Instructions For Use

On

ECG & Respiration Module

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Signatures

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Approval	Department	Date	Signature
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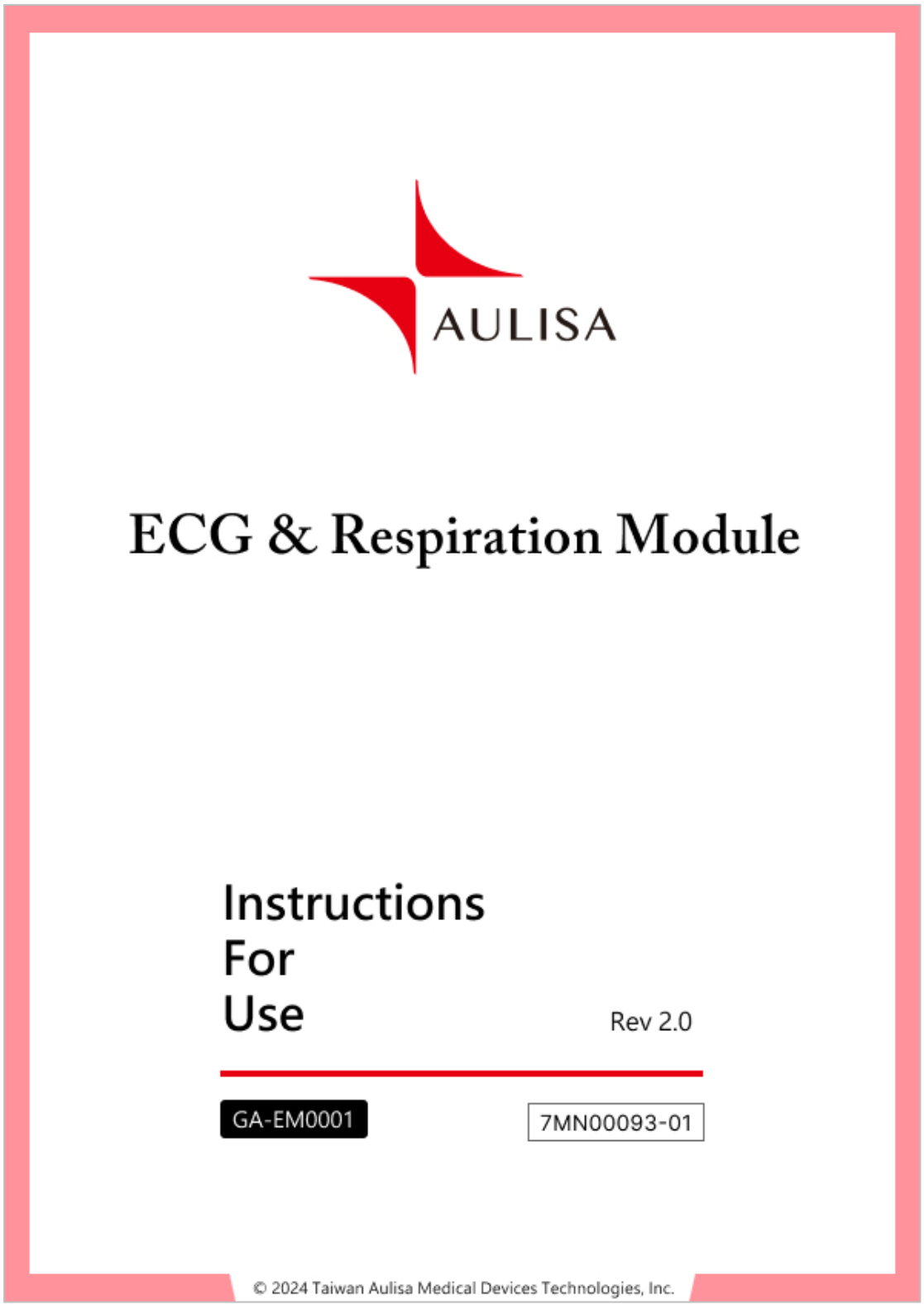
Revision History

Revision	Date	Author	Description
1	2024-09-09	Lox Ou	Initial draft
2	2024-11-21	Lox Ou	Modify Cleaning and Disinfection

Attachment


AULISA
ECG & Respiration Module
Instructions
For
Use
Rev 2.0
GA-EM0001
7MN00093-01
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Disclaimer

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CAUTION !

