



Aura Glide

User Manual

Model Number: FC 40

Version: A/24 12.19.2025

Bringing together science and luxury, the Aura Glide ensures your skin looks as radiant as it feels.

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Descriptive Information

General Warning — Important Safety Information, Warnings, Precautions, Background
Before using the Aura Glide, review all Warnings and Precautions.



WARNING



- Never conduct servicing and maintenance while Aura Glide is in use.
- Simultaneous connection of a user to a high frequency surgical device while using Aura Glide may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
- Operation in close proximity to a shortwave or microwave therapy device may cause instability to the stimulator output of the Aura Glide.
- Do not use this device if you have a history of epilepsy, seizures, or cardiopathy.
- The device is unsuitable for users with electronic implants (e.g., pacemakers), cardiac arrhythmia, tumors, or acute inflammatory diseases.
- Avoid use on areas with arteriosclerosis, thrombosis, or unhealed implants. Ensure dental implants are securely anchored.
- Do not use on the eyelids.
- Avoid treating areas with dark brown or black spots, such as large freckles, birthmarks, moles, or warts.
- Do not use on eczema, psoriasis, open wounds, or active infections, excluding mild to moderate acne.

- Do not use if you experience abnormal sensations, such as numbness, or have photo allergies, extreme light sensitivity, or severe acne which requires medication.
- Consult your physician before use if pregnant or nursing. Stop use at the first sign of discomfort.
- Do not use on areas with suspicious lesions or potential skin cancer without consulting a physician.
- The device is not intended to be used by anyone under the age of 22 years and should be kept out of reach of children.
- If you have any medical concerns, are taking any medications that cause light sensitivity, or have had any facial surgery or other surgical procedures, please consult your physician before using the device.
- Store the device in a cool, dry location, away from direct sunlight, high humidity, or extreme temperatures.
- Avoid areas near water, fire, or strong electromagnetic fields.
- Keep the device out of reach of children, pets, to prevent accidental damage or injuries.
- Monitor for any small, detachable parts that could pose a choking hazard to children.
- Do not store near corrosive substances, explosive materials, or in conditions exceeding 55°C / 104°F.



PRECAUTIONS



- The Aura Glide is an OTC device designed for home use.
- Allow 30 minutes for the device to acclimate from its minimum storage temperature or cool

from its maximum storage temperature before use, assuming an ambient temperature of 20°C.

- Use only as directed. If you have any specific medical conditions or concerns, consult your physician before using the device.

Background

- The device is intended to be used only on the face.
- If you have any specific medical conditions or concerns, please consult your physician before using this device. The following documents highlights these for each modality or treatment attachment included with the Aura Glide as of the date or printing.

Intended Use

The Aura Glide is an over-the-counter handheld device for aesthetic purposes.

1. The microcurrent mode is indicated for facial stimulation.
2. LED mode is intended for the treatment of periorbital wrinkles (red light) and for the treatment of mild to moderate inflammatory acne (blue light).



Product Overview

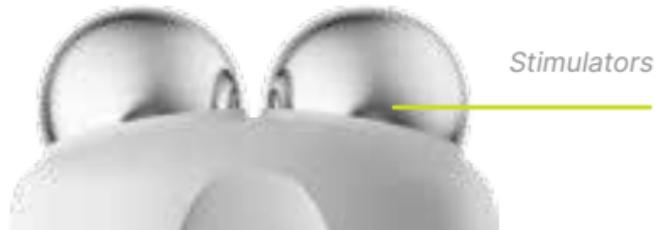
The Aura Glide is a 2-in-1 handheld device that elevates your facial wellness routine.

The device features a Microcurrent Head and an LED Head for Blue and Red light therapy.



LED & Microcurrent Attachments

Microcurrent Head



LED Head



Glide ON Primer Gel



Microcurrent Head

The Microcurrent attachment is designed for facial stimulation.

LED Head

Red light (633 nm):
treatment of periorbital wrinkles.

Blue light (415 nm):
treatment of mild to moderate inflammatory acne.

Both the LED and Microcurrent attachments are essential components of the Aura Glide system which are included in the device application.

Glide ON Primer Gel

After thoroughly washing and drying your face, apply the Glide ON Primer Gel on your face to maximize results prior to Microcurrent treatment.

