 beeps, and 5-second pause. This sequence repeats until the alarm is cleared or silenced.

Tap on “PAUSE AUDIO” button to pause the alarm audio for 2 minutes. Tap on “AUDIO OFF” button to permanently silence the alarm audio.

See “Alarm Limits” section to learn adjusting the alarm limit.

Medium Priority Alarms

Medium priority alarms are those that signal potential problems with the equipment or other non-life-threatening situations. See the figure below, medium priority alarms are indicated with an alarm notification on Aulisa-developed software applications.



NOTE :

- The following table describes alarm conditions and visual indicators.

Alarm Condition (Medium Priority Alarm)	Visual Indicator
Sensor Probe Detached from Patient	1. Alarm notification on the Aulisa-developed software applications.
Aulisa Infant Oximeter module battery low	
Aulisa Infant Oximeter module data update period exceeds 25 seconds	2. Relevant icon highlighted in yellow on the screen.
Bluetooth disconnected	

Medium priority audio alarms are: 3 beeps and 25-second pause. This sequence repeats until the alarm is cleared or silenced.
Tap on “PAUSE AUDIO” button to pause the alarm audio for 2 minutes. Tap on “AUDIO OFF” button to permanently turn off the alarm audio.
See “Alarm Limits” section to learn adjusting the alarm limit.

Multiple Alarms

When there are high and medium priority alarms triggered simultaneously, the Aulisa-developed software applications will display all the alarm notifications but will only sound the high priority alarm (see figure below). The alarm notification will be shown both of them on the Aulisa-developed software applications.

CAUTION !

- Silencing alarms does not mean the situation has been resolved.
- Tap on Off "AUDIO OFF" button to permanently silence the alarm audio until the module is reconnected.
- A potential hazard exists if different alarm presets are used for the same or similar equipment in any single area.
- Do not plug a headphone into headphone jack of mobile device, as this will significantly reduce the volume of alarm audio.

Alarm Limits

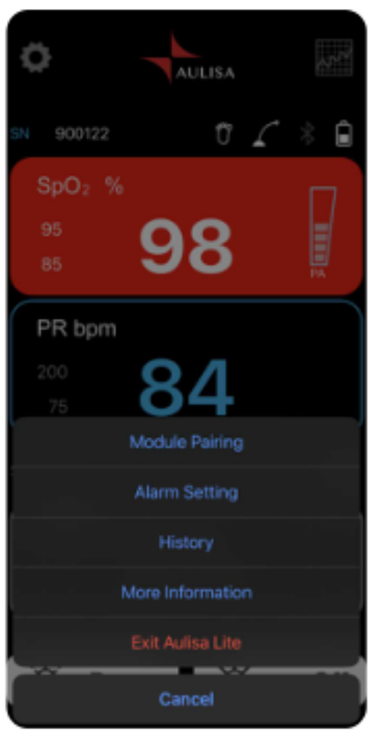
NOTE :

- Alarm Limits only function if the device is paired with mobile application.

Follow the instructions below to review or set alarm limits.

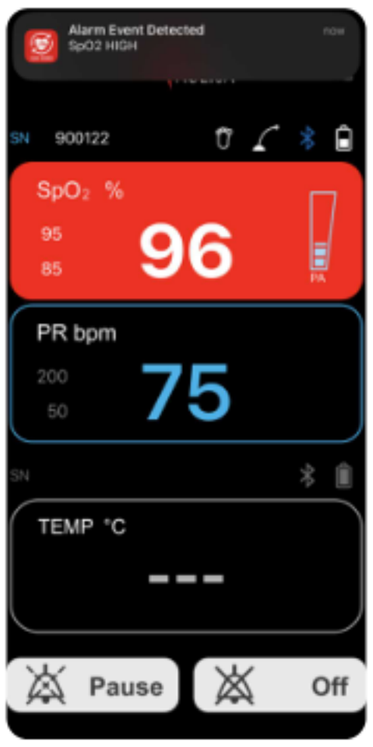
Step 1 : Ensure the Bluetooth connection is established. (See “Device Pairing” section.)

Step 2 : Tap on " " SETTING icon on the MAIN screen, and then tap on “ALARM SETTING”. Select the designated Aulisa Infant Oximeter module.



