Instruction For Use

On

Aulisa Temperature Module

Document Name:	GA-TM0002 Instructions For Use	
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Signatures

Author	Department	Date	Signature
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Revision History

Revision	Date	Author	Description
1	2023-12-26	Lox Ou	Initial Draft
2	2024-01-23	Lox Ou	Add alarm limit table
3	2024-01-26	Lox Ou	Modify "disposable patch" name
4	2024-01-31	Lox Ou	Modify Antenna Info

Attachment

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Guardian Angel®
Guardian Angel® Lite

Aulisa Temperature Module

Instructions For Use

7MN00083-01

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® or Guardian Angel® Lite.

Guide to Symbols

	Refer to instruction manual
	Non-ionizing electromagnetic radiation. Equipment includes RF transmitters Interference may occur in the vicinity of equipment marked with this symbol
	Type BF-Applied Part (patient isolation from electrical shock)
	Manufacturer
LOT	Lot number
NON STERILE	Non-sterile
	Date of Manufacture
SN	Serial number

	Indicates separate colection for electrical and electronic equipment (WEEE)
	Temperature limit
	Humidity limitation
IP23	Classification for water ingress and particulate matter
	warning
	Do not reuse
	Federal Communications Commission (FCC)
	National Communications Commission (NCC)
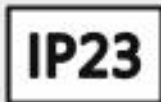
Welcome

This manual will help you get started with monitoring using the Temperature Module of Aulisa Guardian Angel® and Guardian Angel® Lite .

GA1000 Series

The Temperature Module is intended for use with the Display Unit/Aulisa mobile application installed on mobile devices. Refer to the GA1000 Series Instructions for Use (7MN00026-02) for detailed instructions.

GA2000 Series

The Temperature Module is intended for use with the Display Unit/Aulisa mobile application installed on mobile devices and the Receiver/Transponder. Refer to the GA2000 Series Instructions for Use (7MN00027-02) 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/mobile device (for GA1000 Series), or to the Receiver/Transponder (for GA2000 Series). Moving outside this range may cause missing, lost, and/or inaccurate data.
14. Follow local governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
15. Batteries might explode if used or disposed of improperly.
16. User may only change the battery. No user serviceable part is provided for this device.

17. 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.
18. System connection failure (Bluetooth connection) may result in loss of data transfer.
19. Only connected the sensor module to a trusted device installed with Aulisa-developed software application.
20. Only use official app stores to download the Aulisa—developed software application. If in doubt, contact Aulisa by going online at www.aulisa.com .

Device Overview

Device Components

Aulisa Temperature Module	Disposable Patch	Waterproof Patch

Device Description

The Temperature module is a small Temperature. Approximate size 3x3 cm Easy to use on babies 120 hours of continuous use It must be used within 32.8 feet (10 meters) of the display unit/ mobile device (for GA1000 series) or receiver/transponder (for GA2000 series).

Aulisa Temperature Module

The reusable, compact-sized, battery-operated Aulisa Temperature Module is embedded with a Bluetooth module. The battery is changeable.

1. Power LED •
2. Power Button
3. Temperature Sensor
4. Battery Chamber

Disposable Patch

The medical grade and disposable Patch 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.
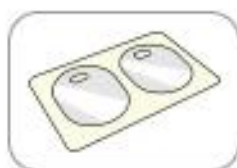
Device Intended Use

Aulisa Temperature Module is a battery-operated electronic device with indication for use in continuously measuring and monitoring armpit body temperature of adults, pediatrics, and infants and transmission of the measuring result via wireless signal. Aulisa Temperature Module is a non-invasive and reusable device for single patient use with intended environments of use are hospitals, medical facilities, home care, and subacute environments.

Device Principle of Operation

The Temperature 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 Temperature Module and become familiar with its parts.

Step 1 : Make sure to place a CR1216 battery in the Aulisa Temperature Module.

