Aulisa Guardian Angel™ Rx GA2000
Digital Vital Sign Monitoring System
Instruction For Use

Version: 1.0

CAUTION! Read this entire manual carefully before using Aulisa GA2000 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
	Prescription use 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. Only use the sensors manufactured by Aulisa. These sensors are manufactured to meet the accuracy specifications for Aulisa GA2000 Digital Vital Sign Monitoring System. Using other manufacturers' sensors can result in improper pulse oximeter performance and patient injury may occur.
5. The operator must verify the compatibility of the sensor with Aulisa GA2000 Digital Vital Sign Monitoring System before use, otherwise patient injury can result.
6. As with all medical equipment, carefully route all cables to reduce the possibility of entanglement, strangulation or injury to the patient.
7. Be careful with small parts that can be removed from the device and swallowed, such as port covers. They are hazardous to children.
8. Excessive pressure to the sensor application site for prolonged periods may cause damage to the skin beneath the sensor.
9. Do not use a damaged sensor. If the sensor is damaged in any way, discontinue use immediately and replace the sensor.
10. Do not use in or around water or any other liquid when AC power adaptor is used.
11. Only use Aulisa GA2000 Digital Vital Sign Monitoring System with Charging Adaptors provided by Aulisa.
12. Aulisa GA2000 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 and carboxyhemoglobin, may affect the accuracy of the measurement.
13. Anemia may affect the accuracy of the measurement.

14. Use Aulisa GA2000 Digital Vital Sign Monitoring System only when the components are installed within the specified distances from the monitored patient – Sensor Module must be approximately 10 meters (10.9 yards) from the Receiver/Transponder (RT). Moving outside this range may cause missing, lost, and/or inaccurate data.
15. Loss of monitoring can result if any objects hinder the pulse measurement. Ensure that no blood flow restrictors (e.g., blood pressure cuff) hinder pulse measurements.
16. This product is not a substitution for physician supervision.
17. Always refer to instructions for use for full warnings and instructions.
18. Failure to follow instructions and warnings may result in serious injury or death.

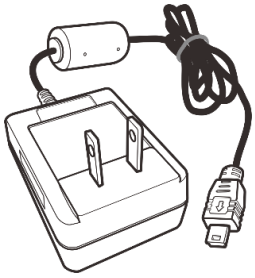
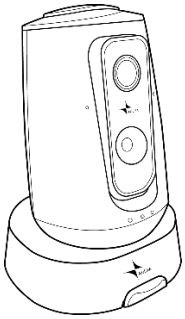
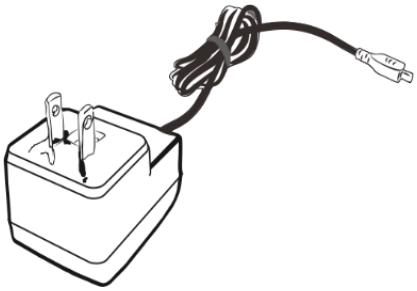
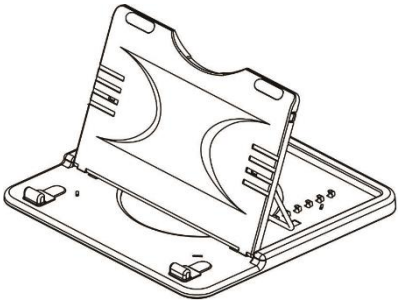
Cautions

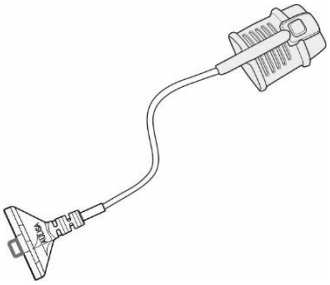
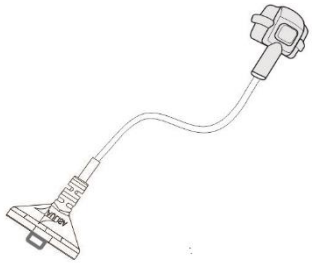
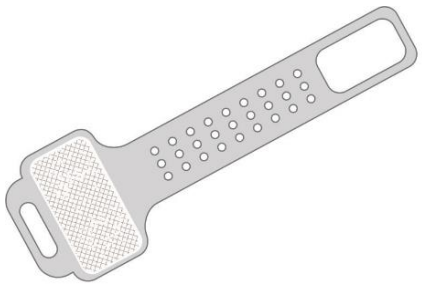
1. This equipment complies with International Standard EN 60601-1-2: 2014 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the 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.
2. If Aulisa GA2000 Digital Vital Sign Monitoring System 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. The sensor might not work on cold extremities due to reduced circulation. Warm or rub the finger to increase circulation or reposition the sensor.
5. Aulisa GA2000 Digital Vital Sign Monitoring System 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. Some nail polish colors or artificial nails can reduce light transmission and affect SpO_2 accuracy.
8. Inspect and relocate the sensor application site at least every 6 to 8 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 Sensor Module too tightly around the patient's wrist. Inaccurate readings and patient discomfort could result.
17. *Caution: Exposure to Radio Frequency Radiation.* The radiated output power of the device is far below FCC radio frequency exposure limits. Nevertheless, the device must be used in such a way that the potential for human contact during normal operation is minimized. To avoid the possibility of exceeding FCC radio frequency exposure limits, remain at least 20 cm (8 inches) away from the Display Unit's internal antenna during normal operation. The Sensor Module has been tested and meets allowed limits for exposure.
18. System connection failure (Bluetooth/ Wi-Fi wireless connection) may result in loss of data transfer.

Using Aulisa GA2000 Digital Vital Sign Monitoring System

This chapter describes how to use Aulisa GA2000 Digital Vital Sign Monitoring System (hereinafter referred to as Aulisa GA2000 system). The system includes the following components and accessories:

Sensor Module (2 pcs)	Charging Adaptor - Sensor Module
	
Receiver/Transponder	Charging Adaptor - Display Unit & Receiver/Transponder (2 pcs)
	
Display Unit	Stand - Display Unit
	

Finger Sensor - Adult	Finger Sensor - Pediatric
	
Wristband	
	

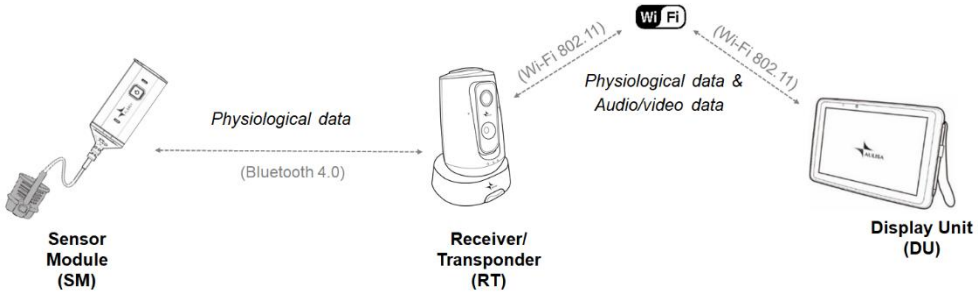
Intended Use

The Guardian Angel Rx GA2000 Digital Vital Sign Monitoring System is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult and pediatric patients. It is indicated for spot-checking and/ or continuous monitoring of patients 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 GA2000 Digital Vital Sign Monitoring System measures SpO_2 and pulse rate based on non-invasive light-emitting diode (LED) transmittance 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



