AULISA

Combo Sensor Module-ECG and PPG

Instructions For Use

7MN00050-01

Disclaimer

At the time of publication, this manual is believed to be accurate and up-to-date. In the interest of continued product development, Taiwan Aulisa Medical Devices Technologies, Inc. reserves the right to make changes and improvements to this manual and the products described within at any time, without notice or obligation.

References to “Aulisa” in this manual shall imply Taiwan Aulisa Medical Devices Technologies, Inc.

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CAUTION!!! Read this entire manual carefully before using Guardian Angel® Rx Digital Vital Sign Monitoring System.

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Table of Content

Guide to Symbols

Symbol	Description
	Refer to instruction manual
	Indicates separate collection for electrical and electronic equipment (WEEE).
	Non-ionizing electromagnetic radiation. Equipment includes RF transmitters. Interference may occur in the vicinity of equipment marked with this symbol.
	Manufacturer
	Serial number
	Lot number
	Federal law (USA) restricts this device to sale by or on the order of a licensed health care professional only.
	Temperature limit
	Non-sterile

IP23	Classification for water ingress and particulate matter
	Date of Manufacturer
	Type CF applied part
	MR Unsafe

Welcome

This manual will help you get started with monitoring using the Combo Sensor Module of Aulisa Guardian Angel® Rx Digital Vital Sign Monitoring System, GA1000/ GA2000 Series.

GA1000 Series
The Combo Sensor Module is intended for use with the Display Unit. Refer to the GA1000 Series Instructions for Use (7MN00026-02) for detailed instructions.

GA2000 Series
The Combo Sensor Module is intended for use with the Display Unit and Receiver/Transponder. Refer to the GA2000 Series Instructions for Use (7MN00022-02) for detailed instructions.

Contradictions

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

Warnings

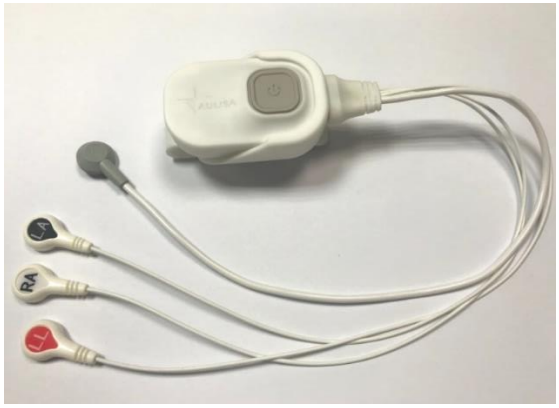
1. The Combo Sensor Module is a secondary, adjunct patient monitor and is not intended to replace existing standard-of-care patient monitoring practices.
2. Depending on wireless connectivity, a temporary interruption of data transmission is possible, which may impact continuous or real-time monitoring.
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 Combo Sensor Module on a patient.
5. Do not use the Combo Sensor Module during an MRI scan or in a location where it will be exposed to strong electromagnetic forces.
6. Only place the Combo Sensor Module on intact skin.

7. Clinical validation has not been performed on patients who are pregnant or breastfeeding.

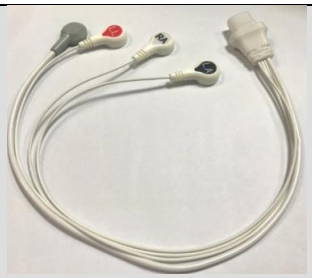
Precautions

1. To acquire physiological data properly:
    - The Combo Sensor Module must be properly adhered to the patient.
    - The patient must remain within 32.8 feet (10 meters) to the Display Unit (for GA1000 series), or to the Receiver/Transponder (for GA2000 series).
    - The Combo Sensor Module must have adequate power for data transmission. Notification of the Combo Sensor 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 Combo Sensor Module signal quality or produce erroneous results from the biosensor.
4. Do not use the Combo Sensor Module if the package has been opened or appears used or damaged.
5. Wear only one Combo Sensor Module at a time.
6. If discomfort or irritation occurs, the Combo Sensor 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.
7. Incorrect handling, excessive force, or dropping the Combo Sensor Module may cause malfunction or permanent damage.
8. Keep the Combo Sensor Module away from children and pets. The device may be a choking hazard and may be harmful if swallowed.
9. Do not place liquids on top of the device.
10. Do not immerse the device or any of the components in any liquids.
11. Do not use this device while taking a shower.
12. If the Combo Sensor Module fails to operate, contact your healthcare provider immediately.
13. Dispose of the Combo Sensor Module per local laws, care facility laws or hospital laws for routine/non-hazardous electronic waste.