1.	4.	5.
Gently push open the battery cover.	Replace it with a new battery (CR1216) , ensuring the correct orientation with the "+" symbol facing upward as indicated on the product.	Close the battery cover.

Step 2 : Attach a sensor patch to the back of the temperature main body.

1.	2.
Tear off the patch.	Align the holes on the patch with the main unit's sensor probe, adhere it, and press firmly.

Step 3 : Please press the button to confirm whether the green light is always on.

NOTE :

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

Step 4 : Peel off the patch release paper, and position the sensor probe in the center of the armpit and affix it.

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 (7MN00027-02) 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 Temperature Module status information will appear on the MAIN screen.

NOTE :

- The Temperature Module only measures axillary (armpit) temperature
- Refer to "Device Pairing" section below for more information.
- If the patch is used continuously for 24 hours , it needs to be replaced with a new patch.

Device Pairing

Automatic Pairing

GA1000 Series

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

> NOTE :
> - The Temperature Module must be placed within 32.8 feet (10 meters) to the Display Unit/ mobile device (for GA1000 Series), or to the Receiver/Transponder (for GA2000 Series).

Manual Pairing

Follow the below instructions to manually setup pairing.

> NOTE :
> - Up to two (2) Temperature Modules can be stored on the Display Unit. Up to one (1) Temperature Module can be stored on the Aulisa mobile application.

Step 1 : Turn on the Display Unit/Aulisa mobile application.

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 Aulisa Temperature Module.

Step 4 : Check if the serial number (SN) displayed matches with the one on the Aulisa Temperature Module.

Step 5 : Press "CONFIRM" on the Display Unit/Aulisa mobile application.

Step 6 : Press the button on Aulisa Temperature Module 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 is lit blue..

> NOTE :
> - Make sure the battery is installed before use.
> - The Temperature Module remains paired with the system until the serial number is deleted from the list.
> - The Temperature Module must be placed within 32.8 feet (10 meters) to the Display Unit/ mobile device (for GA1000 Series), or to the Receiver/Transponder (for GA2000 Series).

Device Power Off

Press and hold the Aulisa Temperature Module button and the Power LED will go off.

Device Battery Replacement

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

	1.	2.	3.

Gently push open the battery cover.

Use a needle or a similar object to insert it deeply into the battery slot, then lever the battery upward.

Remove the battery.

4.

5.

Replace it with a new battery, ensuring the correct orientation with the "+" symbol facing upward as indicated on the product.