- Read this entire manual carefully before using Aulisa ECG & Respiration Module of Aulisa-developed software applications.

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Guide to Symbols

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

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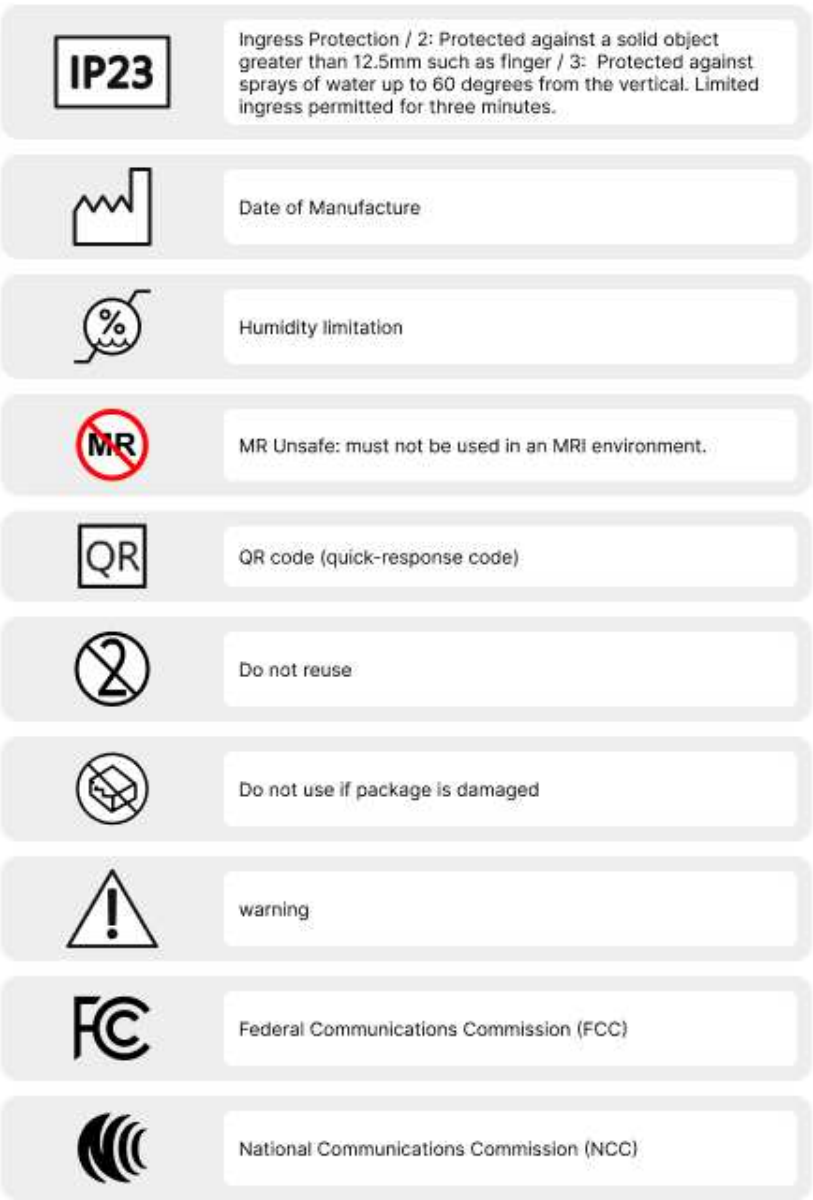
IP23
Ingress Protection / 2: Protected against a solid object greater than 12.5mm such as finger / 3: Protected against sprays of water up to 60 degrees from the vertical. Limited ingress permitted for three minutes.
Date of Manufacture
Humidity limitation
MR
MR Unsafe: must not be used in an MRI environment.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

Welcome

This manual will help you get started with monitoring using the Aulisa ECG & Respiration Module. Aulisa ECG & Respiration Module is one of the components of the Aulisa-developed software application that measures Heart Rate (HR), Respiration Rate (RR), and Electrocardiography (ECG) and is sent out to display via the Aulisa-developed software application. The Aulisa ECG & Respiration Module is intended for use with Aulisa-developed software applications. Refer to the system Instructions for Use for detailed instructions.

