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Model: CT1-STR, CT1-STL, CT1-BSR, CT1-BMR, CT1-BLR, 
CT1-BSL, CT1-BML, CT1-BLL, CT1-STB, CT1-RSR, CT1-RSL, 
CT1-RBS

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unauthorized personnel.
1.0 LIST OF SYMBOLS

- Use by date
- Caution: Protected against intrusion from fingers and small objects, and from water drops vertically falling on Cala Trio when it is tilted up to 15° from vertical. Do not immerse in a bathtub or use while swimming.
- IP22
- Conforma to AAMI STD ES60601-1, IEC 60601-2-10, IEC 60601-1-11, Certified to CSA STD C22.2#60601-1
- MEE: Medical Electrical Equipment
- Sold by prescription only. Caution: Federal law restricts this device to sale by or on the order of a physician.
- Type BF Applied Part(s)
- Manufacturer
- Date of manufacture
- Class II Equipment
- Catalogue number
- Batch code
2.1 Indications for Use

Cala Trio is indicated to aid in the transient relief of hand tremors in the treated hand following stimulation in adults with essential tremor (ET).

- Cala Trio is a non-invasive, wrist-worn device for adults with essential tremor.
- Meaningful relief is usually observed after use.
- Electrodes embedded in a cloth band (Cala Trio Band), deliver therapy to nerves in the wrist.
- Cala Trio therapy is delivered during 40-minute stimulation sessions, which can be started and stopped on demand.
- Cala Trio therapy should be applied when transient relief of hand tremor is desired (i.e. before activities involving your hands such as meals or writing).
- Cala Trio therapy is recommended for use at least twice daily to help with the activities listed above.

2.2 Cala Trio™ Therapy Components

Your Cala Trio Therapy System contains the following:

**Cala Trio Stimulator**
- Snaps into the Cala Trio Band
- Is worn around your wrist like a wristwatch secured with the Cala Trio Band
- Is worn on the wrist of the prescribed hand

**Cala Trio Band**
- Contains electrodes
- Delivers therapy to nerves in your wrist
- Designed for either right- or left-handed use
- Needs to be replaced to maintain effective therapy delivery

**Cala Trio Base Station**
- AC-powered base station in which Cala Trio sits for recharging
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.

### 3.3 Cautions

- 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.
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 not wear the device during x-ray examinations.

• 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:

• Wet your wrist before donning Cala Trio.
• 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.
The initial prescription for Cala Trio therapy includes a stimulator, a three-month band supply, and a base station for charging. A refill prescription for Cala Trio therapy includes a three-month band supply every three months for one year.

There are three steps in writing a prescription:

1. Select hand to treat
2. Determine band size
3. Select “Tremor Task”

4.1 Choosing the Hand to Treat
Cala Trio is indicated to aid in the transient relief of hand tremors in the treated hand following stimulation in adults with essential tremor (ET).

Cala Trio is designed to stimulate nerves in the left OR right wrist. The device is not interchangeable between the left and right hand.

4.2 Determining Band Size
Cala Trio Band comes in three sizes: Small, Medium, and Large. To determine the appropriate band size, measure the subject’s wrist circumference of the hand chosen for treatment.

To select the correct band size:

1. Measure the subject’s wrist circumference with a wrist measurement device/measuring tape. Measure over the wrist bone.
2. Wrap the measuring tape around the wrist. There should be no visible gaps between the measuring tape and the skin.
3. Select the appropriate band size according to the following:
   - Small: 13.6 – 16.4 cm
   - Medium: 16.5 – 18.4 cm
   - Large: 18.5 – 20.4 cm

4.3 Determining “Tremor Task”
The “Tremor Task” is a postural hold that helps characterize the patient’s tremor. It is integral to the therapy as the patient will perform the hold:

- during setup to define the patient’s baseline tremor before starting therapy and to calibrate the individualized therapy.
- before and after therapy to characterize its impact.

You shall determine the tremor task to be the more severe of the following two postural holds: outstretched OR wing-beating.

Before using the device, assess both postural holds with your patient and determine their tremor task. Choose the more severe postural hold. Advise the patient that this specific “Tremor Task”, either the outstretched OR wing-beating hold, will be done when the device prompts them for a tremor task.
5.0
SETTING UP Cala Trio™

View instructional videos at my.CalaTrio.com

Setting up Cala Trio is as simple as 1, 2, 3...

1. Positioning and fastening it on your wrist
2. Calibrating
3. Setting therapy intensity

5.1 Positioning and Fastening Cala Trio™

Positioning and fastening Cala Trio on your wrist correctly is important to therapy success.

• Check your delivery ticket to verify the size and handedness of the band.

• It is essential that the Cala Trio Stimulator and Band be snapped together correctly. If they become detached, align the half circle cut outs on the back of the stimulator and band as you attach them together.

Step 1: Dampen entire wrist circumference with ample amounts of water before positioning Cala Trio

• This ensures a good connection between the electrodes and wrist.

• Never submerge Cala Trio in water.

• If there is any excess oil or lotion on your wrist, wash with soap and water and rinse well before wearing Cala Trio.

Step 2: Insert your prescribed hand through the band making sure the MAIN button points toward the elbow—not the hand

Step 3: Center the stimulator on the back of your wrist—as close to the hand as possible without hindering wrist movement

Note: Correct placement of the Cala Trio Band electrodes is essential to therapy success.

Step 4: Ensure that the blue mark on the band is aligned with the center of the inside of your wrist and that the white mark is in line with your thumb. Reposition if necessary

Step 5: Pull the end of the Cala Trio Band to tighten—fasten the Velcro securely and tightly
• Should be snug enough so it does not slide along or around the wrist.

Left Handed Device

Right Handed Device

• The electrodes should be flush to the skin.

5.2 Calibrating Cala Trio™

During stimulator setup, Cala Trio learns about your tremor and personalizes therapy according to its characteristics.

• Calibration happens over the course of three measurements taken while you perform the "Tremor Task" prescribed by your physician.

Note: In order to conserve battery, Cala Trio goes into SLEEP mode and fades to black if you are not actively pressing any buttons. Press any button to wake up Cala Trio.

Determine your "Tremor Task" by checking your prescription information.

Step 1: Press the MAIN button to wake up the stimulator. You should see Cala Trio displayed.

Step 2: From Cala Trio, press and hold the MAIN button for 3 seconds to start setup. You will see "press main to measure 1"

Step 3: Get in position to do your "Tremor Task" (see above) You can find your "Tremor Task" in your prescription information

Step 4: Press the MAIN button to start the measurement

Step 5: Perform your "Tremor Task" until all dots are blue (~20 seconds). Cala Trio will vibrate when the "Tremor Task" is complete

Step 6: If you correctly performed your "Tremor Task" for the full measurement, press the MAIN button to save the measurement

Note: If you were moving in a way unrelated to your tremor during the "Tremor Task", like walking or talking, press the DOWN button and then the MAIN button to remeasure.
Step 7: Once Measure 1 is saved, Cala Trio will prompt you for Measures 2 and 3

- Repeat the same process for Measures 2 and 3.

**Note:** If you accidentally save a poor measurement (e.g. you were walking or talking during the "Tremor Task"), reset Cala Trio by pressing and holding the UP and MAIN buttons simultaneously for 3 seconds.

### 5.3 Setting Stimulation Intensity for Therapy

After calibrating Cala Trio to your tremor, you will set the stimulation intensity preset.

- Cala Trio automatically ramps to the intensity preset during all subsequent therapies.
- It is important to find the maximum level of therapy that you can comfortably tolerate for 40 minutes.