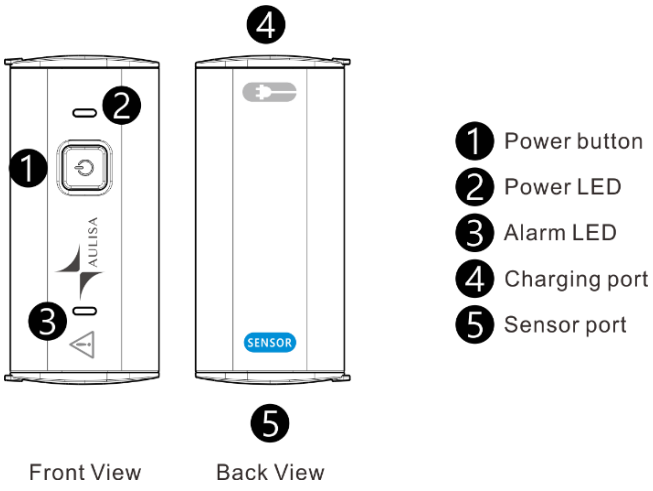
NOTE: Aulisa GA2000 System utilizes a customer Wi-Fi network to communicate between RT and DU. The customer Wi-Fi network is to be implemented and managed by end users.

Device Overview

Sensor Module

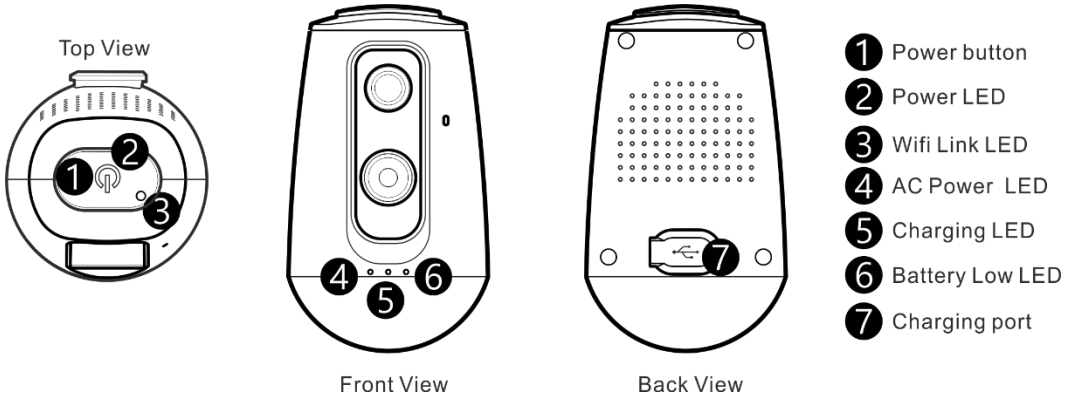
The Sensor Module includes a Bluetooth transmitter and a sensor, which is worn by the patient for vital sign monitoring. It features sensors and electronics for vital sign measuring and analyzing.

The Sensor Module must be used within 10 meters from the Receiver/Transponder.



Receiver/Transponder

The Receiver/Transponder features Bluetooth/Wi-Fi communication interfaces and an audio/video camera. It receives vital signs monitoring data from the Sensor Module via Bluetooth, integrates audio and video of the patient, and then converts the data to Wi-Fi signals, which are transmitted to and displayed by the Display Unit.

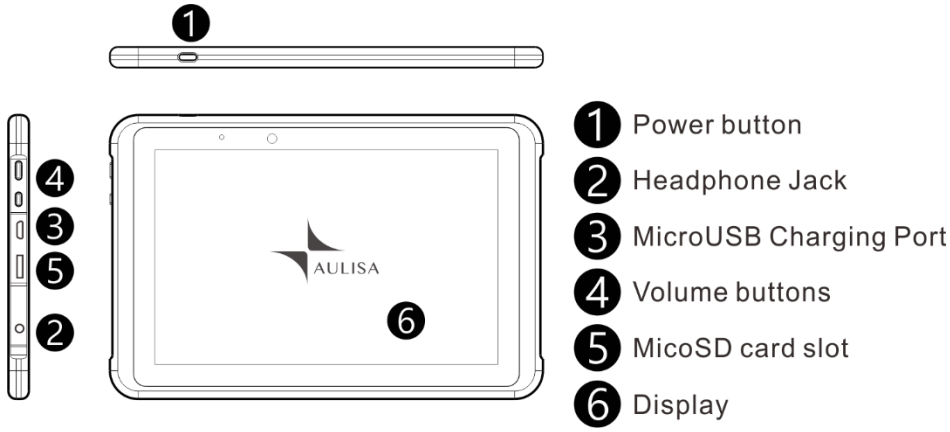


Display Unit

The Display Unit features a 10.1" HD LCD multi-touch display with Wi-Fi connectivity capability. The Display Unit displays real-time vital signs measured by the Sensor Module.

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

The Display Unit will incorporate a push to talk and speaker function that allows audio messages to be received and sent via the Receiver/ Transponder.



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.

Displays, Indicators, and Controls

This section describes the display, indicators, and controls for the Aulisa GA2000 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 Sensor Module and RT are connected via Bluetooth. It will turn blue once the Sensor Module is paired with RT.

Measurement Site Status
This icon displays whether there is a finger inserted in the sensor. A system alarm will be displayed on the Display Unit if no fingers are detected.

Sensor Cable Connection Status
This icon displays whether the sensor cable is connected to the Sensor Module. A system alarm will be displayed on the Display Unit if the cable is disconnected.

Battery Level of Sensor 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 Sensor 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.

RT Connection Indicator
This icon indicates whether there is a connection established between the Display Unit and RT. This icon will turn blue when there is a connection between the Display Unit and RT and turn red when there is connection loss.

Wi-Fi Connection Indicator
This icon indicates whether there is a connection between the Display Unit and customer Wi-Fi Network.

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

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 25 for more information on adjusting the alarm limits.)

NOTE: The button is operable only when the system connection is established.

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.

