AULISA™

# Guardian Angel™ Rx
# GA2000

Digital Vital Sign
Monitoring System

## Instructions For Use

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.



AULISA™

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# Guide to Symbols

| | |
|---|---|
|  | 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 |

| | |
|---|---|
| Rx Only | Prescription use only |
|  | Temperature limit |
|   | Non-sterile |
| IP22 | Classification for water ingress and particulate matter |
|  | Date of Manufacturer |
|  | Warning |
|  | Charging Port |

# Precautions for Use


Caution!

### 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.


Warning!

### Warnings

1. Aulisa GA2000 Digital Vital Sign Monitoring System is intended only as an adjunct in patient assessment. It must be used in with other methods of assessing clinical signs and symptoms.
2. A functional tester cannot be used to assess the accuracy of an oximeter sensor cable or an oximeter box. Aulisa GA2000 Digital Vital Sign Monitoring System does not require calibration.
3. Aulisa GA2000 Digital Vital Sign Monitoring System readings may be affected by the use of an electrosurgical unit.
4. Only use the sensor cables manufactured by Aulisa. These sensor cables are manufactured to meet the accuracy specifications for Aulisa GA2000 Digital Vital Sign Monitoring System. Using other manufacturers' sensor cables can result in improper pulse oximeter performance and patient injury may occur.
5. The operator must verify the compatibility of the sensor cable 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. Significant levels of dysfunctional hemoglobin, such as methemoglobin, might 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-Oximeter Box must be approximately 10 meters (10.9 yards) from the Receiver/ Transponder. 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.

Caution!

## Cautions

1. This equipment complies with International Standard IEC 60601-1-2: 2014 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare, home care 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 GA2000 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 probe might not work on cold extremities due to reduced circulation. Warm or rub the finger to increase circulation, or reposition the sensor probe.
6. Aulisa GA2000 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. Some nail polish colors or artificial nails can reduce light transmission and affect $SpO_2$ accuracy.
9. 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.
10. Do not place liquids on top of the device.
11. Do not immerse the device or any of the

components in any liquids.
12. Do not use caustic or abrasive cleaning agents on the device.
13. Do not gas sterilize or autoclave this pulse oximetry system.
14. Batteries might leak or explode if used or disposed of improperly.
15. Follow local governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
16. Do not subject the system to extreme hot or cold temperatures, humidity, or direct sunlight.
17. Do not fasten the Wristband too tightly around the patient's wrist. Inaccurate readings and patient discomfort could result.
18. System connection failure (Bluetooth/ Wi-Fi wireless connection) may result in loss of data transfer.
19. The device is not for use during exercise.

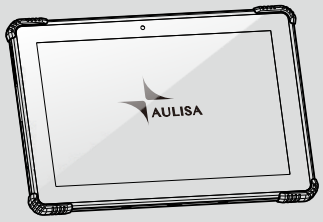
# Using Aulisa GA2000 Digital Vital Sign Monitoring System

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*:

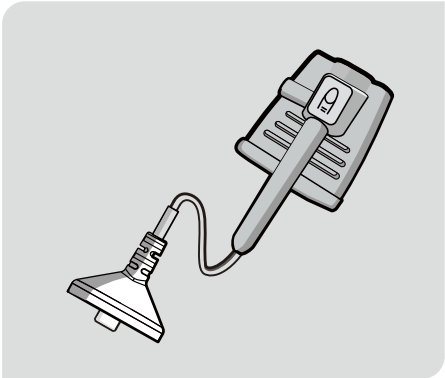
*The system comes with either two Pediatric or two Adult Oximeter Sensor Cables.


