Aulisa Guardian Angel™ Rx GA1001
Digital Vital Sign Monitoring System
Instructions For Use

Version: 1.0

CAUTION! Read this entire manual carefully before using Aulisa GA1001 Digital Vital Sign Monitoring System.

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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Table of Contents

Guide to Symbols

Symbol	Description
	Refer to instruction manual
	Type BF-Applied Part (patient isolation from electrical shock)
	Indicates separate collection 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

	Non-sterile
IP22	Classification for water ingress and particulate matter

Precautions for Use

Contraindications

1. Do not use any part of this system in an MRI environment.
2. Explosion Hazard: Do not use this system 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 system 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 a pulse oximeter probe or a pulse oximeter monitor. Pulse oximeters do not require calibration.
3. Oximeter readings may be affected by the use of an electrosurgical unit.
4. As with all medical equipment, carefully route all cables to reduce the possibility of entanglement, strangulation or injury to the patient.
5. Be careful with small parts that can be removed from the device and swallowed, such as port covers. They are hazardous to children.
6. Excessive pressure to the sensor application site for prolonged periods may cause damage to the skin beneath the sensor.
7. Do not use a damaged sensor. If the sensor is damaged in any way, discontinue use immediately and replace the sensor.
8. Do not use in or around water or any other liquid when AC power adaptor is used.
9. Only use Aulisa GA1001 Digital Vital Sign Monitoring System with Charging Adaptors provided by Aulisa.
10. Aulisa GA1001 Digital Vital Sign Monitoring System is designed to determine functional oxygen saturation, the percentage of arterial oxygen saturation of functional hemoglobin (SpO_2). Significant levels of dysfunctional hemoglobin, such as methemoglobin, might affect the accuracy of the measurement.
11. Anemia may affect the accuracy of the measurement.
12. Use Aulisa GA1001 Digital Vital Sign Monitoring System only when the components are installed within the specified distances from the monitored patient – approximately 10 meters (32.8 feet) spherical radius from the Infant Oximeter Module to the Display Unit. 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 product is not a substitution for physician supervision.
15. Always refer to Instructions For Use for full warnings and instructions.

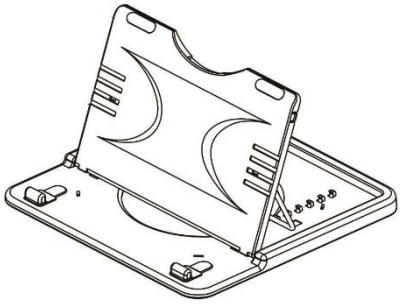
16. Failure to follow instructions and warnings may result in serious injury or death.

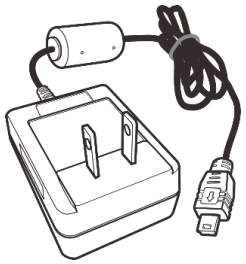
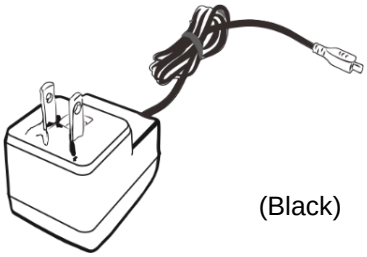
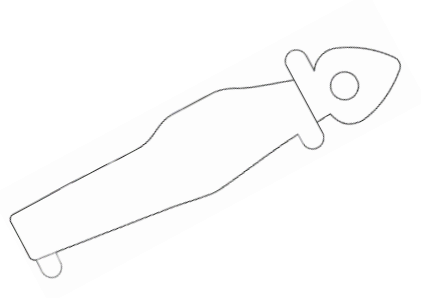
Cautions

1. 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, homecare 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 the system and must be kept at least 2 meters (6.5 feet) away from the system.
3. If Aulisa GA1001 Digital Vital Sign Monitoring System 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. The sensor might not work on cold extremities due to reduced circulation. Warm or rub the foot to increase circulation or reposition the sensor.
6. Aulisa GA1001 Digital Vital Sign Monitoring System 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 10 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to sensors 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 pulse oximetry system.
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 system to extreme hot or cold temperatures, humidity, or direct sunlight.
16. Do not fasten the Infant Oximeter Module too tightly around the patient's foot. Inaccurate readings and patient discomfort could result.

Using Aulisa GA1001 Digital Vital Sign Monitoring System

This chapter describes how to use Aulisa GA1001 Digital Vital Sign Monitoring System (hereinafter referred to as Aulisa GA1001 system). The system includes the following components and accessories:

Infant Oximeter Module	Wireless Charging Case- Infant Oximeter Module
	
Display Unit	Stand- Display Unit
	
Charging Adaptor- Wireless Charging Case	Charging Adaptor- Display Unit

 (White)	 (Black)
Adhesive Patch- Infant Oximeter Module	
	

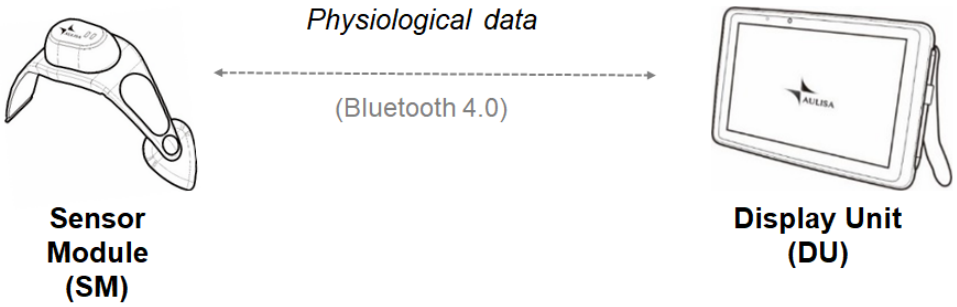
Intended Use

The Guardian Angel Rx GA1001 Digital Vital Sign Monitoring System is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. It is indicated for spot-checking and/or continuous monitoring of pediatrics and infants during non-motion and under well-perfused conditions. The intended environments of use are hospitals, medical facilities, home care, and subacute environments. This system is a reusable device.

Principle of Operation

Aulisa GA1001 Digital Vital Sign Monitoring System 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. It can be operated by the caregiver or by the patient.