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

Alarm History
Tap on this button on the top right corner of the MAIN screen to view alarm history list.

Edit Profile
In the settings menu, tap on this button to edit or create the patient's profile.

RT Setting
In the settings menu, tap on this button to input password for RT or to reset RT.

Scan Sensor QR Code
In the settings menu, tap on this button and scan the barcode on the back of the Sensor Module to manually pair the Sensor Module with RT. (See "System Connection" section on page 18 for more information.)

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

Set Timezone
In the settings menu, tap on this button to select the correct time zone.

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

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

Set Wi-Fi Network of DU
In the settings menu, tap on this button to select the desired customer Wi-Fi network for the Display Unit to link to.

Push to Talk Function
Press and hold this button to talk to the patient via the Display Unit.

Speaker Function
Tap on this button to turn on the Receiver/Transponder's microphone.

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 triggered alarm event for 2 minutes.

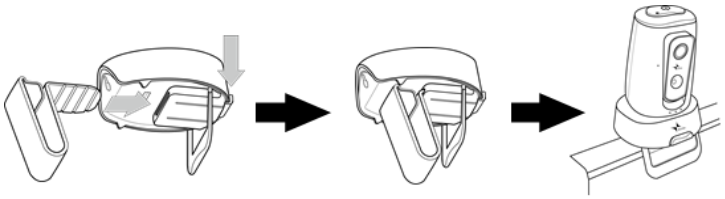
Turn Off Alarm Audio
The button appears on the MAIN screen when an alarm is triggered. Tap on the button to permanently silence the alarm audio of the current triggered alarm event.

Setting up Aulisa GA2000 System

Use the following procedure to set up the Aulisa GA2000 System:

It is recommended to charge the Sensor Module fully prior to setting up Aulisa GA2000 System as it takes around 3 hours to fully charge and cannot be operated while charging (See "Powering and Charging" section on page 33 for more information).

1. Follow the instructions below to assemble the Receiver/ Transponder.

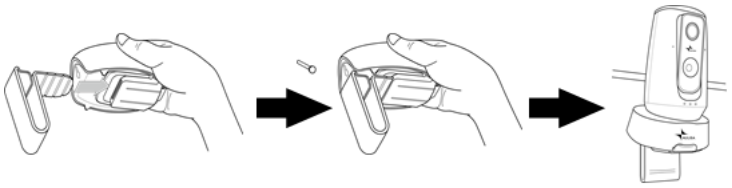


STEP 1
Pull down the clip and slide the holder into the slot.

STEP 2
Check to ensure the holder is secure.

STEP 3
Clamp onto furniture. Place RT on the stand

OR



STEP 1
Slide the holder into the slot.

STEP 2
Hang the stand on the wall.

STEP 3
Check to ensure the stand is secure. Place RT on the stand.

2. Connect the charging adaptor (black) to RT and a power outlet. (See "Power and Charging" section on page 33 for more information)

3. Click the power On/Off button of RT to turn on.

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

4. Connect the charging adaptor (black) to the Display Unit and a power outlet.

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

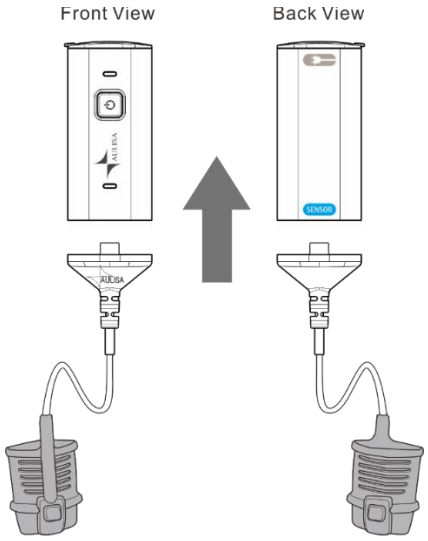
CAUTION! ***For long-term monitoring (over 3 hours of continuous use), the Display Unit must be connected to the charging adaptor.***

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

6. Establish a Wi-Fi connection between the Display Unit and RT. (See "System Connection" section on page 18 for more information).

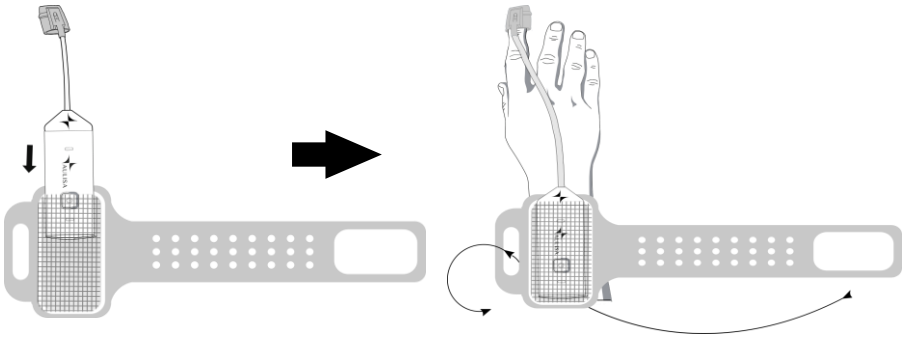
7. Attach the connector end of Finger Sensor to the end marked with SENSOR of the Sensor Module.

NOTE: Pediatric finger sensor is intended for use in patients weighing from 10 to 40 kilograms. Adult finger sensor is intended for use in patients weighing more than 40 kilograms.



8. Insert the Sensor Module onto the mesh pocket. Attach the Sensor's probe to the thumb or finger, making sure that the Finger Sensor cable runs over the top of the patient's hand.

9. Secure the wristband onto the patient's wrist with the mesh pocket facing outwards. Slip the velcro end through the hole and loop around to secure the wristband. Adjust the wristband according to wrist size, leaving proper space of about one or two fingers to allow ventilation.



10. Click the power On/ Off button to turn on the Sensor Module.

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

11. Ensure the Sensor Module is paired with the Display Unit. (See "Bluetooth Connection" section on page 21 for more information.

    NOTE: Verify System Operation before every use. (See "Verifying System Operation" section on page 22 for more information.)

System Connection

Wi-Fi Connection

For first time users, use the following procedures to establish a Wi-Fi connection between the Display Unit and Receiver/ Transponder.

1. Ensure DU and RT are turned on. (See “Powering and Charging” section on page 33 for more information).

NOTE: The Wi-Fi Link LED on RT will blink red when there is no Wi-Fi connection established.

NOTE: RT will play a notification sound when it is ready to connect to a customer Wi-Fi network.

2. Select a secure customer Wi-Fi network from the list of available connections displayed on the MAIN screen. Enter the network security password. Then, press “CONFIRM”.

NOTE: Beware of connecting to an unsecured network provides no security and exposes all your network traffic.