The Glide ON Primer Gel is only used with the Microcurrent attachment. Thoroughly remove gel prior to LED Treatment.

Operation Information

Getting to Know Your Aura Glide





Magnetic Buckle

Ensures the attachments are securely attached in the correct position.

Power Button

Controls the device's ON/OFF function.

Attachment Controls

For the Microcurrent Head: Based on your preference, adjust the microcurrent intensity Level 1 (Gentle; Default), Level 2 (Standard), and L3 (Strong) by pressing the Power Button to increase the intensity level.

For the LED Head: Activate light therapy with a short press to switch between Red and Blue light therapy.

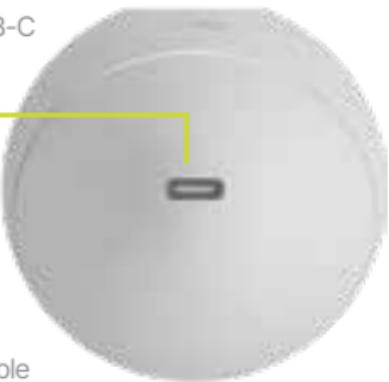
Aura Light Indicator

Refer to page 17 for further details.

Charging the Aura Glide

The Aura Glide is equipped with a USB-C charging port located on the bottom of the main body.

Plug the USB-C cable provided with your Aura Glide device into an external power adapter.



The USB-C cable provided is compatible with any standard USB adapter.

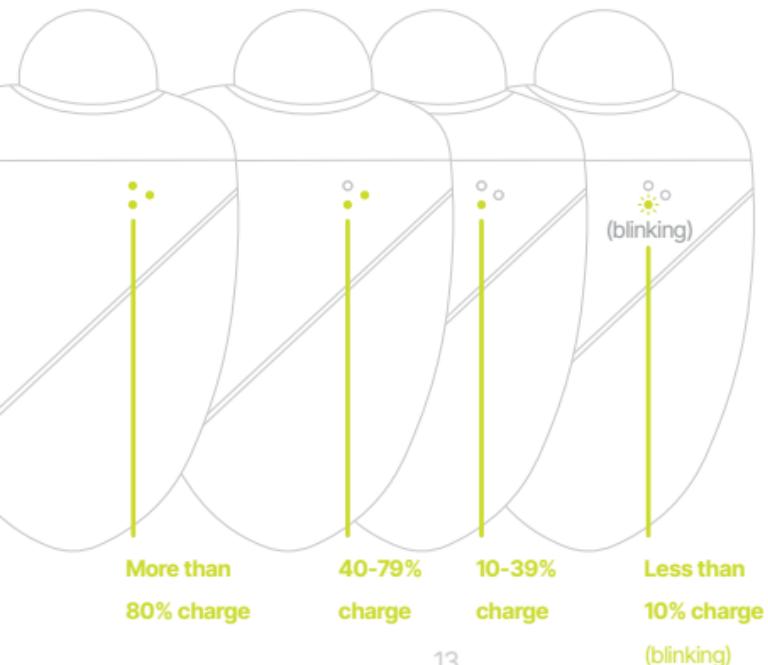
Fast charging is supported when using a USB-C adapter.

Plug the adapter to an outlet keeping it away from any source of water.

NOTE



Use only certified chargers without visible structural damage. The device will not function while charging.



When the device should not be used (Precautions & Contraindications)



PRECAUTIONS

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- Do not use the device after recent injury, surgery, or facial treatments (e.g., neurotoxins, dermal fillers, microneedling, laser treatments, or chemical peels) until the skin has fully healed.
- Do not use during active Herpes Simplex Virus outbreaks.
- Ensure the treatment area is clean-shaven, as facial hair may affect conductivity.
- Do not use if you have a heart condition or other cardiovascular concerns.
- Do not use the device directly over the thyroid, breasts, chest, or groin areas.