Contradictions

1. This device is not defibrillation-proof. Please remove the device before defibrillating a patient during an emergency.
2. The Aulisa ECG & Respiration Module is not intended for use on users who have implanted defibrillators or pacemakers.
3. The Aulisa ECG & Respiration Module is not intended as a stand-alone diagnostic monitor.

Warnings

1. The Aulisa ECG & Respiration Module is a secondary, adjunct patient monitor and is not intended to replace existing standard-of-care patient monitoring practices.
2. Depending on wireless connectivity, a temporary interruption of data transmission is possible, which may impact continuous or real-time monitoring.
3. The nature of the hydrocolloid adhesives may cause adverse skin reactions. Healthcare providers should advise patients to seek medical attention if either of the following occurs:
   - a. A severe adverse event
   - b. An allergic reaction persisting beyond 2-3 days
4. Histories of skin irritations should be considered before placing the Aulisa ECG & Respiration Module on a patient.
5. Do not use the Aulisa ECG & Respiration Module during an MRI scan or in a location where it will be exposed to strong electromagnetic forces.
6. Only place the Aulisa ECG & Respiration Module on intact skin.
7. Clinical validation has not been performed on patients who are pregnant or breastfeeding.
8. No modifications to this device are allowed.
9. No modifications to this device-embedded software are allowed.
10. As with all medical equipment, carefully route all cables to reduce the possibility of entanglement, strangulation or injury to the patient.
11. Be careful with small parts that can be removed from the device and swallowed. They are hazardous to children.
12. Keep small cells and batteries which are considered swallowable out of the reach of children.
13. Swallowing may lead to burns, perforation of soft tissue, and death. Severe burns can occur within 2 h of ingestion.
14. In case of ingestion of a cell or battery, seek medical assistance promptly.
15. Use only FDA-approved accessories to replace Adult ECG Electrodes.

Precautions for Use

1. To acquire physiological data properly:
   - The Aulisa ECG & Respiration Module must be properly adhered to the patient.
   - The patient must remain within 32.8 feet (10 meters) to the Aulisa-developed software application.
   - The Aulisa ECG & Respiration Module must have adequate power for data transmission. Notification of the Aulisa ECG & Respiration Module battery level will indicate when the battery power is low.
2. Wireless electronic devices may cause signal interference during data transmission. Avoid close proximity with interfering devices.
3. Medical electrical equipment or electrical stimulators attached to the patient's body may degrade Aulisa ECG & Respiration Module signal quality or produce erroneous results from the biosensor. The potential interaction must be evaluated and authorized by the responsible organization.
4. Do not use the Aulisa ECG & Respiration Module if the package has been opened or appears used or damaged.
5. Healthcare professionals are intended operators.
6. Patients are intended operators if they have been given instruction by healthcare professionals.
7. Not intended for infants weighing less than 10 Kg.
8. Wear only one Aulisa ECG & Respiration Module at a time.
9. If discomfort or irritation occurs, the Aulisa ECG & Respiration Module should be removed. If mild soreness or redness is experienced after removing the device, do not apply a new device in the same location. Choose another recommended location.
10. Incorrect handling, excessive force, or dropping the Aulisa ECG & Respiration Module may cause malfunction or permanent damage.
11. The performance of the device may be degraded if:
    - a. the operation or storage is outside the manufacturer's stated temperature and humidity range;
    - b. mechanical shock occurs (e.g. accidental drop)
12. Keep the Aulisa ECG & Respiration Module away from children and pets. The device may be a choking hazard and may be harmful if swallowed.
13. Do not place liquids on top of the device.
14. Do not immerse the device or any of the components in any liquids.
15. Do not use this device while taking a shower without Waterproof Patch.
16. If the Aulisa ECG & Respiration Module fails to operate, contact your healthcare provider immediately.
17. Dispose of the Aulisa ECG & Respiration Module per local laws, care facility laws or hospital laws for routine/non-hazardous electronic waste.
18. The product is not used in Category AP or Category APG in an anesthetic gas environment.
19. Avoid being in a high-temperature environment while wearing the device, as this may increase its temperature; if it does, stop using the product immediately.
20. This device has limitations regarding temperature, humidity, and Ingress Protection. If exposed to high temperature (including sunlight) or high humidity, the device's adhesive performance may be affected, causing it to fall off.
21. According to IEC 60529 IP23, the product is protected against the ingress of objects and fluids. However, do not expose the product directly to heavy rain and do not keep it in a space where dust less than 12.5mm accumulates.