NOTE: Ensure the customer Wi-Fi Network connection has a strong and reliable signal.

NOTE: A QR code will be generated on the Display Unit for RT to scan.

3. Place RT in front of QR Code at a distance, just enough for RT to fit the frame on screen and a ‘beep’ sound to be heard.

NOTE: Hold Display Unit steadily during the scanning of QR code.

NOTE: Wait about 30 seconds for RT to play a sound indicating the start of the connection.

NOTE: The Wi-Fi Link LED on RT will turn solid red when a Wi-Fi connection has been successfully established.

4. Create a password for RT. Then, press “CONFIRM”.

NOTE: If this step is skipped, the default password will be used.

NOTE: The default password for RT is **Aulisa2000**.

5. Select the correct timezone for RT.

NOTE: On the top right of the MAIN screen, check that the Wi-Fi connection indicator has a strong signal and for the RT connection Indicator RT to be lit blue to verify that a system connection has been established.

Reset RT- Wi-Fi Connection

When to reset RT- Wi-Fi Connection

1. Re-installing Aulisa GA2000 system
2. Wi-Fi connection problems between DU and RT
3. Installing a new router in the customer Wi-Fi Network

Use the following procedures to reset RT- Wi-Fi Connection:

1. Ensure the DU and RT are turned on. (See “Powering and Charging” section on page 33 for more information).

2. In the settings menu, tap on “RT SETTING”.

3. Tap on “RESET RT”.

4. Press and hold the power On/ Off button of RT for 10 seconds until “RESET” is heard. Then, press “CONFIRM” on the MAIN screen.

NOTE: Wait for 30 seconds or more for RT to play a melody, signaling that RT is now ready to scan the QR code generated on the Display Unit.

5. Select a secure customer Wi-Fi network from the list of available connections displayed on the MAIN screen. Enter the network security password. Then, press “CONFIRM.”

NOTE: Beware of connecting to an unsecured network provides no security and exposes all your network traffic.

NOTE: Ensure the customer Wi-Fi Network connection has a strong and reliable signal.

NOTE: A QR code will be generated on the Display Unit for RT to scan.

6. Place RT in front of QR Code at a distance, just enough for RT to fit the frame on screen and a 'beep' sound to be heard.

NOTE: Hold Display Unit steadily during the scanning of QR code.

NOTE: Wait about 30 seconds for RT to play a sound indicating the start of the connection.

NOTE: The Wi-Fi Link LED on RT will turn solid red when a Wi-Fi connection has been successfully established.

NOTE: If connection to RT fails, a pop-up window will appear. Click on "RETRY" and repeat from Step 4.

7. Create a password for RT. Then, press "CONFIRM."

NOTE: If this step is skipped, the default password will be used.

NOTE: The default password for RT is **Aulisa2000**.

8. Select the correct timezone for RT.

Bluetooth Connection

The RT will automatically scan and connect to the Sensor Module from the same starter kit.

NOTE: The Bluetooth connection status icon will turn blue once the RT is paired with the Sensor Module.

NOTE: The status indicator of Sensor Module will blink green when link with Display Unit is established, and data is being transmitted.

NOTE: The Sensor Module must be placed within 10 meters from RT.

Use the following procedure to switch among Sensor Modules and establish a connection between the RT and the desired Sensor Module.

1. Ensure the desired Sensor Module is turned on. (See “Power and Charging” section on page 33 for more information)

   NOTE: The desired Sensor Module must be placed within 10 meters from the RT.

2. In the settings menu, select “SENSOR PAIRING”.

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

4. Press “CONFIRM” if the serial number (SN) displayed matches with the SN on the back of the desired Sensor 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 desired Sensor Module is paired to RT, it will remain paired until the above process is repeated.

Verifying System Operation

Use the following procedure to verify that the alarm systems are working properly.

1. Set up Aulisa GA2000 system according to instructions above (See “Setting up Aulisa GA2000 system” section on page 15 for more information)

2. Ensure there is a system connection established between the Sensor Module, RT and Display Unit. (See “System Connection” section on page 18 more information)

3. Detach the sensor cable from Sensor Module.

4. Verify that an alarm message is displayed and that an alarm audio is generated (See “Troubleshooting” section on page 38 if an alarm message and audio signal is not generated).

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

6. After alarm signal is regenerated, press on the “AUDIO OFF” button 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) in order to verify that the device is functioning properly.

1. Set up Aulisa GA2000 system according to instructions above (See “Setting up Aulisa GA2000 system” section on page 15 for more information)

2. Press firmly on the application site to make sure it securely attached to the finger.

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

4. Verify that customer Wi-Fi network connection is stable.

   NOTE: On the top right of the MAIN screen, ensure the RT connection Indicator RT is lit blue and the Wi-Fi connection indicator has a strong signal.

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

6. Verify the live video is displayed on the MAIN screen.

Shutting off the System

Use the following procedure to shut down the Display Unit, the Sensor Module, and the Receiver/ Transponder.

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 into sleep mode by pressing the “SLEEP” button on the top left corner of the MAIN screen.

Sensor Module

Click the power On/ Off button to turn off the Sensor Module

NOTE: When the power is turned off the status indicator lit green will turn off.

NOTE: The Sensor Module will automatically power off when the adaptor is plugged in for charging.

NOTE: The Sensor Module will automatically power off when it detects no finger is in the sensor for 3 minutes.

Receiver/Transponder

Click the power On/ Off button to turn off.

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

Alarms and Limits

This chapter describes alarms and limits for Aulisa GA2000 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 Sensor 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 29 for more information.)

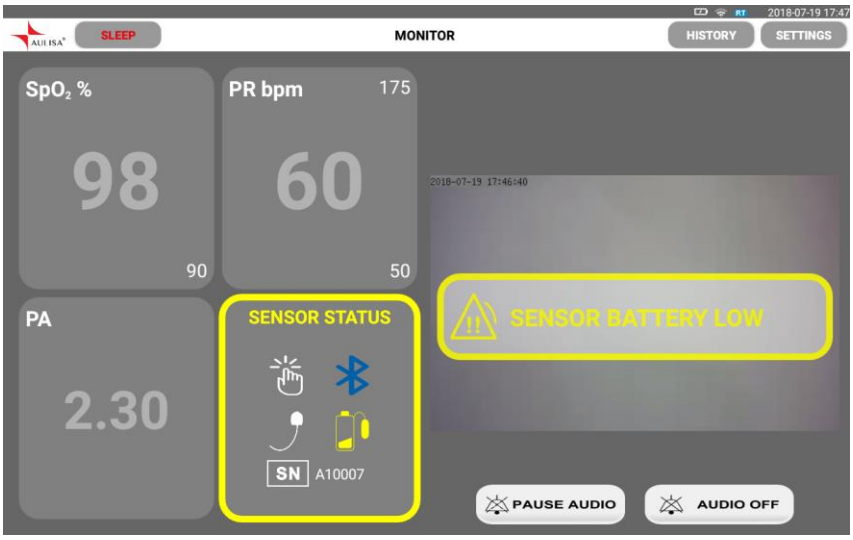
Medium Priority Alarms

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 Sensor Module will blink yellow along with displays on the Display Unit.