CONTRAINdications

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The following circumstances may present a potential risk that outweighs of benefit. Consult a medical professional before using the device:

- Do Not use with pacemakers, neurostimulators, artificial metal heart valves, or other implanted electronic devices;
- Do Not use with aneurysm clips (excluding non paramagnetic materials such as titanium alloys);
- Do Not use if you have intraocular metal foreign bodies, inner ear implants, metal prostheses,

metal joints, or ferromagnetic foreign bodies in the body;

- Do Not use if you have metal plates or pins in the treatment area;
- Do Not use if you are pregnant;
- Do Not use with metal foreign objects (metal implants, dentures, contraceptive rings);
- Do Not use if you require the use of Critical life support systems;
- Do Not use over a skin rash, open wounds, blisters, local tissue inflammation, infections, bruises, or tumors;
- Do Not use if you have Melasma or hyperpigmentation (especially if exacerbated by mild warmth);
- Do Not use if you have Epilepsy (epilepsy patients);
- Do Not use if you have cancer or tumors.



WARNINGS



- If you are under the care of a physician, consult your physician before using the Aura Glide.
- The Aura Glide is not intended for use by those with reduced physical, sensory, or mental capabilities.
- Treat only normal, intact, healthy skin, Do Not use over swollen, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, broken capillaries, etc...).
- To avoid potential thermal damage to the skin, it is recommended that prior to the use of the LED function, thoroughly remove cosmetic gels, cremes, ointments, lotions, etc., which may conduct heat from the LED light. The heat that they conduct may lead to skin burns.

Getting Started

- Powering On

Press the Power Button for three seconds to turn on the device. The main body will vibrate briefly.

- Powering Off

Press the Power Button again to turn off the device. The main body will vibrate briefly.

- Automatic Shut-Off

The Aura Glide will automatically shut off when the preset treatment time ends, unless powered off manually by pressing the Power Button.

Preset time:

- 10 minutes for LED Treatment
- 8 minutes for Microcurrent Treatment

Using the Aura Glide

1. Begin by thoroughly cleansing your face and rinsing twice to remove all residue. Dry your face thoroughly before starting treatment.

2. There are two treatment options with the Aura Glide:

LED Treatment —

in order to start, attach the LED Head.

Microcurrent Treatment —

in order to start, attach the Microcurrent Head.

3. Select and attach the desired treatment head.
4. Turn on the device (the main body will vibrate briefly).
5. Begin your treatment.

NOTE



The Aura Glide features an Aura Light Indicator to help you set treatment intensity and status, as well as alert you when a treatment ends. The indicator light will turn off automatically at the end of treatment time.

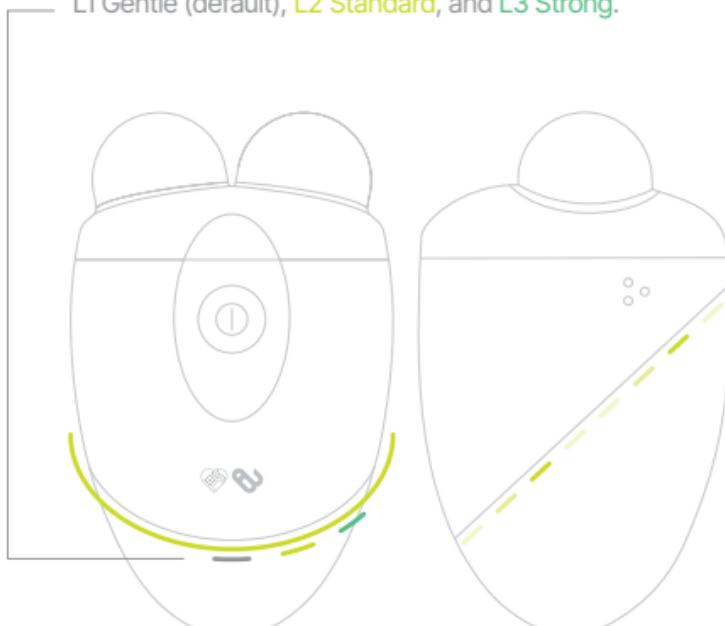
LED Treatment Head

Short press Power Button to switch between Red and Blue light therapy modes. The main body will vibrate briefly.

Microcurrent Treatment Head

Offers three intensity levels:

L1 Gentle (default), **L2 Standard**, and **L3 Strong**.



The Aura Light Indicator operates in the following manner:

For LED Treatment

When the LED Head touches your skin, the Aura Light Indicator will rotate in complete circles until the LED attachment no longer touches your skin or treatment time has ended.