22. For applied parts to exceed the temperature limits of Table 24, The device has less than 10% of the skin contact surface of healthy adult body. The clinical effects with body surface of risk management evaluated and documentation (operating mode at temperature rise less than 1 degree during Internal verification) demonstrating that the benefits of exceeding these temperature limits outweigh any potential risks.
23. Cybersecurity related cautions
    ECG & Respiration Module is a wireless, battery-operated wearable sensor attached to the chest to continuously record the electrocardiography (ECG) and heart rate (HR) of adult patients. During normal operation, data is collected by the device and transmitted immediately to the Aulisa-developed software applications (Aulisa Lite GA1000) for display and review. The data package is via LE Secure Connections and encrypted by private 64-bit encryption on ECG & Respiration Module and BLE 128-bit encryption. No clinical or personally identifiable information (PII) is stored on your iOS devices.
    The product needs to install an application named Aulisa Lite GA1000 on your iOS or Android device with OS version under support. Please ensure that you download the Aulisa Lite GA1000 from the official App Store or Goolge Play based on your device OS type. Do not download it from unknown sources to install. You will receive an update notification through App Store or Goolge Play when new version release. You shall keep Aulisa Lite GA1000 updated to the latest version.

    Strongly suggest that you can install antivirus software on your device to protect the system security. The WIFI, wired, and cellular network (4G/5G) capabilities depend on the smartphone or mobile device used. Users should be cautious about their usage and data exporting practices. Please reject connection with any kind of unknown or suspicious devices.

    Please sets a suitable password on your device to avoid unwanted access into your device.

    If a suspected incident or issues found, please contact Taiwan Aulisa Medical Devices Technologies, Inc. Technologies Limited.

Device Overview

Device Components

Waterproof Patch	Charging Adaptor
	

* Off-the-shelf, round-shaped ECG electrodes must be purchased separately.

Device Description

The Aulisa ECG & Respiration Module is one of the components of the Aulisa-developed software application that measures Heart Rate (HR), Respiration Rate (RR), and Electrocardiography (ECG) and sends out to display via the Aulisa-developed software application. The Aulisa ECG & Respiration Module is a wireless, battery-operated wearable sensor attached to the chest to continuously record the electrocardiography (ECG) and heart rate (HR) of adult patients.It is indicated for use on patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety.

The device continuously gathers physiological data from the person being monitored and then transmits the encrypted data to the Aulisa-developed software applications. The data provided by Aulisa ECG & Respiration Module is intended to aid caregivers in making diagnoses by providing additional information to standard-of-care patient monitors.

During normal operation, data is collected by the device and transmitted immediately to the Aulisa-developed software applications. Data is stored on an SD card; the data can be transferred for viewing or printing only through Aulisa-developed software application.

Measuring principles

An electrocardiogram (abbreviated as ECG) records the heart's electrical activity. The Aulisa-developed software application shows the patient's heart rate when transferring ECG signals. The heart rate is determined by the previous R-R interval (RRI). Also, a Pause is defined as an RR interval greater than 3 seconds. The computing details were shown using the following formula.

$$HR = \frac{60\ sec}{RRI}$$

ECG & Respiration Box

The reusable, compact-sized, battery-operated ECG & Respiration Box is embedded with a Bluetooth module. It includes a built-in SD Card for the storage of data. The battery is rechargeable.

NOTE :

- The battery is built-in in the ECG & Respiration Box which cannot removable.

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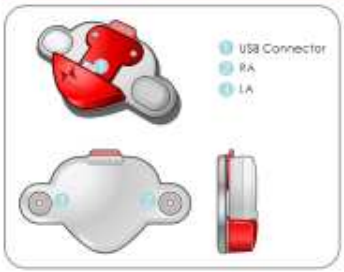
Adult ECG Base

The Adult ECG Base contains two ECG electrodes and a USB connector. The USB connector is to be connected to the ECG & Respiration Box, and two ECG electrodes are to be attached to the Adult ECG Electrodes and placed on the chest.