NOTE: The following table describes alarm conditions and visual indicators.

Alarm Condition (Medium Priority Alarm)	Visual Indicator
Sensor Probe Detached from Patient	The Sensor Module blinks yellow light along with blinking yellow displays and alarm text message on the Display Unit.
Sensor Module Battery Low	
Sensor Cable Detached	
Display Unit Battery Low	On the Display Unit, it blinks yellow displays and alarm text message.
Data Update Period Exceeds Limit (More Than 30 Seconds)	
Bluetooth Disconnected	
BLE Connection Lost. Reconnecting…	
Wi-Fi Connection Lost	
RT Connection Lost	



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

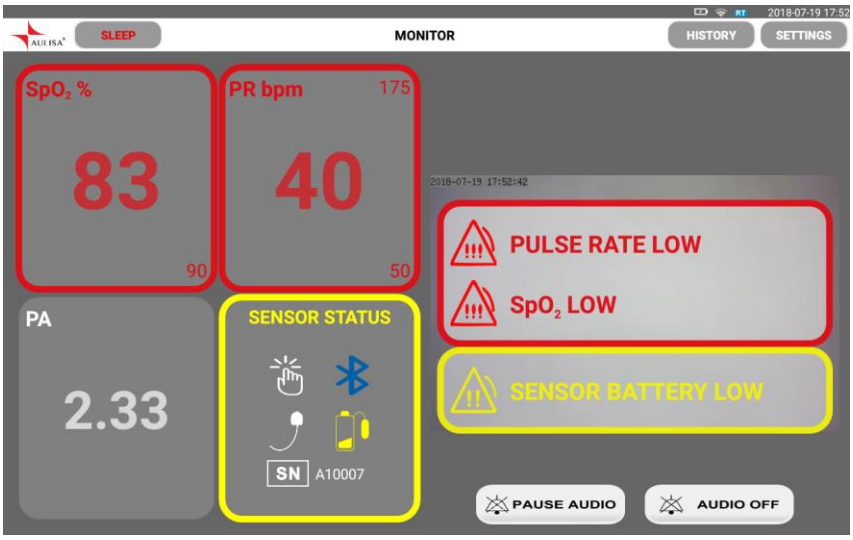
Tap on "PAUSE AUDIO" button to pause the alarm audio for 2 minutes. Tap on "AUDIO OFF" button to permanently turn off the alarm audio.

Alarm limits may be adjusted by pressing "ALARM LIMITS" button after silencing the alarms. (See "Adjusting Alarm Limits" section on page 29 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" button will permanently silence the alarm audio of the current triggering alarm event.***

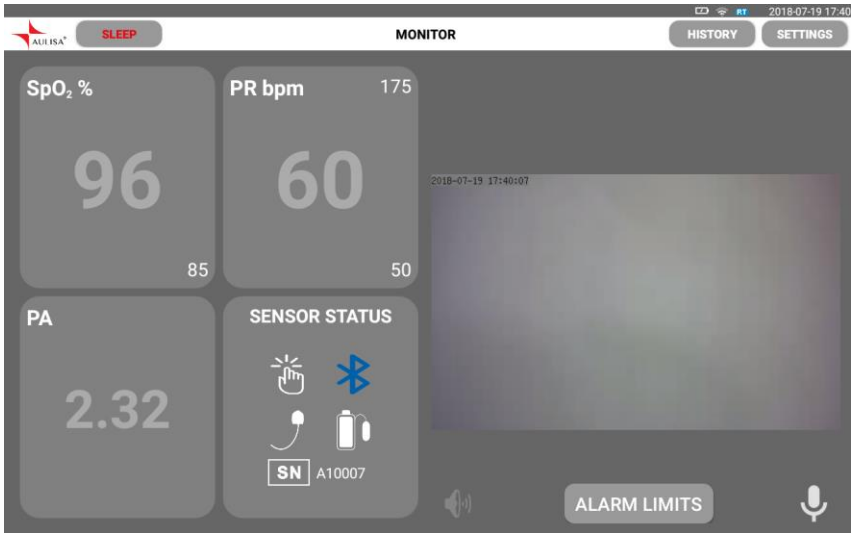
WARNING! ***A potential hazard exists if different alarm presets are used for the same or similar equipment in any single area.***

CAUTION! ***Do not plug a headphone into 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.”

1. Ensure there is a system connection established between the Sensor Module, RT and Display Unit. (See “System Connection” section on 15 for more information)
2. Tap on “ALARM LIMITS” button on the MAIN screen.



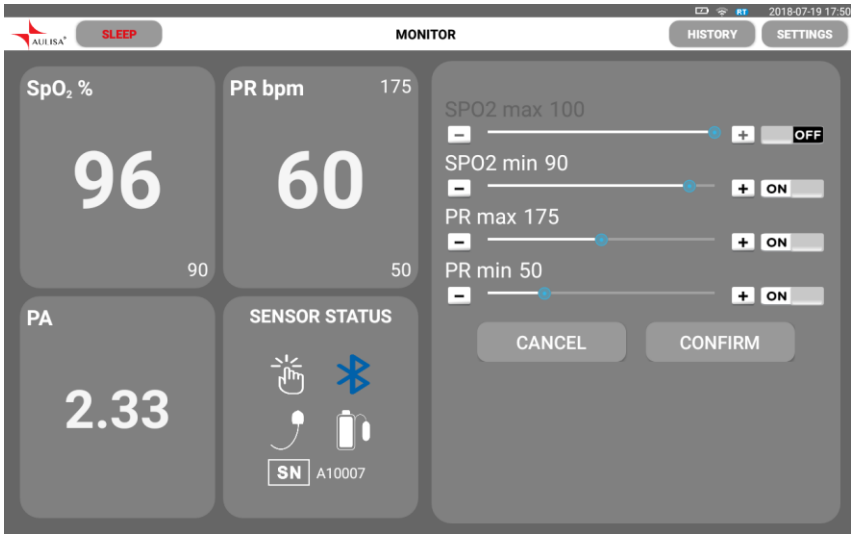
NOTE: Alarm limits can be adjusted only when the Display Unit is connected to the Sensor Module.