**Note:** You will always be able to increase or decrease the intensity during therapy sessions as needed.

#### To set the intensity:

**Step 1:** Press the MAIN button from "press main to set intensity". Wait 3 seconds before moving to step 2.

**Step 2:** Press the UP button to slowly increase intensity. You may not feel the sensation right away.

**Step 3:** As you continue to press the UP button, you should feel a tingling sensation in your hand and fingers in the areas highlighted in the images above.

**Note:** Tingling sensation varies depending on Cala Trio positioning and amount of water on the wrist.

» You may feel a stinging sensation if you did not wet your wrist sufficiently before fastening Cala Trio. See the note below to add more water.

» You should not feel the tingling sensation in your pinky. Additionally, if you do not feel the tingling sensation in the fingers highlighted in step 3, see the note below to reposition Cala Trio.

**If needed, to add more water and reposition Cala Trio:**

» Press the MAIN button and wait for therapy to stop.

» Press the DOWN button to highlight 'reset intensity' and the MAIN button to select.

» Add water to your wrist (see section 5.1, page 8) or adjust the placement of the band (see section 5.1, step 3, page 8).

» Repeat steps 1-3 when you are ready to set your intensity again (see section 5.3, page 10).

**Step 4:** Once you find the highest intensity level that you can comfortably tolerate for a 40-minute therapy session, press the MAIN button to stop stimulation.

**Note:** Choose an intensity below a level that causes discomfort or muscle contraction.

**Step 5:** Press the MAIN button to save the intensity preset.

Your Cala Trio therapy is personalized and ready to use!
6.0
A THERAPY SESSION WITH Cala Trio™
View instructional videos at my.CalaTrio.com

A therapy session with Cala Trio is easy to start and fit into your day.

Step 1: To start a therapy session, from the time display, press the MAIN button. You will now see "start session"

Step 2: Press the MAIN button again to start a session

Note: "Tremor Task" measurements will be prompted periodically before and after therapy sessions. Cala Trio will prompt you in a similar way as described in section 5.2, steps 3-5, on page 9.

Step 3: If prompted, press the MAIN button to do your prescribed "Tremor Task", or if you would like to skip and are given the option, press the DOWN button and then MAIN to skip until next session

Step 4: If prompted, do your "Tremor Task" (i.e., outstretched postural hold or wing-beating postural hold)

To complete your "Tremor Task"
• You can find your "Tremor Task" in your prescription information.
• Get in position to do your "Tremor Task".
• Press the MAIN button to start the measurement.

• Perform "Tremor Task" until all dots are blue (~20 seconds).

Step 5: After collecting your "Tremor Task", Cala Trio will ask if you want to start therapy. Press the MAIN button to start therapy

Note: Once therapy starts, it automatically ramps to your intensity preset while displaying "starting therapy." Therapy is then 40 minutes of stimulation.

Note: The "tingling" sensation of stimulation will naturally vary from day to day. You can adjust the intensity as needed to maintain a consistent sensation during therapy and across sessions.

» To stop the ramp to your preset, press any button.

» Press the UP button to increase intensity.

» Press the DOWN button to decrease intensity.

Step 6: The 40-minute timer will begin countdown
6.1 How to Stop Cala Trio™ Therapy

After 40 minutes, Cala Trio Therapy will automatically stop when the countdown timer reaches zero minutes and Cala Trio displays "therapy complete".

**Step 1:** To stop therapy early, press and hold the MAIN button until you see "therapy stopped"

- When therapy stops, Cala Trio vibrates to indicate therapy has stopped or is complete.
- If you were prompted to do your "Tremor Task" before therapy, it will prompt you to perform your "Tremor Task" again after therapy (repeat section 6.0, steps 3 and 4 on page 11).

6.2 How to Rate Your Tremor with Cala Trio™

After collecting your "Tremor Task", Cala Trio will ask you if your "Tremor Task":

To rate how your tremor level has changed compared to before therapy:

**Step 1:** Press the MAIN button to bring up the rating display

**Step 2:** Press UP button or DOWN button to highlight the rating you want

**Step 3:** Press MAIN button to save your rating

You have successfully completed a therapy session with Cala Trio!

6.3 How to Remove Cala Trio™

**AVOID REMOVING Cala Trio DURING THERAPY**

Between sessions, you can remove Cala Trio by:

**Step 1:** Make sure therapy has stopped. If you are in the middle of a session, press and hold the MAIN button until you see "therapy stopped" (see section 6.1)

**Step 2:** Unfasten the band to release the Velcro connection

**Step 3:** Remove Cala Trio from wrist

**Note:** Leave the stimulator and band attached until you are prompted to replace the band. Cala Trio will display "replace band" in order to maintain effective therapy (see section 7.2 on page 13).
7.0 CARING FOR Cala Trio™
View instructional videos at my.CalaTrio.com

7.1 How to Charge Cala Trio™

Charge Cala Trio
• Overnight
• With band attached to the stimulator

Note: The band must be attached to the stimulator in order to charge.

Step 1: Place the stimulator with the band attached into the base station
» Cala Trio displays that it is charging and then fades to sleep after a few seconds.
» The base station will also communicate its status via a light. The table below shows the status light options:

<table>
<thead>
<tr>
<th>Light</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>white light</td>
<td>device connecting, ready to charge</td>
</tr>
<tr>
<td>green light</td>
<td>charging</td>
</tr>
<tr>
<td>yellow light</td>
<td>device updating, do not remove from base station</td>
</tr>
<tr>
<td>red light</td>
<td>replace Cala Trio Band</td>
</tr>
</tbody>
</table>

7.2 How to Replace Cala Trio™ Band
Cala Trio will display “replace band” in order to maintain effective therapy.

Step 1: Check that the size and the handedness of the band matches your prescription information.

Step 2: Remove the used band by unsnapping it from the stimulator
Step 3: For the new one, align the half circle cut outs on the back of the band and stimulator as you snap them together
Step 4: Place the stimulator attached to the new band in the base station for 15 seconds in order to clear the “replace band” message

7.3 How to Change Stimulation Intensity Preset
Change the preset if you would prefer a different stimulation intensity for therapy.

Step 1: From the time display, press the UP or DOWN buttons until you see “intensity setting”. Press the MAIN button
Step 2: Press the DOWN button to highlight ‘reset.’ Then press the MAIN button
Step 3: Use the UP button to increase the therapy to an appropriate level. See steps 2-3 in section 5.3 on page 10 for more detail
Step 4: Press the MAIN button to stop the therapy. Then press the MAIN button again to save the intensity. You will now see the clock
7.4 How to Recalibrate Cala Trio™

In order to ensure effective therapy, or if the device is calibrated incorrectly Cala Trio may need to be recalibrated after initial setup.

**Step 1:** From the time screen, press the **UP** and **DOWN** buttons simultaneously for three seconds to enter the Calibration Menu.

**Step 2:** Instruct the patient to perform their prescribed “Tremor Task” and press the **MAIN** button to start the calibration. Have the patient continue their “Tremor Task” until all dots are blue (20 secs). The device will vibrate to indicate when the “Tremor Task” is complete.

**Step 3:** After calibration, press **MAIN** to save. If you do not want to save the calibration, press **DOWN** and then **MAIN** to exit.

*Cala Trio therapy is re-calibrated and ready to use!*

---

7.5 How to Reset Cala Trio™

If Cala Trio is frozen or otherwise performing in a way that you do not expect, you may perform a reset.

**Step 1:** Press and hold the **MAIN** and **UP** buttons at the same time for a few seconds until Cala Trio displays “powering down”.

**Step 2:** Release the buttons and Cala Trio will automatically restart displaying Cala Trio.

---

7.6 How to Clean and Store Cala Trio™

To clean Cala Trio Therapy components, use a disinfecting wipe as often as once per week.