Oximeter Box

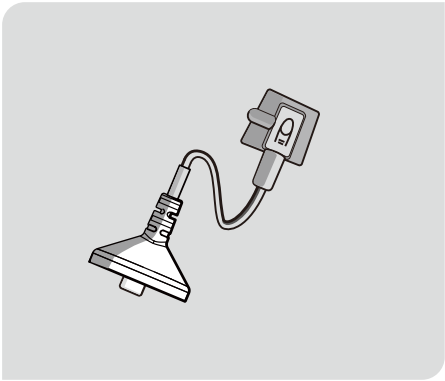
Display Unit




Receiver/Transponder

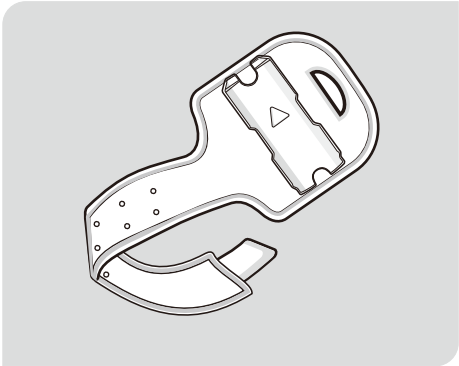


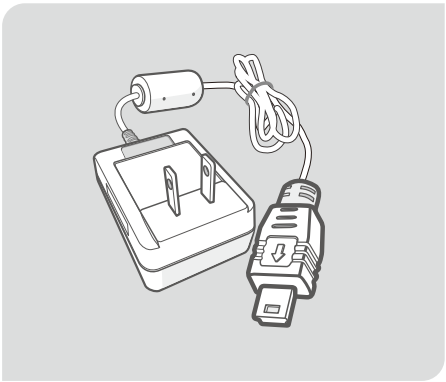
Adult Oximeter Sensor Cable



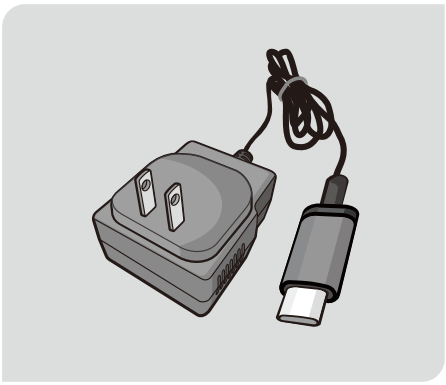
Pediatric Oximeter Sensor Cable

Wristband



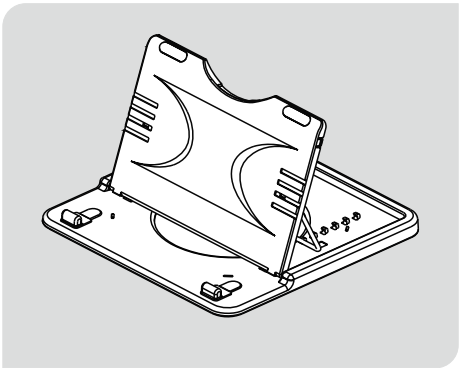


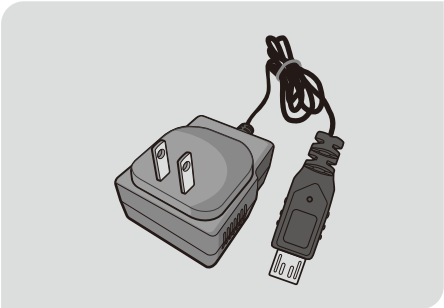
Charging Adaptor-
Oximeter Box



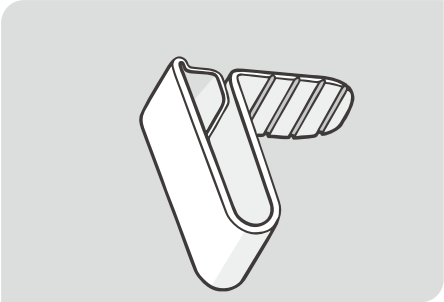
Charging Adaptor-
Display Unit

Stand-Display Unit



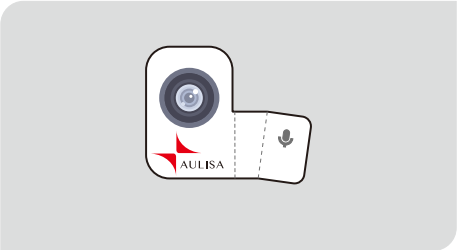


Charging Adaptor-
Receiver/Transponder

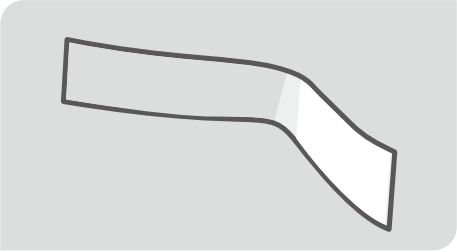


Clamp-
Receiver/Transponder

Sticker-
Receiver/Transponder




Velcro Strap-
Receiver/Transponder



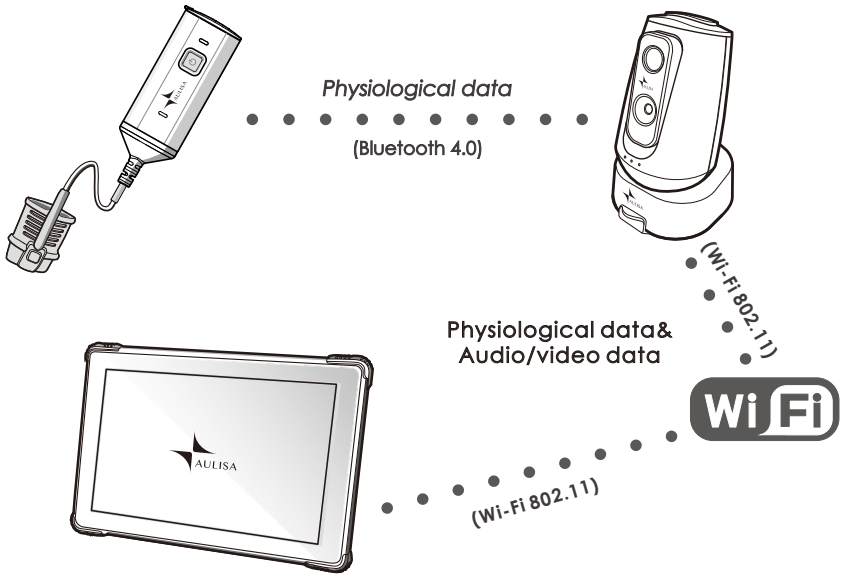
## Intended Use

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 environment of use is hospital, 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



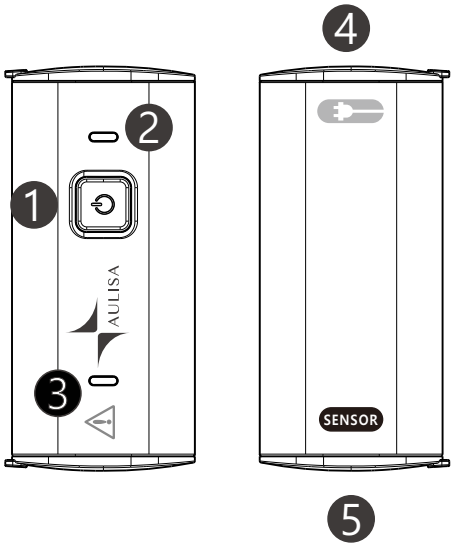

NOTE: Aulisa GA2000 System utilizes a customer Wi-Fi network to communicate between the Receiver/Transponder and the Display Unit. The customer Wi-Fi network is to be implemented and managed by end users.

## Device Overview

### Oximeter Box

The Oximeter box includes a Bluetooth transmitter and a sensor chip, which is worn by the patient for vital sign monitoring. It features a sensor chip, along with electronics for vital sign measuring and analyzing.

The Oximeter Box must be used within 10 meters from the Receiver/Transponder.

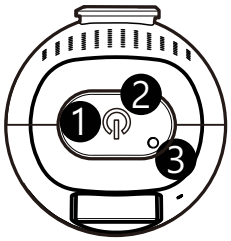



Front View Back View

1. Power On/Off button
2. Power On/Off LED
3. Alarm LED
4. Charging port
5. Sensor cable port

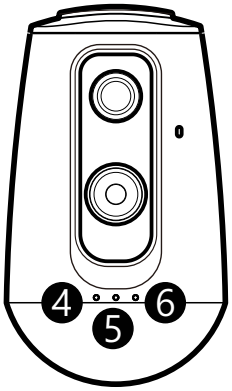
**Receiver/Transponder**

The Receiver/Transponder features Bluetooth/Wi-Fi communication interfaces and an audio/video camera. It receives vital signs monitoring data from the Oximeter Box 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.

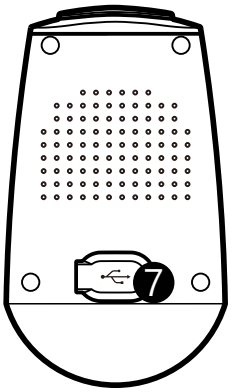



Top View

1. Power On/Off button
2. Power On/Off LED
3. Wi-Fi Link LED
4. AC Power LED
5. Charging LED
6. Battery Low LED
7. Charging port




Front View



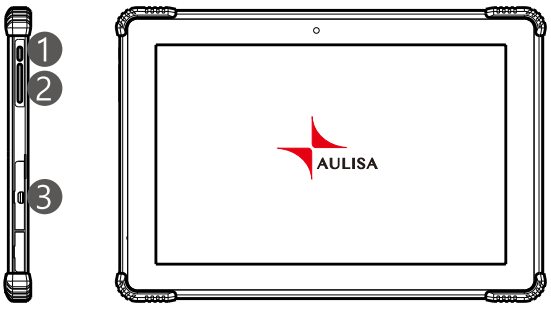

Back View

**Display Unit**

The Display Unit features a 10.1” LCD multi-touch display with Wi-Fi connectivity capability. The Display Unit displays real-time vital signs measured by the Oximeter Box.

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

The Display Unit incorporates a talking and listening function that allows audio messages to be received and sent via the Receiver/ Transponder.




1. Power On/Off button
2. Volume button
3. Charging port

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

NOTE: Only use fingers 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 displays, indicators, and controls for the Aulisa GA2000 System.

| Display Icons and Indicators | | |
|---|---|---|
| **Indicator** | **Name** | **Description** |
| $SpO_2$ % | 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. |
|  | Pulse Amplitude Indicator | This icon displays the pulse signal strength.<br><br>NOTE: When the vital sign values are inadequate, the pulse amplitude indicator will turn yellow. |
|  | Bluetooth Connection Status of Oximeter Box | This icon displays whether the Oximeter Box is connected to the system via Bluetooth. It will turn blue once the Oximeter Box is paired with the system. |

| Indicator | Name | Description |
|---|---|---|
|  | 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 Oximeter Box. A system alarm will be displayed on the Display Unit if the cable is disconnected. |
|  | Battery Level of Oximeter Box | 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 Oximeter Box 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. |
|  | Receiver/ Transponder Connection Indicator | This icon indicates whether there is a connection established between the Display Unit and the Receiver/ Transponder. This icon will turn blue when there is a connection between the Display Unit and the Receiver/ Transponder and turn red when the connection is lost. |

| Indicator | Name | Description |
|---|---|---|
|  | Wi-Fi Strength Indicator | This icon indicates whether there is a strong connection between the Display Unit and customer Wi-Fi Network. |
|  | Alarm Indicator | This icon identifies an alarm condition exists.<br>!!! 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 | | |
|---|---|---|
| Button | Name | Description |
|   | 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 38 for more information on adjusting the alarm limits.)<br><br>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 screen to return to the previous page. |
|  | Alarm History | Tap on this button on the top right corner of the MAIN screen to view the alarm history list. |
|  | Edit Profile | Tap on this button to edit a patient profile, including name, weight, gender, date of birth, and location. |
|  | Sleep Mode | Tap on this button on the top right corner of the MAIN screen to let the Display Unit enter sleep mode. To wake up the Display Unit, use finger to swipe to the right. |

| Button | Name | Description |
|---|---|---|
| CONNECTION | Connection Setup | In the settings menu, tap on this button to change the Wi-Fi network of the Display Unit or of the Receiver/Transponder, and to modify the password for the Receiver/Transponder. |
| PAIRING | Pair new Oximeter Box or Receiver/ Transponder | In the settings menu, tap on this button to pair to a new Oximeter Box or Receiver/Transponder either by scanning the barcode or manually keying in the code found on the back of the said device. (See “System Connection” section on page 25 for more information.) |
| DEFAULT ALARM | Restore Default Alarm | In the settings menu, tap on this button to restore alarm limits to manufacturer-configured values. |
| TIMEZONE | Set Time Zone | In the settings menu, tap on this button to select the correct time zone for the Display Unit. |
| BRIGHTNESS | Set Display Brightness | In the settings menu, tap on this button to set the brightness of the display. |
|  | Talking Function | Press and hold this button to talk to the patient via the Display Unit. |
|  | Listening Function | Tap on this button to receive patient's audio via the Receiver/Transponder's microphone. |

| Button | Name | Description |
| --- | --- | --- |
|  | 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. |

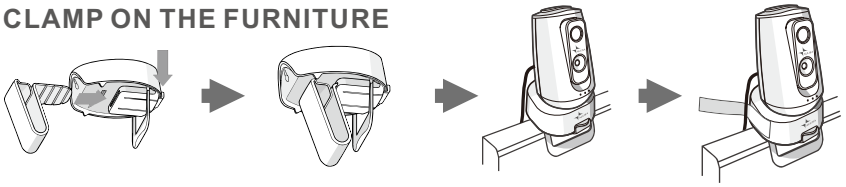
## Setting up Aulisa GA2000 System

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

It is recommended to charge the Oximeter Box 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 44 for more information.)