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

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 higher 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	150 bpm	Off, 75 to 275	1 bpm
Pulse Rate Lower Alarm Limit	50 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 area.***

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

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

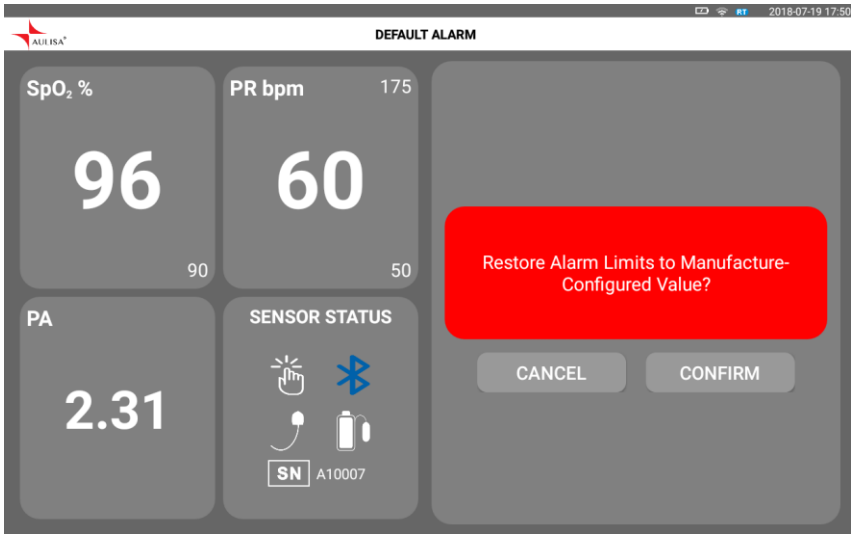
Default Alarm Settings

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

1. Ensure there is a system connection established between the Sensor Module, RT and Display Unit (See “System Connection” section on page 18 for more information).

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

2. Tap on “SETTINGS” button located on the top right corner of the MAIN screen.
3. Tap on “DEFAULT ALARM” button.
4. Tap on “CONFIRM” button to restore alarm limits to default alarm presets to manufacture-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	150 bpm
Pulse Rate Lower Alarm Limit	50 bpm

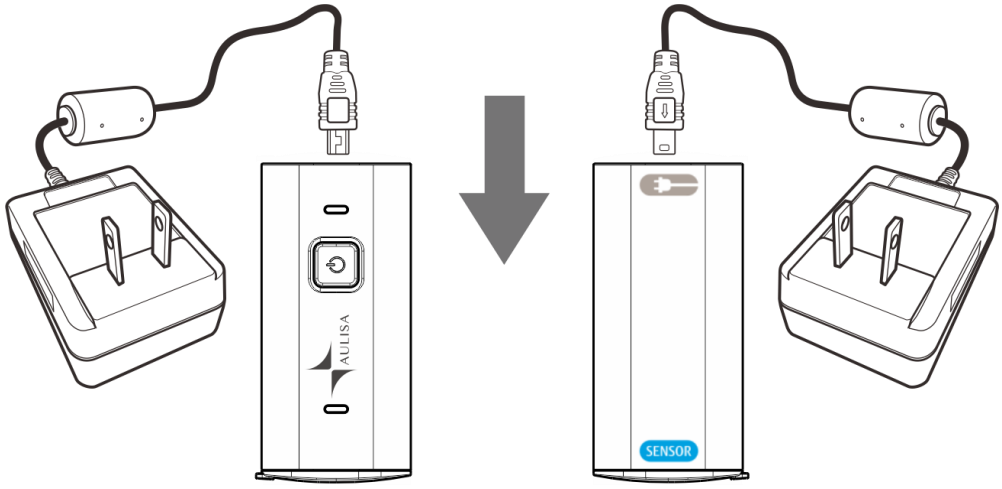
Powering and Charging

Charging the Sensor Module

Charge the Sensor Module with the charging adaptor (white) by following the steps below.

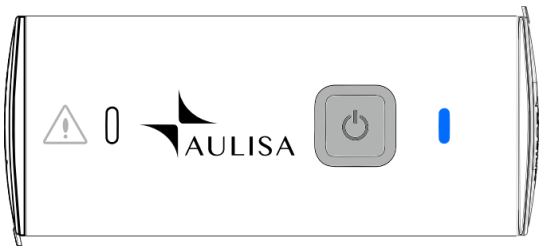
NOTE: The Display Unit will alarm the user when the Sensor Module is low on battery. Once on low battery, the Sensor Module will work for up to another 2 hours (working time on low battery depends on user)

1. Plug the mini-USB end of the cable into the charging port on the Sensor Module marked by .



2. Attach the wall adaptor to a power outlet.

NOTE: The power LED indicator will light blue while charging and turn off when fully charged.



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

NOTE: Verify operation of the system (See “Verifying System Operation” section on page 22 for more information) and check the battery status on the MAIN screen of the Display Unit.

NOTE: The Sensor Module cannot be used to measure vital signs while it is being charged

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

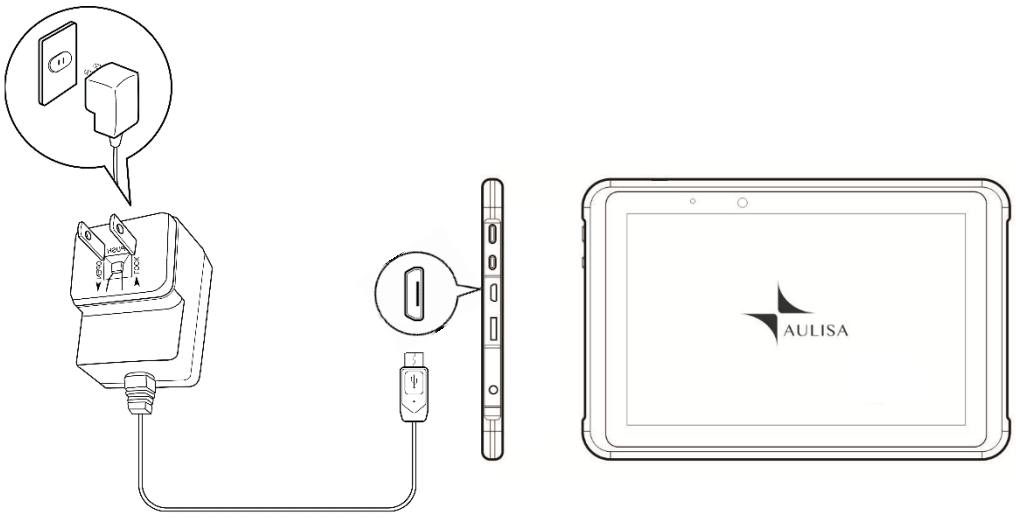
Powering the Display Unit

The Display Unit is meant to be used with the charging adaptor (black) 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 charging adaptor (black) 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.