When not using therapy, charge Cala Trio overnight on the base station. Alternatively, store Cala Trio in the included microfiber bag at room temperature.

**Note:** Do not place or store a Cala Trio band on top of the base station unless it is attached to a Cala Trio stimulator.
8.0 TROUBLESHOOTING
View instructional videos at my.CalaTrio.com

If you have any issues using Cala Trio such as unexpected events or changes in performance, please first refer to the content in this section. If issues continue, please contact Cala Health at 888-699-1009 or CustomerSuccess@CalaTrio.com

Band Not Connected
Therapy has stopped. To resolve the issue:

Step 1: Press MAIN button to exit the warning

Step 2: If prompted, complete the post therapy “Tremor Task” and rating

Step 3: Remove Cala Trio from your wrist

Step 4: Ensure the stimulator is securely and correctly snapped into the band (*half circles should be aligned as shown in section 5.1 on page 8*)

Step 5: Dampen your wrist

Step 6: Tightly secure Cala Trio on your wrist

Step 7: Restart therapy. If warning persists, stop using Cala Trio and contact Cala Health at 888-699-1009 or CustomerSuccess@CalaTrio.com

Error
Cala Trio has stopped functioning due to an internal error. Press and hold the MAIN button for a few seconds to reset the stimulator. Use stimulator as instructed. If the error persists, contact Cala Health at 888-699-1009 or CustomerSuccess@CalaTrio.com.

Charge Device
Cala Trio needs to be charged. Place Cala Trio, with the band attached, into the base station. Note the band must be attached in order for the device to charge.

Adjust Band on Wrist
Follow the same steps listed on above for Band Not Connected warning.

Replace Band
Replace band as soon as possible. Therapy will be available for ten days after the first appearance of this message. See section 7.2 on page 13 for directions on disconnecting and connecting the stimulator and band.

Powering Down
Appears when the stimulator resets.

Temperature Exceeded
Cala Trio has stopped working because the temperature is too high inside the stimulator. Remove it from your wrist and allow the stimulator to cool down.
9.1 Study Overview
The study was multi-center, prospective, randomized, double-blinded, and sham-stimulation controlled. Each subject was seen for a single three-hour appointment at a study site. Subjects were randomized one-to-one to either the investigational TAPS stimulation ("treatment" group) or sham stimulation ("sham" group). The TAPS stimulation amplitude for the treatment group was based on each subject’s stimulation threshold. The sham group received 0-amplitude stimulation. The study site personnel and investigator were not blinded and knew the subject’s therapy allocation. However, the subject and the raters assessing the primary effectiveness endpoint were blinded. The subjects’ tremor severity was assessed before, during, and immediately after the 40-minute stimulation session using various metrics. Safety was assessed using adverse event data collected during the study.

9.2 Key Inclusion Criteria
1. At least 22 years of age
2. A diagnosis of essential tremor as confirmed from clinical history and examination by a movement disorder neurologist
3. At least one hand exhibiting kinetic tremor ≥ 2 as assessed by the Essential Tremor Rating Assessment Scale (TETRAS) Archimedes spiral task completed during the baseline evaluation, as assessed by the Investigator in-person.
4. Score of 3 or above in any one of the items of the Bain & Findley Activities of Daily Living Scale

9.3 Key Exclusion Criteria
1. Implanted electrical medical device, such as a pacemaker, defibrillator, or deep brain stimulator
2. Previous thalamotomy procedure, including Stereotactic Thalamotomy, Gamma Knife Radiosurgical Thalamotomy, and focused ultrasound, for the treatment of tremor
3. Suspected or diagnosed epilepsy or other seizure disorder
4. Pregnant
5. Swollen, infected, inflamed areas, or skin eruptions, open wounds, or cancerous lesions of skin at stimulation site
6. Peripheral neuropathy affecting the tested upper extremity
7. Alcoholism (score of 4 or higher on DSM-5)
8. Other possible causes of tremor, including Parkinson’s disease, drug-induced, enhanced physiological tremor, dystonia
9. Other neurodegenerative disease like Parkinson-plus syndromes suspected on neurological examination. These include: multisystem atrophy, progressive supranuclear palsy, dementia with Lewy bodies, and cortical basal ganglionic degeneration
10. Changes in medication for tremor within 1 month prior to study enrollment
11. Change in antidepressant medication within 3 months prior to study enrollment
12. Botulinum Toxin injection for hand tremor within 6 months prior to study enrollment
13. Alcohol or caffeine consumption within 12 hours of study enrollment

Subjects already taking medications for their essential tremor remained on their medications during the study.

9.4 Study Endpoints
Safety
The primary safety endpoint was an analysis of adverse events types and rates for all enrolled subjects.

Effectiveness
• The primary effectiveness endpoint was a significantly greater change in the treatment group compared to the sham group in the TETRAS Archimedes spiral rating after stimulation compared to baseline. An analysis of covariance (ANCOVA) model was used to assess the statistical significance of the difference in the mean change between the treatment and sham groups. The model included the baseline score as a continuous covariate, and randomization assignment as a classification variable.
» **TETRAS Archimedes Spiral Task**

The TETRAS Archimedes Spiral Task requires subjects to copy a spiral drawing in a 10-cm sized square. At baseline, the investigator rated the spiral. To determine if the subject met the inclusion criteria of a minimum score of 2, the investigator rated the spirals on the 5-point (0-4) TETRAS scale with 1-point resolution:

- **0** = normal
- **1** = slight: tremor barely visible.
- **2** = mild: obvious tremor
- **3** = moderate: portions of figure not recognizable.
- **4** = severe: figure not recognizable

**Note:** The investigators were required to rate the spirals using a 1-point resolution to assess inclusion into the study, whereas the blinded raters could use a 0.5-point resolution using the same scale for the assessment of baseline and subsequent measures.

In order to account for multiplicity, the secondary effectiveness endpoints were to be analyzed using a stepwise gate-keeping approach, whereby each subsequent hypothesis would only be tested if the preceding null hypothesis was rejected and secondary endpoint hypotheses would only be tested if the primary endpoint null hypothesis was rejected.

- **The secondary effectiveness endpoints** were:
  - a significantly greater change in the treatment group compared to the sham group in the TETRAS Archimedes spiral rating during stimulation compared to baseline
  - a significantly greater self-reported improvement in the treatment group (CGI-I scale) compared to the sham group.

**CGI-I Scale**

The Clinical Global Impression-Improvement (CGI-I) scale is a 7-point self-report scale that required the subject to assess how much their tremor level has improved or worsened relative to their baseline state prior to the session. The subject reported their improvement on the 7-point CGI-I scale defined as follows:

- **1** = Very much improved
- **2** = Much improved
- **3** = Minimally improved
- **4** = No change
- **5** = Minimally worse
- **6** = Much worse
- **7** = Very much worse

**Bain & Findley ADL Scale**

To thoroughly document tremor severity, the complete 25-item scale was administered at baseline. A subset of 7 Bain & Findley ADL tasks that can be performed unilaterally (using one hand) and do not require the dominant hand were performed by the subject at baseline and after the session to evaluate functional improvements in activities of daily living. These 7 tasks were:

- Use a spoon to drink soup
- Hold a cup of tea
- Pour milk from a bottle or carton
- Dial a telephone
- Pick up your change in a shop
- Insert an electric plug into a socket
- Unlock your front door with a key

The subjects (blinded as to whether they received stimulation or sham) performed the tasks and rated themselves from 1-4 on the following Bain & Findley ADL scale:

- **1** = Able to do the activity without difficulty
- **2** = Able to do the activity with a little effort
- **3** = Able to do the activity with a lot of effort
- **4** = Cannot do the activity by yourself

**TETRAS Upper Limb Tremor (ULT)**

The TETRAS Upper Limb Tremor assessment included three tasks to assess tremor severity: forward outstretched posture, lateral “wing beating” posture, and kinetic finger-nose-finger testing. At baseline, each upper limb was assessed and scored individually by the investigator using the TETRAS rating scale (0-4 scale with 8-point resolution) described below. The TETRAS Upper Limb Tremor tasks were repeated during and after stimulation, and scored by the investigator using the same TETRAS rating scale.