Close the battery cover.
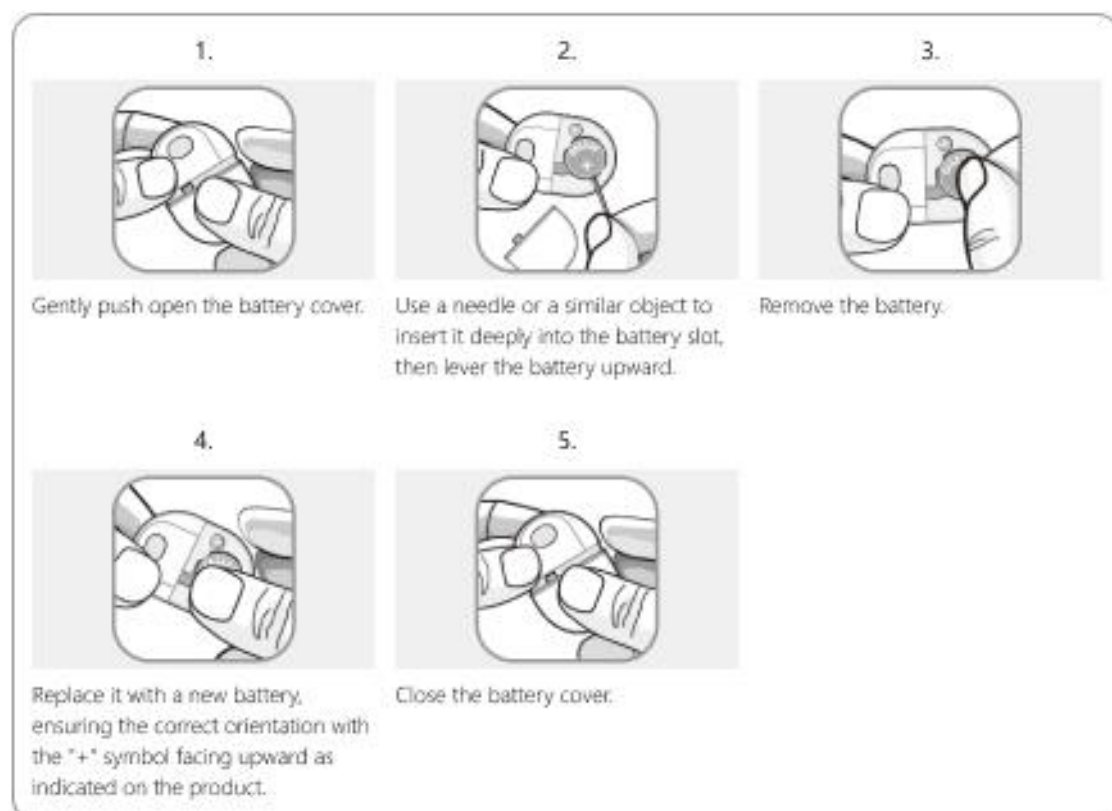
Waterproof Patch operation process

1.

2.

3.

Remove one side of the release paper.

Adhere it to the surface of the mainframe.

Remove the remaining release paper.

4.

5.

Press the patch firmly to ensure complete adhesion to the skin.

Peel off the patch release film to complete the procedure.
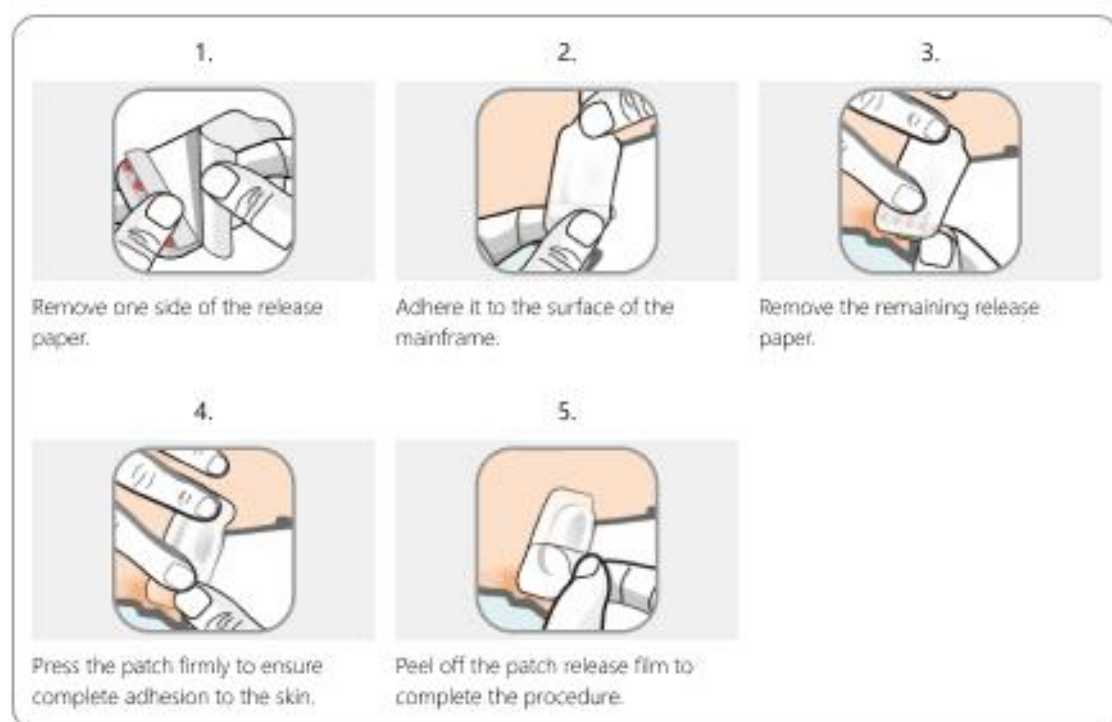
Normal Body Temperature Ranges