For Microcurrent Treatment

The Microcurrent Head has three levels of intensity for you to choose from. The Aura Light Indicator will indicate the intensity level you selected, L1 (partial circle), L2 (half circle) and L3 (full circle). The indicator light will remain on until the treatment has ended.



Microcurrent Treatment

These recommendations are based on consultation with medical experts and published literature regarding

Warnings, Precautions, and Contraindications
as of the date of printing.

The Glide ON Primer Gel is required when using
the device for microcurrent treatment.

Before starting the Microcurrent treatment, perform
a skin sensitivity test by applying a small amount
of primer gel to a patch of skin. Leave the primer
on for 15-30 minutes before washing it off. If an allergic
reaction (rash, redness, etc.) develops, wash off the
primer and contact Aura Medical for recommendations.



Glide ON Primer Gel

Glide ON Primer Gel ensures safe and effective microcurrent
treatment when used with the Aura Glide device.

- Apply a thin, even layer of Glide ON Primer Gel to clean, dry facial skin. Reapply gel as needed to maintain smooth gliding and even conductivity.
- Attach the Microcurrent Head to the device and turn it ON by pressing the Power Button for 3 seconds. The main body will vibrate briefly.
- The treatment will begin at the default L1 Gentle intensity level.
- Adjust the intensity level to your preference by pressing the Power Button for 1 second (the main body will vibrate briefly). To increase the intensity to the next level press the Power Button again until you reach your desired intensity level.
 - L1 Gentle (Default)
 - L2 Standard
 - L3 Strong
- The device will automatically shut off after 8 minutes of use.
- To end the treatment manually, press the Power Button for 3 seconds. The main body will vibrate briefly.

TIPS



- Use light to medium pressure and glide the device slowly, ensuring both Stimulators remain in contact with your skin.
- Limit treatments to 5-8 minutes per treatment area in a 24-hour period.

NOTE



- Applying deeper pressure against the skin may result in stronger microcurrent sensations. Start with minimal

pressure and gradually increase to your preferred comfort level.

- While the device is compatible with other conductive gels, for optimal results, we recommend using **the Glide ON Primer Gel** supplied with the device and available online.



Post-Treatment Care

After completing an Aura Glide treatment, wash your face with a warm damp washcloth and follow your normal skincare routine.



LED Light Treatment

The LED Head offers two light therapy modes:
Red Light, Blue Light.

These recommendations are based on consultation with medical experts and published literature regarding precautions and contraindications as of the date of printing.

- Securely attach the LED Head to the Aura Glide main body.
- Turn the device ON by pressing the Power Button for 3 seconds. The main body will vibrate briefly. Then, press the button briefly again to activate light therapy; the main body will vibrate briefly once more.

- Switch between Red and Blue light modes with a short press of the Power Button. The main body will vibrate briefly.
- The device turns off automatically after 10 minutes of use. To manually turn off the LED Head, press the Power Button for 3 seconds. The main body will vibrate briefly.

Post-Treatment Care

Gently cleanse your face with a warm, damp washcloth.

Device Cleaning and Maintenance

To maintain optimal performance of your device, follow these steps:

1. Visually inspect the main body and attachments for any visible debris or residue.
2. Do not submerge the main body or attachments in water or rinse them under running water.
3. Thoroughly clean the main body and attachments with a damp cloth or alcohol cleaning wipe. After cleaning, visually inspect the main body and attachments for any residual debris. If residual debris is present, repeat cleaning with a lint free cloth slightly dampened with 70% isopropyl alcohol. If the device cannot be cleaned, safely dispose of the device.
4. Ensure all components are thoroughly dry prior to storage.
5. Store the device in a cool, dry environment within the specified temperature and humidity range.

6. Prevent exposure to corrosive substances that could damage the functionality or appearance of the device.

NOTE

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- Ensure the device is powered off before cleaning.
- Store the device in a cool, dry place (temperature: -20°C to +55°C / -4°F to 131°F; relative humidity: 10% - 90% RH).
- Do not store the device or battery where temperatures may exceed 55°C / 131°F, such as in direct sunlight or in a vehicle.