- **0** = no tremor
- **1** = tremor is barely visible
- **1.5** = tremor is visible, but less than 1 cm
- **2** = tremor is 1- < 3 cm amplitude
- **2.5** = tremor is 3- < 5 cm amplitude
- **3** = tremor is 5- < 10 cm amplitude
- **3.5** = tremor is 10- < 20 cm amplitude
- **4** = tremor is > 20 cm amplitude
9.5 Protocol

For each subject's single in-clinic visit, baseline measurements of the study effectiveness endpoints were taken prior to stimulation with treatment or sham. After 20 seconds at a specific stimulation level, the device automatically transitioned into a 40-minute stimulation session of treatment with TAPS (Cala ONE device will continue stimulating at the same level) or sham (Cala ONE device will transition to 0 amplitude stimulation). The device continued operating for 40 minutes. Endpoint measurements were taken during and after stimulation. During stimulation the subject repeated the same set of TETRAS tasks that were performed during baseline, at 30 +/- 5 minutes into the session. A study-trained neurologist rated all performed TETRAS tasks in-person, except for the Archimedes spiral task, which was rated later by blinded raters.

After the 40-minute stimulation session, the Cala ONE device automatically turned off. With the Cala ONE device remaining on the subject's wrist, the neurologist instructed each subject to repeat the same set of TETRAS tasks in-person, except for the Archimedes spiral task, which was rated later by blinded raters.

Next the subject repeated the same Bain & Findley ADLs completed during baseline, and rated themselves on each task. The subject also assessed any changes in their tremor level (compared to baseline) using the Clinical Global Impression– Improvement (CGI-I) scale.

For the effectiveness endpoints and to assess whether the subject met the criteria to be included in the Effectiveness Analysis Population (see below), 3 independent blinded raters evaluated the Archimedes spirals collected at baseline, during, and after stimulation as described above. The raters were board certified neurologists trained in movement disorders, and were blinded to the therapy allocation (sham or treatment) and to the spiral order (e.g., baseline, during, or after stimulation). The independent blinded raters rated the spirals using the 5-point (0-4) TETRAS scale using a 0.5-point resolution. The scores from all three raters were averaged to get the final rating for each spiral.

9.6 Statistical Analysis Plan (SAP)

• Analysis populations

  » The primary and secondary effectiveness endpoints were assessed on the Effectiveness Analysis Population (EAP), which was defined as the enrolled subjects with a baseline TETRAS spiral rating ≥ 2 as assessed by the average score from 3 independent blinded raters.

  » Per protocol (PP) analysis set included subjects who had no major protocol deviation and was done as sensitivity analysis for primary and effectiveness endpoints.

• Safety analysis included all enrolled subjects.

• Safety Analysis

  Adverse event (AE) rates were planned to be presented on all enrolled subjects, overall as well as by treatment group. The rates of events and type were presented and compared between groups using the Fisher's Exact test.

• Blinding Assessment

  The successfulness of the blinding of subjects was assessed at the end of the study visit using a blinding assessment questionnaire. Subjects were asked whether they thought they were in the active or sham group or if they do not know on a three-point scale. The sponsor calculated the distribution of the responses to this assessment.

9.7 Study Results

Subject Disposition

The first subject was enrolled on 11-Apr-2016 and the last subject completed on 4-Nov-2016. The subject disposition is provided in Figure 9. A total of 111 subjects were screened for the study, and 93 subjects were enrolled and randomized. 48 subjects were randomized to receive TAPS stimulation (“treatment” group), and 45 subjects were randomized to receive 0-amplitude sham stimulation (“sham” group). 92 of the 93 enrolled subjects completed the study; one subject discontinued because the subject's wrist circumference was outside the range of wrist circumferences for which the Cala ONE is designed. Of the 92 subjects who completed the study, 77 (37 in the sham group and 40 in the treatment group) met the pre-specified EAP criteria of having a baseline TETRAS Archimedes spiral rating ≥ 2, as assessed by the three blinded raters.

As prespecified in the investigational plan, effectiveness was assessed on the Effectiveness Analysis Population,
which is defined as the enrolled subjects with a baseline TETRAS spiral rating ≥ 2, as assessed by the average score from three independent blinded raters. Due to potential differences between the in-person spiral rating from the investigator and the spiral rating averaged across 3 blinded raters, it was possible that a few enrolled subjects who met the inclusion criteria of a baseline TETRAS spiral rating ≥ 2 as assessed by the investigator, would not meet the criteria of a baseline TETRAS spiral rating ≥ 2 as assessed by the average score from the three raters. In this situation, these subjects were not included in the Effectiveness Analysis Population (EAP).

Analysis Populations
The numbers of subjects in each of the pre-specified analyses populations are summarized in Table 3 and described in the subsections below.

TABLE 2
Analysis Populations of Subjects

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Treatment</th>
<th>Sham</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrolled Population</td>
<td>93</td>
<td>48</td>
<td>45</td>
</tr>
<tr>
<td>Effectiveness Analysis Population (EAP)</td>
<td>77</td>
<td>40</td>
<td>37</td>
</tr>
<tr>
<td>Per-Protocol (PP) Analysis Population</td>
<td>6</td>
<td>30</td>
<td>30</td>
</tr>
</tbody>
</table>

Subject Demographics
Subjects enrolled in the study were on average 70.2 years old (range: 35 – 89 years) and had been diagnosed with ET for an average 31.4 years (range: 2 – 77 years). 61% of subjects were currently taking at least 1 medication for their tremor, and 59% had received at least one prior form of treatment for ET. Subjects enrolled in the study

TABLE 3
Baseline characteristics of Effectiveness Analysis Population (N = 77)