1. Connect the charging adaptor (black with a micro USB end) to the Receiver/Transponder and a power outlet. (See “Power and Charging” section on page 47 for more information.) Follow the instructions below to assemble the Receiver/Transponder.

**CLAMP ON THE FURNITURE**



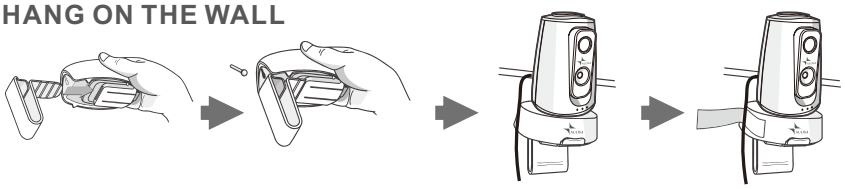
**STEP 1**
Pull down the clip and slide the clamp into the holder.

**STEP 2**
Check to ensure the clamp is secure.

**STEP 3**
Clamp on furniture. Place the device on the holder.

**STEP 4**
Secure the power cable to the holder with Velcro strap.

**HANG ON THE WALL**



**STEP 1**
Slide the clamp into the holder.

**STEP 2**
Hang the holder on the wall.

**STEP 3**
Check to ensure the holder is secure. Place the device on the holder.

**STEP 4**
Secure the power cable to the holder with Velcro strap.

NOTE: Securing the power cable to the holder with the Velcro strap can prevent the Receiver/Transponder body from falling down when it accidentally falls off the holder.

Caution!

Keep the Receiver/Transponder plugged in at all times.

2. Press and hold the power On/Off button for three (3) seconds to turn on the Receiver/Transponder.

NOTE: The power On/Off LED will light green when the power is on.

3. Connect the charging adaptor (black with Type-C end) to the Display Unit and a power outlet. (See “Power and Charging” section on page 46 for more information.)

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

Caution!

Keep the Display Unit plugged in at all times.

Caution!

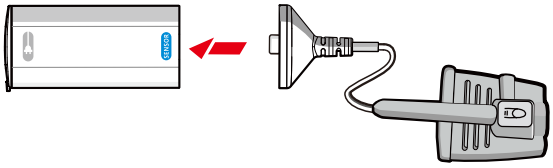
Do not plug the adaptor into a switched outlet to prevent accidental switching power off.

5. Follow the onscreen instructions on the Display Unit to complete the system setup (See “System Connection” section on page 25 for more information.)

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

6. Assemble the Oximeter Module by attaching the connector end of sensor cable to the end marked with SENSOR of the Oximeter Box.

NOTE: Pediatric Oximeter Sensor Cable is intended for use in patients weighing from 10 to 40 kilograms. Adult Oximeter Sensor Cable is intended for use in patients weighing more than 40 kilograms.



Caution!

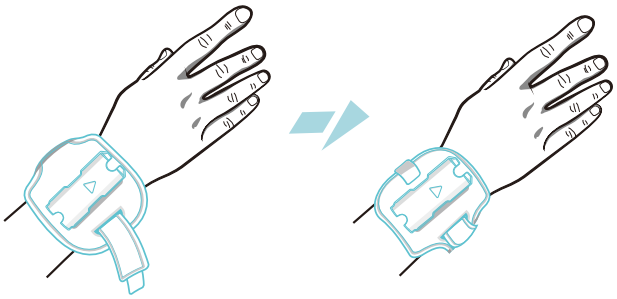
Only use sensor cables supplied or manufactured by Taiwan Aulisa Medical Devices Technologies, Inc.

Caution!

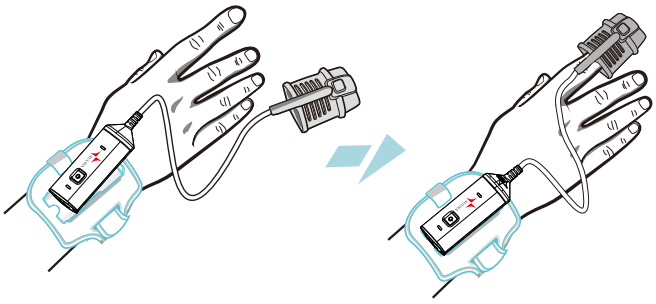
Do not charge the device via this port. Charging through this port will cause permanent damage to the device.

7. Secure the wristband onto the patient's wrist with the holder 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.

NOTE: The wristband should be worn with the arrow indicator facing towards the patient's hand.



8. Insert the Oximeter Box into the holder. Attach the sensor probe to the thumb or finger, making sure that the sensor cable runs over the top of the patient's hand.



9. Click the power On/Off button to turn on the Oximeter Box.

NOTE: The power On/Off LED will light green when the power is on.

10. The Receiver/Transponder will automatically connect to a paired Oximeter Box under the control of the Display Unit.

NOTE: The Oximeter Box must be placed within 10 meters (32.8 feet) from the Receiver/Transponder.

NOTE: The Bluetooth connection status on the Display Unit will turn blue once the connection between the Oximeter Box and the system is established.

NOTE: The power On/Off LED of Oximeter Box will blink green when the data are being transmitted.

## System Connection

**Wi-Fi Network Setup**

**First-Time Users**

Use the following procedures to establish a Wi-Fi connection between the Display Unit and the Receiver/Transponder:

1. Power the Display Unit and the Receiver/Transponder with their respective charging adaptors. (See “Powering and Charging” section on page 44 for more information.)

2. Press and hold the power On/ Off button for three (3) seconds to turn on the Receiver/Transponder. Wait until the Wi-Fi Link LED on the Receiver/ Transponder blinks red.

3. Press and hold the power On/ Off button of Receiver/Transponder for ten (10) seconds until “RESET” is heard. Wait until the Receiver/Transponder plays a melody (around a minute).

4. Select a secure customer Wi-Fi network from the list of available connections displayed on the Display Unit. 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: Wait until the setting up of the Wi-Fi connection for the Display Unit and the Receiver/Transponder has been completed.

   NOTE: The Wi-Fi Link LED on Receiver/Transponder will turn solid red, indicating the Wi-Fi connection has been established.

5. Create a password for the Receiver/Transponder. Then, press “CONFIRM”.

   NOTE: This step cannot be skipped.

   NOTE: The password must contain a combination of numbers and letters.

6. Select the correct time zone.

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

## Reset Wi-Fi Network

**For Display Unit**
Use the following procedures to change the Wi-Fi network of the Display Unit:

1. On the Display Unit, tap on the “SETTINGS” icon. Then, tap on “CONNECTION”.

2. Tap on “DISPLAY UNIT”.

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

**For Receiver/ Transponder**
Use the following procedures to reset the Receiver/Transponder to link to the desired Wi-Fi network:

NOTE: The Wi-Fi network of the Display Unit will be changed, together with that of the Receiver/Transponder.

1. On the Display Unit, tap on the “SETTINGS” icon, then tap on “CONNECTION”.

2. Tap on “RECEIVER/TRANSPONDER”. Then, tap on “CONFIRM”.

3. Press and hold the power On/ Off button of Receiver/Transponder for ten (10) seconds until “RESET” is heard. Wait until the Receiver/ Transponder plays a melody (around a minute).