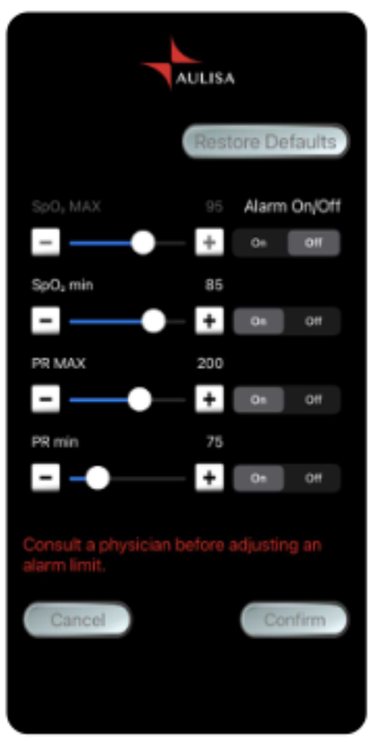
NOTE :

- Alarm limits can be adjusted only when the Aulisa Infant Oximeter module is paired.
- In an alarm event, “ALARM LIMITS” button will appear on the Aulisa-developed software applications after you select "AUDIO PAUSE" button or "AUDIO OFF" button.



Step 3： To turn alarms on or off, tap on “ON/OFF” button. (Turn on the alarm before adjusting the value.)

Step 4： Tap on “ + ” or “– ” buttons or drag the “seekbar” to adjust the values OR tap on “RESTORE DEFAULTS” to restore alarm limits to manufacturer configured values.



NOTE :

- SpO_2/PR min alarm limits are turned on as default settings.

CAUTION !

- A potential hazard exists if different alarm presets are used for the same or similar equipment in any single area.
- When turned off, the alarms will no longer be displayed or sound. Follow the instructions above to turn on the alarms.
- Consult a physician about the appropriate alarm limits for the user before adjusting them.

NOTE :

- The following table describes the default settings, adjustment ranges, and intervals.

High Priority Alarm	Factory Default	Adjustment Options	Adjustment Interval
SpO_2 Upper Alarm Limit	Off, 95 %	85 to 100 %	1 % SpO_2
SpO_2 Lower Alarm Limit	On, 85 %	50 to 95 %	1 % SpO_2
Pulse Rate Upper Alarm Limit	On, 200 bpm	75-275 bpm	1 bpm
Pulse Rate Lower Alarm Limit	On, 75 bpm	30-110 bpm	1 bpm

Step 5： Tap on “CONFIRM” to save the alarm limits.

CAUTION !

- The new alarm limits do not go into effect until the “CONFIRM” button is tapped.

Care and Maintenance

The advanced digital circuitry within the Infant Oximeter Module 2nd Gen. requires no calibration or periodic maintenance. Field service or repair of this system is not possible. Do not attempt to open the case other than the battery cover for that will cause damage and void the warranty. If the Infant Oximeter Module 2nd Gen. is not functioning properly, see “Troubleshooting” section for more information.
The expected service life of the Infant Oximeter Module 2nd Gen. is 1.5 years.

Cleaning and Disinfection

Lightly wipe the surface of the Infant Oximeter Box and Infant Reusable Oximeter Sensor if applicable with a soft cloth dampened with rubbing alcohol for cleaning. Allow the device to dry thoroughly. Visual inspection is necessary at the end of cleaning. Repeat the previous steps to remove visible residual soil on the device. Do not use a visibly soiled device again.

Clean surface of Infant Oximeter Box and clean and disinfect the Infant Reusable Oximeter Sensor before each use. For surface cleaning and disinfection, follow the recommended actions below.

Surface cleaning: Clean the surface of the Infant Oximeter Box and Infant Reusable Oximeter Sensor with a soft cloth dampened with rubbing alcohol. Lightly wipe the surface of the device.

Disinfection: Use a soft cloth saturated with a solution of 10% chlorine bleach in tap water, lightly wiping the surface of the Infant Reusable Oximeter Sensor.

Reuse Life

The Infant Oximeter Box and the Infant Reusable Oximeter Sensor are 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.
- Do not immerse the device in liquid and do not use caustic or abrasive cleaning agents on the device.