Aura Glide Warranty Section Limited Warranty

Aura Glide products are covered under a 1-year limited warranty from the date of original retail purchase. During this warranty period, we will replace your Aura Glide device free of charge if it develops a defect in materials or workmanship.

Conditions

- The warranty is valid only when the product is used in accordance with the user manual and guidelines provided by Aura Glide.
- Any attempt to disassemble or modify the device will void the warranty and may cause injury.
- Normal wear and tear, accidents, misuse, or unauthorized repairs are not covered under this warranty.

Limitations of Liability

Aura Medical is not responsible for loss due to product failure. Our liability is limited to replacing the defective product. In no event shall Aura Medical be liable for damages caused by external factors, such as accidents, misuse, or attempted repair.

Important

For the most up-to-date warranty information, please visit our website or contact our support team directly.



Product Data

- Dimensions: 61 x 59 x 99 mm
- Weight: 7 oz (198 gr)
- Battery Type: 3.7V / 600mAh lithium-ion
- Charging Requirements: 5V, 1A

- Charge Time: Approximately 90 minutes (+/- 10 minutes)
- Operational Duration: Up to 33 cycles of LED Blue Light Therapy, 15 cycles of LED Red Light Therapy, or 105 cycles of Microcurrent Therapy per charge.

Product Specifications

- Product Name: Aura Glide
- Product Model: FC 40
- Applied Part: Type BF
- Software Version: V1
- Life Cycle: 2 years

Microcurrent Treatment:

- Modes: 1
- Output Intensity Levels: 3
 - L1 = 140 mV
 - L2 = 300 mV
 - L3 = 480 mV
- Waveform: Pulsed Biphasic Shape, Modulated Square
- Maximum Output Voltage: $22V \pm 10\%$ (non-load voltage)
- Maximum Output Current: $420\mu A$ to $504\mu A$ @ 500 Ohm
- Basic Pulse Duration: 100ms
- Frequency ($\pm 20\%$): 8.33Hz
- Maximum Current Density ($\pm 20\%$): 0.315 mA.cm^2 @ 500Ω
- Maximum Power Density ($\pm 20\%$): $3.97\mu W/cm^2$ @ 500Ω

LED Treatment:

- Modes: 1
- Light Wavelengths:
 - Red Light (633 ± 10 nm)
 - Blue Light (415 ± 10 nm)
- LED Power Density:
 - Red light 73 ± 5 mW/cm²
 - Blue light 64 ± 5 mW/cm²

Operating Environment:

- Temperature: 0°C to 35°C (32°F to 95°F)
- Relative Humidity: 15% to 90% RH
- Pressure: 70.0kPa to 106.0kPa

Transport & Storage Environment:

- Temperature: -20°C to +55°C (-4°F to 131°F)
- Relative Humidity: 10% to 90% RH
- Pressure: 70.0kPa to 106.0kPa

Battery Specifications & Performance

Operating Conditions:

- Ambient Temperature: 26.0 °C (78.8 °F)
- Relative Humidity: 70%
- Power Supply: 5V / 1A via dedicated USB cable

Charging Characteristics:

- Average Charging Current: 540–560 mA
- Average Charging Time: 1 hour 30 minutes

Tested Battery Duration (Fully Charged):

LED Treatment Head — Blue Light Therapy

- Test Parameters: 33 cycles \times 10 min + 2 min extra
- Runtime: 5 hours 30 minutes

LED Treatment Head — Red Light Therapy

- Test Parameters: 15 cycles \times 10 min + 5 min extra
- Runtime: 2 hours 30 minutes

Microcurrent Treatment Head —

Output Intensity Level 3

- Test Parameters: 105 cycles \times 8 min + 4 min extra
- Runtime: 14 hours

NOTE



Microcurrent Treatment with Intensity Level 3 was tested using a 500Ω load and oscilloscope verification to ensure proper waveform delivery during each cycle.

For best performance and safety, always use the provided cable and certified 5V / 1A power adapter (not included). The device has built-in protection to prevent overcharging.

Troubleshooting information

Problem: Device Fails to Power On

Solution: Ensure the battery is charged.

Recharge if necessary.

Problem: Automatic Shut-Off

Solution: The device may have reached its preset treatment time or has a low battery. Recharge to resume use.