System Overview

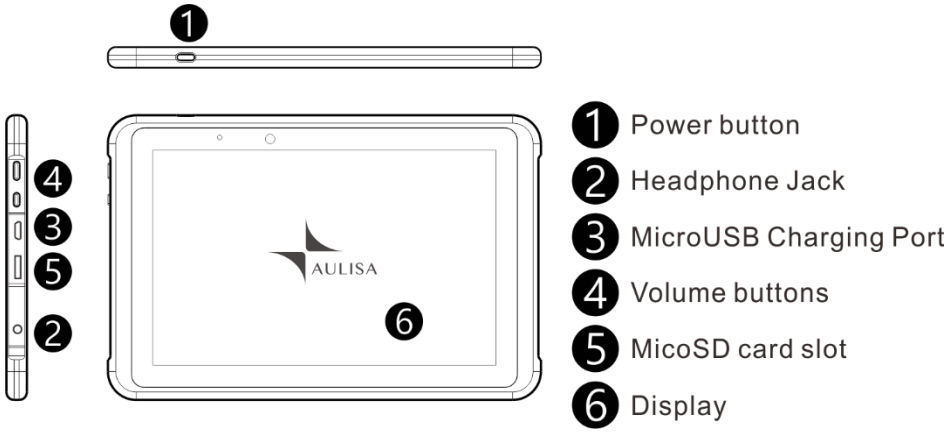


Device Overview

Display Unit

The Display Unit features a 10.1” HD LCD multi- touch display with Bluetooth technology. The Display Unit displays real-time vital signs measured by the Infant Oximeter Module.

The Display Unit will display informational text messages, alarm text messages, and beep audibly upon an alarm condition trigger event.



NOTE: It is recommended that the Display Unit be placed on the stand provided.

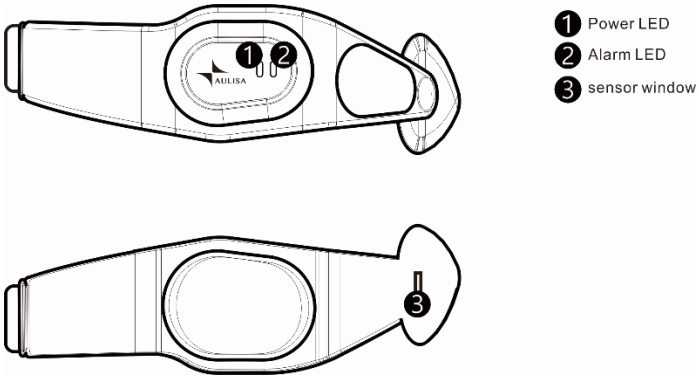
NOTE: Only use fingers or the stylus pen provided to operate keys on the touch screen.

NOTE: Close the cover of charging port when the charging adaptor is not in use.

Infant Oximeter Module

The Infant Oximeter Module includes a Bluetooth transmitter and a sensor, which is worn by the patient for vital sign monitoring. It features sensors and electronics for vital sign measuring and analyzing.

The Infant Oximeter Module must be used within 10 meters (32.8 feet) from the Display Unit.



Displays, Indicators, and Controls

This section describes the displays, indicators, and controls for Aulisa GA1001 System.

Display Icons and Indicators

SpO_2 %

Blood Oxygen
This icon identifies the window showing the functional blood oxygen saturation in percent.

PR bpm

Pulse Rate
This icon identifies the window showing the pulse rate in bpm.

PA

Pulse Amplitude
This icon identifies the window showing the pulse amplitude.

No data
When the vital signs cannot be measured, the Display Unit shows dashes (- - -) in each of the vital sign windows.

Inadequate data
When the vital sign values are inadequate, the Display Unit shows (?) beside the value.

Bluetooth Connection Status
This icon displays whether the Infant Oximeter Module and the Display Unit are connected via Bluetooth. It will turn blue once the Infant Oximeter Module is paired with Display Unit.

Measurement Site Status
This icon displays whether the sensor is attached to the patient's foot. A system alarm will be displayed on the Display Unit if no contact is detected between the sensor and the patient's foot.

Motion Indicator
This animated icon detects excessive motion of the measurement site.

Battery Level of the Infant Oximeter Module
These icons signify the battery level at Full, Medium, or Low. A medium priority system alarm will be displayed on the Display Unit when the Infant Oximeter Module battery is low.

Battery Level of Display Unit
These icons signify the battery level of the Display Unit. A medium priority system alarm will be displayed on the Display Unit when the Display Unit battery is low.

Alarm Indicator
This icon identifies an alarm condition exists.
!!! represents high priority and
!! represents medium priority

Alarm Off
This icon indicates that the alarm is turned off for the corresponding physiological condition.

Audio Paused
This icon indicates that the alarm audio is silenced for 2 minutes.

Audio Off
This icon indicates that the alarm audio is silenced permanently.

Software Control Buttons

ADD PROFILE

Create Patient Profile
Tap on this button on the MAIN screen to add a patient profile, including name, weight, gender, date of birth, and location.

EDIT PROFILE

Edit Profile
This button replaces “ADD PROFILE” button when a patient profile already exits. Tap on the button to edit the existing patient profile.

ALARM LIMITS

Set Alarm Limits
Tap on this button on the MAIN screen to adjust the alarm limits for each vital sign. (See “Alarm and Limits” section on page 19 for more information on adjusting the alarm limits.)

NOTE: The button is operable only when wireless connection is established.

Device Pairing
This button appears on the top right corner of the MAIN screen when the system is disconnected. Tap on the button to force the system to pair.

NOTE: The Infant Oximeter Module must be placed within 10 meters (32.8 feet) from the Display Unit.

System Settings
Tap on this button on the top right corner of the MAIN screen to access the settings menu of the system.

Return to Previous Screen
Tap on this button on the top right corner of the MAIN screen to return to the previous page.

Set Timezone
In the settings menu, tap on this button to set the local time and date.

Sleep Mode
Tap on this button on the top left corner of the MAIN screen to let the Display Unit enter sleep mode. To wake up the Display Unit, tap on the blank screen and use finger to swipe to the right.

Set Display Brightness
In the settings menu, tap on this button to set the brightness of the display.

Restore Default Alarm
In the settings menu, tap on this button to restore alarm limits to manufacture-configured values.

Scan QR Code
In the settings menu, tap on this button and scan the barcode on the back of the Infant Oximeter Module to manually pair the desired Infant Oximeter Module to the Display Unit. (See “Device Pairing” on page 16 for more information.)

Choose Theme
In the settings menu, tap on this button to choose the desired theme.

Infant Oximeter Module Tutorial
In the settings menu, tap on this button to open the Infant Oximeter Module Tutorial.

Pause Alarm Audio
This button appears on the MAIN screen when an alarm is triggered. Tap on the button to temporarily silence the alarm audio of the current triggering alarm event for 2 minutes.

Turn Off Alarm Audio
The button appears on the MAIN screen when an alarm is triggered. Tap on the button to permanently silence the alarm audio of the current triggering alarm event.

Setting up Aulisa GA1001 System

Use the following procedure to set up the Aulisa GA1001 System:

It is recommended to charge the Infant Oximeter Module fully prior to setting up Aulisa GA1001 System as it takes around 3 hours to fully charge. (See “Powering and Charging” section on page 27 for more information.)