4. Select the desired 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 al your network traffic.

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

5. Wait until the setting up of the Wi-Fi connection for the Display Unit and the Receiver/Transponder has been completed.

   NOTE: The Wi-Fi Link LED on Receiver/Transponder will turn solid red, indicating the Wi-Fi connection has been established.

6. Create a password for the Receiver/Transponder. Then, press “CONFIRM”.

   NOTE: This step cannot be skipped.

   NOTE: The password must contain a combination of numbers and letters.

7. Select the correct time zone.

## Pairing

**Oximeter Box**
The system will automatically scan and pair to the Oximeter Box from the same starter kit only when the connection between the Display Unit and the Receiver/Transponder has been established.

NOTE: The Oximeter Box must be used within 10 meters (32.8 feet) from the Receiver/Transponder.

NOTE: The Bluetooth connection status icon on the Display Unit will turn blue once the Oximeter Box is paired.

NOTE: The power On/Off LED on the Oximeter Box will blink green when the data are being transmitted.

Use the following procedure to manually setup pairing of a new Oximeter Box:

NOTE: Up to four Oximeter Boxes can be stored on the Display Unit.

1. Ensure the desired Oximeter Box is turned on. (See “Power and Charging” section on page 44 for more information.

   NOTE: The power On/Off LED on Oximeter Box lights green when the power is on.

2. In the settings menu of the Display Unit, select “PAIRING”. Then, select “OXIMETER BOX.”

3. Scan the QR Code or manually key in the serial number SN located on the back of the desired Oximeter Box.

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

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: The Oximeter Box must be used within 10 meters (32.8 feet) from the Receiver/Transponder.

**Receiver/Transponder**
Use the following procedure to manually setup pairing of a new Receiver/ Transponder:

NOTE: Only one Receiver/Transponder can be stored on the Display Unit at a time.

NOTE: The alarm event history on the Display Unit is managed via the Receiver/Transponder, so you won't be able to see the current alarm event history when the Display Unit is paired to a new Receiver/ Transponder.

1. Turn on the desired Receiver/Transponder by pressing and holding the power On/ Off button for 3 seconds. Wait until the Wi-Fi Link LED lights red. (See "Power and Charging"section on page 47 for more information.)

   NOTE: The power On/Off LED on Receiver/Transponder lights green when the power is on.

2. In the settings menu of the Display Unit, select "PAIRING". Then, select "Receiver/Transponder."

3. Scan the QR Code or manually key in the CODE located on the back of the desired Receiver/Transponder.

4. Press "CONFIRM" if the pairing code displayed matches with the CODE on the back of desired Receiver/Transponder.

5. Follow the onscreen instructions on the Display Unit to setup the Wi-Fi connection of the Receiver/Transponder.

## 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 21 for more information.)

2. Ensure there is a system connection established between the Oximeter Box, Receiver/Transponder and Display Unit. (See “System Connection” section on page 25 for more information.)

3. Detach the sensor cable from Oximeter Box.

4. Verify that an alarm message is displayed and that an alarm audio is generated (See “Troubleshooting” section on page 49 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 21 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 power On/Off button on the Oximeter Box is blinking green.

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

NOTE: On the top right of the MAIN screen, ensure the Receiver/ Transponder connection indicator RT is lit blue and the Display Unit 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 pulse amplitude reading is displayed.

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

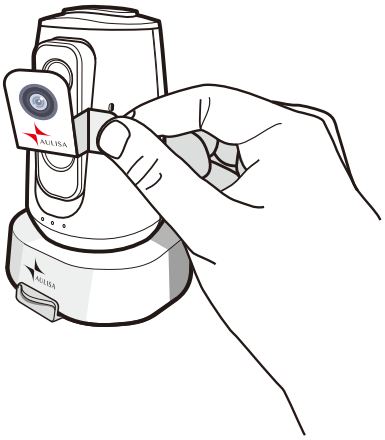
## Audio/ Video Feature


1 **Video:** View patient's video

2 **Listening:** Tap to turn on and receive patient's audio

3 **Talking:** Press and hold to send an audio message to patient

NOTE: When patient privacy is desired, follow the instructions below to place the sticker over the camera and microphone of Receiver/Transponder. The sticker completely blocks the image but may not significantly block the sound.



## Shutting off the System

Use the following procedure to shut down the Display Unit, the Oximeter Box, and the Receiver/Transponder.

**Display Unit**

1. Press and hold 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 MAIN screen.

**Oximeter Box**

Click the power On/Off button to turn off the Oximeter Box.

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

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

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

**Receiver/Transponder**

Press and hold the power On/Off button for at least three (3) seconds to turn off the Receiver/Transponder.

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

# Alarms and Limits

This chapter describes alarms and limits for Aulisa GA2000 System.

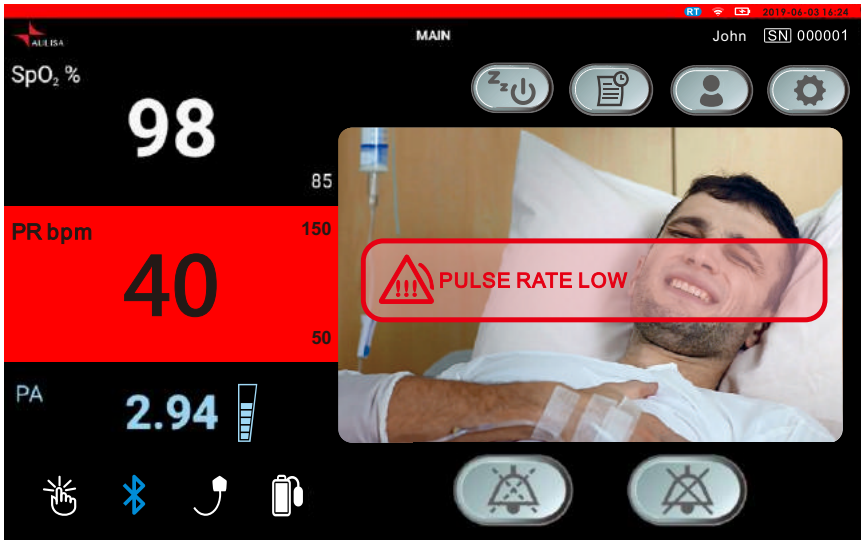
## Alarms

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 Oximeter Box 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 33 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 Oximeter Box will blink yellow along with displays on the Display Unit.

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

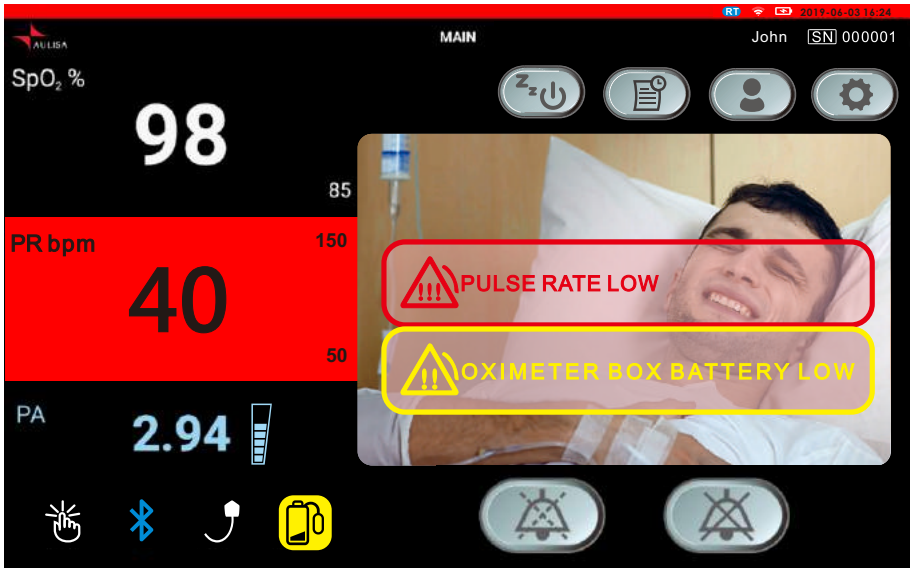
| Alarm Condition (Medium Priority Alarm) | Visual Indicator |
|---|---|
| Sensor Probe Detached from Patient | The Oximeter Box blinks yellow light along with blinking yellow displays and alarm text message on the Display Unit. |
| Oximeter Box Battery Low | |
| Sensor Cable Detached | |
| Detection Error | |
| Display Unit Battery Low | On the Display Unit, it blinks yellow displays and alarm text message. |
| Data Not Updated For 30 seconds | |
| Oximeter Box Disconnected | |
| Display Unit Wi-Fi Lost | |
| Receiver/Transponder Disconnected | |


