

## SAFETY INFORMATION

This section lists Contraindications and general Warnings, and Cautions related to the use of Cala Trio therapy. Those Warnings and Cautions pertaining to specific functions or procedures are included throughout this Guide.

### 3.1 Contraindications

The device should **NOT** be used:

- » by patients with an implanted electrical medical device, such as a pacemaker, defibrillator, or deep brain stimulator.
- » by patients that have suspected or diagnosed epilepsy or other seizure disorder.
- » by patients who are pregnant.
- » on swollen, infected, inflamed areas, or skin eruptions, open wounds, or cancerous lesions.

### 3.2 Warnings

- Do not use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted electronic device, or implanted metal in the wrist, because this may cause electric shock, burns, electrical interference, or death.
- Do not use the device while sleeping, driving, bathing, operating machinery, or during any activity in which possible involuntary muscle contractions due to stimulation may cause undue risk of injury.
- Do not use the device near the head, directly on the eyes, covering the mouth, upper back, crossing over the heart, or on diseased skin.
- Do not use the device on the neck because this could cause severe muscle spasm resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm.
- Do not use the device on the chest because introduction of electric current into the chest may cause rhythm disturbances to the patient's heart, which could cause death.

- Do not apply the device near the thorax, as this may increase the risk of arrhythmia.
- Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., *phlebitis, thrombophlebitis, varicose veins, etc.*).
- Do not apply stimulation over, or in proximity to, cancerous lesions.
- To prevent electrical shock, do not immerse the device in water or wear while performing activities where the device is under water, such as swimming or bathing.
- Do not use the device simultaneously with:
  - » high frequency surgical equipment, as this may result in electrical burns and/or possible damage to the device.
  - » electronic monitoring equipment (e.g., *cardiac monitors, ECG alarms*), which may not operate properly when the electrical stimulation device is in use.
- To prevent an explosion hazard and possible patient injury, instruct the patient to stop stimulation from the device when at a refueling place (e.g., *gas station*). Do not use the device near flammable fuel, fumes, or chemicals.
- Implanting-physician approval should be obtained by the prescribing physician before using on patients with implanted devices at the site of stimulation. Use of the device with some implants is contraindicated – see Contraindications for details.
- The long-term effects of chronic electrical stimulation are unknown.

### 3.3 Cautions

- The device has only been evaluated in subjects diagnosed with essential tremor and the effectiveness of the device has not been evaluated for tremor associated with other conditions.
- Do not use Cala Trio if you have suspected or diagnosed epilepsy or other seizure disorder.
- Use the device only as directed by the Health Care Professional Guide and the Patient Guide.
- The safety of electrical stimulation during pregnancy has not been established.

- Higher stimulation levels may be associated with potential for increase in skin irritation, including electrical stimulation burns of the skin, which may cause focal pinpoint edema, erosion and crusting.
- Store the device to prevent exposure to dust, direct sunlight, and pests. It is recommended to store the device in the original packaging when not in use or being charged.
- To prevent damage to the device and/or performance issues:
  - » Keep the device dry. Cala Trio can withstand some splashing.
  - » Avoid the formation of condensation on the device. When moving the device between hot and cold temperatures, place it in an airtight plastic bag and let it slowly adjust to the temperature change before use.
  - » Do not use the device in places with high humidity, such as the bathroom.
  - » Do not store or transport the device or its accessories in temperatures that exceed the recommended storage temperature range: -20°C to 45°C (-4°F to 113°F). Do not operate the device in temperatures that exceed the recommended operation temperature range of 5°C to 40°C (41°F to 104°F). Temperature extremes can damage the device and accessories.
  - » Do not tamper with, modify, or attempt to perform maintenance or servicing on the device.
  - » Do not use the device **within 3 1/2 feet** (e.g., *within 1 meter*) of shortwave or microwave therapy equipment.
- To prevent damage, performance issues, increased emissions, or decreased immunity of the device only use the accessories recommended by Cala Health with the device. The device claims compliance for electromagnetic compatibility levels in conjunction with the charger (see *Section 11*).
- Advise patients to use the device with caution:
  - » If the patient has a tendency to bleed following an injury.
  - » Over areas of the skin that lack normal sensation.
- Keep out of the reach of children and pets.
- The device is single-patient use by the individual for whom it has been prescribed. It should not be worn by anyone else or on any other part of the body.

- To avoid interfering with diagnostic assessments, advise the patient to not wear the device during x-ray examinations.
- To prevent Cala Trio band damage, do not pinch, pull, or twist the Band with too much force.
- Should any technical problem occur that is not covered in the Healthcare Professional Guide or the Patient Guide, please contact Cala Health at 888-699-1009 or CustomerSuccess@CalaTrio.com.

### 3.4 Adverse Reactions

The following are possible minor/moderate risks or adverse reactions that may occur with the use of the device:

- Discomfort with stimulation (e.g. *stinging, sensation of weakness, etc.*).
- Allergic reaction to electrodes or other materials.
- Skin irritation, including electrical stimulation burns, redness and/or itching.

In the unlikely event that any of the following more significant issues occur, advise the patient to stop using the device immediately and to consult a physician:

- Signs of significant and persistent skin irritation, sores, electrical stimulation burns or lesions at the site of stimulation.
- Significant and persistent increase in muscle tightness or stiffness.
- A feeling of chest pressure during stimulation.
- Swelling of the arm, wrist, or hand.

### 3.5 Skin Care Guidelines

The device works by electrically stimulating nerves through the skin. It is important for the patient to inspect their skin where it contacts the electrodes to minimize risk of skin irritation. To promote good electrode connection and healthy skin, instruct the patient to follow these skin care guidelines:

- If there is any excess oil or lotion on your wrist, wash with soap and water and rinse well before wearing Cala Trio.
- Always check the skin for irritation, redness, or rash when putting on and taking off Cala Trio.