1. Turn on the Infant Oximeter Module by removing it from the wireless charging case.

NOTE: The Infant Oximeter Module will turn itself on automatically when The wireless charging case is opened.

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

2. Connect the GA-CD0002 Charging Adaptor- Display Unit to the Display Unit and a power outlet.

3. Press and hold the power On/Off button for at least three (3) seconds to turn on the Display Unit.

CAUTION! For long term monitoring (over 3 hours of continuous use), the Display Unit must be connected to the charging adaptor.

CAUTION! Do not plug adaptor into a switched outlet to prevent accidental switching power off.

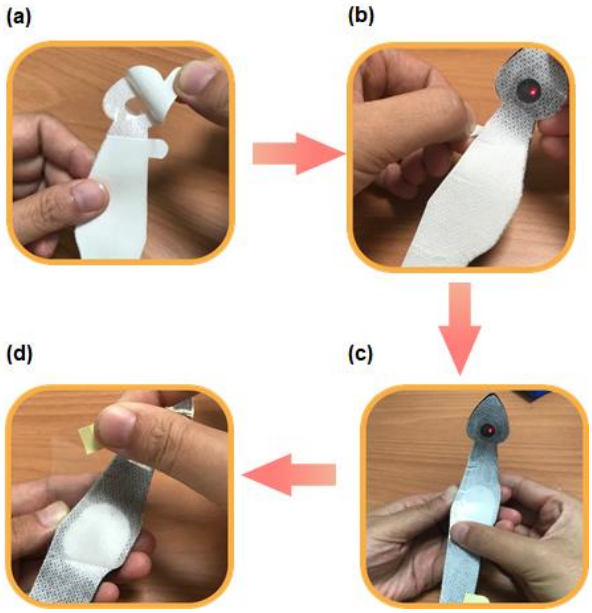
4. Select the correct timezone. The MAIN screen will show up after completion.

5. Wait for the wireless connection between the Infant Oximeter Module and the Display Unit to be established. (See “Device Pairing” section on page 16 for more information.)

NOTE: The Bluetooth connection status icon will turn blue once the Infant Oximeter Module is paired with the Display Unit.

6. Verify System Operation. (See “Verifying System Operation” section on page 17 for more information.)

7. Attach the adhesive patch onto the back of the Infant Oximeter Module following the instructions below.



a. Remove the top paper liner of the adhesive patch
b. Attach the top of the adhesive patch onto the back of the Infant Oximeter Module

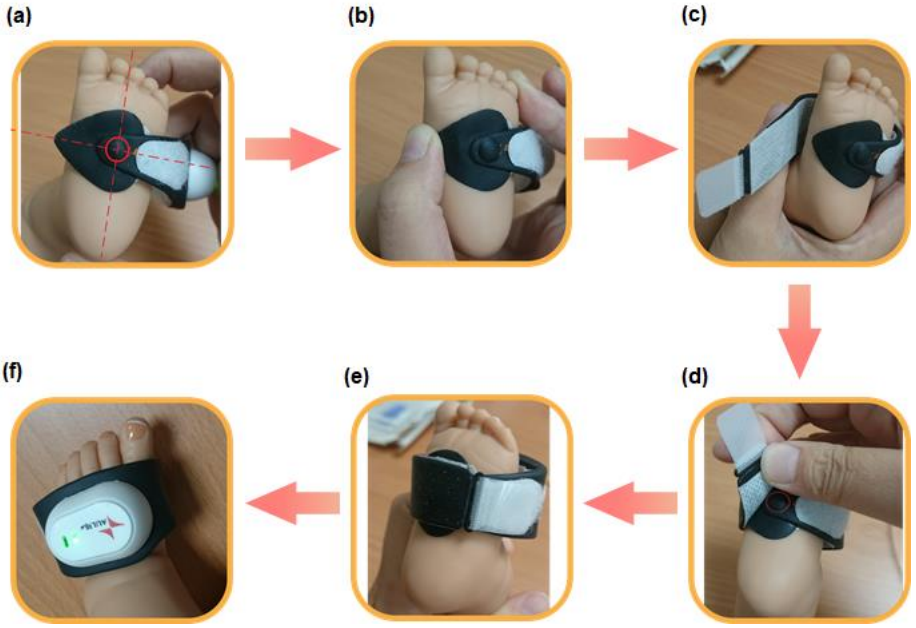
IMPORTANT! ***The clear window on the Infant Oximeter Module Adhesive Patch must align with the sensor probe of the Infant Oximeter Module.***

Remove the bottom paper liner of the adhesive patch

c. Attach the bottom of the adhesive patch onto the back of the Infant Oximeter Module, pressing down to smooth out the surface so no air bubbles remain
d. Remove the plastic liner of the adhesive patch

NOTE: Infant Oximeter Module Adhesive Patches are disposable and for
single use only.

8. Attach the Infant Oximeter Module (SM) to the patient's foot following the instructions below.



a. Align the sensor probe on the center of the baby's foot.
b. Press and hold the end of the strap until it has adhered to the skin.
c. Gently wrap the strap around the baby's foot.
d. Slightly fasten the strap.
e. Stick the Velcro ends together.
f. All done! Ready to use.

NOTE: The LED indicator will blink green when valid vital sign data is detected.

CAUTION! Do not wrap the Infant Oximeter Module around the foot too tightly as it may affect blood circulation.

CAUTION! Do not twist, bend or pull the end of the strap with the sensor probe.

CAUTION! Inspect and relocate the sensor application site at least every 10 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to sensors may vary due to medical status or skin condition.

Device Pairing

The Display Unit will automatically scan and connect to the Infant Oximeter Module from the same starter kit. If the connection is not established automatically, press “PAIR” button on the MAIN screen of the Display Unit to force the system to pair.

NOTE: The Bluetooth connection status icon will turn blue once the Display Unit is paired with the Infant Oximeter Module.
NOTE: The Infant Oximeter Module must be placed within 10 meters (32.8 feet) from the Display Unit.

Use the following procedure to switch among Infant Oximeter Modules and establish a connection between the Display Unit and the desired Infant Oximeter Module.

1. Ensure the desired Infant Oximeter Module is turned on.

NOTE: The desired Infant Oximeter Module must be placed within 10 meters (32.8 feet) from the Display Unit.
NOTE: The power LED lights green when the power is ON.

2. In the settings menu, select “Sensor Pairing”.

3. Scan the QR Code located on the back of the desired Infant Oximeter Module.

4. Press “CONFIRM” if the serial number (SN) displayed matches with the SN on the back of the desired Infant Oximeter Module.

5. To confirm that the process was successful, ensure that the Bluetooth connection status icon on the MAIN screen of the Display Unit is lit blue.

NOTE: After the Display Unit is paired to a Infant Oximeter Module, it will remain paired until the above process is repeated.