<table>
<thead>
<tr>
<th></th>
<th>Overall (N=77)</th>
<th>Treatment (N=40)</th>
<th>Sham (N=37)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age of onset in years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>38.8 (21.2)</td>
<td>40.2 (21.7)</td>
<td>37.2 (20.7)</td>
</tr>
<tr>
<td>Range</td>
<td>5 – 71</td>
<td>5 - 70</td>
<td>5 – 71</td>
</tr>
<tr>
<td>Age of diagnosis in years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>53.4 (14.6)</td>
<td>54.3 (13.9)</td>
<td>52.4 (15.4)</td>
</tr>
<tr>
<td>Range</td>
<td>12 – 78</td>
<td>18 - 78</td>
<td>12 – 75</td>
</tr>
<tr>
<td>Family history of ET, yes, n(%)</td>
<td>59 (77%)</td>
<td>32 (80%)</td>
<td>27 (73%)</td>
</tr>
<tr>
<td>Current Tremor co-therapy, n(%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>28 (36%)</td>
<td>13 (33%)</td>
<td>15 (41%)</td>
</tr>
<tr>
<td>1 medication</td>
<td>29 (38%)</td>
<td>15 (38%)</td>
<td>14 (38%)</td>
</tr>
<tr>
<td>&gt;1 medication</td>
<td>20 (26%)</td>
<td>12 (30%)</td>
<td>8 (22%)</td>
</tr>
<tr>
<td>Prior Treatments of ET, n(%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication</td>
<td>48 (62%)</td>
<td>24 (60%)</td>
<td>24 (65%)</td>
</tr>
<tr>
<td>Botox</td>
<td>4 (5.2%)</td>
<td>3 (7.5%)</td>
<td>1 (2.7%)</td>
</tr>
<tr>
<td>DBS</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (3.9%)</td>
<td>2 (5.0%)</td>
<td>1 (2.7%)</td>
</tr>
<tr>
<td>Baseline TETRAS Spiral (min score=0, max score=4)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>2.8 (0.6)</td>
<td>3.0 (0.7)</td>
<td>2.6 (0.5)</td>
</tr>
<tr>
<td>Range</td>
<td>2.0 – 4.0</td>
<td>4.0 – 2.0</td>
<td>2.0 – 4.0</td>
</tr>
<tr>
<td>Baseline TETRAS Performance Subscale, total score (min score=0, max score=64)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>26.2 (5.9)</td>
<td>26.7 (5.9)</td>
<td>25.7 (5.9)</td>
</tr>
<tr>
<td>Range</td>
<td>16 – 42</td>
<td>17 - 39</td>
<td>16 – 42</td>
</tr>
<tr>
<td>Baseline Bain &amp; Findley ADL, total score (min score=25, max score=100)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>44.9 (9.4)</td>
<td>45.7 (9.0)</td>
<td>44.0 (9.8)</td>
</tr>
<tr>
<td>Range</td>
<td>30 – 69</td>
<td>31 - 67</td>
<td>30 – 69</td>
</tr>
<tr>
<td>QUEST summary index (min score=0, max score=1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>0.32 (0.15)</td>
<td>0.30 (0.13)</td>
<td>0.33 (0.17)</td>
</tr>
<tr>
<td>Range</td>
<td>0.03 - 0.65</td>
<td>0.11 - 0.63</td>
<td>0.03 - 0.65</td>
</tr>
</tbody>
</table>

1The total score is the sum of the scores from the 16 TETRAS tasks.
2The total score is the sum of the scores from the 25 ADL tasks.
3The summary index is calculated as the average of the percentage for each of the 5 domains.
on average had moderate tremors, as demonstrated by an average baseline Bain & Findley ADL total score of 45.4 (out of 100), an average baseline upper-limb TETRAS score of 25.3 (out of 64), and an average Quality of life in Essential Tremor Questionnaire (QUEST) score of 0.31 (out of 1). There were no statistical differences between the treatment and sham groups in the enrolled population related to subject demographics or baseline characteristics.

In the EAP and PP, there was a statistical difference or borderline statistical difference between the treatment and sham groups in their baseline TETRAS Spiral rating \((p = 0.021\) and \(p = 0.065\), respectively). Baseline spiral rating was accounted for in the primary effectiveness endpoint analysis of covariance model.

**Primary Endpoint**

After 40 minutes of device use, the treatment group improved by an estimated 0.56 points, whereas the sham group improved by an estimated 0.39 points. The improvement in both groups was highly statistically significant compared to their own baseline (\(p < 0.0001\) and \(p = 0.0096\), respectively), and the baseline score was not a significant covariate. However, the improvement in the treatment group was not statistically significantly greater than the improvement in the sham group (\(p = 0.263\)). Therefore, the primary effectiveness endpoint was not met. Further, the observed difference in improvement between the groups (0.17 points) was not considered to be clinically meaningful.

Sensitivity analyses on the primary effectiveness endpoint were performed using the Enrolled Population and the Per-Protocol Population. For both populations, the treatment group experienced a greater improvement in tremor compared to the sham group, and the baseline score was not significant in the model; however, the difference between the treatment and sham groups was not found to be statistically significant.

**Secondary Endpoints**

To account for multiplicity, the statistical analysis plan specified that secondary endpoints may only be tested if the primary endpoint was met. Since the primary endpoint was not met p-values are not provided.

1. **Change in spiral ratings during stimulation:**
   
   The average, standard deviation, and ranges of the spiral ratings before (at baseline) and during stimulation for EAP are provided in Table 7. On average, subjects in the treatment group had a baseline spiral rating of 2.95, and subjects in the sham group had a baseline rating of 2.63; both
ratings corresponding to moderate tremor. During stimulation, the spiral rating was 2.58 in the treatment group and 2.26 in the sham group. During stimulation, the treatment and sham groups improved similarly by an estimated 0.37 points (Table 8).

### TABLE 8
Secondary Endpoint: Change in TETRAS Spiral ratings during stimulation (EAP; N = 77)

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean Change (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>40</td>
<td>-0.37 (-0.53 - -0.21)</td>
</tr>
<tr>
<td>Sham</td>
<td>37</td>
<td>-0.37 (-0.54 - -0.20)</td>
</tr>
</tbody>
</table>

#### 2. Clinical Global Impression-Improvement (CGI-I) Scale:
A greater percentage of subjects in the treatment group (88%, 35/40) reported an improvement after stimulation compared to the sham group (62%, 23/37). No subjects in the treatment group reported worsening, compared to 1 subject in the sham group. More subjects with TAPS therapy felt they had experienced an improvement in tremor than subjects who received sham stimulation.

### TABLE 9
Secondary Endpoint: Self-assessed improvement (CGI-I) (EAP; N = 77)

<table>
<thead>
<tr>
<th>Improvement Level</th>
<th>Treatment</th>
<th>Sham</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very much improved</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Much improved</td>
<td>13</td>
<td>8</td>
</tr>
<tr>
<td>Minimally improved</td>
<td>19</td>
<td>14</td>
</tr>
<tr>
<td>No change</td>
<td>5</td>
<td>13</td>
</tr>
<tr>
<td>Minimally worse</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Much worse</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Very much worse</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

### Additional Effectiveness Analyses

» **Change in TETRAS Upper Limb Tremor Tasks**
Both the treatment and sham groups improved across all 3 tasks during and after stimulation. The treatment group improvement was greater than the sham group both during and after stimulation and there was a difference between the treatment and sham groups for the upper limb total during and after stimulation (an average improvement of 1.58 vs 1.00, and 1.84 vs 1.05 respectively).

### TABLE 10
Change in TETRAS Upper Limb during and after stimulation (EAP; N=77)

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Change During Stimulation</th>
<th>Change After Stimulation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Forward Postural</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment</td>
<td>2.95 ± 0.68</td>
<td>-0.56 ± 0.59</td>
<td>-0.75 ± 0.65</td>
</tr>
<tr>
<td>Sham</td>
<td>2.63 ± 0.52</td>
<td>-0.35 ± 0.41</td>
<td>-0.35 ± 0.51</td>
</tr>
<tr>
<td><strong>Lateral Postural</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment</td>
<td>2.29 ± 0.70</td>
<td>-0.51 ± 0.70</td>
<td>-0.56 ± 0.72</td>
</tr>
<tr>
<td>Sham</td>
<td>2.16 ± 0.57</td>
<td>-0.34 ± 0.44</td>
<td>-0.36 ± 0.54</td>
</tr>
<tr>
<td><strong>Kinetic</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment</td>
<td>2.29 ± 0.47</td>
<td>-0.50 ± 0.51</td>
<td>-0.53 ± 0.59</td>
</tr>
<tr>
<td>Sham</td>
<td>2.27 ± 0.47</td>
<td>-0.31 ± 0.38</td>
<td>-0.34 ± 0.43</td>
</tr>
<tr>
<td><strong>Upper Limb Total</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment</td>
<td>6.54 ± 1.34</td>
<td>-1.58 ± 1.46</td>
<td>-1.84 ± 1.64</td>
</tr>
<tr>
<td>Sham</td>
<td>6.34 ± 1.28</td>
<td>-1.00 ± 0.92</td>
<td>-1.05 ± 1.14</td>
</tr>
</tbody>
</table>

