



PATIENT GUIDE



Manufactured by Cala Health, Inc.

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Patent: CalaTrio.com/Patents

Model: CTS100, CTB101, CTB102, CTB103, CTB104,
CTB105, CTB106



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1.0

LIST OF SYMBOLS



Caution



Refer to instructions for use.



Contains electronic equipment Properly dispose in accordance with local regulations.



Complies with United States Product Safety Standards.



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



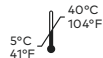
Date of manufacture



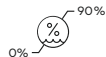
Use by date

IP22

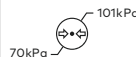
Protected against intrusion from fingers and small objects, and from water drops vertically falling on Cala Trio when it is tilted up to 15° from vertical. Do not immerse in a bathtub or use while swimming.



Cala Trio is rated for these temperature limits. For more information on environmental parameters, refer to the Technical Specifications in this User Guide.



Cala Trio is rated for these humidity limits. For more information on environmental parameters, refer to the Technical Specifications in this User Guide.



Cala Trio is rated for these atmospheric pressure limits. For more information on environmental parameters, refer to the Technical Specifications in this User Guide.



Serial number



Catalogue number



Batch code



Class II Equipment

INTRODUCING Cala Trio

View instructional videos at my.CalaTrio.com

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



SAFETY INFORMATION

This section lists general Warnings and Cautions related to using Cala Trio.

3.1 Warnings

- To avoid the risk of electric shock, burns, electrical interference, or death, do not use Cala Trio if you have:
 - » A pacemaker
 - » An implanted defibrillator
 - » Other implanted electronic devices, or implanted metal in the wrist
- Do not use Cala Trio while:
 - » Sleeping
 - » Driving
 - » Bathing
 - » Operating machinery
 - » Doing any activity in which possible involuntary muscle contractions due to therapy may cause undue risk of injury.
- Do not use Cala Trio:
 - » Near the head
 - » Directly on the eyes
 - » Covering the mouth
 - » On your upper back
 - » Over the heart area
 - » On diseased skin
- Do not use Cala Trio on the neck.
 - » Doing so can cause severe muscle spasm, resulting in closure of the airway, difficulty with breathing, or

adverse effects on heart rhythm.

- Do not use Cala Trio on the chest.
 - » Introduction of electric current into the chest may cause rhythm disturbances to the heart, which could cause death.
- Do not apply Cala Trio near the chest.
 - » This may increase the risk of abnormal heart rhythm (*arrhythmia*).
- Do not apply Cala Trio 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 Cala Trio over—or in proximity to—cancerous lesions.
- To prevent electrical shock, do not immerse Cala Trio in water.
- Do not wear Cala Trio while performing activities where Cala Trio is under water (e.g., *swimming or bathing*).
- Do not use Cala Trio simultaneously with

- » High-frequency surgical equipment, as this may result in electrical burns and/or possible damage to Cala Trio
 - » Electronic- monitoring equipment (e.g., *cardiac monitors, ECG alarms*), which may not operate properly when Cala Trio is in use
- To prevent an explosion hazard and possible injury, stop Cala Trio therapy when at a refueling place (e.g., *gas station*).
 - Do not use Cala Trio near flammable fuel, fumes, or chemicals.
 - Physician approval should be obtained by your prescribing physician before using Cala Trio if you have any implanted devices at the site of stimulation.
 - Cala Trio provides chronic electrical stimulation, the long-term effects of which are unknown.
 - To prevent uncomfortable therapy, skin irritation and/or shock, the user should wet their wrist before donning Cala Trio.
 - Therapy at an intensity that is too high can cause

discomfort in your wrist and/or hand, muscle contraction, or skin irritation.

- Some may experience skin irritation, an allergic reaction, or hypersensitivity to the therapy or the band.
- Avoid removing Cala Trio from your wrist during therapy.
- To charge Cala Trio, use only the Cala Trio Base Station.
- The cord on the charger may present a choking hazard. Keep away from children.

3.2 Cautions

- Use Cala Trio only as directed by this Patient Guide or your physician.
- Do not use Cala Trio if you have suspected or diagnosed epilepsy or other seizure disorder.
- Do not use Cala Trio if you are pregnant.
- 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 Cala Trio in the included microfiber bag to prevent exposure to dust and pests.
- To prevent damage and/or performance issues to Cala Trio:
 - » Keep Cala Trio dry. Cala Trio can withstand some splashing.
 - » Do not use in places with high humidity (e.g., *the bathroom*).
 - » Do not store or transport Cala Trio 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 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 Cala Trio.
 - » Do not use Cala Trio **within 3 ½ feet** of shortwave or microwave equipment.
- To prevent damage, performance issues, increased

emissions, or decreased immunity of Cala Trio, only use the accessories recommended by Cala Health with the device.