Verifying System Operation

Use the following procedure to verify that the alarm system is working properly.

1. Ensure the Infant Oximeter Module and Display Unit are both turned on.

2. Ensure there is a connection established between the Infant Oximeter Module and Display Unit. (See “Device Pairing” section on page 16 for more information.)

3. Place the Infant Oximeter Module on a flat surface.

4. Verify that an alarm message is displayed and that an alarm audio is generated. (See “Troubleshooting” section on page 31 if an alarm message and audio signal is not generated.)

5. Press on the “PAUSE AUDIO” to temporarily silence for 2 minutes.

6. After the alarm signal is regenerated, press on the “AUDIO OFF” to silence permanently the alarm signal.

   NOTE: Alarm systems should be checked before use.

Use the procedure below to monitor the readings (SpO_2, pulse rate, pulse amplitude) to verify that the device is functioning properly.

1. Set up Aulisa GA1001 system according to instructions above. (See “Setting up Aulisa GA1001 system” section on page 13 for more information.)

2. Ensure the Infant Oximeter Module is securely attached to the foot.

3. Verify the status indicator on the Infant Oximeter Module is blinking green and that the Bluetooth connection status icon on the Display Unit is blue.

4. Verify that a SpO_2 reading is displayed, that a pulse rate value appears, and that a PA reading is displayed.

Shutting off the System

Use the procedure below to shut down the Display Unit and the Infant Oximeter Module.

Display Unit

1. Press the power On/ Off button for at least one (1) second. (A display message will appear.)
2. Choose “Power off” on the display message to turn off the Display Unit.

NOTE: The Display Unit can also be put to sleep by pressing the SLEEP button on the top left corner of the MAIN screen.

Infant Oximeter Module

Placing the Infant Oximeter Module inside the wireless charging case and closing the cover will automatically turn the power off.

NOTE: When the power is turned off, the power LED lit green will turn off.

NOTE: The Infant Oximeter Module is automatically activated when the wireless charging case is opened.

NOTE: Charge the Infant Oximeter Module when it is not in use.

Alarms and Limits

This chapter describes alarms and limits for Aulisa GA1001 System.

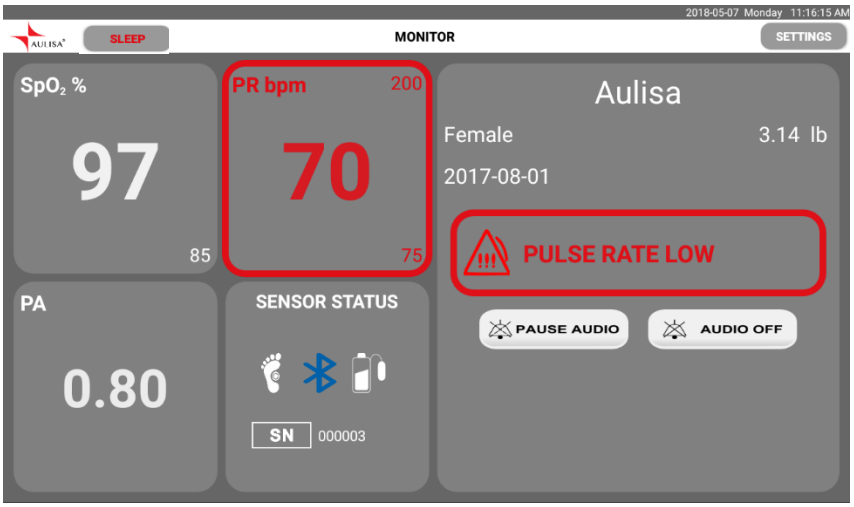
Alarms

The Display Unit provides high and medium priority audible and visual alarms.

High Priority Alarms

High priority alarms are those that require immediate attention to the patient. They include SpO_2 and pulse rate alarms. On the Display Unit, high priority alarms are indicated with rapid blinking vital sign readings in red color and with alarm text message when alarm limits are met or exceeded.

NOTE: Alarm LED indicator on the Infant Oximeter Module will blink red along with displays on the Display Unit.



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.

Alarm limits may be adjusted by pressing ‘‘ALARM LIMITS’’ button after silencing the alarms. (See “Adjusting Alarm Limits” section on page 23 for more information.)

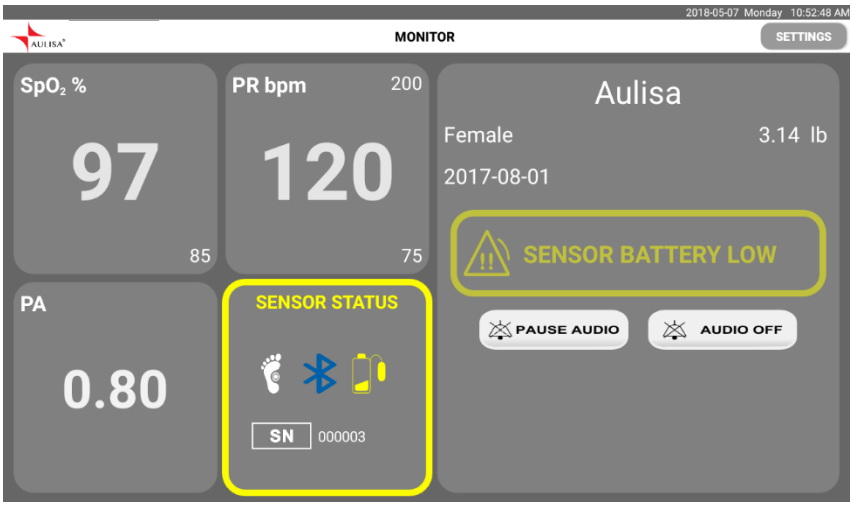
Medium Priority Alarms

Medium priority alarms are those that signal potential problems with the equipment or other non-life-threatening situations. On the Display Unit, medium priority alarms are indicated with slow blinking yellow displays and with alarm text message.

NOTE: Alarm LED indicator on the Infant Oximeter Module will blink red along with displays on the Display Unit.

The following table describes alarm conditions and visual indicators.