NOTE :

- Ensure there are no loosened electrodes from the Adule ECG Base.
- If it occurs, contact us.



Device Indications for Use

The Aulisa ECG & Respiration Module is intended to measure heart rate (HR), Respiration Rate (RR) and electrocardiography (ECG) of adult patients noninvasively and continuously. It is intended for use by healthcare professionals in hospitals, medical facilities, home care, and subacute environments. All parameters derived by Aulisa ECG & Respiration Module are reported to Aulisa-developed software applications via standard radio transmission protocols.

Device Principle of Operation

The Aulisa ECG & Respiration Module captures the bio-signals of electrocardiography (ECG) and computes heart rate (HR) from QRS complexes of ECG.

Device Set Up

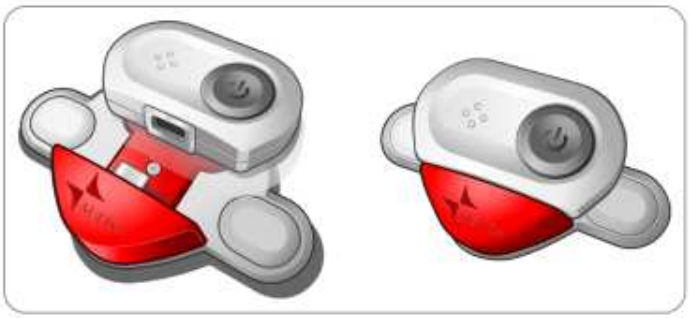
Before you begin your monitoring session, unpack the Aulisa ECG & Respiration Module and become familiar with its parts. It is recommended to fully charge the Aulisa ECG & Respiration Module's battery before set up. It takes approximately 2.5 hours to charge fully.

NOTE :

- Refer to "Device Charging" section below for detailed instructions.

Step 1. Assemble Aulisa ECG & Respiration Module.

Connect the USB slot of the ECG & Respiration Box to the USB connector of the Adult ECG Base. Secure the ECG & Respiration Box to the Adult ECG Base as shown below.



Step 2: Prepare skin.

NOTE :

- Ensure hands are clean and dry before handling the Aulisa ECG & Respiration Module. Gloves are recommended when handing the device.
- When handling the Aulisa ECG & Respiration Module, do not touch the adhesive. The steps below should minimize the chance of touching the adhesive. Contact with the adhesive prior to application to the patient will deteriorate the adhesive and compromise adhesion.

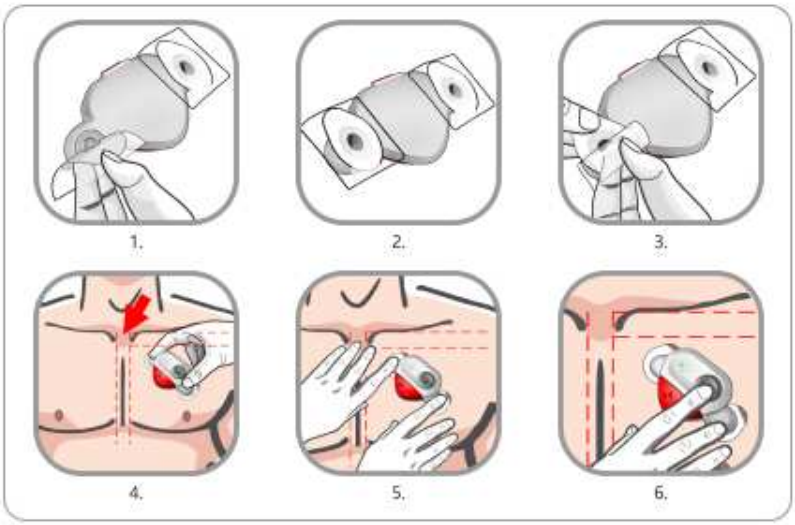
The application site is located on the upper left chest as shown below. For a good connection and proper operation, the device should NOT be worn over areas with a high concentration of body hair. Remove body hair in the area of device placement before applying the device.

NOTE :

- For all patients, use an alcohol wipe to clean skin where the adhesives will contact skin and allow site to dry. The application site should be free of oils and lotions to maximize adhesion.

Step 3: Setup and Place Aulisa ECG & Respiration Module on the body.