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

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

Alarm limits may be adjusted by pressing ‘‘ALARM LIMITS’’ button after silencing the alarms. (See “Adjusting Alarm Limits” section on page 33 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.




| | |
|---|---|
| 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. |

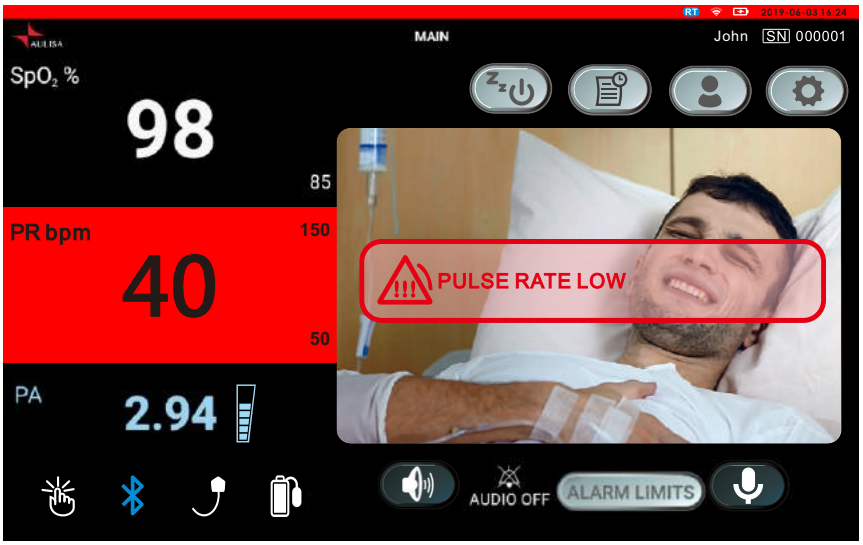
## Adjusting Alarm Limits

Follow the instructions below to review or set alarm limits. To restore alarm settings to default values, refer to “Default Alarm Settings.”

1. Ensure the system connection is established. (See “System Connection” section on page 25 more information.)
2. Tap on "SETTINGS" button on the MAIN screen, and then tap on “ALARM LIMITS” button.


NOTE: Alarm limits can be adjusted only when the Oximeter Box has been paired.

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

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

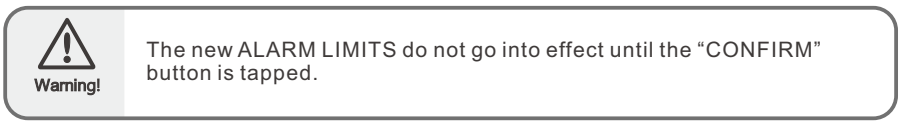
NOTE: The minimum alarm limit cannot exceed the max alarm limit, even if the max alarm limit is turned off. For example, if the max $SpO_2$ limit is turned off but was previously set at 90%, the min $SpO_2$ limit cannot be set higher than 90%. If you want to set min $SpO_2$ limit at 90%, turn on the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

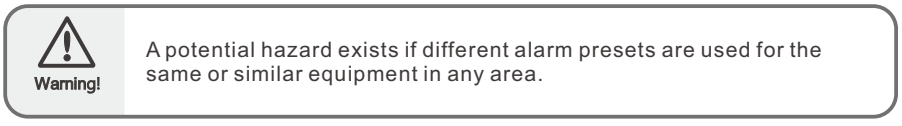
NOTE: The following table describes the default settings, adjustment ranges, and intervals.

| 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!

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 signlimits for the user before adjusting an alarm.

## Alarm Delay Function

In the traditional alarm management system, upper and lower alarm limits are set so alarms are issued at specific $SpO_2$ levels. When the $SpO_2$ level fluctuates near an alarm limit, each breach will trigger an alarm. Aulisa GA2000 monitors the gradient, the depth and the duration of $SpO_2$ reduction as the factors to determine the alarm riggering delay. Therefore, it helps to distinguish between major clinical events and minor and brief $SpO_2$ alarm limit violations that may trigger an alarm.

NOTE: The following table lists the alarm triggering delay statistics for $SpO_2$ Low Alarm Limit.

| $SpO_2$ Low Alarm Limit | Average Delay (seconds) | Maximum Delay (seconds) |
|---|---|---|
| ≥90 | 50 | 74 |
| 86-90 | 16 | 20 |
| 81-85 | 6 | 7 |
| 76-80 | 4 | 6 |
| ≤75 | 4 | 5 |

Likewise, when the pulse rate fluctuates near an alarm limit, each breach will trigger an alarm. With the pulse rate alarm delay feature, Aulisa GA2000 allows a period of threshold violation of 7 seconds before an alarm is triggered. Thus, it greatly reduces alarms reported for minor and brief alarm limit violations.

NOTE: A countdown timer and “AUDIO OFF” will be displayed on the MAIN screen when the alarm limit has been breached and the alarm is being delayed. The alarm will be delayed until the timer counts down to zero.

## Default Alarm Settings

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

1. Ensure there is a system connection established between the Oximeter Box, the Receiver/Transponder and the Display Unit. See “System Connection” section on page 25 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 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 | 150 bpm |
| Pulse Rate Lower Alarm Limit | 50 bpm |

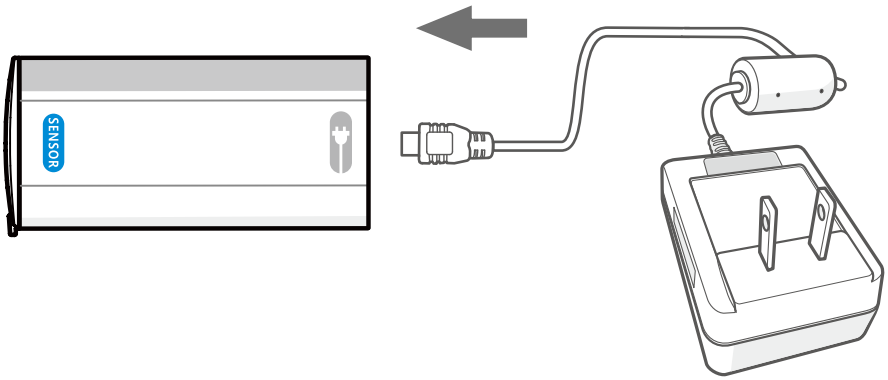
# Powering and Charging

## Charging the Oximeter Box

Charge the Oximeter Box with the charging adaptor (white) by following the steps below.

NOTE: The Display Unit will alarm the user when the Oximeter Box is low on battery. Once on low battery, the Oximeter Box 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 Oximeter Box marked by .



2. Attach the wall adaptor to a power outlet.

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

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

NOTE: Verify operation of the system (See “Verifying System Operation” section on page 30 for more information) and check the battery status on the MAIN screen of the Display Unit.

NOTE: The Oximeter Box cannot be used to measure vital signs while it is being charged.


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

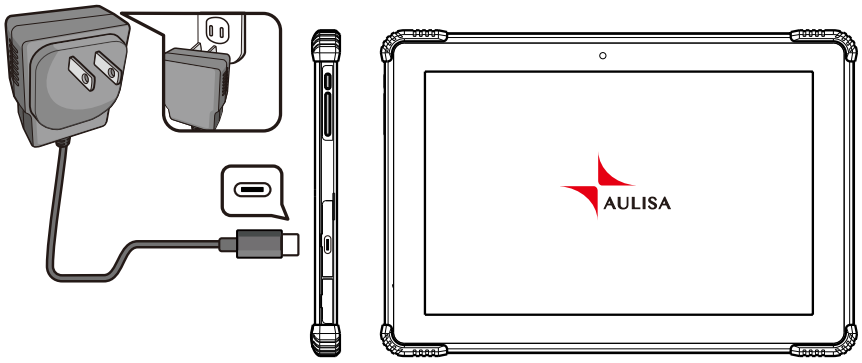
## Powering the Display Unit

The Display Unit is meant to be used with the charging adaptor (black with a Type-C end) 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. Plug the Type-C end of the charging adaptor (black with a Type-C end) into the Display Unit.
2. Attach the wall adaptor to a power outlet.
3. Place the Display Unit on the stand provided.