» **Change in Activities of Daily Living**
The treatment group improved compared to baseline on all 7 activities. The sham group improved compared to baseline for 5 of the 7 activities (*use a spoon to drink soup, hold a cup of tea, pour milk from a bottle or carton, dial a telephone, and insert an electric plug into a socket*). There was aggregate improvement across all 7 activities (a total improvement of 4.65 (treatment) vs 2.51 (sham)).
### TABLE 11
Change in ADLs after stimulation (EAP; N=77)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>N</th>
<th>Baseline mean ± SD</th>
<th>Change mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use a spoon to drink soup</td>
<td>40</td>
<td>3.18 ± 0.78</td>
<td>-0.78 ± 0.89</td>
</tr>
<tr>
<td>Hold a cup of tea</td>
<td>40</td>
<td>2.95 ± 0.85</td>
<td>-1.03 ± 0.73</td>
</tr>
<tr>
<td>Pour milk from a bottle or carton</td>
<td>40</td>
<td>2.78 ± 1.03</td>
<td>-0.70 ± 0.76</td>
</tr>
<tr>
<td>Dial a telephone</td>
<td>40</td>
<td>2.23 ± 0.89</td>
<td>-0.70 ± 0.79</td>
</tr>
<tr>
<td>Pick up your change in a shop</td>
<td>40</td>
<td>2.03 ± 0.86</td>
<td>-0.53 ± 0.68</td>
</tr>
<tr>
<td>Insert an electric plug into a socket</td>
<td>40</td>
<td>1.83 ± 0.78</td>
<td>-0.33 ± 0.69</td>
</tr>
<tr>
<td>Unlock your front door with a key</td>
<td>40</td>
<td>2.23 ± 0.86</td>
<td>-0.60 ± 0.87</td>
</tr>
<tr>
<td>ADL subset total</td>
<td>40</td>
<td>17.20 ± 4.10</td>
<td>-4.65 ± 2.80</td>
</tr>
</tbody>
</table>

#### Sham

<table>
<thead>
<tr>
<th>N</th>
<th>Baseline mean ± SD</th>
<th>Change mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use a spoon to drink soup</td>
<td>37</td>
<td>3.00 ± 0.85</td>
</tr>
<tr>
<td>Hold a cup of tea</td>
<td>37</td>
<td>2.65 ± 0.92</td>
</tr>
<tr>
<td>Pour milk from a bottle or carton</td>
<td>37</td>
<td>2.59 ± 0.86</td>
</tr>
<tr>
<td>Dial a telephone</td>
<td>37</td>
<td>2.00 ± 0.91</td>
</tr>
<tr>
<td>Pick up your change in a shop</td>
<td>37</td>
<td>1.92 ± 0.89</td>
</tr>
<tr>
<td>Insert an electric plug into a socket</td>
<td>37</td>
<td>1.76 ± 0.80</td>
</tr>
<tr>
<td>Unlock your front door with a key</td>
<td>37</td>
<td>1.86 ± 0.67</td>
</tr>
<tr>
<td>ADL subset total</td>
<td>37</td>
<td>15.78 ± 3.87</td>
</tr>
</tbody>
</table>

### TABLE 12
TETRAS Spiral responder rates during and after stimulation (EAP; N=77)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>During Stimulation</th>
<th>After Stimulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responders Rate (%) 95% CI)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment (N=40) Sham (N=37)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% of subjects with a ≥ 0.5-point improvement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>47.5% (31.5% - 63.9%)</td>
<td>37.8% (22.5% - 55.2%)</td>
<td></td>
</tr>
<tr>
<td>50.0% (33.8% - 66.2%)</td>
<td>38.9% (23.1% - 56.5%)</td>
<td></td>
</tr>
<tr>
<td>% of subjects with a ≥ 1.0-point improvement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.0% (2.8% - 23.7%)</td>
<td>16.2% (6.2% - 32.0%)</td>
<td></td>
</tr>
<tr>
<td>27.5% (14.6% - 43.9%)</td>
<td>16.7% (6.4% - 32.8%)</td>
<td></td>
</tr>
</tbody>
</table>

### TABLE 13
TETRAS Upper Limb responder rates during and after stimulation (EAP; N=77)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>During Stimulation</th>
<th>After Stimulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responders Rate (%) 95% CI)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment (N=40) Sham (N=37)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forward Postural</td>
<td>65.0% (48.3% - 79.4%)</td>
<td>51.4% (34.4% - 68.1%)</td>
</tr>
<tr>
<td>Lateral Postural</td>
<td>57.5% (40.9% - 73.0%)</td>
<td>48.6% (31.9% - 65.6%)</td>
</tr>
<tr>
<td>Kinetic</td>
<td>62.5% (45.8% - 77.3%)</td>
<td>51.4% (34.4% - 68.1%)</td>
</tr>
<tr>
<td>Average TETRAS Upper Limb tremor</td>
<td>52.5% (36.1% - 68.5%)</td>
<td>32.4% (18.0% - 49.8%)</td>
</tr>
</tbody>
</table>

1 Responsor rate defined as percentage of subjects with improvement of ≥ 0.5 points.

» TETRAS Spiral Responder Rates:
During stimulation, the responder rate (% of subjects with a ≥ 0.5-point improvement) in the TAPS treatment group was 47.5% compared to 37.8% in the sham group. After stimulation, the responder rate was 50.0% compared to 38.9% in the sham group. During stimulation, the responder rate (% of subjects with a ≥ 1.0-point improvement) in the TAPS treatment group was 10.0% compared to 16.2% in the sham group. After stimulation, the responder rate was 27.5% compared to 16.7% in the sham group.

» TETRAS Upper Limb Tremor Responder Rates
The majority of the treatment subjects were responders (% of subjects with a ≥ 0.5 point improvement) for each of the TETRAS Upper Limb Tremor tasks (forward postural, lateral postural, and kinetic) both during and after stimulation. Moreover, for each of the tasks, the responder rate in the treatment group was higher than the responder rate in the sham group. There was a difference in the responder rates between the treatment and sham groups for the average TETRAS Upper Limb score (65.0% vs 32.4%).
9.8 Adverse Events

No Serious Adverse Events (SAEs) or Unanticipated Adverse Device Effects (UADEs) were reported. Of the 93 enrolled subjects, there were 4 non-serious adverse events amongst 3 subjects. The 4 adverse events were mild, anticipated, and resolved within 24 hours without any intervention or sequelae:

» **One subject (Treatment)** reported 2 adverse events:
  - a feeling of weakness in the wrist with stimulation
  - skin irritation
  During the stimulation session, the subject reported a sensation of weakness around the treated wrist. The sensation resolved after the session with no intervention and no sequelae. After the device was removed, the subject noted skin redness in the area where the gels were adhered. The redness resolved the same day with no intervention and no sequelae.

» **A second subject (Treatment)** reported skin irritation, which was described as swelling in the stimulated hand. The adverse event was reported the day following the stimulation session. The swelling resolved the next day with no intervention and no sequelae.

» **A third subject (Sham)** reported stinging pain in the wrist during the sham stimulation session. The subject requested that the stimulation level be decreased, thus the sham stimulation level was simulated to be "decreased" from 3.75 mA to 3.5 mA as displayed on the device, but the device remained at 0-amplitude stimulation during the entire 40-minute session. The subject reported that the stinging sensation was tolerable once the stimulation level was decreased, and the sensation had completely resolved when the device was removed. The incident was resolved without sequelae.