1. Attach the Adult ECG Electrodes to the AdultECG Base as shown below.
2. Ensure they are well secured.
3. Remove the releasing paper of the off-the-shelf Adult ECG Electrodes.



4. Hold the device as shown, aim the front to the meeting place of the sternum and one finger below the left collarbone. (The device is attached inclined.)
5. As shown, inhale and straighten the surroundings, then Press the patch by finger to ensure it is tight to the skin.
6. Locate the Power On/Off Button.

Step 5: Power-on Aulisa ECG & Respiration Module.

Press the Power On/Off Button. Look for Power Indicator, a green LED light illuminating to confirm the device is powered on.

Step 6: Set up connection with Aulisa-developed software applications.

NOTE :

- Refer to the Instructions for Use of Aulisa-developed software applications for set up instructions and verifying system operation.

Step 7: Connect Aulisa ECG & Respiration Module to the Aulisa-developed software application.

Wait for the wireless connection of the system to be established. Once connected, the vital signs of the Aulisa ECG & Respiration Module status information will appear on the MAIN screen.

NOTE :

- Refer to "Device Pairing" section below for more information.
- The device must be used within 32.8 feet (10 meters) spherical radius to Aulisa-developed software applications.
- The Power Indicator on the ECG & Respiration Box will blink green when pairing succeeds, and data transmission starts.

Waterproof Patch

The Waterproof Patch is a medical transparency waterproof tape that is pasted on the Aulisa ECG & Respiration Module to improve the shower situation.

NOTE :

- Do not use the Waterproof Patch all the time. This should be used when taking a shower only.

Device Pairing

Automatic Pairing

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

NOTE :

- The device must be placed within 32.8 feet (10 meters) spherical radius to Aulisa-developed software applications.
- The Bluetooth connection status icon will turn blue once the pairing succeeds.
- The Power Indicator on the Sensor Box will blink green when pairing succeeds, and data transmission starts.

Manual Pairing

Follow the below instructions to manually setup pairing.

NOTE :

- Up to two (2) Aulisa ECG & Respiration Modules can be stored in the system.

step 1: Turn on the Aulisa-developed software applications.

step 2: In the Setting menu, select "PAIRING" → "SENSOR MODULE".

step 3: Scan the QR Code or key in the serial number located on the back of the Aulisa ECG & Respiration Module.

step 4: Press "CONFIRM" if the serial number (SN) displayed matches with the one on the Aulisa ECG & Respiration Module.

step 5: Assemble the Aulisa ECG & Respiration Module and position on to the body to power on the device.

step 6: To confirm that the process is successful, ensure that the Bluetooth connection status on the MAIN screen of the Aulisa-developed software applications is lit blue.

NOTE :

- Make sure the battery is fully charged before use.
- The device remains paired with the system until the serial number is deleted from the list.
- The device must be placed within 32.8 feet (10 meters) spherical radius to Aulisa-developed software applications.
- The Power Indicator lights green when the power is ON.

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Device Power Off and Removal

The device will be turned off by either:

1. Pressing the Power button on the ECG & Respiration Box until Power Indicator is off.

NOTE :

- The Power Indicator goes off when power off.

When removing the device, use of an adhesive tape remover is recommended. Gently sweep the remover pad under the device and pull away from the skin.

Device Charging

The Aulisa ECG & Respiration Module is powered by a rechargeable battery. When the low battery alarm appears on the MAIN screen of the Aulisa-developed software applications, the battery is exhausted and needs recharging. Follow the instructions below to recharge the battery.

1. Plug the connector end of the charging adaptor into t the USB slot of the ECG & Respiration Box. Attach the wall adaptor to a power outlet.

NOTE :

- The Charging Indicator, a blue LED lights on while charging when it is plugged in.
- The Charging Indicator lights off when the battery is fully charged.

Alarms and Limits

Alarm Features

NOTE :

- Optional: only if device is paired with mobile application and fully functioned.

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

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NOTE :

- The volume for high priority alarms cannot be adjusted on the Aulisa-developed software applications.

High Priority Alarms

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

NOTE :

- Alarm LED indicator on the Aulisa ECG & Respiration Module will blink red along with displays on the screen.

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

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

See "Alarm Limits" section to learn adjusting the alarm limit.