Alarm Condition (Medium Priority Alarm)	Visual Indicator
Sensor Probe Detached from Patient	The Infant Oximeter Module blinks yellow light along with blinking yellow displays and alarm text message on the Display Unit.
Infant Oximeter Module Battery Low	
Data Update Period Exceeds Limit (More Than 25 Seconds)	On the Display Unit, it blinks yellow displays and alarm text message.
Display Unit Battery Low	
Bluetooth Disconnected	
BLE Connection Lost. Reconnecting…	



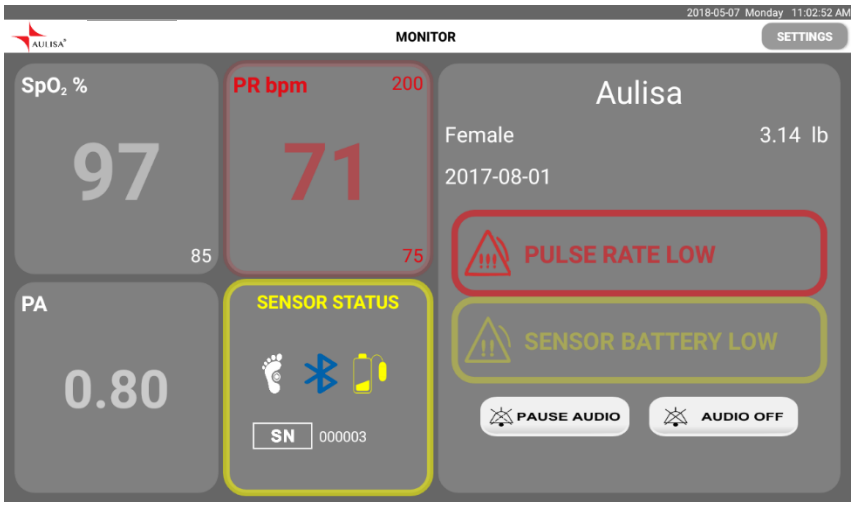
Medium priority audio alarms are: 3 beeps and 25-second pause. This sequence repeats until the alarm is cleared or silenced.

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.

Alarm limits may be adjusted by pressing ‘‘ALARM LIMITS’’ button after silencing the alarms. (See “Adjusting Alarm Limits” section on page 23 for more information.)

Multiple Alarms
When there are high and medium priority alarms triggered simultaneously, the system will display all the alarm text messages but will only sound the high priority alarm.

NOTE: The volume for audio alarms cannot be adjusted.



WARNING! Silencing alarms does not mean the situation has been resolved.

WARNING! Tapping on “AUDIO OFF” will permanently silence the alarm audio of the current triggering alarm event.

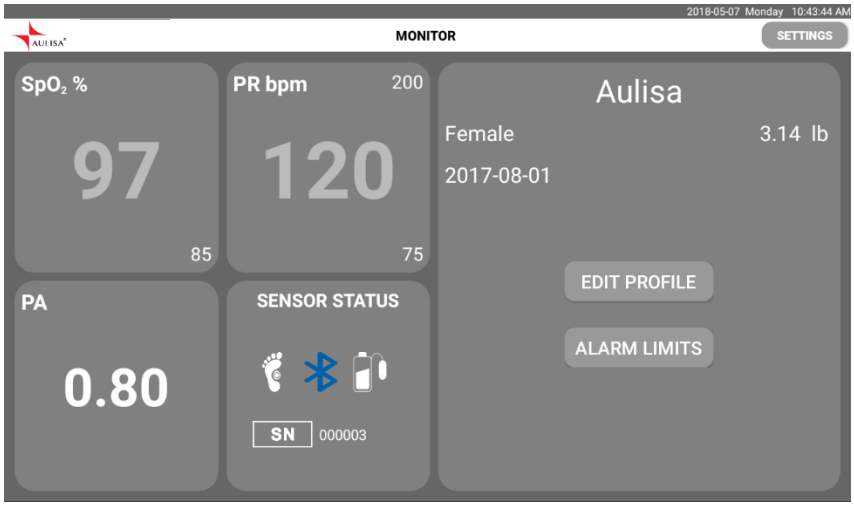
WARNING! A potential hazard exists if different alarm presets are used for the same or similar equipment in any single area.

CAUTION! ***Do not plug a headphone into the headphone jack of the Display Unit, as this will significantly reduce the volume of alarm audio.***

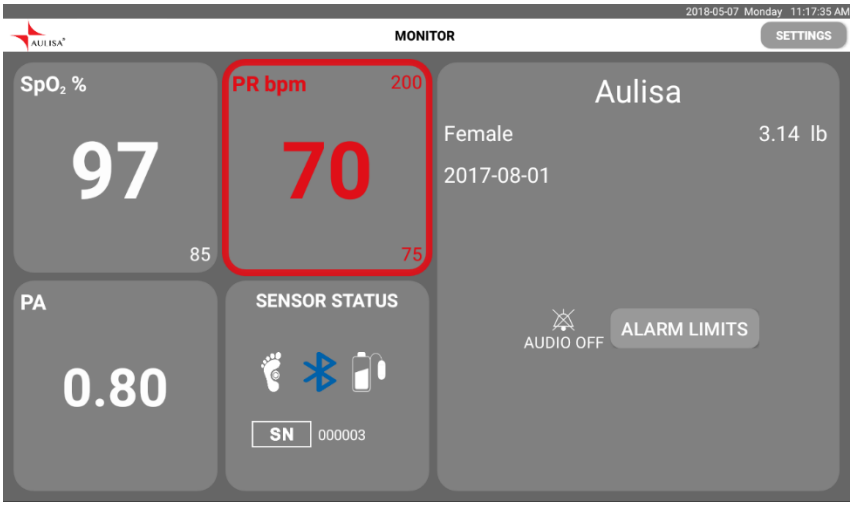
Adjusting Alarm Limits

Follow the instructions below to review or set alarm limits. To restore alarm settings to default values, refer to “Default Alarm Settings” section on page 26 for more information.

1. Ensure there is a connection established between the Display Unit and the Infant Oximeter Module. (See “Device Pairing” section on page 16 for more information.)
2. Tap on ‘‘ALARM LIMITS’’ button on the MAIN screen.



In an alarm event, ‘‘ALARM LIMITS’’ button will appear after you select ‘‘PAUSE AUDIO’’ or ‘‘AUDIO OFF.’’

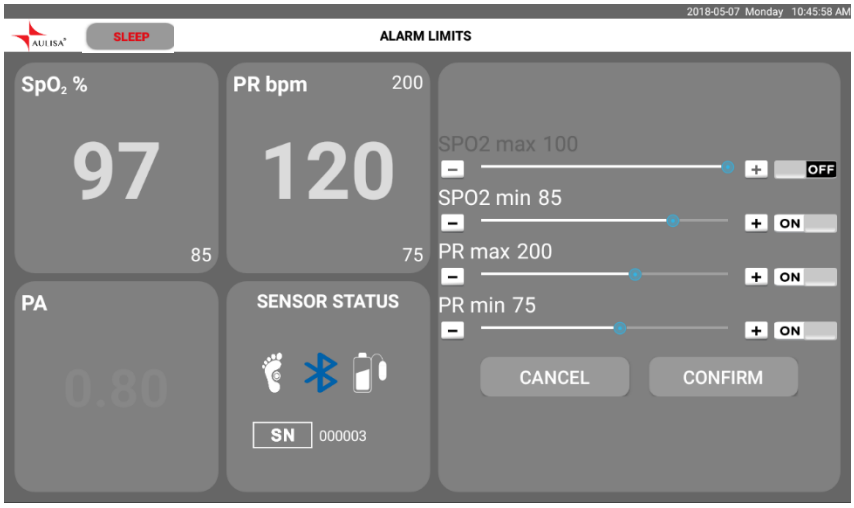


NOTE: Alarm limits can be adjusted only when the Display Unit is connected to the Infant Oximeter Module.