NOTE: Keep the Display Unit plugged in at all times.




Caution!

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

## Powering the Receiver/ Transponder

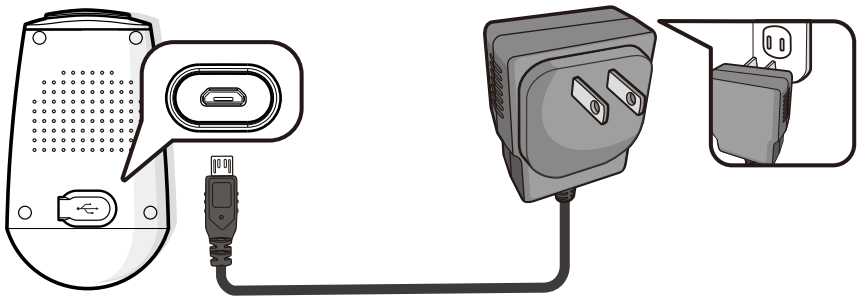
The Receiver/Transponder is meant to be used with the charging adaptor (black with micro-USB end) plugged in.

1. Plug the micro-USB cable end of the charging adaptor into Receiver/Transponder.
2. Plug the wall adaptor to a power outlet.

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. (See “Device Overview” section on page 12 for more information.)



Caution!

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

# Care and Maintenance

The advanced digital circuitry within the Oximeter Box 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 Oximeter Box, the Receiver/Transponder or the Display Unit will damage the device and void the warranty. If the system is not functioning properly, see “Troubleshooting” section on page 48 for more information.

The expected service life of Aulisa GA2000 System is 18 months.

## 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.


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.


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 Oximeter Box | Click the power On/Off button. |
| | Fully charge the Oximeter Box 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 and the Display Unit. |
| Cannot turn on the Receiver/Transponder | Press and hold the power On/Off button for three (3) seconds. |
| | Make sure the power cord is properly connected to the outlet and the Receiver/ Transponder. |
| Unable to obtain a valid $SpO_2$ or pulse rate reading<br><br>NOTE: In some instances, patient perfusion may be inadequate for pulse detection. | Reposition the sensor probe or reinsert the finger and keep the hand motionless for at least ten (10) seconds. |
| | Warm the finger by rubbing or covering with a blanket. |
| | Position the sensor probe at a different site. |
| | Allow the hand to rest comfortably without squeezing or pressing the sensor probe on a hard surface. |

| Problem | Possible Solution |
|---|---|
| Unable to obtain a valid $SpO_2$ or pulse rate reading.<br><br>NOTE: In some instances, patient perfusion may be inadequate for pulse detection. | 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 sensor probe is attached to the finger securely. |
| | Make sure the sensor cable is securely attached to the Oximeter Box. |
| | Check the Display Unit for any alarms or error messages. |
| | Check the Oximeter Box for power. |
| | Ensure that the Oximeter Box is within 10 meters spherical radius to the Receiver/Transponder. |
| | Check the sensor cable for any visible signs of deterioration. |
| Unstable/Constant $SpO_2$ and Pulse Rate readings | Shield the finger sensor from the light source. |
| | Insert the sensor probe to a finger without artificial or polished nails. |
| | Position the sensor probe at a different site. |

| Problem | Possible Solution |
|---|---|
| Unstable/Constant $SpO_2$ and Pulse Rate readings | Make sure the sensor probe is attached to the finger securely. |
| | Make sure the sensor cable is securely attached to the Oximeter Box. |
| | Check the sensor cable for any visible signs of deterioration. |
| | Reduce patient motion. |
| A dash “---” appears in the vital sign display. | Make sure the sensor cable is securely attached to the Oximeter Box. |
| | Make sure the sensor probe is attached to the finger securely. |
| | Ensure that the Oximeter Box is within 10 meters spherical radius to the Receiver/Transponder. |
| | Relocate the sensor at a different site. |
| | Turn off the system, check system connections, and retry. |
| Data has not been updated for 30 seconds. | Reposition the sensor probe or reinsert the finger and keep the hand motionless for at least ten (10) seconds. |
| | Relocate the sensor probe at a different site. |
| | Insert the sensor probe to a finger without fingernail polish or an artificial nail. |

| Problem | Possible Solution |
|---|---|
| The unit is in Alarm mode, but no audible alarms can be heard. | Wait for two minutes and alarm tones will automatically re-engage if it was silenced temporarily. |
| | Make sure there are no headphones inserted into the headphone jack of the Display Unit. |
| Cannot establish system connection | Ensure that the Oximeter Box is within 10 meters spherical radius to Receiver/ Transponder while being paired. |
| | Check network usage/bandwith of other interfaces within the Wi-Fi network that may prevent the system from establishing a connection. |
| | Turn off the system, verify system connections, and retry. |
| | Reset the Wi-Fi network for the Display Unit. |
| | Reset the Wi-Fi network for the Receiver/Transponder. |

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

Warning!

This system is a precision electronic instrument andmust 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 bias1 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:

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

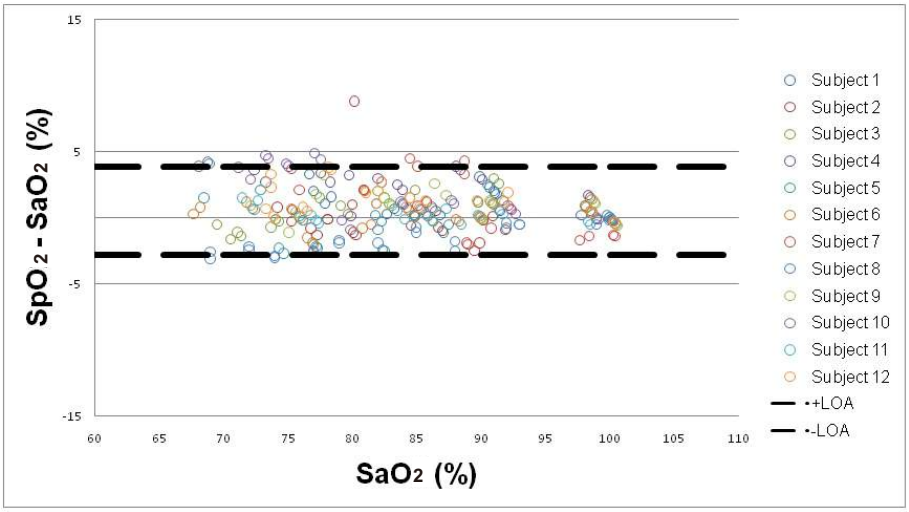
[1]Bias is defined as the monitor under test reading minus the hemoximeter reading.