Device Overview



Device Components

Sensor Box	Holder
	
Sensor Cable	**ECG Electrode**
	
PPG Adhesive Patch	**ECG/PPG Position Guide**

	
Battery Charger	**Charging Adaptor- Battery Charger**
	

Device Description

The Combo Sensor Module is a component of the Aulisa Digital Vital Sign Monitoring System. The Combo Sensor Module is a wireless, battery operated wearable biosensor, attached to the chest to continuously record blood pressure (BP), heart rate (HR), respiration rate (RR), electrocardiography (ECG) and fall detection of adult patients. The device continuously gathers physiological data from the person being monitored and then transmits the encrypted data to the Aulisa Digital Vital Monitoring System, GA1000/ GA2000 Series. The data provided by Combo Sensor 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 Digital Vital Monitoring System. Data is stored on a SD card and the data can be easily transferable to a personal computer to be viewed or printed.

Sensor Box

The reusable, compact-sized, battery-operated Sensor Box is embedded with a Bluetooth module. It includes a slot for a SD Card for the storage of data. The battery is rechargeable.

1 **Power On/Off Button**

2 **Power LED**

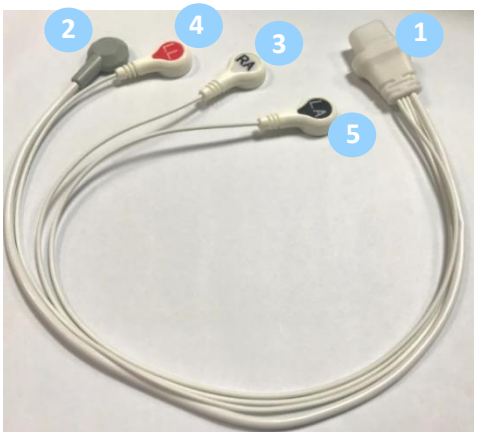
3 **Battery Chamber**

4 **SD card**

5 **Cable port**

Sensor Cable

The reusable double-ended cable contains three ECG leads and a PPG probe on one end and a Sensor Box connector on the other end. The Sensor Box connector is to be connected to the Sensor Box and, the ECG leads and PPG probe are to be attached to the chest.



1 **Sensor Box connector**

2 **PPG Probe**

3 **Right Arm ECG Lead**

4 **Left Leg ECG Lead**

5 **Left Arm ECG Lead**

Device Indications for Use

The Aulisa Combo Sensor Module is intended to non-invasively and continuously measure blood pressure (BP), heart rate (HR), respiration rate (RR), and electrocardiography (ECG) of adult patients. It is intended for use by healthcare professionals in hospitals, medical facilities,

home care, and subacute environments. The Aulisa Combo Sensor Module is calibrated using a manual method or any AAMI 81060 compliant BP device. All parameters derived by Aulisa Combo Sensor Module are reported to Aulisa's Digital Vital Sign Monitoring System via standard radio transmission protocols.

Device Principle of Operation

The Combo Sensor Module captures the bio-signals of electrocardiography (ECG) and Photoplethysmography (PPG). The device computes heart rate (HR) and respiration rate (RR) from QRS complexes of ECG, and it estimates blood pressure via Pulse Transit Time (PTT) measurement from ECG and PPG.

Device Setting Up

Before you begin your monitoring session, unpack the Combo Sensor Module and become familiar with its parts. It is recommended to fully charge the battery of the Combo Sensor Module prior to setting up. It takes approximately 2.5 hours to fully charge.

NOTE: Refer to "Device Charging" section below for detailed instructions.

Step 1. Assemble Combo Sensor Module.

Secure the Sensor Box to the holder with the cable port of the Sensor Box inserted inward. Connect the Sensor Box connector of the Sensor Cable with the Sensor Box as shown below.