3. To turn alarm limits on or off, tap on ‘‘ON/OFF’’ button. (Turn on the alarm before adjusting the value.)

   NOTE: SpO_2 max limit is turned off by default.

   NOTE: There is no alarm setting for PA (pulse amplitude).



4. Tap on ‘‘ + ’’ or ‘‘– ’’ buttons or drag the ‘‘seekbar’’ to adjust the values.

   NOTE: The minimum alarm limit cannot exceed the max alarm limit, even if the max alarm limit is turned off. For example, if the max SpO_2 limit is turned off but was previously set at 90%, the min SpO_2 limit cannot be set high than 90%. If you want to set min SpO_2 limit at 90%, turn on the max SpO_2 limit, set it above 90% and turn it off again as you wish.

   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	Off, 85 to 100	1% SpO_2
SpO_2 Lower Alarm Limit	85%	Off, 50 to 95	1% SpO_2
Pulse Rate Upper Alarm Limit	200 bpm	Off, 75 to 275	1 bpm
Pulse Rate Lower Alarm Limit	75 bpm	Off, 30 to 110	1 bpm

5. Tap on ‘‘CONFIRM’’ to save the alarm limits.

NOTE: The SpO_2 and pulse rate upper and lower alarm limits appear as smaller values to the top right and bottom right of their respective window on the MAIN screen.

WARNING! The new ALARM LIMITS do not go into effect until the "CONFIRM" button is tapped.

WARNING! A potential hazard exists if different alarm presets are used for the same or similar equipment in any single area.

WARNING! When turned off, the alarms will no longer be displayed or sound. Follow instructions above to turn on the alarms.

CAUTION! Consult a physician the appropriate vital sign limits for the user before adjusting an alarm.

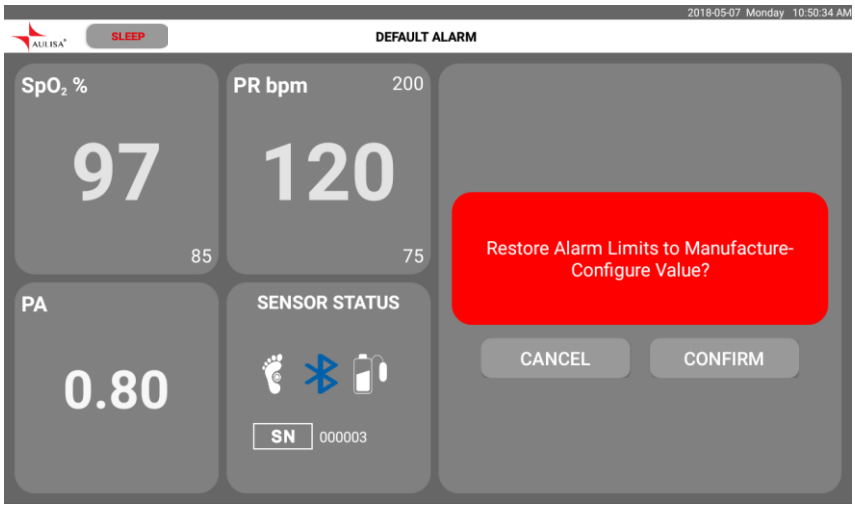
Default Alarm Settings

Follow the instructions below to restore alarm settings to default values.

1. Ensure there is a connection established between the Display Unit and the Infant Oximeter Module. (See “Device Pairing” section on page 16 for more information.)

   NOTE: Default alarm can be restored only when the connection is established.

2. Tap on “SETTING” button located on the top right corner of the MAIN screen.
3. Tap on “DEFAULT ALARM.”
4. Tap on “CONFIRM” to restore alarm limits to manufacturer-configured values.



NOTE: The following table describes the default alarm presets.

Alarm	Factory Default
SpO_2 Upper Alarm Limit	Off
SpO_2 Lower Alarm Limit	85%
Pulse Rate Upper Alarm Limit	200 bpm
Pulse Rate Lower Alarm Limit	75 bpm

Powering and Charging

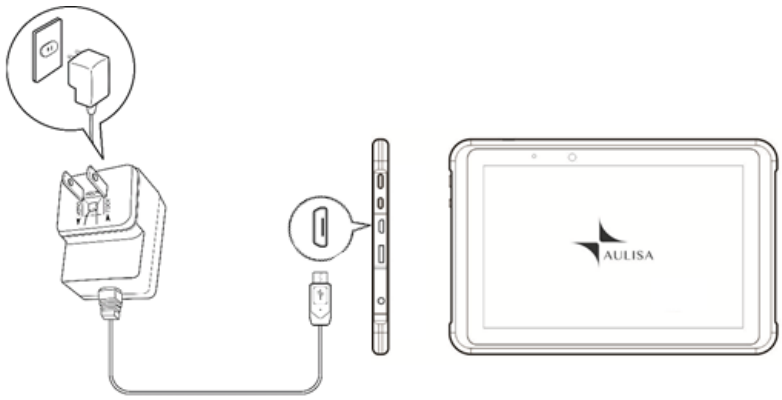
Powering the Display Unit

The Display Unit is meant to be used with the GA-CD0002 Charging Adaptor- Display Unit plugged in. If, for some reason, the Display Unit is disconnected from the charging adaptor, proceed with the following steps to charge and power the Display Unit.

The Display Unit will alarm the user when the Display Unit itself is low on battery.

1. Insert the micro-USB cable end of the GA-CD0002 Charging Adaptor- Display Unit into the Display Unit and plug the wall adaptor to a power outlet.
2. Place the Display Unit on the stand provided.

NOTE: The LED indicator will light red when charging and light blue when fully charged.



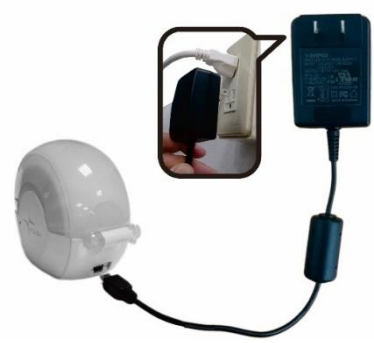
CAUTION! Only use adaptors supplied or manufactured by Taiwan Aulisa Medical Devices Technologies, Inc.

Charging the Infant Oximeter Module

Charge the Infant Oximeter Module with the wireless charging case by following the steps below.