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**

| | | |
|---|---|---|
| Accuracy ($A_{rms}$) | 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 Aulisa GA2000 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 | Delay (Seconds) |
|---|---|
| Data Averaging | ≤ 4 seconds |
| Alarm Condition Delay | ≤ 4 seconds |
| Alarm Signal Generation Delay | 0 seconds |
| Data Update Period | 1 second |

## Manufacturer's Declaration

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

**Guidance and Manufacturer's Declaration - Electromagnetic Emissions - for all EQUIPMENT and SYSTEMS**

| Guidance and Manufacturer's Declaration- Electromagnetic Emission | | |
|---|---|---|
| This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment. | | |
| **Emissions test** | **Compliance** | **Electromagnetic environment -guidance** |
| RF emissions CISPR 11 | Group 1 | This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | This device is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Complies | |
| Voltage fluctuations/ flicker Emissions IEC 61000-3-3 | Complies | |

**Guidance and Manufacturer's Declaration-Electromagnetic Immunity - for all EQUIPMENT and SYSTEMS**

| Guidance and Manufacturer's Declaration-Electromagnetic Immunity | | | |
|---|---|---|---|
| This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601-1-2 test level** | **Compliance level** | **Electromagnetic environment-guidance** |
| Electrostatic Discharge (ESD) IEC 61000-4-2 | ±8 kV contact ±15 kV air | ±8 kV contact ±15 kV air | Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%. |
| Electrical Fast Transient/ Burst IEC 61000-4-4 | ±2 kV for power supply lines ±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 commom mode | ±1 kV differential mode ±2 kV commom mode | Mains power quality should be that of a typical commercial or hospital environment. |

| Immunity test | IEC 60601-1-2 test level | Compliance level | Electromagnetic environment-guidance |
|---|---|---|---|
| Voltage dips, short interruptions, and voltage variations on power supply input lines<br><br>IEC 61000-4-11 | ±0% UT in 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>±0% UT in 1 cycle at 0°<br>±70% UT in 25/30 cycles at 0°<br>±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°<br>±70% UT in 1 cycle at 0°<br>±0% UT in 25/30 cycles at 0°<br>±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<br><br>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 Manufacturer's Declaration-Electromagnetic Immunity | | | |
|---|---|---|---|
| This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601-1-2 test level** | **Compliance level** | **Electromagnetic environment-guidance** |
| Conducted RF IEC 61000-4-6 | 3 V/m 150 kHz to 80 MHz | 3 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. |
| Conducted RF IEC 61000-4-3 | 10 V/m 80MHz to 2.7 GHz | 10 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.

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## FCC Compliance

### For Oximeter Box

**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**

**For Display Unit**

This equipment 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.

**For Receiver/Transponder**

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator & your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

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.

# Service, Support, and Warranty

## Warranty

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

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

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

Under this Warranty, the purchaser is responsible for the cost of delivery of the product to Aulisa's place of repair as designated by Aulisa, and Aulisa is responsible for the cost of delivery back to the purchaser. Aulisa reserves the right to charge a fee for a warranty repair request on an Aulisa product that is found to be within specifications and without material defect.

# Device Privacy Policy

## This Privacy Policy was last updated on March 22, 2019.

**Our Policy**

This privacy policy applies to personal information collected by Taiwan Aulisa Medical Devices Technologies, Inc. (”Aulisa”, “we”, “us” and/or “our”) from users of the Aulisa remote patient monitoring devices (the “Devices”). “Personal Information” includes any information that can be used on its own or with other information to identify or contact a single person or to identify an individual in context. If we can link particular information (directly or indirectly) to an individual, we will consider this information “Personal Information”, and we will protect it.

WE AT AULISA VALUE KEEPING YOUR PERSONAL INFORMATION CONFIDENTIAL AND USING IT SOLELY IN THE CONTEXT OF OUR MISSION TO PROVIDE CONTINUOUS MONITORING OF VITALS IN ORDER TO AID PATIENTS, HEALTHCARE PROVIDERS (“PROVIDERS”), AND CAREGIVERS MAKE INFORMED DECISIONS ABOUT YOUR CARE.

THE PERSONAL INFORMATION WE COLLECT AND TRANSMIT MAY INCLUDE HEALTHCARE INFORMATION, INCLUDING MEDICAL INFORMATION. THEREFORE, OUR PRIVACY PRACTICES ARE INTENDED TO COMPLY WITH THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (“HIPPA”). WE WILL MAINTAIN THE PRIVACY OF YOUR HEALTH INFORMATION AS REQUIRED BY HIPPA AND THE REGULATIONS PROMULGATED UNDER THAT ACT. FOR ADDITIONAL INFORMATION RELATED TO YOUR HEALTHCARE INFORMATION, PLEASE CONTACT information@aulisa.com.

**Changes:**

PLEASE NOTE THAT WE OCCASIONALLY UPDATE THIS PRIVACY POLICY AND THAT IT IS YOUR RESPONSIBILITY TO STAY UP TO DATE WITH ANY AMENDED VERSIONS. IF WE MODIFY THIS PRIVACY POLICY, WE WILL NOTIFY YOU OF THE CHANGES ON OUR WEBSITE, AN IN-SERVICE NOTICE OR OTHER REASONABLE MEANS. YOU CAN STORE THIS POLICY AND/OR ANY AMENDED VERSION(S) DIGITALLY, PRINT IT, OR SAVE IT IN ANY OTHER WAY. ANY CHANGES TO THIS PRIVACY POLICY WILL BE EFFECTIVE IMMEDIATELY UPON POSTING, AND SHALL APPLY TO ALL INFORMATION WE MAINTAIN, USE AND DISCLOSE. IF YOU CONTINUE TO USE THE DEVICES FOLLOWING SUCH NOTICE, YOU ARE AGREEING TO THOSE CHANGES.

Capitalized terms, if not defined in this Privacy Policy, are defined in the documentation that came with your Devices.

What Information Do We Collect and Why?

**Personal Data that You Provide Through the Devices**
We collect Personal Information (e.g. demographic information) from you when you voluntarily provide such information to us, use the Devices (including without limitation, the software featured on the Devices and/or platforms), contact us with inquiries, or use certain features of the Devices. We use this information to allow the Devices to provide the information to you and/or your Provider.

In addition to demographic information, if you are a Patient, we collect Health Data through the Devices. Such Health Data may include information about your vital signs, health conditions, age, gender, weight, and height. We collect this information to communicate information to your healthcare provider.

Primarily, the collection of your Personal Information assists us in providing a means to track your vital signs in order to better enable you to communicate information with caregivers and healthcare providers and be an active participant with those providers in monitoring your care, tailoring interventions, and assessing treatment outcomes. We may also use your Personal Information to (1) store data; (2) comply with the law; (3) respond to requests from public and government authorities; (4) to enforce our terms and conditions; (5) manage and improve our operations and applications; (6) provide additional functionality;

(7) protect our rights, privacy, safety or property, and/or
that of yours or others; and (8) allow us to pursue available remedies or limit the damages we may sustain.

Failure to Provide Information
Providing your Personal Information is not statutorily or contractually mandated. If you choose not to provide this information, we cannot monitor your vital signs, and you will be unable to use our Devices.

Support Information
If you contact Aulisa for support or to lodge a complaint, we may collect technical or other information from you. Such information will be used for the purposes of troubleshooting, customer support, software updates, and improvement of the Devices in accordance with this Privacy Policy. Calls with Aulisa may be recorded or monitored for training, quality assurance, customer service, and reference purposes.

Aggregated Personal Data: In an ongoing effort to better understand and serve our customers, other users of the Devices, and communities of patients with similar health conditions, Aulisa may conduct research on its user demographics and behavior based on the Personal Information we collect from you and the other information provided to us. This research may be compiled and analyzed on an aggregate basis, and Aulisa may share this research and related information in aggregated, de-identified and/or anonymized format with its affiliates, agents and other healthcare research and services entities, including without limitation insurance and pharmaceutical companies. For the avoidance of doubt, this aggregate information does not identify you personally. Aulisa may also disclose aggregated, de-identified and/or anonymized information in order to describe our business and the Devices to current and prospective business partners and Customers, and to other third parties for other lawful purposes.

Where Is My Personal Information Stored And/Or Processed?

Information Aulisa collects through the Devices will be processed and/or stored on secure third- party cloud-based servers or through a Wi-Fi network. All of the information you share with us through the Devices is double-encrypted during transmission using AES-128 data encryption as well as an Aulisa private encryption method.

Will You Share My Personal Information with Anyone Else?

We consider your information to be a vital part of our relationship with you. There are, however, certain circumstances in which we may share your Personal Information with certain third parties without further notice to you. Those circumstances are described below:

With Our Provider Customers: If you are a Patient, we will share your Personal Information and Health Data with our Provider Customer(s) that provide healthcare services to you. This will enable your Provider to track your Health Data and combine such Health Data with other information about you that your Provider obtains in providing healthcare services to you.

With Caregivers: If you are a Patient, family and/or friends may view certain of your Personal Information and/or Health Data and related alerts.

In the Event of a Business Transfer: We might sell or buy businesses or assets. In the event of a corporate sale, merger, reorganization, dissolution or similar event, Personal Information may be part of the transferred assets.