Powering the Receiver/ Transponder

The Receiver/ Transponder is meant to be used with the charging adaptor (black) plugged in.

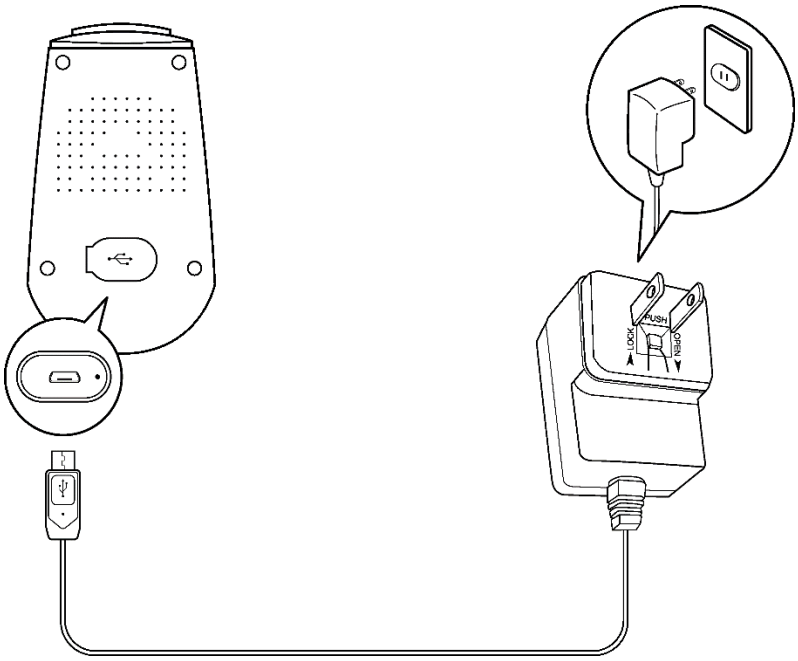
1. Insert the micro-USB cable end of the charging adaptor (black) into RT and plug the wall adaptor to a power outlet.

   See “Device Overview” section on page 9 for more information.

NOTE: The AC power LED indicator will light green when AC adaptor is ON.

NOTE: The charging LED indicator will light blue when internal battery is charging and will turn off when it is fully charged.

NOTE: The battery low LED indicator will light yellow when the battery is low.



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

Care and Maintenance

The advanced digital circuitry within the Sensor Module of this system requires no calibration or periodic maintenance, neither does the Display Unit or the Receiver/ Transponder.

Field service or repair of this system is not possible. Do not attempt to open the case. Opening the SM, RT or DU will damage the device and void the warranty. If the system is not functioning properly, see "Troubleshooting" section on page 38 for more information.

The expected service life of Aulisa GA2000 System is 3 years.

Cleaning and Disinfection

Clean surface of and disinfect the finger sensor before each use. For surface cleaning and disinfection, follow the recommended actions below.

Surface cleaning: Clean the surface of the finger 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 device.

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 Sensor Module	Click the power On/Off button.
	Fully charge the Sensor Module until the blue LED goes off.
Cannot turn on the Display Unit	Press and hold the power On/Off button for at least three (3) seconds.
	Make sure the power cord is properly connected to the outlet.
Cannot turn on the Receiver/ Transponder	Click the power On/Off button.
	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 finger sensor probe or reinsert the finger and keep the sensor motionless for at least 10 seconds.
	Warm the finger by rubbing or covering with a blanket.
	Relocate the finger sensor at a different site.
	Allow the hand to rest comfortably without squeezing or pressing the sensor on a hard surface.
	Make sure the system connection is established.
	Reduce or eliminate any interference. Make sure that the finger sensor is not placed on the same wrist being used for other patient therapies or diagnostics (e.g. blood pressure cuff).
	Make sure the finger sensor is attached to the finger securely.
	Make sure the finger sensor is securely attached to the Sensor Module.
	Check the Display Unit for any alarms or error messages.
	Check the Sensor Module for power.
	Ensure that the Sensor Module is within 10 meters spherical radius to RT while being paired
	Check the finger sensor for any visible signs of light.
Unstable/Constant SpO_2	Shield the finger sensor from the light

Problem	Possible Solution
and Pulse Rate readings	source.
	Apply the finger sensor to a finger without artificial or polished nails.
	Position the finger sensor at a different site.
	Make sure the finger sensor is attached to the finger securely.
	Make sure the finger sensor is securely attached to the Sensor Module.
	Check the finger sensor for any visible signs of deterioration.
	Reduce patient motion.
A dash "---" appears in the vital sign display.	Make sure the finger sensor is attached to the finger securely.
	Make sure the finger sensor is securely attached to the Sensor Module.
	Reposition the finger sensor probe or reinsert the finger and keep the sensor motionless for at least 10 seconds.
	Relocate the sensor at a different site.
	Turn off the system, check system connections, and retry.
Data update period has exceeded limit	Reposition the finger sensor probe or reinsert the finger and keep the sensor motionless for at least 10 seconds.
	Relocate the finger sensor at a different site.
	Insert the finger sensor to a finger without fingernail polish or an artificial nail.
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 device.	Turn off the system, verify system connections, and retry
	Ensure that the Sensor Module is within 10 meters spherical radius to RT while being paired
	Connect to a new Customer Wi-Fi Network.

Problem	Possible Solution
	Reset RT.

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:

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

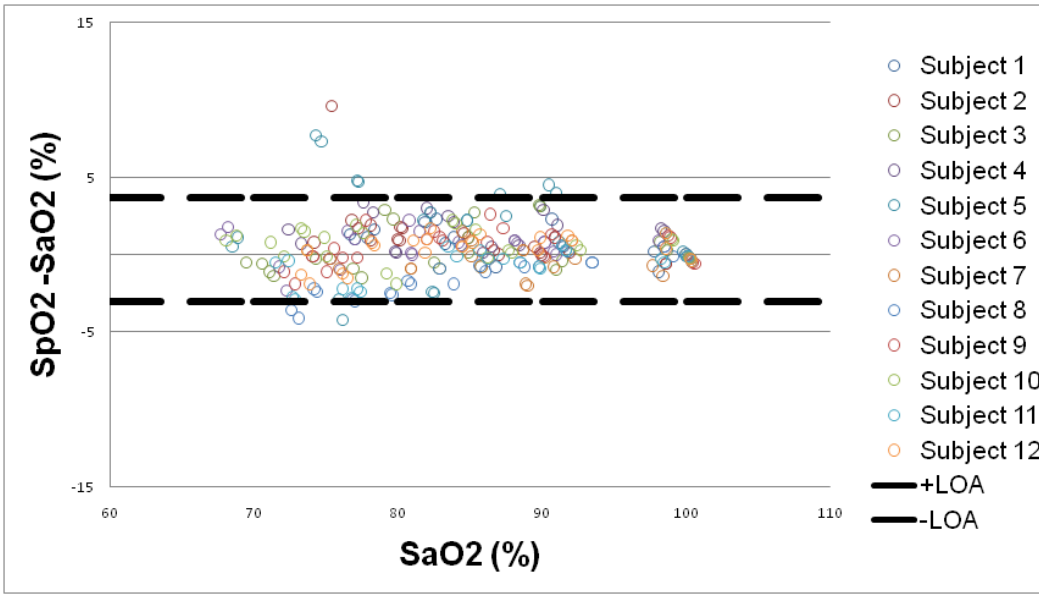
[1]Bias is defined as the monitor under test reading minus the hemoximeter reading.