Problem: Charging Issues

Solution: Verify that the charging cable is properly connected to the port and undamaged.

Problem: Weak or No Sensation during microcurrent treatment

Solution:

1. Increase the intensity setting.
2. Push the probes deeper into skin.
3. Ensure skin is adequately moisturized with Glide ON Primer Gel.
4. Note that skin sensitivity and resistance may vary across different facial areas.

Symbols Explanation:

| Symbol | Description |
|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | Type BF Applied Part |
|  | <p>Date of manufacture</p> <p>To indicate the date on which a product was manufactured.</p> |
|  | <p>WEEE (Waste Electrical and Electronic Equipment)</p> <p>The symbol for separated collecting of electrical and electronic equipment shows a crossed out bin on wheels.</p> |
|  | <p>Manufacturer</p> <p>Indicates the medical device manufacturer.</p> |
|  | <p>Caution</p> <p>Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness operator action in order to avoid undesirable consequences.</p> |

| Symbol | Description |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>Serial number</p> <p>Indicates the manufacturer's serial number so that a specific medical device can be identified.</p> |
| IP22 | <p>Protected against solid objects over 12mm such as a finger, and vertically falling water drops when enclosure tilted up to 15°</p> |
|  | <p>Read user manual prior to use</p> |
|  | <p>Warning: Non-ionizing radiation</p> |
|  | <p>This way up</p> <p>To indicate correct upright position of the transport package.</p> |
| CE | <p>In accordance with Directive 2014/30/ EU electromagnetic compatibility</p> |
|  | <p>Keep away from rain</p> |

| Symbol | Description |
|--------|--------------------------------|
| | Fragile, handle with care |
| | Trade mark of Aura Medical LLC |

Disposal Instructions



Dispose of batteries and electronic devices
in compliance with local regulations.
Do not dispose of them with household waste.

Additional Information

EMC Guidance



WARNING



- Do not use near active HF surgical equipment or in the RF-shielded room of an ME system for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high.
- Avoid using this equipment adjacent with other equipment, as it may result in improper operation. If such use is necessary, both this equipment

and the other equipment should be monitored to ensure normal operation.

- Using accessories, transducers, and cables other than those specified or provided by the manufacturer may increase electromagnetic emissions or decrease electromagnetic immunity, potentially leading to improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be kept at least 12 inches (30 cm) away from any part of this equipment, including manufacturer-specified cables. Failure to do so may degrade the performance of the equipment.

Guidance and Manufacturer's Declaration –
Electromagnetic Emissions

| Emissions test | Compliance |
|-------------------------------------------------------------|------------|
| RF emissions CISPR 11 | Group 1 |
| RF emissions CISPR 11 | Class B |
| Harmonic emissions IEC 61000-3-2 | Class A |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies |

| Guidance and Manufacturer's Declaration – Electromagnetic Immunity | | |
|-----------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|
| Immunity Test | IEC 60601-1-2 Test level | Compliance level |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air | ±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air |
| Electrical fast transient/burst IEC 61000-4-4 | ±2 kV for power supply lines | ±2 kV for power supply lines |
| Surge IEC 61000-4-5 | ±0.5 kV, ±1 kV line(s) to line(s) | ±0.5 kV, ±1 kV line(s) to line(s) |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | 0% Ut; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% Ut; 1 cycle 70% Ut; 25/30 cycle 0% Ut; 250/300 cycle | 0% Ut; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% Ut; 1 cycle 70% Ut; 25/30 cycle 0% Ut; 250/300 cycle |
| Power frequency magnetic field IEC 61000-4-8 | 30 A/m 50Hz/60Hz | 30 A/m 50Hz/60Hz |
| Conduced RF IEC61000-4-6 | 3 V r.m.s. 150 kHz to 80 MHz 6 V RMS in the ISM and amateur bands between 0.15 MHz and 80 MHz | 3 V r.m.s. 150 kHz to 80 MHz 6 V RMS in the ISM and amateur bands between 0.15 MHz and 80 MHz |

| Immunity Test | IEC 60601-1-2 Test level | Compliance level |
|-----------------------------|------------------------------------------------|------------------------------------------------|
| Radiated RF IEC61000-4-3 | 10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz | 10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz |

NOTE



U_T is the a.c. mains voltage prior to application of the test level.

| Guidance and Manufacturer's Declaration - IMMUNITY to proximity fields from RF wireless communications equipment | | | | | |
|------------------------------------------------------------------------------------------------------------------|-------------------------------|-----------------------------------|---------------|----------------|------------------|
| Immunity Test | IEC60601 test level | | | | Compliance level |
| | Test frequency | Modulation | Maximum power | Immunity level | |
| Radiated RF IEC 61000-4-3 | 385 MHz | **Pulse Modulation: 18 Hz | 1.8W | 27 V/m | 27 V/m |
| | 450 MHz | *FM+ 5Hz deviation: 1 kHz sine | 2W | 28 V/m | 28 V/m |
| | 710 MHz 745 MHz 780 MHz | **Pulse Modulation: 217 Hz | 0.2W | 9 V/m | 9 V/m |

Guidance and Manufacturer's Declaration - IMMUNITY to proximity fields from RF wireless communications equipment

| Immunity Test | IEC60601 test level | | | | Compliance level |
|---------------------------|---------------------|----------------------------|---------------|----------------|------------------|
| | Test frequency | Modulation | Maximum power | Immunity level | |
| Radiated RF IEC 61000-4-3 | 810 MHz | **Pulse Modulation: 18 Hz | 2W | 28 V/m | 28 V/m |
| | 870 MHz | Modulation: 18 Hz | | | |
| | 930 MHz | | | | |
| | 1720 MHz | **Pulse Modulation: 217 Hz | 2W | 28 V/m | 28 V/m |
| | 1845 MHz | Modulation: 217 Hz | | | |
| | 1970 MHz | | | | |
| | 2450 MHz | **Pulse Modulation: 217 Hz | 2W | 28 V/m | 28 V/m |
| | 5240 MHz | **Pulse Modulation: 217 Hz | 0.2W | 9 V/m | 9 V/m |
| | 5500 MHz | | | | |
| | 5785 MHz | | | | |

NOTE



*— As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used. Although it does not represent actual modulation, it serves as a worst-case scenario.

**— The carrier must be modulated using a 50% duty cycle square wave signal.

**Guidance and Manufacturer's Declaration -
IMMUNITY to proximity magnetic fields**

| Test frequency | Modulation | Immunity level (A/m) |
|----------------|-------------------------------|----------------------|
| 30 kHz | CW | 8 |
| 134.2 kHz | * Pulse Modulation 2.1 kHz | ** 65 |
| 13.56 MHz | * Pulse Modulation 50 kHz | ** 75 |

NOTE

* – The carrier shall be modulated using
a 50 % duty cycle square wave signal..

** – r.m.s., before modulation is applied.

Manufacturer



Manufacturer Contact Details:

Aura Medical LLC

2 Skillman Street Suite 512, Brooklyn, NY 11205

Customer Service: support@camar.com

Made in China

User Assistance Information

Reporting adverse events to FDA

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors involving human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you believe that you or a family member has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your healthcare provider can supply clinical information from your medical record that may assist the FDA in evaluating your report.

However, we understand that, for various reasons, you may prefer not to have your healthcare provider complete the form, or your provider may choose not to do so. It's important to note that healthcare providers are not required to report to the FDA. In such cases, you may complete the Online Reporting Form yourself.

You will receive an acknowledgment from the FDA once your report is received. Reports are reviewed by FDA staff, and you will only be contacted if additional information is needed.

Submitting Adverse Event Reports to FDA

You can use one of the following methods to submit voluntary adverse event reports:

Online:

Submit your report at

www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home.

Consumer Reporting Form (FDA 3500B):

Follow the instructions on the form to submit it by fax or mail. For help filling out the form, visit MedWatchLearn.

The form is available at

www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf.

By Telephone:

Call the FDA at 1-800-FDA-1088 to report by phone.

Healthcare Professional Reporting Form (FDA 3500):

Commonly used by health professionals.

The form is available at

www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm163919.pdf.

FCC Caution

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following conditions:

This device may not cause harmful interference.

This device must accept any interference received, including interference that may cause undesired operation.