- Use Cala Trio with caution:
 - » If you tend to bleed following an injury.
 - » Over areas of the skin that lack normal sensation.
- Keep out of the reach of children and pets.
- Cala Trio 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 your body.
- To avoid interfering with diagnostic assessments, do not wear Cala Trio 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 Patient Guide, please contact Cala Health at 888-699-1009 or CustomerSuccess@CalaTrio.com

3.3 Adverse Reactions

The following are possible minor/moderate risks or adverse reactions that you may experience with the use of Cala Trio:

- 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 happen, immediately stop using Cala Trio and contact your 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 your arm, wrist, or hand

4.0

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

4.1 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

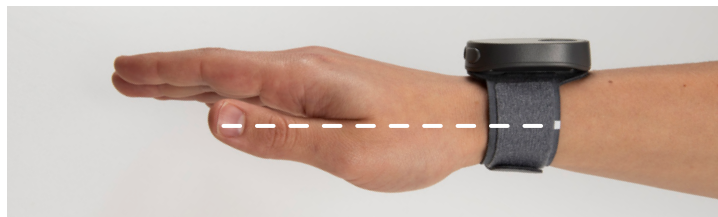
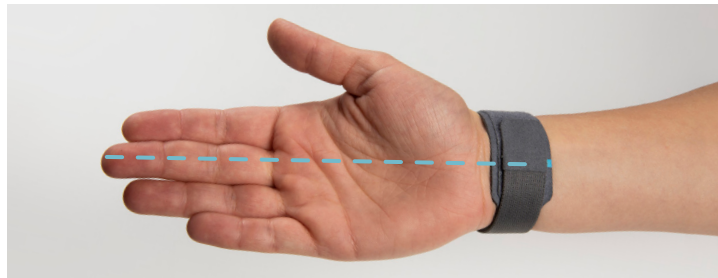
- This ensures a good connection between the electrodes and wrist.
- **Never** submerge Cala Trio in water.
- If there is any excess oil or lotion on your wrist, wash with soap and water and rinse well before wearing Cala Trio.



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.
- The electrodes should be flush to the skin.

4.2 Calibrating Cala Trio

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

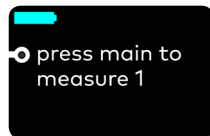
- Calibration happens over the course of three measurements taken while you perform the "Tremor Task" prescribed by your physician.

Before calibrating, determine your "Tremor Task" by checking your prescription information.

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.*



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"



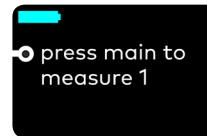
*Outstretched
postural hold*

OR

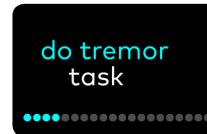


*Wing-beating
postural hold*

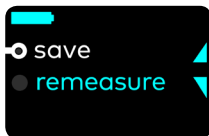
Step 3: Get in position to do your "Tremor Task" (see *left*)
You can find your "Tremor Task" in your prescription information or at my.CalaTrio.com



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.

4.3 Setting Stimulation Intensity for Therapy

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

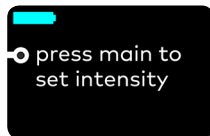
- Cala Trio automatically ramps to the intensity preset during all subsequent therapies.
- **It is important to find the maximum level of therapy that you can comfortably tolerate for 40 minutes.**

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



Reminder: Ensure you have dampened the entire circumference of your wrist with ample amounts of water before setting stimulation intensity.

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.*

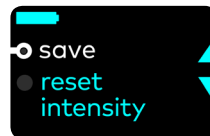
- » You may feel a stinging sensation if you did not wet your wrist sufficiently before fastening Cala Trio. See the note below to add more water.
- » You should **not** feel the tingling sensation in your pinky. Additionally, if you do not feel the tingling sensation in the fingers highlighted in step 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 4.1, page 12) or adjust the placement of the band (see section 4.1, step 3, page 13)
- » Repeat steps 1-3 when you are ready to set your intensity again (see section 4.3, pages 16-18)

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!

5.0

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.

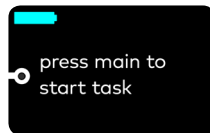


Step 1: To start a therapy session, from the time display, press the **MAIN** button. You will now see "start session"

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 4.2, steps 3-5, on page 15.