During active enrollment, the study was monitored by an independent Safety Reviewer who is a board-certified neurologist and movement disorder specialist. The Safety Reviewer could make recommendations for protocol modifications or trial discontinuation for safety-related reason. However, during the study, there were no such recommendations made. On 1 December, 2016 (after all subjects had been exited from the study), the Safety Reviewer reviewed the adverse events (AE) and confirmed the Investigator’s assignment of AE classification, device relatedness and severity for all 4 events described.

### TABLE 14

<table>
<thead>
<tr>
<th></th>
<th>All (N=93)</th>
<th>Treatment (N=48)</th>
<th>Sham (N=45)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Any adverse event</strong></td>
<td>3.2% (3)</td>
<td>4.2% (2)</td>
<td>2.2% (1)</td>
</tr>
<tr>
<td><strong>Significant and persistent skin irritation (including redness, itchiness, and/or swelling)</strong></td>
<td>2.2% (2)</td>
<td>4.2% (2)</td>
<td>0.0% (0)</td>
</tr>
<tr>
<td><strong>Other: feeling of weakness around the wrist</strong></td>
<td>1.1% (1)</td>
<td>2.1% (1)</td>
<td>0.0% (0)</td>
</tr>
<tr>
<td><strong>Other: Stinging pain in wrist</strong></td>
<td>1.1% (1)</td>
<td>0.0% (0)</td>
<td>2.1% (1)</td>
</tr>
</tbody>
</table>

» **Blinding Assessment**

Subjects were blinded to whether they received stimulation or not. After the stimulation session, subjects were asked whether they believed they received treatment, sham, or did not know.

### TABLE 15

<table>
<thead>
<tr>
<th></th>
<th>Investigational Device</th>
<th>Don't Know</th>
<th>Sham Device</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treatment</strong></td>
<td>18</td>
<td>23</td>
<td>7</td>
</tr>
<tr>
<td><strong>Sham</strong></td>
<td>9</td>
<td>17</td>
<td>18</td>
</tr>
</tbody>
</table>

9.9 Study Limitations

- 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.
- Many participants in the study were also taking medication for their tremor and it was difficult to assess the effect of the device compared to medication.
- Effectiveness was only evaluated within one clinic visit immediately after a 40 minute stimulation session.
- The active device provided stimulation that could be felt by the patient while the sham device was inactive. Therefore, it is possible that some patients could have correctly identified the treatment group they were in which could have biased study results.
9.10 Benefit/Risk Discussion

The risks of the device are based on nonclinical laboratory studies as well as data collected in the clinical study described above. Three percent (3/93) of enrolled subjects experienced 4 non-serious adverse events (one subject reported 2 AEs.) The 4 adverse events were mild, anticipated, and resolved within 24 hours without any intervention or sequelae, specifically, weakness, skin irritation, and pain (reported in a sham patient).

Should any adverse reactions occur, the Cala ONE therapy level can be reduced (e.g., turning down stimulation level or reducing duration). In addition, the device is easily removed from the patient’s wrist.

The probable benefits of the device are also based on data collected in the clinical study. Subjects had an improvement in tremor severity. In addition, subjects had an improvement in ADLs compared to baseline. Fifty-percent of the Treatment patients had a 0.5-point improvement in tremor severity while 27.5% had a 1.0-point improvement directly after 40 minutes of device use. These differences are clinically meaningful. The duration of the effect was not assessed beyond the assessments five minutes after stimulation ended.

Additional factors to be considered in determining probable risks and benefits for the Cala ONE include uncertainty in: the results as a result of the lack of statistical significance between active and sham groups for both tremor severity and ADLs; the potential for subjects correctly identifying their study arm due to stimulation in the active group which may have biased these subjects; and many participants in the study were also taking medication for their tremor, and it was difficult to assess the effect of the device compared to medication. Finally, the device was only assessed during one clinic visit. It is unknown if repeated treatment will provide better, worse or similar benefit. However, the available alternatives (e.g., medications, deep brain stimulation and focused ultrasound) have the potential for many adverse effects, some of which can be serious and/or cause death. The Cala ONE device uses non-invasive technology which has been available for many years with a more favorable risk profile.
## THERAPY SESSION

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>40 min per session</td>
</tr>
<tr>
<td>Start Therapy</td>
<td>Press MAIN button on therapy display</td>
</tr>
<tr>
<td>Stop Therapy</td>
<td>Press and hold MAIN button</td>
</tr>
<tr>
<td>Manual Intensity</td>
<td>≤ 0.5 mA per step</td>
</tr>
<tr>
<td>Increase/Decrease</td>
<td></td>
</tr>
</tbody>
</table>

## CONDITIONS THAT WILL TERMINATE OUTPUT

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>40 min per session</td>
</tr>
</tbody>
</table>

## OUTPUT

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Waveform</td>
<td>Biphasic symmetric, rectangular</td>
</tr>
<tr>
<td>Regulated Current or Voltage</td>
<td>Constant Current</td>
</tr>
<tr>
<td>D. C. Component</td>
<td>None, zero net current</td>
</tr>
<tr>
<td>Maximum Output Voltage (+/- 20%)</td>
<td>200 V</td>
</tr>
<tr>
<td>Maximum Output Current (+/- 20%)</td>
<td>8 mA at 10 kΩ</td>
</tr>
<tr>
<td>Pulse Duration (+/- 20%)</td>
<td>300 μsec (Fixed)</td>
</tr>
<tr>
<td>Pulse Repetition Frequency (+/- 20%)</td>
<td>150 Hz (Fixed)</td>
</tr>
<tr>
<td>Pulse Pattern</td>
<td>Continuous, bursts tuned to tremor frequency between 4-12 Hz</td>
</tr>
</tbody>
</table>

## POWER

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery Type</td>
<td>Permanent rechargeable battery, not serviceable or replaceable</td>
</tr>
</tbody>
</table>
| Power Source         | AC 50/60 Hz  
Rated Voltage: 100-240V  
Max Current: 0.5 A |
| Duration             | Fully charged battery lasts 5 therapy sessions |

## ELECTRODES

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
<td>Cala Trio Band with multiuse electrodes embedded</td>
</tr>
<tr>
<td>Number of Electrodes</td>
<td>3</td>
</tr>
<tr>
<td>Dimensions</td>
<td>22mm x 22mm</td>
</tr>
</tbody>
</table>

## MEASUREMENT ACCURACY

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>+/- 20% in the 4-12 Hz range</td>
</tr>
</tbody>
</table>

## ENVIRONMENTAL

<table>
<thead>
<tr>
<th>Operating Parameters:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature Range</td>
<td>5-40°C (41-104°F)</td>
</tr>
<tr>
<td>Relative Humidity Range</td>
<td>15-90%</td>
</tr>
<tr>
<td>Atmospheric Pressure Range</td>
<td>700-1060 hPa</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Transport and Storage Parameters (Cala Trio):</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature Range</td>
<td>-20-45°C (-4-113°F)</td>
</tr>
<tr>
<td>Relative Humidity Range</td>
<td>≤ 90%, non-condensing</td>
</tr>
<tr>
<td>Atmospheric Pressure Range</td>
<td>700-1060 hPa</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Shelf-life and Storage Parameters (Electrodes):</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature Range</td>
<td>20-27°C (68-81°F)</td>
</tr>
<tr>
<td>Relative Humidity Range</td>
<td>≤ 90%</td>
</tr>
<tr>
<td>Atmospheric Pressure Range</td>
<td>700-1060 hPa</td>
</tr>
</tbody>
</table>

Expected Service Life of Stimulator and Base Station: 3 years
11.0 ELECTROMAGNETIC COMPATIBILITY DECLARATION

Cala Trio Stimulator claims compliance for electromagnetic compatibility in conjunction with Cala Trio Base Station.