Troubleshooting

Problem	Possible Solution
Cannot power on the Infant Oximeter Module	1. Make sure the Infant Oximeter Module is kept away from any magnetic devices while using. 2. Fully charge the Infant Oximeter Module until the LED blue light 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 Infant Oximeter Sensor(s) and keep it motionless for at least 10 seconds. 2. Position the Infant Oximeter Sensor(s)) to a different site. 3. Make sure the Infant Oximeter Module 2nd Gen. is attached to the leg and foot securely. 4. Check the accessories for any visible signs of deterioration. 5. Warm the foot by rubbing or covering with a sock. 6. Allow the foot to rest comfortably without squeezing or pressing the sensor probe on a hard surface. 7. Make sure the Infant Oximeter Module 2nd Gen. is within 32.8 feet (10 meters) spherical radius to the Aulisa-developed software application. 8. Reduce or eliminate any interference. Make sure the Infant Oximeter Module 2nd Gen. is NOT placed on the same leg being used for other medical therapies or diagnostics (e.g. blood pressure cuff). 9. Check the Aulisa-developed software application for any alarms or error messages. 10. Check if the Infant Oximeter Module 2nd Gen. is in low power. 11. Verify the system connection with the Aulisa-developed software application. 12. Make sure that the Infant Oximeter Module 2nd Gen. 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. Position the Infant Oximeter Sensor(s) to a different site. 3. Make sure the Infant Oximeter Module 2nd Gen. is attached to the leg and foot securely. 4. Check the sensor probe for any visible signs of deterioration. 5. Reduce motion of person being monitored.
"---" appears on the vital sign displays	1. Make sure the Infant Oximeter Module 2nd Gen. is attached to the leg and foot securely. 2. Reposition the Infant Oximeter Sensor(s) and keep it motionless for at least 10 seconds. 3. Position the Infant Oximeter Sensor(s) to a different site. 4. Make sure the Infant Oximeter Module 2nd Gen. is within 32.8 feet (10 meters) spherical radius to the Aulisa-developed software application. 5. Verify the system connection with the Aulisa-developed software application.
Data update period has exceeded the limit	1. Reposition the Infant Oximeter Sensor(s) and keep it motionless for at least 10 seconds. 2. Position the Infant Oximeter Sensor(s) to a different site.
Cannot establish system connection	1. Make sure the device is within 32.8 feet (10 meters) to the Aulisa-developed software application. 2. Power off the Aulisa-developed software application and retry.

For additional troubleshooting, refer to the 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 other than the battery cover 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 adult 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.

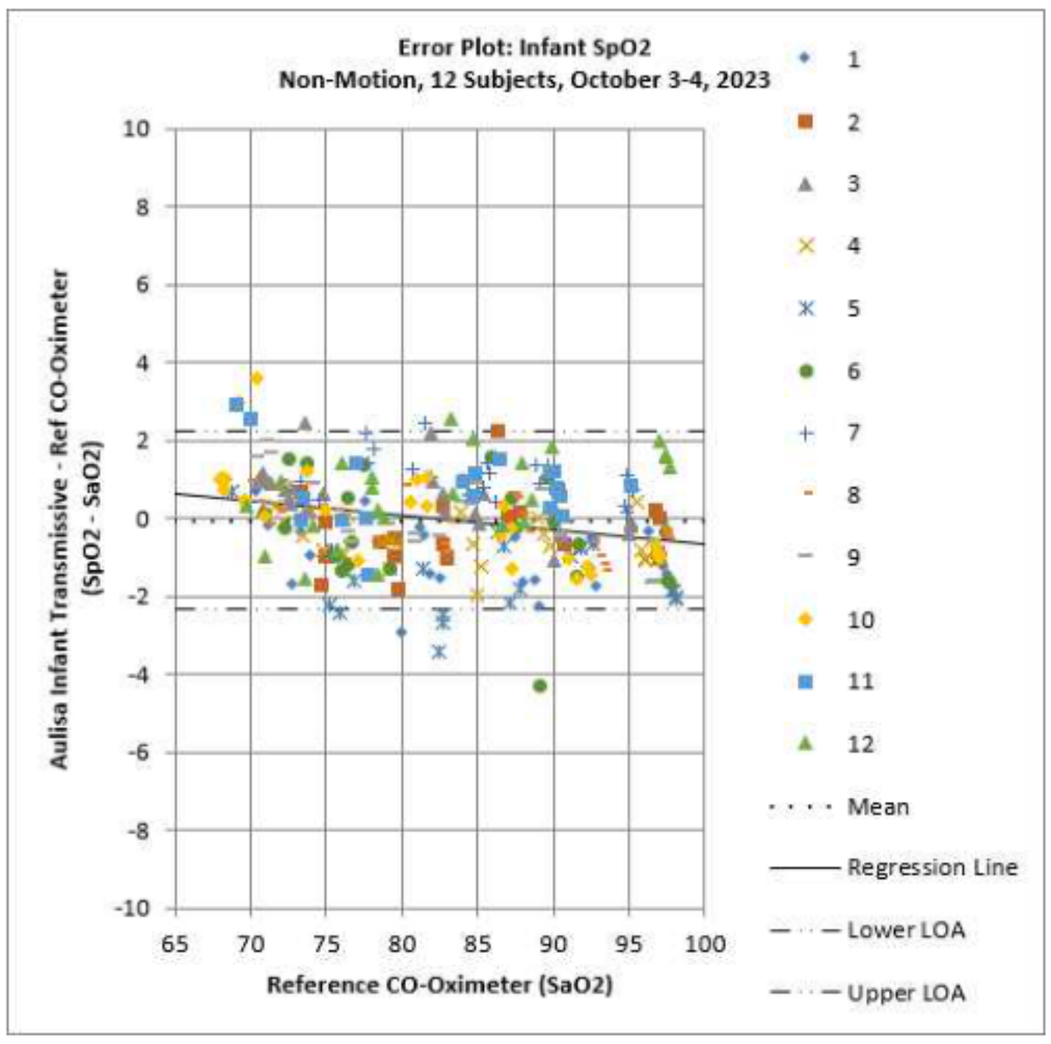
NOTE :

- 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.