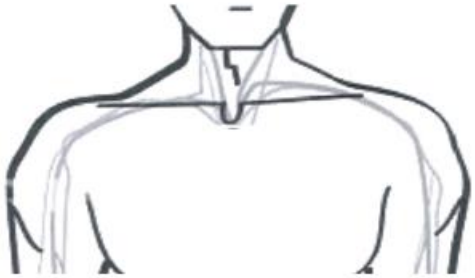
Attach the holder to the patient.

Step 2: Prepare skin.

NOTE: Ensure hands are clean and dry before handling the Combo Sensor Module. Gloves are recommended when handing the device.

NOTE: When handling the Combo Sensor 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 wear

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.



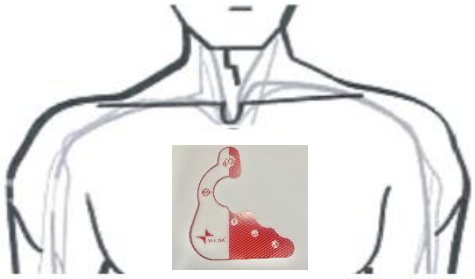
NOTE: For all patients, use an alcohol wipe to clean skin where the adhesives will contact skin and allow site to dry. The application site should be free of oils and lotions to maximize adhesion.

Step 3: Position Combo Sensor Module on the body.

Attach the ECG electrodes to the ECG leads of the Sensor Cable as shown below. Ensure they are well secured.

Place the ECG/PPG Position Guide flat on the chest. Align the upper section of the ECG/PPG Position Guide to the center of the torso as shown on the diagram below. Remove the releasing

paper of the ECG electrodes. Attach the ECG electrodes onto the positions indicated by the ECG/PPG Position Guide.



Then, place the PPG probe per the ECG/PPG Position Guide. Remove the ECG/PPG Position Guide and secure the PPG probe with the adhesive tape.

Step 5: Power-on Combo Sensor Module.

Locate and press the Power On/Off Button. Look for a green light illuminating to confirm the device is powered on.

Step 6: Set up the GA1000 Series or GA2000 Series.

NOTE: Refer to the GA1000 Series Instructions for Use (7MN00026-02) or GA2000 Series Instructions for Use (7MN00022-02) for setting up instructions and verifying system operation.

Step 7: Connect Combo Sensor Module to the system.

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

NOTE: Refer to "Device Pairing" section below for more information.

NOTE: The Power LED on the Sensor Box will blink green when pairing succeeds, and data transmission starts.

Device Pairing

Automatic Pairing

GA1000 Series

The Display Unit automatically detects and connects to the Combo Sensor Module in the same starter kit. Press the "PAIR" button on the MAIN screen to force the system pairing when the connection is not established automatically.

GA2000 Series

The Receiver/Transponder automatically detects and connects to the Combo Sensor Module in the same starter kit only when the connection between the Display Unit and the Receiver/Transponder has been established first.

NOTE: The Combo Sensor Module must be placed within 32.8 feet (10 meters) to the Display Unit (*for GA1000 Series)*, or to the Receiver/Transponder *(for GA2000 Series)*.
NOTE: The Bluetooth connection status icon will turn blue once the pairing succeeds.

Manual Pairing

Follow the below instructions to manually setup pairing.

NOTE: Up to two (2) Combo Sensor Modules can be stored on the Display Unit.

Step 1: Turn on the Display Unit.
Step 2: In the Setting menu, select “PAIRING”. *(for GA1000 Series)*
In the Setting menu, select “PAIRING” → “COMBO SENSOR MODULE”. *(for GA2000 Series)*
Step 3: Scan the QR Code or key in the serial number located on the back of the Aulisa X Box.
Step 4: Check if the serial number (SN) displayed matches with the one on the Aulisa X Box.
Step 5: Press “CONFIRM” on the Display Unit.
Step 6: Assemble the Combo Sensor Module and position on to the body to power on the device.
Step 7: To confirm that the process as successful, ensure that the Bluetooth connection status on the MAIN screen of the Display Unit is lit blue.