Age \ Type	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

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

High Priority Alarm	Factory Default		Adjustment Options	Adjustment Interval
Temperature Upper Alarm Limit	Adult/ Pediatric	98.6°F (37°C)	Off, 89.6-107.6°F (32 to 42°C)	0.1°F (0.1°C)
	Infant	99.3°F (37.4°C)		
Temperature Lower Alarm Limit	Off		Off, 89.6-107.6°F (32 to 42°C)	0.1°F (0.1°C)

For more information about the alarm, refer to the GA1000 Series Instructions for Use (7MN00026-02) or GA2000 Series Instructions for Use (7MN00027-02).

Care and Maintenance

The advanced digital circuitry within the Temperature 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 Temperature Module is not functioning properly, see "Troubleshooting" section for more information.

Cleaning

Aulisa Temperature Module - it is reusable. The Aulisa Temperature Module is expected to be cleaned before use, i.e., once per day. It has been tested to withstand 600 times of cleaning within 3 years of re-use life. Do not use the Aulisa Temperature Module that has exceeded its re-use life.
We recommend you clean the Aulisa Temperature Module with the instructions below.

Lightly wipe the surface of the Aulisa Temperature Module with a soft cloth dampened with rubbing alcohol. 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.
Disposable Patch - it is for single use. No cleaning is necessary

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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 Temperature Module	1. Change a new battery. 2. Make sure the Aulisa Temperature Module 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. 6. Make sure that the system is not in proximity with other RF radiating devices (such as diathermy, electrocautery, RFID, and security systems).
Cannot establish system connection	1. 1. Make sure the Infant Thermometer Module is within 32.8 feet (10 meters) spherical radius to the Display Unit/mobile device (for GA1000 Series), or to the Receiver/Transponder (for GA2000 Series). 2. 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 (7MN00027-02).
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

*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 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.
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%.

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.

*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
Radiated RF IEC 61000-4-3	10 V 80MHz to 2.7 GHz	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. Interference may occur in the vicinity of equipment marked with the following symbol: $\left(\left(\underset{\underset{\blacktriangle}{\bullet}}{\bullet}\right)\right)$

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

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.

Specifications

Dimensions	
Aulisa Temperature Module	24mm x 32.8mm x 5.5mm
Disposable Patch	25.0mm x 33.8mm
Waterproof Patch	50.0mm x 70.0mm
Weight	3.5 g (Module Only) 4.2 g (Module & battery)
Ingress Protection	IP23
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	Under 37°C: ±0.2°C 37.1–39.0°C: ±0.1°C 39°C and above: ±0.2°C
Battery Type	CR1216
Battery Life	5 years
Duration of Continuous Sensor Patch Use	up to 24 hours
Measurement Time	120 hours
Measurement Mode	direct mode

Temperature	
Operating	+5°C to +40°C
Storage/Transportation	-25°C to +70°C
Humidity	
Operating	15% 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 MHz
Protocol	BT5.2
Power Output	3V
Antenna Info	Chip, -0.3dBi
Security	AES-128
Range	32.8 feet (10 meters) spherical radius
Direction	Bi-direction
Data rate	Up to 1M Bps

Parts and Accessories

Parts and Accessories	Model Number
Aulisa Temperature Module	GA-TM0002
Disposable Patch	GA-AP0014
Waterproof Patch	GA-AP0015

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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