Guardian Angel® Rx

Thermometer Module

Instructions For Use

7MN00025-01

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.

Aulisa is a registered trademark of Taiwan Aulisa Medical Devices Technologies, Inc.

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

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Table of Contents

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	Lot number
	Temperature limit
	Non-sterile
IP22	Classification for water ingress and particulate matter
	Date of Manufacturer

Welcome

This manual will help you get started with monitoring using the Thermometer Module of Aulisa Guardian Angel® Rx Digital Vital Sign Monitoring System.

GA1000 Series
The Thermometer Module is intended for use with the Display Unit. Refer to the GA1000 Series Instructions for Use (7MN00021-01) for detailed instructions.

GA2000 Series
The Thermometer Module is intended for use with the Display Unit and Receiver/Transponder. Refer to the GA2000 Series Instructions for Use (7MN00022-01) for detailed instructions.

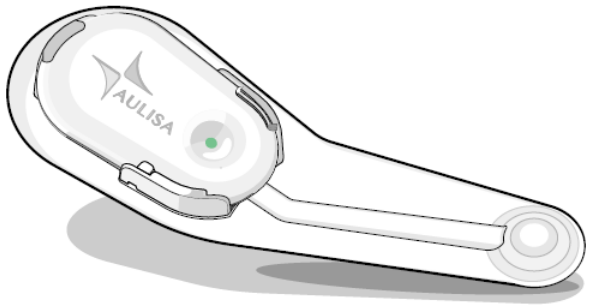
Precautions for Use

1. Any form of modification to this device is forbidden.
2. Do not use this device in an MRI or CT environment.
3. It is intended only as an adjunct in patient assessment and must be used in conjunction with other methods of assessing clinical signs and symptoms.
4. Do not use the device on wounded or irritated skin. In case of skin discomfort, remove the device immediately.
5. It is recommended for indoor use only
6. The device is to be worn under the armpit. Exposure to ambient temperature may cause inaccurate temperature readings.
7. Do not submerge the device in the water or any other liquid.
8. Do not use this device while taking a shower.
9. Do not excessively bend or twist the device.
10. Be careful with small parts that can be removed from the device and swallowed, such as battery cover. They are hazardous to children.
11. Device setup shall be performed by adults.
12. 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)
    c) body temperature is below ambient temperature.
13. Use this device only when it is within the specified distances, approximately

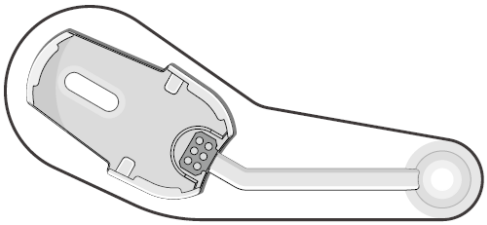
32.8 feet (10 meters) spherical radius to the Display Unit (*for GA1000 Series)*, or to the Receiver/Transponder *(for GA2000 Series)*. Moving outside this range may cause missing, lost, and/or inaccurate data.

14. This device 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 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.
15. Follow local governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
16. Batteries might explode if used or disposed of improperly.
17. User may only change the battery. No user serviceable part is provided for this device.

Device Overview



Device Components

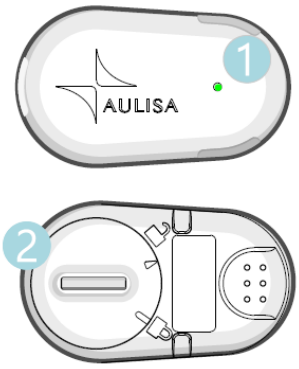
Thermometer Box	Sensor Patch
	

Device Description

The Thermometer Module is composed of Thermometer Box and Sensor Patch. It must be used within 32.8 feet (10 meters) to the Display Unit (*for GA1000 Series)*, or to the Receiver/Transponder *(for GA2000 Series)*.

Thermometer Box

The reusable, compact-sized, battery-operated Thermometer Box is embedded with a Bluetooth module. The battery is changeable.