NOTE: Make sure the battery is installed and fully charged before use.
NOTE: The Combo Sensor Module remains paired with the system until the serial number is deleted from the list.
NOTE: The Combo Sensor Module must be placed within 32.8 feet (10 meters) to the Display Unit *(for GA1000 Series)*, or to the Receiver/Transponder *(for GA2000 Series)*.
NOTE: The Power LED lights green when the power is ON.

Device Power Off and Removal

The device will be turned off by either way:

1. Press the Power button on the Sensor Box.
2. When the Combo Sensor Module detects no signal for 3 minutes.

NOTE: The power LED 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.

NOTE: The adhesives are for Single Use Only. Do not reapply to the ECG electrode once it is removed.

Device Charging

The Combo Sensor Module is powered by a rechargeable battery. When the low battery alarm appears on the MAIN screen of the Display Unit, the battery is exhausted and needs recharging. Follow the instructions below to recharge the battery.

1. Slide to remove the back cover of Sensor Box. Remove the battery by lifting the outward end of the battery upward.

2. Plug the connector end of the charging adaptor into the cable port of the Battery Charger. Attach the wall adaptor to a power outlet.

NOTE: The power LED of the battery charger lights green when it is plugged in.
NOTE: The charging LED of the battery charger lights blue when the battery is charging.

Device SD card Installation and Removal

The Combo Sensor Module contains a SD card for data storage. The SD card needs to be installed before using the device. Follow the instructions below to install the SD card.

1. Slide to remove the back cover of Sensor Box. Insert the SD card into the slot of Sensor Box until it is fully in.

To transfer the data to a computer, follow the instructions below to remove the SD card.

1. Slide to remove the back cover of Sensor Box.
2. Click on the SD card. The SD card will automatically pop out.

Alarm

For more information about the alarm, refer to the GA1000 Series Instructions for Use (7MN00026-02) or GA2000 Series Instructions for Use (7MN00022-02).

Care and Maintenance

The advanced digital circuitry within the Combo Sensor Module requires no calibration or periodic maintenance, except for the blood pressure feature which needs to be calibrated manually or with any AAMI 81060 compliant BP device for the first time use and every 4 hours of use. Field service or repair of this system is not possible. Do not attempt to open the case other than the battery cover for that will cause damage and void the warranty. If the Combo Sensor Module is not functioning properly, see “Troubleshooting” section for more information.

The expected service life of the Combo Sensor Module is 3 years.

Cleaning and Disinfection

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

Surface cleaning: Clean the surface of the sensor box and Sensor Cable 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 Sensor Cable.

CAUTION!!! Do not pour or spray any liquids onto this device, and do not allow any liquids to enter any openings in the device.

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

Troubleshooting

Problem	Possible Solution
Cannot power on the Combo Sensor 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 Sensor Cable is connected firmly to the Sensor Box. 3. Reduce patient motion. 4. Check the Sensor Cable for any visible signs of deterioration. 5. Use this device under instructed operation conditions.
Cannot establish system connection	1. Make sure the Combo Sensor Module is within 32.8 feet (10 meters) spherical radius to the Display Unit *(for GA1000 Series)*, or to the Receiver/Transponder *(for GA2000 Series)*. 2. Power off the system and retry.

For additional troubleshooting, refer to the GA1000 Series Instructions for Use (7MN00026-02) or GA2000 Series Instructions for Use (7MN00022-02).

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

CAUTION!!! This system is a precision electronic instrument and must be repaired by knowledgeable and specially trained Aulisa personnel only. Do not attempt to open the case other than the battery cover or repair the electronics.

Manufacturer's Declaration

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

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

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

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

Guidance and manufacture's declaration - electromagnetic immunity			
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.			
Immunity test	**IEC/ EN 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of a typical commercial

	±2 kV common mode	±2 kV common mode	or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	±0% UT in 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° ±0% UT in 1 cycle at 0° ±70% UT in 25/30 cycles at 0° ±0% UT in 250/300 cycles at 0° and 180°	±0% UT in 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° ±0% UT in 1 cycle at 0° ±70% UT in 25/30 cycles at 0° ±0% UT in 250/300 cycles at 0° and 180°	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the AC mains voltage before application of the test level.			