Medium Priority Alarms

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

NOTE :

- The following table describes alarm conditions and visual indicators.

Alarm Condition (Medium Priority Alarm)	Visual Indicator
Sinus Arrhythmia	1. Alarm notification on the Aulisa-developed software applications.
Sinus Tachycardia	
Sinus Bradycardia	
LEAD-OFF / Pause	
Aulisa ECG & Respiration module battery low	1. Alarm notification on the Aulisa-developed software applications. 2. Relevant icon highlighted in yellow on the screen.
Aulisa ECG & Respiration module data update period exceeds 30 seconds	
Bluetooth disconnected	

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

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

See "Alarm Limits" section to learn adjusting the alarm limit.

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Multiple Alarms

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

CAUTION !

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

Alarm Limits

NOTE :

- Optional: only if device is paired with mobile application and fully functioned.

Follow the instructions below to review or set alarm limits.

step 1: Ensure the Bluetooth connection is established. (See "Device Pairing" section.)

step 2: Tap on " " SETTING icon on the MAIN screen, and then tap on "ALARM SETTING". Select the designated Aulisa ECG & Respiration module.

NOTE :

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

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

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

NOTE :

- HR/RR alarm limits are turned on as default settings.

CAUTION !

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

NOTE :

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

High Priority Alarm	Factory Default	Adjustment Options	Adjustment Interval
Heart Rate Upper Alarm Limit	150 bpm	Off, 75-275 bpm	1 bpm
Heart Rate Lower Alarm Limit	50 bpm	Off, 30-110 bpm	1 bpm
Respiration Rate Upper Alarm Limit	20 brpm	Off, 15-40 bpm	1 brpm
Respiration Rate Lower Alarm Limit	10 brpm	Off, 5-15 bpm	1 brpm

step 5: Tap on "CONFIRM" to save the alarm limits.

CAUTION !

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

NOTE :

- The upper and lower alarm limits appear as small-sized numbers next to the measured value.

Indicators

Indicator	Blinking Status	Lights On Status	Lights Off Status
Green LED	Bluetooth Connected	Power On	Power Off
Yellow LED	Battery Low	LEAD-OFF	NA
Blue LED	NA	Charging	Fully Charged
Red LED	Alarm limits such as: Heart rate high/low limits, Respiration rate high/low limits	NA	NA

NOTE :

- Optional: only if the device is paired with a mobile application and fully functioning.

Care and Maintenance

The advanced digital circuitry within the Aulisa ECG & Respiration Module requires no calibration. Field service or repair of this system is not possible. Do not attempt to open the Aulisa ECG & Respiration Box for that will cause damage and void the warranty. If the Aulisa ECG & Respiration Module is not functioning properly, see "Troubleshooting" section for more information.

The expected service life of the Aulisa ECG & Respiration Module is 24 months.

Cleaning and Disinfection

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

Clean surface of ECG & Respiration Box and clean and disinfect the Adult ECG Base before each use. For surface cleaning and disinfection, follow the recommended actions below.

Surface cleaning: Clean the surface of the ECG & Respiration Box and Adult ECG Base 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 Adult ECG Base.

CAUTION !

- Do not pour or spray any liquids onto this device, and do not allow any liquids to enter any openings in the device.
- Do not immerse the device in liquid and do not use caustic or abrasive cleaning agents on the device.

Troubleshooting

Problem	Possible Solution
Cannot power on the Aulisa ECG & Respiration Module	1. Recharge the battery. 2. Press the Power button again.
Unusual vital sign data	1. Recheck device's location or contact with the skin. 2. Ensure Adult ECG Base is connected firmly to the ECG & Respiration Box. 3. Reduce patient motion. 4. Check Adult ECG Base for any visible signs of deterioration. 5. Use this device under instructed operation conditions.
Cannot establish system connection	1. Make sure the device is within 32.8 feet (10 meters) spherical radius to the Aulisa-developed software applications. 2. Power off the system and retry. 3. See the "Device Pair" section and retry step-by-step
The electrodes are loosened from the Adule ECG Base	1. Don't use the device and contact us.

For additional troubleshooting, refer to the Aulisa-developed software applications Instructions for Use.
If these solutions do not correct the problem, please contact your distributor, or contact Aulisa by going online at www.aulisa.com under "Contact Us".