(1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Do not tamper with, modify, or attempt to perform maintenance or servicing on Cala Trio.

RF Exposure Evaluation Guidance for Mobile Conditions

A minimum separation distance of 20 cm is required between the Cala Trio Base Station and nearby person to qualify for mobile exposure limits.

---

**GENERAL RADIO COMPLIANCE**

<table>
<thead>
<tr>
<th>ITEM</th>
<th>SPECIFICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stimulator Bluetooth</td>
<td>FCC ID: 2AA9B05</td>
</tr>
<tr>
<td>Radio Frequency (RF) Range</td>
<td>2402 MHz to 2480 MHz</td>
</tr>
<tr>
<td>Base Station</td>
<td>FCC ID: 2AT2D-BASE0017</td>
</tr>
<tr>
<td>Radio Frequency (RF) Range</td>
<td>13.56 MHz</td>
</tr>
<tr>
<td>LTE Module</td>
<td>FCC ID: XPY2AGQN4NNN</td>
</tr>
<tr>
<td>Radio Frequency (RF) Range</td>
<td>Device operates within approved frequencies overlapping with the following cellular bands: LTE 2,1900 PCS UP</td>
</tr>
</tbody>
</table>

---

**GUIDANCE AND MANUFACTURER’S DECLARATION - ELECTROMAGNETIC EMISSIONS**

Cala Trio is intended for use in the electromagnetic environment specified below. The customer or the user of Cala Trio should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>EMISSIONS TESTS</th>
<th>COMPLIANCE</th>
<th>EMISSIONS TESTS</th>
<th>COMPLIANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Class A</td>
<td>Voltage Fluctuations/ Flicker emissions</td>
<td>Complies</td>
</tr>
</tbody>
</table>

Cala Trio 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.

Cala Trio is suitable for use in all establishments, including domestic establishments 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**

Cala Trio is intended for use in the electromagnetic environment specified below. The customer or the user of Cala Trio should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>IMMUNITY TEST</th>
<th>IEC 60601 TEST LEVEL</th>
<th>COMPLIANCE LEVEL</th>
<th>ELECTROMAGNETIC ENVIRONMENT GUIDANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>±8 kV contact ±15 kV air</td>
<td>±8 kV contact ±15 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical fast transient/burst IEC 61000-4-4</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines</td>
<td>±2 kV for power supply lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>±1 kV differential mode ±2 kV common mode</td>
<td>±1 kV differential mode ±2 kV common mode</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>(50/60 Hz) magnetic field IEC 61000-4-8</td>
<td>30 A/m</td>
<td>30 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>
GUIDANCE AND MANUFACTURER’S DECLARATION - ELECTROMAGNETIC IMMUNITY

<table>
<thead>
<tr>
<th>IMMUNITY TEST</th>
<th>IEC 60601 TEST LEVEL</th>
<th>COMPLIANCE LEVEL</th>
<th>ELECTROMAGNETIC ENVIRONMENT GUIDANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</td>
<td>Voltage Dips 30% reduction, 25/30 periods At 0°</td>
<td>Voltage Dips 30% reduction, 25/30 periods At 0°</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of Cala Trio requires continued operation during power mains interruptions, it is recommended that Cala Trio be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td>Voltage Dips &gt; 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°</td>
<td>Voltage Dips &gt; 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage Dips &gt; 95% reduction, 1 period At 0°</td>
<td>Voltage Dips &gt; 95% reduction, 1 period At 0°</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage Interruptions &gt; 95% reduction, 250/300 periods</td>
<td>Voltage Interruptions &gt; 95% reduction, 250/300 periods</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

GUIDANCE AND MANUFACTURER’S DECLARATION - ELECTROMAGNETIC IMMUNITY

<table>
<thead>
<tr>
<th>IMMUNITY TEST</th>
<th>IEC 60601 TEST LEVEL</th>
<th>COMPLIANCE LEVEL</th>
<th>ELECTROMAGNETIC ENVIRONMENT GUIDANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF IEC 61000-4-6</td>
<td>3 Vrms 150 kHz to 80 MHz (6 Vrms in ISM and amateur radio Bands within 150kHz – 80MHz)</td>
<td>3 Vrms</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of Cala Trio, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance</td>
</tr>
<tr>
<td>Radiated RF IEC 61000-4-3</td>
<td>10 V/m 80 MHz to 2.7 GHz</td>
<td>10 V/m</td>
<td>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</td>
</tr>
</tbody>
</table>

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Cala Trio is used exceeds the applicable RF compliance level above, Cala Trio should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating Cala Trio. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

IMMUNITY TO RF WIRELESS COMMUNICATIONS EQUIPMENT

<table>
<thead>
<tr>
<th>Test Frequency (MHz)</th>
<th>Band a(MHz)</th>
<th>Service a)</th>
<th>Modulation b)</th>
<th>Maximum Power (W)</th>
<th>Distance (m)</th>
<th>IMMUNITY TEST LEVEL (V/m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2450</td>
<td>2400 – 2570</td>
<td>Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7</td>
<td>Pulse modulation b) 217 Hz</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
</tr>
<tr>
<td>5240</td>
<td>5100 – 5800</td>
<td>WLAN 802.11 a/n</td>
<td>Pulse modulation b) 217 Hz</td>
<td>0.2</td>
<td>0.3</td>
<td>9</td>
</tr>
<tr>
<td>5500</td>
<td>5785</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.
RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND Cala Trio

Cala Trio is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Cala Trio can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Cala Trio as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter W</th>
<th>Separation distance according to frequency of transmitter M</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 kHz to 80 MHz</td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td>d = 1.2 √P</td>
<td>d = 1.2 √P</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.

IMMUNITY TO RF WIRELESS COMMUNICATIONS EQUIPMENT

<table>
<thead>
<tr>
<th>Test Frequency (MHz)</th>
<th>Band (MHz)</th>
<th>Service</th>
<th>Modulation</th>
<th>Maximum Power (W)</th>
<th>Distance (m)</th>
<th>IMMUNITY TEST LEVEL (V/m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>385</td>
<td>380 – 390</td>
<td>TETRA 400</td>
<td>Pulse modulation b) 18 Hz</td>
<td>1.8</td>
<td>0.3</td>
<td>27</td>
</tr>
<tr>
<td>450</td>
<td>430 – 470</td>
<td>GMRS 460, FRS 460</td>
<td>FM c) ± 5 kHz deviation 1 kHz sine</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
</tr>
<tr>
<td>710</td>
<td>704 – 787</td>
<td>LTE Band 13, 17</td>
<td>Pulse modulation b) 217 Hz</td>
<td>0.2</td>
<td>0.3</td>
<td>9</td>
</tr>
<tr>
<td>810</td>
<td>800 – 960</td>
<td>GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5</td>
<td>Pulse modulation b) 18 Hz</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
</tr>
<tr>
<td>870</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>930</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1720</td>
<td>1700 – 1990</td>
<td>GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS</td>
<td>Pulse</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
</tr>
<tr>
<td>1845</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1970</td>
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WARRANTY INFORMATION

Cala Health, Inc. ("Cala") warrants, to the original purchaser only, that the Cala Trio™ that such customer purchased (the “Product”) shall be free from defects in materials and workmanship under normal use and will perform in accordance with the Product specifications set forth in the Product Patient Guide.

You can find conditions and details for this Limited Warranty at CalaTrio.com/Warranty.