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

Guidance and Manufacture's declaration - electromagnetic immunity			
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.			
Immunity test	**IEC/ EN 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V/m 150 kHz to 80 MHz 10 V/m 80 MHz to 2.7 GHz	3 V/m 10 V/m	**Recommended Separation Distance** The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $$E = 6/d\sqrt{P}$$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.

FCC Compliance

Declaration of Conformity with FCC for Electromagnetic Compatibility

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

Service, Support, and Warranty

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 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 PEOPLE BEING MONITORED, 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

("HIPAA"). WE WILL MAINTAIN THE PRIVACY OF YOUR HEALTH INFORMATION AS REQUIRED BY HIPAA AND THE REGULATIONS PROMULGATED UNDER THAT ACT. FOR ADDITIONAL INFORMATION RELATED TO YOUR HEALTHCARE INFORMATION, PLEASE CONTACT information@aulisa.com.

We believe that transparency about the use of your personal information is important. In this privacy policy, we provide you detailed information about our collection, use, maintenance, and disclosure of your personal information. The policy explains what kind of information we collect, when and how we might use that information, how we protect the information, and your rights regarding your personal information.

Please read the following carefully to understand our views and practices regarding your Personal Information and how we will treat it. For the purposes of Applicable Data Protection Laws including the European Economic Area data protection law (the "Data Protection Law"):

Non-Provider Users: The data controllers are the Provider and Taiwan Aulisa Medical Devices Technologies, Inc., No. 218-2, Chong Yang Rd., Nangang Dist., 11573 Taipei City, Taiwan

Provider Users: The data controller is Taiwan Aulisa Medical Devices Technologies, Inc., No. 218-2, Chong Yang Rd., Nangang Dist., 11573 Taipei City, Taiwan

Data Protection Officer: Paul Liu

BY USING THE DEVICES, YOU ARE ACKNOWLEDGING THAT YOU HAVE READ AND AGREE TO THE TERMS OF THIS PRIVACY POLICY. IF YOU DO NOT AGREE, PLEASE DO NOT USE THE DEVICES AND DO NOT SUBMIT ANY INFORMATION TO US.

Access to and use of the Devices by a Provider who is an Aulisa customer (a "Customer") and such Customer's authorized users is subject to and governed by the agreement between Aulisa and the applicable Customer executed by authorized representatives of each party (the "Customer Agreement"). Aulisa may collect, use and disclose information from a Customer and such Customer's authorized users as set forth in the Customer Agreement. If you would like more information about the Devices or becoming a Customer, please contact us at 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 person being monitored, 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 people 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 person being monitored, 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 person being monitored, 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 e mail 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

Dimensions	61.8mm x 60.7mm x 21.0mm
Weight	63.5 g
Ingress Protection	IP23
Display range	
Systolic Blood Pressure	75 to 225 mmHg
Diastolic Blood Pressure	45 to155 mmHg
Heart Rate	30 to 290 bpm
Respiration Rate	10 to 30 bpm
Accuracy	
Blood Pressure	± 5 mmHg
Heart Rate	±3%
Respiration Rate	±3 rpm
Battery Type	Lithium Polymer Battery
Battery Life	38 hours of continuous operation
Temperature	
Operating	+5°C to +40°C
Storage/Transportation	-25°C to +70°C
Humidity	
Operating	15% to 90% R.H. non-condensing
Storage/Transportation	10% to 93% R.H. non-condensing
Operating Altitude	altitude ≤ 3 000 m
Atmospheric Pressure	700 hPa to 1013 hPa
Wireless Communication	
Range	32.8 feet (10 meters) spherical radius
Protocol	Bluetooth 4.0
Direction	Bi-direction
Data rate	Up to 100k Bps

Parts and Accessories

Parts and Accessories	Model Number
Combo Sensor Box	GA-CB0001
Combo Sensor Cable	GA-CA0001
Combo Sensor Battery	GA-BA0001
ECG Electrode	GA-AP0012
PPG Adhesive Patch	GA-AP0004
Battery Charger	GA-BC0001
Charging Adaptor- Battery Charger	GA-CR0002

For more information about the Display Unit and Receiver/Transponder, refer to the GA1000 Series Instructions for Use (7MN00026-02) or GA2000 Series Instructions for Use (7MN00022-02).

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.