CAUTION !

- This module is a precision electronic instrument and must be repaired by knowledgeable and specially trained Aulisa personnel only. Do not attempt to open or repair the Aulisa ECG & Respiration Module.

Manufacturer's Declaration

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

*For all EQUIPMENT and SYSTEMS

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

*For all EQUIPMENT and SYSTEMS

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

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Surge IEC 61000-4-5	±1 kV Line to Line	±1 kV Line to Line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% UT in 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT in 1 cycle at 0° 70% UT in 25/30 cycles at 0° 0% UT in 250/300 cycles at 0° and 180°	0% UT in 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT in 1 cycle at 0° 70% UT in 25/30 cycles at 0° 0% UT in 250/300 cycles at 0° and 180°	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the AC mains voltage before application of the test level.			

*For EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.			
Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V 150 kHz to 80 MHz 6 V ISM and amateur radio bands 10 V 80MHz to 2.7 GHz	3 V 150 kHz to 80 MHz 6 V ISM and amateur radio bands 10 V 80MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter...

			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

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.

1. 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.
2. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V.

FCC Compliance

Declaration of Conformity with FCC for Electromagnetic Compatibility
This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesignated operation.

Federal Communications Commission (FCC) Notice
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy.
If not installed and used in accordance with the instructions, it may cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on. The user is encouraged to try to correct the interference by one or more of the following 9measures:
(1) Reorient or relocate the receiving antenna.
(2) Increase the separation between the equipment and receiver.
(3) Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

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

FCC Radiation Exposure Statement
For body worn operation, to maintain compliance with FCC RF exposure guidelines, use only accessories that contain nonmetallic components. RF exposure separation distance is 5 mm. Use of other accessories may violate FCC RF exposure guidelines and should be avoided.
The FCC requires the user to be notified that any changes or modifications to this device that are not expressly approved by Taiwan Aulisa Medical Devices Technologies, Inc. may void the user's authority to operate the equipment.

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

Specifications

Model Name	GA-EM0001
Medical Equipment Type	BF Applied Part
ECG Characteristics	
Channels	1 channel/Single Lead
Dynamic Input Range	-5mV to +5mV
Input Impedance	> 10MΩ
CMRR	> 80 dB
Frequency Response	0.67 to 40 Hz
Sample Rate	500 sps
Resolution	24 bits
Signal Noise Level	< 30 μV
Measurement Range/ Accuracy	
Heart Rate	30 to 300 bpm ± 3%
Respiration Rate	5 to 40 brpm ± 4 brpm

Gain	10 mm/mV < 10%
Sweep Speed	25 mm/s < 10%
Dimensions	
ECG & Respiration Box	32.8mm x 56.0mm x 14.0mm
Adult ECG Base	48.6mm x 85.0mm x 19.5mm
Weight	40.3 g
Ingress Protection	IP23
Charging Adaptor	Input: 100-240Vac, 50/60Hz, 0.3-0.12A Output: 5Vdc, 2A max
Battery Type	Lithium-ion Polymer Rechargeable Battery 3.7V 1.74Wh 470mAh
Battery Service Life	72 hours of continuous operation
Shelf Life	24 months
Temperature	
Operating	+5°C to +45°C (operating mode at temperature rise less than 1 degree)
Storage/Transportation	-20°C to +60°C
Humidity	
Operating	10% to 95% R.H. non-condensing
Storage/Transportation	10% to 95% R.H. non-condensing
Operating Altitude	altitude ≤ 3000 m
Atmospheric Pressure	700 hPa to 1013 hPa
Wireless Communication	
Frequency	2402-2480
Protocol	Bluetooth 5.2
Antenna Info	Chip, 2.5 dBi
Security	AES-128
Range	32.8 feet (10 meters) spherical radius
Direction	Bi-direction
Data rate	Up to 2M Bps

Aulisa-developed software applications	
Operation System Requirement	
iOS	Above 15.0
Android	Above 12.0

Parts and Accessories

Parts and Accessories	Model Number
ECG & Respiration Box	GA-EB0001
Adult ECG Base	GA-AP0016
Charging Adaptor	SINGOF-10U-050200 (GA-AD0001)
Waterproof Patch	GA-AP0018

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

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

CAUTION !

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

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