Arms from the Clinical Studies

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.

Infant Reusable Transmissive Oximeter Sensor



Individual Participant Demographics

Participant ID#	Gender	Age	Weight	Height	BMI	Race	Ethnicity	Fitzpatrick	Skin Tone
S01	M	26	180	69	26.6	Black/African-American	Non-Hispanic	6	Very Dark
S02	F	22	155	68	23.6	Black/African-American	Non-Hispanic	5	Dark
S03	F	36	150	61	28.3	White	Non-Hispanic	3	Medium
S04	F	25	150	67	23.5	White	Non-Hispanic	2	Medium Light
S05	F	43	171	65	28.5	White	Non-Hispanic	3	Medium
S06	F	21	127	66	20.5	Black/African-American	Non-Hispanic	6	Very Dark
S07	M	42	210	70	30.1	White	Non-Hispanic	1	Light
S08	F	31	110	62	20.1	White	Non-Hispanic	2	Medium Light
S09	M	19	145	73	19.1	White	Non-Hispanic	1	Light
S10	M	24	180	71	25.1	White	Non-Hispanic	3	Medium
S11	M	46	135	69	19.9	White	Non-Hispanic	3	Medium
S12	M	20	178	73	23.5	White	Non-Hispanic	2	Medium Light

Comparison to Reference CO-Oximetry Functional Oxygen Saturation

Comparison to Reference CO-Oximetry (Functional Oxygen Saturation)					
Aulisa Infant Transmissive Oximeter Sensor	70-100%	90-100%	80-90%	70-80%	ARMS Spec of 3.0 for range of 70-100%
# pts	292	81	94	106	PASS
Bias	0.0	-0.5	0.1	0.1	
ARMS	1.2	1.0	1.2	1.1	

Comparison to Reference ECG Heart Rate

Aulisa Infant Transmissive Oximeter Sensor	54—108 bpm	ARMS Spec of 3.0
# pts	292	PASS
Bias	0.1	
ARMS	2.4	

Pulse Rate Accuracy

Pulse rate accuracy has been functionally tested against an electronic pulse simulator at 30, 50, 80, 100, 150, 200, 250, and 290 bpm, with combinations of pulse amplitude settings of 0.5, 1, 3, 5, 7, 10, 13, 15, 17 and 20, and SpO_2 settings of 100%, 90%, 80%, 70%, 60%, 50%, 40%, 30%, 20%, 10%, and 1%. All 880 combinations of testing points (=8 x 10 x 11) of pulse rate passed the ± 3% 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**

*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) 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.
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.
Radiated RF IEC 61000-4-3	10 V 80MHz to 2.7 GHz	10 V 80MHz to 2.7 GHz	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: 
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 the device. b. Over the frequency range 150 kHz to 80 MHz, field strengths 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 9measures:
(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

This device contains transmitters and receivers which emit Radio Frequency (RF) energy. The device is designed to comply with the limits for exposure to RF energy set by the Federal Communications Commission (FCC) of the United States, Industry Canada (IC) of Canada, and the regulating entities of other countries.

To comply with the FCC RF exposure compliance requirements, no change to the antenna or the device is permitted. Any change to the antenna or the device could result in the device exceeding the RF exposure requirements and void user’s authority to operate the device.

The FCC requires the user to be notified that any changes or modifications to this device that are not expressly appoved by Taiwan Aulisa [1]edical 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.

Specifications

Dimensions	49.98mm x 43.35mm x 19.45mm
Weight	23.1 g
Ingress Protection	IP23
Display range	
Blood Oxygen Saturation (SpO_2)	1% to 100%
Pulse Rate	30 to 290 bpm
Accuracy	
Blood Oxygen Saturation (SpO_2)	70% to 100% ±3 digits
Pulse Rate	±3 digits
Update Response Time	Every second
Measurement Wavelengths and Output Power	
Red	660 nanometers
Infrared	905 nanometers (GA-OM0018)
Output Power	5.5dBm
Battery Type	3.7V
Battery Life	24 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	BLE 5.2
Antenna Info	Chip, 2.5dBi
Security	AES-128
Range	32.8 feet (10 meters) spherical radius
Direction	Bi-direction
Data rate	Up to 1M Bps

Classifications per IEC 60601- 1	
Type of Protection	MOPP Class II (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 Plus
Infant Reusable Transmissive Oximeter Sensor	GA-RS0011
Leg Band	GA-LB0003
Charging Adaptor	GA-AD0001

For more information about the Aulisa-developed software application, refer to the system Instructions for Use.

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.