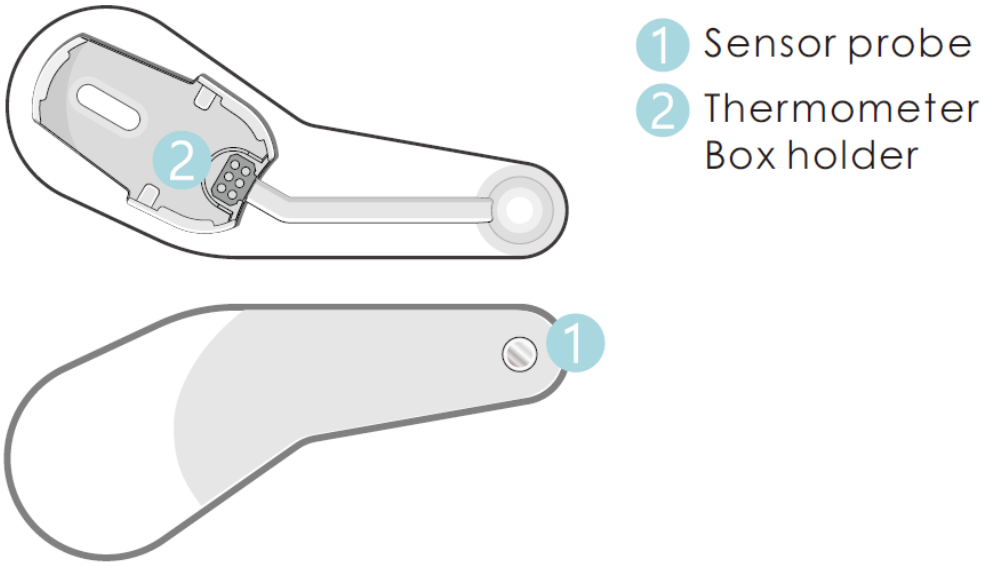


1 Power LED

2 Battery Chamber

Sensor Patch

The medical grade and disposable Sensor Patch which is equipped with a Thermometer Box holder and a Sensor probe can be used up to 24 hours, while some users may want to change adhesives more often depending on skin type and comfortability. Additional Sensor Patch can be purchased separately as needed.



Device Intended Use

The Thermometer Module is indicated for continuous armpit body temperature monitoring for adult, pediatric, and infant patients. The intended environments of use are hospitals, medical facilities, home care, and subacute environments.

Device Principle of Operation

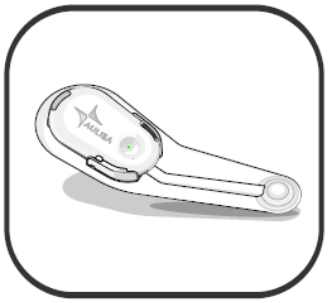
The Thermometer Module applies the digital temperature sensor to detect temperature and convert to a digital read-out.

Device Setting Up

Before you begin your monitoring session, unpack the Thermometer Module and become familiar with its parts.

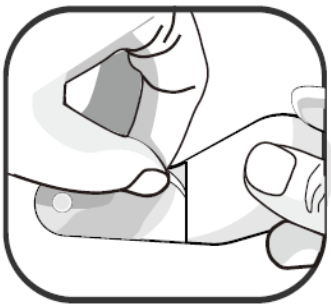
Step 1: Make sure the connector of the Thermometer Box aligns with the connector on the holder.

Step 2: Secure the Thermometer Box onto the holder of the Sensor Patch.

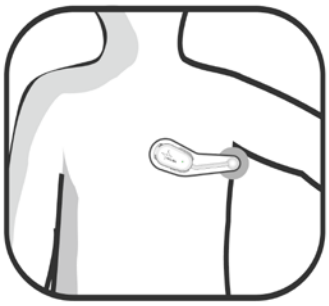


NOTE: The Power LED will blink green when the power is ON.

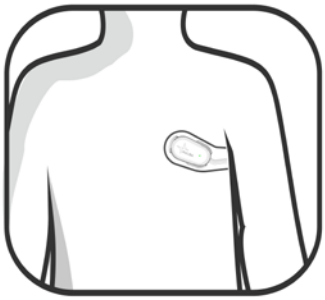
Step 3: Peel the releasing paper off the Sensor Patch.



Step 4: Attach the sensor probe to the center of the armpit, with the Thermometer Box placed on the chest.



Step 5: Let the arm drop naturally at the side to cover the sensor
probe for 12 minutes before attempting a reading.



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

NOTE: Refer to the GA1000 Series Instructions for Use (7MN00021-01) or GA2000 Series Instructions for Use (7MN00022-01) for setting up instructions and verifying system operation.

Step 7: Wait for the wireless connection of the system to be established. Once connected, the vital signs and the Thermometer Module status information will appear on the MAIN screen.

NOTE: The Thermometer Module only measures axillary (armpit) temperature
NOTE: Refer to "Device Pairing" section below for more information.

Device Pairing

Automatic Pairing

GA1000 Series

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

NOTE: The Thermometer 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) Thermometer 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”→“SENSOR MODULE”. *(for GA2000 Series)*
Step 3: Scan the QR Code or key in the serial number located on the back of the Thermometer Box.
Step 4: Check if the serial number (SN) displayed matches with the one on the Thermometer Box.
Step 5: Press “CONFIRM” on the Display Unit.
Step 6: Assemble the Thermometer Box and the Sensor Patch to power on the device.
Step 7: 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.