With Related Companies: We may also share Personal Information with Aulisa Related Companies for purposes consistent with this Privacy Policy.

With Our Agents, Consultants and Related Third Parties: Aulisa, like many businesses, sometimes hires other companies to perform certain business-related functions. Examples of such functions include data hosting and billing management. When we employ another entity to perform a function of this nature, we only provide the entity with the information that it needs to perform its specific function.

To Meet Our Legal Requirements: We may disclose your Personal Information if required to do so by law or if we have a good faith belief that such action is necessary to (i) comply with a legal obligation, (ii) protect and defend our rights or property, (iii) act in urgent circumstances to protect the personal safety of you, us, other users of the Devices or the public, or (iv) protect against legal liability.

NOTE: We may, from time to time, rent or sell aggregated data and/or other information that does not contain any personal identifiers (i.e., if the information has been anonymized by stripping out identifiers such as name, address, phone number, etc.). The purpose of this type of disclosure is to allow research institutions to learn more about symptoms associated with your medical condition(s).

How Long Will You Retain the Information?
We only store certain of your Personal Information for as long as you use the Devices and up to five (5) years after you cease to use the Devices. At the end of this five-year period, we will remove your Personal Information from our databases and will request that our business partners remove your Personal Information from their databases. However, once we disclose your Personal Information to third parties, we may not be able to access that Personal Information any longer and cannot force the deletion or modification of any such information by the parties to whom we have made those disclosures. Written requests for deletion of Personal Information other than as described should be directed to information@aulisa.com. We retain anonymized data indefinitely.

How Do You Protect My Personal Information?

Aulisa is committed to protecting the security and confidentiality of Personal Information. We use a combination of reasonable physical, technical, and administrative security controls to maintain the security and integrity of your Personal Information, to protect against any anticipated threats or hazards to the security or integrity of such information, and to protect against unauthorized access to or use of such information in our possession or control that could result in substantial harm or inconvenience to you. However, Internet data transmissions, whether wired or wireless, cannot be guaranteed to be 100% secure. As a result, we cannot guarantee the security of information you transmit to us. By using the Devices, you are assuming this risk.

**Safeguards**

The information Aulisa collects and stores on secure servers is protected by a combination of technical, administrative, and physical security safeguards, such as authentication, encryption, backups, and access controls. If Aulisa learns of a security concern, we may attempt to notify you and provide information on protective steps, if available, through the email address that you have provided to us or other reasonable notification. Depending on where you live, you may have a legal right to receive such notices in writing.

NOTWITHSTANDING ANY OF THE STEPS WE TAKE, IT IS NOT POSSIBLE TO GUARANTEE THE SECURITY OR INTEGRITY OF DATA TRANSMITTED OVER THE INTERNET. THERE IS NO GUARANTEE THAT YOUR INFORMATION WILL NOT BE ACCESSED, DISCLOSED, ALTERED, OR DESTROYED BY BREACH OF ANY OF OUR PHYSICAL, TECHNICAL, OR ADMINISTRATIVE SAFEGUARDS. THEREFORE, WE DO NOT AND CANNOT ENSURE OR WARRANT THE SECURITY OR INTEGRITY OF ANY INFORMATION YOU TRANSMIT TO US AND YOU TRANSMIT SUCH INFORMATION AT YOUR OWN RISK.

How Can I Protect My Personal Information?

We will NEVER send you an e-mail requesting confidential information such as account numbers, or social security numbers, and you should NEVER respond to any e-mail requesting such information. If you receive such an e-mail purportedly from Aulisa, DO NOT RESPOND to the e-mail and DO NOT CLICK on any links and/or open any attachments in the e-mail, and notify Aulisa support at information@aulisa.com.

You are responsible for taking reasonable precautions to safeguard the Device from exposure to unauthorized third parties, and you are not permitted to circumvent the use of required encryption technologies.

**EU DATA SUBJECT RIGHTS**

If you are an EU data subject, you have the following rights under certain circumstances:

- to receive communications related to the processing of your personal data that are concise, transparent, intelligible and easily accessible;
- to be provided with a copy of your personal data held by us;
- to request the rectification or erasure of your personal data held by us without undue delay;
- to request that we restrict the processing of your personal data (while we verify or investigate your concerns with this information, for example);
- to object to the further processing of your personal data, including the right to object to marketing;
- to request that your personal data be moved to a third party;
- to receive your personal data in a structured, commonly used and machine-readable format;
- to lodge a complaint with a supervisory authority.

Where our processing of your Personal Information is based on consent, you have the right to withdraw that consent without detriment at any time by contacting us at information@aulisa.com. You can also exercise the rights listed above at any time by contacting us at information@aulisa.com.

How Can I Update, Correct or Delete My Personal Information?

If you need to make changes or corrections to your information, you may make such changes or corrections on the Device.

Information Submission by Minors

If the Device is being utilized by a minor, and the Devices are being used to monitor a minor, you represent, warrant and covenant that by

agreeing to the terms of this Privacy Policy, you have the legal authority to accept this Privacy Policy on behalf of such minor as the minor's parent or legal guardian. If you do not have such legal authority, do NOT accept this Privacy Policy and do not use the Devices on behalf of such minor.

How Can I Contact Aulisa?

If you have any questions or comments about this Privacy Policy, our practices, or our Devices, please feel free to e-mail us at information@aulisa.com.

# 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 |
| **Bluetooth Communication** | |
| Range | 10-meter spherical radius |
| Protocol | Bluetooth 4.0 |
| Direction | Bi-direction |
| Data rate | Up to 100kBps |
| **Wi-Fi Communication** | |
| Protocol | 802.11 b/g/n/ac, 2.4GHz/5GHz |
| Direction | Bi-direction |
| **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 |

**Classifications per IEC/ EN 60601-1**

| | |
|---|---|
| Type of Protection | Class II, MOPP (on AC power)<br>Internally powered<br>(on battery power) |
| Degree of Protection | Type BF-Applied Part |
| Mode of Operation | Continuous |

| | |
|---|---|
| **Oximeter Box** | |
| **Internal Power** | |
| Battery | 3.7 V battery |
| Operating Life | 22 hours of continuous operation |
| **Dimensions** | |
| Without sensors | 0.7” x 1.3” x 2.7”<br>16 mm x 32 mm x 68 mm |
| **Weight** | 1 oz<br>28 g |
| **Wireless Communication** | Bluetooth |
| **Ingress Protection** | IP22 |
| **Display Unit** | |
| **Display** | |
| Display panel | 10.1” IPS Touch Panel |
| **Power Requirements** | |
| Mains | 100-240 V AC 50-60 Hz |
| DC Input | 5 V DC/AC adaptor |
| **Internal Power** | |
| Battery | 3.8 V battery |
| Operating Life | 2 hours of continuous operation |
| **Dimensions** | 7.04” x 10.35” x 0.46”<br>179 mm x 263 mm x 11.8 mm |
| **Weight** | 21.87 oz<br>620 g |
| **Wireless Communication** | Wi-Fi |
| **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 |

| | |
|---|---|
| **Dimensions** | |
| Body | 2.6” x 4.6” x 2.7”<br>67 mm x 116 mm x 69 mm |
| Stand | 3.5” x 3.6” x 1.3”<br>90 mm x 91 mm x 32 mm |
| **Weight** | |
| Body | 6 oz<br>171g |
| Stand | 1 oz<br>33 g |
| **Wireless Communication** | Bluetooth & Wi-Fi |
| **Ingress Protection** | IP22 |

# Parts and Accessories

| Parts and Accessories | Model Number |
|---|---|
| Oximeter Box | GA-SM0001 |
| Adult Oximeter Sensor Cable | GA-RS0002 |
| Pediatric Oximeter Sensor Cable | GA-RS0004 |
| Wristband | GA-WB0002 |
| Receiver/Transponder | GA-RT0001 |
| Display Unit | GA-DU0003 |
| Stand- Display Unit | GA-SD0002 |
| Charging Adaptor-Oximeter Box | GA-CS0001 |
| Charging Adaptor-Display Unit | GA-CD0004 |
| Charging Adaptor-Receiver/Transponder | GA-CR0001 |

For more information about Aulisa parts and accessories, contact your distributor, or contact Aulisa by going online at www.aulisa.com under “Contact Us”.

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.