NOTE: The Display Unit will alarm the user when the Infant Oximeter Module is low on battery. Once on low battery, the Infant Oximeter Module will work for up to another 2 hours (working time on low battery depends on user)

1. Connect the GA-CS0001 Charging Adaptor- Wireless Charging Case to wireless charging case and a power outlet.



2. Open the cover of the wireless charging case and place the Infant Oximeter Module inside as shown below.

3. Close the cover of the wireless charging case.

NOTE: The power LED on the Infant Oximeter Module will light blue while
charging and turn off, when fully charged.

NOTE: The charging LED on wireless charging case will automatically light blue when charging SM and turn off, when not in use.

NOTE: It takes about 3 hours to fully charge the Infant Oximeter Module.

NOTE: The Infant Oximeter Module will turn itself on automatically when the wireless charging case is opened; and, the power LED will light green when the power is ON.

CAUTION! ***Only use the charging adaptor and wireless charger supplied or manufactured by Taiwan Aulisa Medical Devices Technologies, Inc.***

Care and Maintenance

Maintenance

The advanced digital circuitry within the Infant Oximeter Module of this system requires no calibration or periodic maintenance, neither does the Display Unit.

Field service or repair of this system is not possible. Do not attempt to open the case. Opening the Infant Oximeter Module and the Display Unit will damage the device and void the warranty. If the system is not functioning properly, see “Troubleshooting” section on page 31 for more information.

The expected service life of Aulisa GA1001 System is 1.5 year.

Cleaning

Clean surface of the sensor probe before each use. Clean the surface of the sensor probe with a soft cloth dampened with rubbing alcohol. Lightly wipe the surface of the sensor probe.

CAUTION! ***Do not pour or spray any liquids onto components, and do not allow any liquids to enter any openings in the device. Allow the unit to dry thoroughly before reuse.***

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

Troubleshooting

Problem	Possible Solution
Cannot turn on the Infant Oximeter Module	Fully charge the Infant Oximeter Module until the charging blue light goes off, then remove SM from the wireless charger.
	Make sure the Infant Oximeter Module is kept away from any magnetic devices while charging.
Cannot turn on the Display Unit	Press the power On/Off button for more than three (3) seconds.
	Make sure the power cord is properly connected to the outlet.
Unable to obtain a valid SpO_2 or pulse rate reading. *NOTE: In some instances, patient perfusion may be inadequate for pulse detection.*	Reposition the Infant Oximeter Module and keep the sensor motionless for at least 10 seconds.
	Warm the foot by rubbing or covering with a sock.
	Allow the foot to rest comfortably without squeezing or pressing the sensor on a hard surface.
	Relocate the Infant Oximeter Module at a different site.
	Make sure the Infant Oximeter Module is within 10 meters (32.8 feet) spherical radius to the Display Unit and that the devices are paired.
	Reduce or eliminate any interference. Make sure that the Infant Oximeter Module is not placed on the same leg being used for other patient therapies or diagnostics (e.g., blood pressure cuff).
	Make sure the Infant Oximeter Module is attached to the foot securely.
	Check the Display Unit for any alarms or error messages.
	Check the Infant Oximeter Module for power.
	Check the sensor for any visible signs of deterioration.
Unstable/Constant SpO_2 and Pulse Rate readings	Shield the sensor probe from the light source.
	Relocate the Infant Oximeter Module at a different site.
	Make sure the Infant Oximeter Module is attached to the foot securely.
	Check the sensor for any visible signs of

Problem	Possible Solution
	deterioration.
	Reduce patient motion.
	Verify that the Infant Oximeter Module is paired with the Display Unit.
Data update period has exceeded limit	Reposition the Infant Oximeter Module and keep the sensor motionless for at least 10 seconds.
	Relocate the Infant Oximeter Module at a different site.
A dash (---) appears in the vital sign displays.	Make sure the Infant Oximeter Module is securely attached to the foot.
	Reposition the Infant Oximeter Module and keep the sensor motionless for at least 10 seconds.
	Relocate the Infant Oximeter Module at a different site.
	Turn off the unit, check all connections, and retry.
	Verify that the Infant Oximeter Module is paired with the Display Unit.
The unit is in Alarm mode, but no audible alarms can be heard.	Wait for two minutes and alarm tones will automatically re-engage.
	Make sure there are no headphones inserted into the headphone jack of the Display Unit.
Cannot connect the devices	Turn off both the Infant Oximeter Module and the Display Unit. Follow instructions in the “Device Pairing” section on page 16.
	Ensure that the Infant Oximeter Module is in range while being paired (approximately 10 meters (32.8 feet) spherical radius).

If these solutions do not correct the problem, please contact your distributor, or contact Aulisa Customer Support at 1 (650) 813-1273 (USA).

WARNING! ***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.***

Technical information

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[1] 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:

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

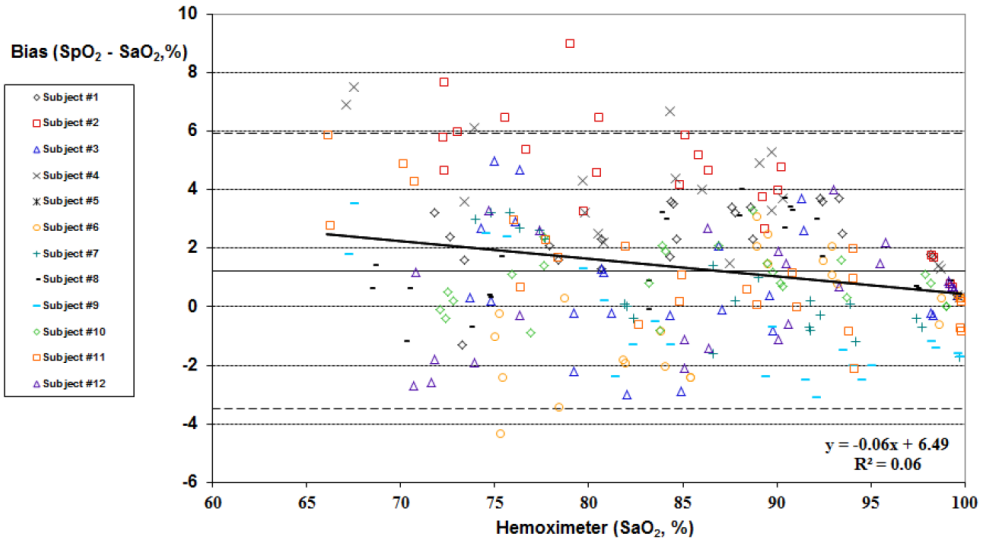
[1]Bias is defined as the monitor under test reading minus the hemoximeter reading.