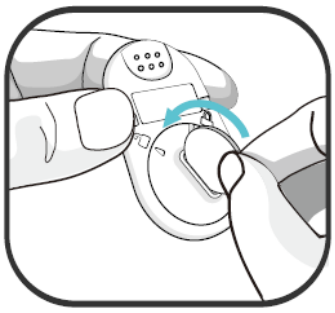
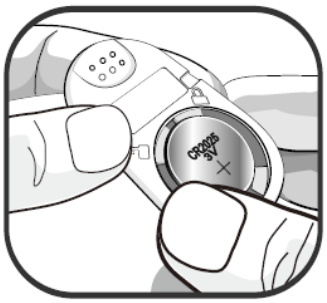
NOTE: Make sure the battery is installed before use.
NOTE: The Thermometer Module remains paired with the system until the serial number is deleted from the list.
NOTE: The Thermometer Module must be placed within 32.8 feet (10 meters) to the Display Unit *(for GA1000 Series)*, or to the Receiver/Transponder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

Device Power Off

Detach the Thermometer Box from the Sensor Patch and the Power LED will go off.

Device Battery Replacement

The Thermometer Module is powered by a button cell. When the low battery alarm appears on the MAIN screen of the Display Unit, the battery is exhausted and needs replacement. Follow the instructions below to replace the battery.

Step 1:	Take off the battery cover by using a coin, turning the cover clockwise, and remove the battery.	
Step 2:	Insert a new CR2025 battery into the battery chamber and replace the cover. Align the mark on the cover with the lock icon .	

Normal Body Temperature Ranges

Type / Age	Axillary (Armpit)	Oral	Ear	Rectal
0-2y	94.5°F – 99.1°F (34.7°C – 37.3°C)	N/A	97.5°F – 100.4°F (36.4°C – 38.0°C)	97.9°F – 100.4°F (36.6°C – 38.0°C)
3-10y	96.6°F – 98.0°F (35.9°C – 36.7°C)	95.9°F – 99.5°F (35.5°C – 37.5°C)	97.5°F – 100.0°F (36.4°C – 37.8°C)	97.9°F – 100.4°F (36.6°C – 38.0°C)
11-65y	95.3°F – 98.4°F (35.2°C – 36.9°C)	97.6°F – 99.6°F (36.4°C – 37.6°C)	96.6°F – 99.7°F (35.9°C – 37.6°C)	98.6°F – 100.6°F (37.0°C – 38.1°C)
> 65y	96.0°F – 97.4°F (35.6°C – 36.3°C)	96.4°F – 98.5°F (35.8°C – 36.9°C)	96.4°F – 99.5°F (35.8°C – 37.5°C)	97.1°F – 99.2°F (36.2°C – 37.3°C)

Source: www.medguidance.com

Alarm

For more information about the alarm, refer to the GA1000 Series Instructions for Use (7MN00021-01) or GA2000 Series Instructions for Use (7MN00022-01).

Care and Maintenance

The advanced digital circuitry within the Thermometer Module requires no calibration or periodic maintenance. 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 Thermometer Module is not functioning properly, see “Troubleshooting” section for more information.

Cleaning

Thermometer Box - it is reusable. Lightly wipe the surface of it with a soft cloth dampened with rubbing alcohol before each use. Allow the device to dry thoroughly before reuse.
Sensor Patch - it is for single use. No cleaning is needed.

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 Thermometer Module	1. Change a new battery. 2. Make sure the Thermometer Box is assembled with the Sensor Patch firmly.
Unusual temperature data	1. Recheck device's location or contact with the armpit. 2. Keep this device attached for twelve (12) minutes before reading temperature. 3. Keep arm in natural dropping position consistently. 4. Use this device under instructed operation temperature. 5. Cover the sensor probe with arm.
Cannot establish system connection	1. Make sure the Infant Thermometer 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 (7MN00021-01) or GA2000 Series Instructions for Use (7MN00022-01).

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 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.

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%.

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 61000-4-3	10 V/m 80MHz to 2.7 GHz	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.			

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.

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 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).

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

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.

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 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	
Thermometer Box	51.5mm x 30.0mm x 6.7mm
Sensor Patch	117.8mm x 42.0mm x 7.4mm
Weight	5.5g
Ingress Protection	IP22
Display range	89.6°F-107.6°F (32°C-42°C) <89.6°F (32.0°C) displays “Lo” >107.6°F (42.0°C) displays “Hi”
Accuracy	89.6°F-107.6°F: ±0.2°F (32°C-42°C: ±0.1°C)
Battery Type	CR2025
Battery Life	7 days
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
Thermometer Box	GA-TB0001
Sensor Patch	GA-AP0011

For more information about the Display Unit and Receiver/Transponder, refer to the GA1000 Series Instructions for Use (7MN00021-01) or GA2000 Series Instructions for Use (7MN00022-01).

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.