Note: Because pulse oximeter equipment measurements are statistically distributed, only about two-thirds of Aulisa GA2000 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

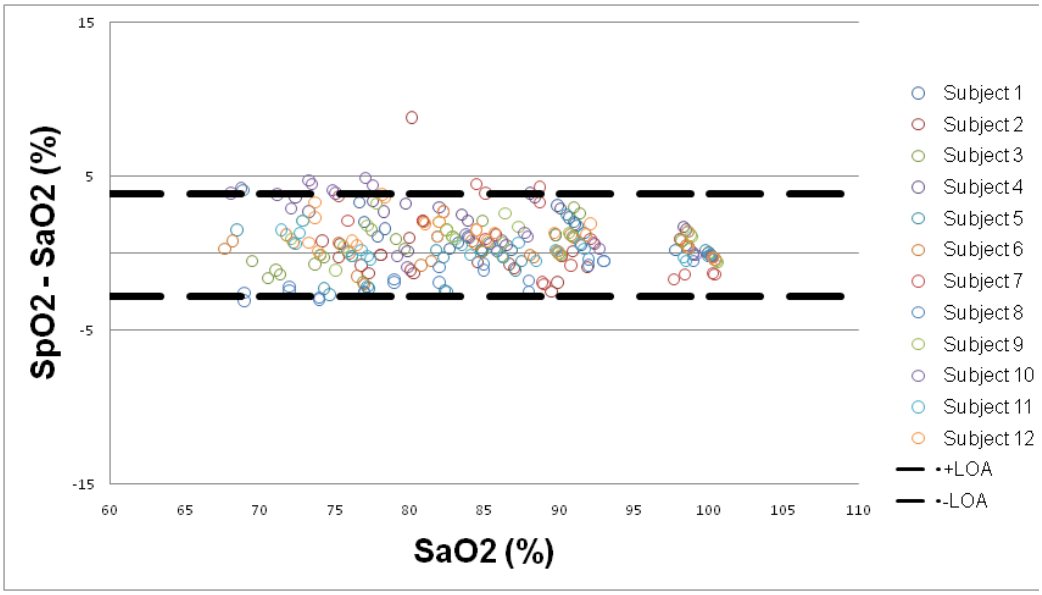
Sensor Accuracy- GA-RS0001		
(A_{rms})	90%-100%	1.70
	80%-90%	1.44
	70%-80%	2.06

The graph below shows the error (SpO_2 – SaO_2) plots of each subject measured by the GA-RS0004 sensor with upper and lower 95% limits of agreement. Each sample data point is from a clinical study in healthy adult volunteers.



Sensor Accuracy- GA- RS0004 (A_{rms})	90%-100%	1.39
	80%-90%	1.77
	70%-80%	2.08

The graph below shows the error (SpO_2 – SaO_2) plots of each subject measured by the GA- RS0001 sensor 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 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

Aulisa GA2000 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 GA2000 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 ±2 kV common mode	±1 kV differential mode ±2 kV common mode	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.			

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

For Sensor Module

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. RF exposure separation distance is 5 mm. Use of other accessories may violate FCC RF exposure guidelines and should be avoided.

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

For Display Unit & Receiver/Transponder

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 A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

FCC Radiation Exposure Statement

This EUT is compliance with SAR for general population/uncontrolled exposure limits in ANSI/IEEE C95.1-1999 and had been tested in accordance with the measurement methods and procedures specified in OET Bulletin 65 Supplement C. The highest reported SAR for the device is 0.116 W/kg.

When suing IEEE 802.11a wireless LAN, this product is restricted to indoor use, due to its operation in the 5.15 to 5.25GHz frequency range. The FCC requires this product to be used indoors for the frequency range of 5.15 to 5.25GHz to reduce the potential for harmful interference to co channel mobile satellite systems. High-power radar is allocated as the primary user of the 5.25 to 5.35GHz and 5.65 to 5.85GHz bands. These radar stations can cause interference with and/or damage to this device.

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 GA2000 Digital Vital Sign Monitoring System. Aulisa warrants the Sensor Module, Receiver/ Transponder and Display Unit for a period of one year from the date of purchase. Aulisa shall repair or replace any Sensor Module and integrated Sensor(s), Receiver/ Transponder 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 GA2000 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 GA2000 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 GA2000 Digital Vital Sign Monitoring System	
Blood Oxygen Saturation Display Range (SpO_2)	1% to 100%
Pulse Rate Display Range	30 to 290 bpm
Accuracy	
Blood Oxygen Saturation (%SpO_2) (± 1 S.D.)	70-100% ± 3 digits
Pulse Rate	± 3%
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	150 bpm
Lower Limit	50 bpm
Alarm Limit Range	
Upper Limit	75-275 bpm
Lower Limit	30-110 bpm
Adjustment Step	
Step Value	1 bpm
Measurement Wavelengths and Output Power	
Red	660 nanometers @ 1.8 mw nominal
Infrared	905 nanometers @ 2 mw nominal
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

Sensor Module (Sensors Integrated)	
Internal Power	
Battery	3.7 V battery
Operating Life	22 hours of continuous operation
Dimensions	
Without sensors	0.7” H x 1.3” W x 2.7” D 16 mm H x 32 mm W x 68 mm D
Weight	1 ounce 28 grams
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
Wireless communication	
Protocol	Wi-Fi
Direction	Bi-direction
Alarm Sound Pressure	>60 dB
Ingress Protection	IP22
Receiver/Transponder	
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
Wireless Communication	
Protocol	Bluetooth 4.0 & Wi-Fi
Direction	Bi-direction
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
Sensor Module	GA-SM0001
Adult Finger Sensor	GA-RS0001
Pediatric Finger Sensor	GA-RS0004
Wristband	GA-WB0001
Receiver/ Transponder	GA-RT0001
Display Unit	GA-DU0002
Stand- Display Unit	GA-SD0002
Charging Adaptor - Sensor Module	GA-CS0001
Charging Adaptor- Display Unit & Receiver/Transponder	GA-CD0002

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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