Note: Because pulse oximeter equipment measurements are statistically distributed, only about two-thirds of Aulisa GA1001 Digital Vital Sign Monitoring System measurements can be expected to fall within $\pm A_{rms}$ of the value measured by a co-oximeter.

A_{rms} from the clinical study

Sensor 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 the Aulisa GA1001 System with upper and lower 95% limits of agreement. Each sample data point is from a clinical study in healthy adult 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

Aulisa GA1001 Digital Vital Sign Monitoring System uses a moving average to determine the Pulse Rate and SpO_2. The following table shows the equipment response time of Aulisa GA1001 Digital Vital Sign Monitoring System.

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

Manufacture's Declaration

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

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

Guidance and manufacture'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	

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

Guidance and manufacture'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 ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode	±1 kV differential mode	Mains power quality should be

	±2 kV common mode	±2 kV common mode	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.			

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

Guidance and Manufacture'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 Radiated RF IEC 61000-4-3	3 V/m 150 kHz to 80 MHz 10 V/m 80 MHz to 2.7 GHz	3 V/m 10 V/m	**Recommended Separation Distance** 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: $E = 6/d\sqrt{P}$

			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.
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/m.			

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 undesired 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).

RF Exposure: For body worn operation, to maintain compliance with FCC RF exposure guidelines, use only accessories that contain non- metallic components. 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.

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

Service, Support, and Warranty

A return authorization number is required before returning any product to Aulisa.

To obtain this return authorization number, contact Aulisa Customer Support:

United States of America
Aulisa Medical Technologies, Inc.
999 Commercial St, Suite 208
Palo Alto, CA 94303 USA
Tel (650) 813-1273

Taiwan
Taiwan Aulisa Medical Devices Technologies, Inc.
No. 218-2, Chong Yang Rd., Nangang Dist, Taipei, 115 Taiwan
Tel +886-2-2655-7297

www.aulisa.com

WARRANTY

Taiwan Aulisa Medical Devices Technologies, Inc., warrants to the purchaser, for a period of one year from the date of purchase, Aulisa GA1001 Digital Vital Sign Monitoring System. Aulisa warrants the Infant Oximeter Module and Display Unit for a period of one year from the date of purchase. Aulisa shall repair or replace any Infant Oximeter Module and integrated Sensor(s) and Display Unit found to be defective in accordance with this warranty, free of charge, for which Aulisa has been notified by the purchaser by serial number that there is a defect, provided said notification occurs within the applicable warranty period. This warranty shall be the sole and exclusive remedy by the purchaser hereunder for any Aulisa GA1001 Digital Vital Sign Monitoring System delivered to the purchaser which is found to be defective in any manner, whether such remedies be in contract, tort, or by law.

This warranty excludes cost of delivery to and from Aulisa. All repaired units shall be received by the purchaser at Aulisa place of business. Aulisa reserves the right to charge a fee for a warranty repair request on any Aulisa GA1001 Digital Vital Sign Monitoring System that is found to be within specifications.

This system is a precision electronic instrument and must be repaired by knowledgeable and specially trained Aulisa personnel only. Accordingly,

any sign or evidence of opening the devices, field service by non- Aulisa personnel, tampering, or any kind of misuse or abuse of the system, shall void the warranty in its entirety. All non-warranty work shall be done according to Aulisa standard rates and charges in effect at the time of delivery to Aulisa.

DISCLAIMER/EXCLUSIVITY OF WARRANTY:

The express warranties set forth in this manual are exclusive and no other warranties of any kind, whether statutory, written, oral, or implied, including warranties of fitness for a particular purpose or merchantability, shall apply.

Specifications

Aulisa GA1001 Digital Vital Sign Monitoring System	
Blood Oxygen Saturation Display Range (SpO_2)	1% to 100%
Pulse Rate Display Range	30 to 300 bpm
Accuracy	
Blood Oxygen Saturation (%SpO_2) (± 1 S.D.)	70-100% ± 3 digits
Pulse Rate	± 3 digits

Alarms	
SpO_2	
Default SpO_2 Limit	
Upper Limit	Off
Lower Limit	85%
Alarm Limit Range	
Upper Limit	85-100%
Lower Limit	50-95%
Adjustment Step	
Step Value	1% SpO_2
Pulse Rate	
Default Pulse Rate Limit	
Upper Limit	200 bpm
Lower Limit	75 bpm
Alarm Limit Range	
Upper Limit	75-275 bpm
Lower Limit	30-110 bpm
Adjustment Step	
Step Value	1 bpm

Measurement Wavelengths and Radiant Power	
Red	660 nanometers @ 9.8 mW nominal
Infrared	880 nanometers @ 6.5 mW nominal
Wireless Communication	
Range	10-meter spherical radius
Protocol	Bluetooth 4.0
Direction	Bi-direction
Data rate	Up to 100k Bps
Temperature	
Operating	+ 5°C to + 40°C
Storage/Transportation	– 25°C to+ 70°C
Operating Altitude	altitude ≤ 3000 m

Atmospheric Pressure	700 hPa to 1013 hPa
Humidity	
Operating	15% to 90%, non-condensing
Storage/ Transportation	10% to 93% relative humidity, non-condensing
Infant Oximeter Module (Sensors Integrated)	
Internal Power	
Battery	3.7 V battery
Operating Life	22 hours of continuous operation
Dimensions	5.6” D x 1.2” W x 0.6” H 142.7 mm D x 31.3 mm W x 15.9 mm H
Weight	0.6 oz 17.5 g
Ingress Protection	IP22
Display Unit	
Display	
Display panel	10.1” TFT Touch Panel
Power Requirements	
Mains	100-240 V AC 50-60 Hz
DC Input	5 V DC/AC adaptor
Internal Power	
Battery	3.7 V battery
Operating Life	2 hours of continuous operation
Dimensions	7.1” H x 10.8” W x 0.5” D 180.8 mm H x 275.5 mm W x 12.3 mm D
Weight	26.5 oz 750 g
Alarm Sound Pressure	60 dB
Ingress Protection	IP22
Classifications per IEC 60601- 1	
Type of Protection	Class II, MOPP (on AC power) Internally powered (on battery power)
Degree of Protection	Type BF-Applied Part
Mode of Operation	Continuous

Parts and Accessories

Parts and Accessories	Model Number
Infant Oximeter Module	GA-SM0002
Display Unit	GA-DU0002
Adhesive Patch – Infant Oximeter Module	GA-AP0001
Wireless Charging Case – Infant Oximeter Module	GA- WS0001
Charging Adaptor - Wireless Charging Case	GA-CS0001
Charging Adaptor - Display Unit	GA-CD0002
Stand - Display Unit	GA-SD0002

For more information about Aulisa parts and accessories, contact your distributor, or contact Aulisa at 1 (650) 813-1273 (USA).

WARNING! ***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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