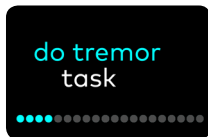


Step 3: If prompted, press the **MAIN** button to do your prescribed "Tremor Task", or if you would like to skip and are given the option, press the **DOWN** button and then **MAIN** to skip until next session

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 or at my.CalaTrio.com.
- 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

5.1 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".

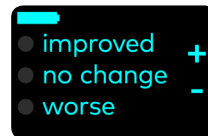
Step 1: To stop therapy early, press and hold the **MAIN** button until you see "therapy stopped"



- 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 5.0, steps 3 and 4 on pages 19-20*).

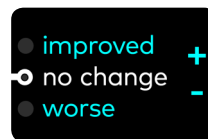
5.2 How to Rate Your Tremor with Cala Trio

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



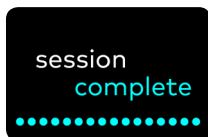
To rate how your tremor level has changed compared to before therapy:

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!

5.3 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 5.1 on page 21)

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 6.2 on page 24).

6.0

CARING FOR Cala Trio

View instructional videos at my.CalaTrio.com

6.1 How to Charge Cala Trio

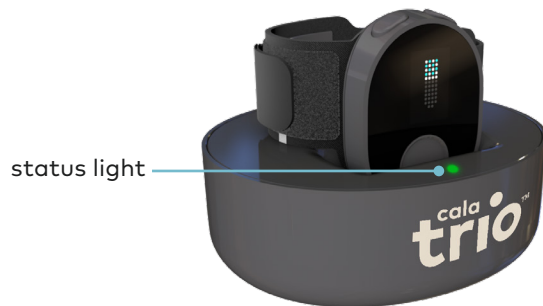
Charge Cala Trio

- 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.



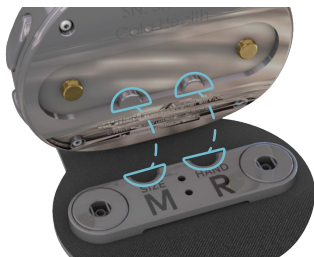
- » The base station will also communicate its status via a light. The table below shows the status light options:

 white light	ready to charge
 green light	charging
 yellow light	device updating , do not remove from base station
 red light	replace Cala Trio Band

6.2 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 found at my.CalaTrio.com



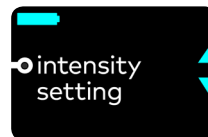
Step 2: Remove the used band by unsnapping it from the stimulator

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

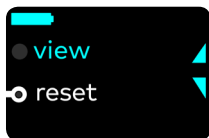
Step 4: Place the stimulator attached to the new band in the base station for 15 seconds in order to clear the "replace band" message

6.3 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 4.3 on page 17 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

6.4 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

6.5 How to Clean and Store Cala Trio

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

Store Cala Trio in the included microfiber bag at room temperature.

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

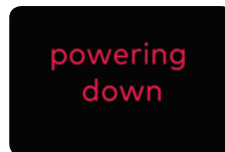
Step 3: Remove Cala Trio from your wrist

Step 4: Ensure the stimulator is securely and correctly snapped into the band (*half circles should be aligned as shown in section 4.1 on page 12*)

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



Powering Down

Appears when the stimulator resets.



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 page 26 for Band Not Connected warning.



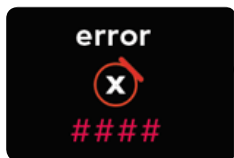
Replace Band

Replace band as soon as possible. Therapy will be available for ten days after the first appearance of this message. See section 6.2 on page 24 for directions on disconnecting and connecting the stimulator and band.



Replace Band

Replace band as soon as possible. Therapy will not be available until a new band is attached. See section 6.2 on page 24 for directions on disconnecting and connecting the stimulator and band.



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



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.

CLINICAL STUDY SUMMARY

A multi-center, prospective, randomized, double-blinded, sham-stimulation controlled study was conducted to assess the safety and effectiveness of the Cala device to aid in the transient relief of hand tremors in adults with essential tremor. The study enrolled 93 patients across four US sites. Each patient was seen for a single three-hour appointment at a study site. Patients were randomized one-to-one to either the investigational stimulation ("treatment" group) or sham stimulation ("sham" group). The stimulation amplitude for the treatment group was based on each patient's stimulation threshold. The sham group received 0-amplitude stimulation. The study site personnel and investigator were not blinded and knew the patient's

therapy allocation. However, the patient and the raters assessing the effectiveness were blinded.

The patients' tremor severity was assessed before, during, and immediately after the 40-minute stimulation session using various metrics, such as spiral drawings and activities of daily living (ADLs). Patients had an improvement in tremor severity, as well as an improvement in ADLs compared to baseline. However, there was a lack of statistical significance between treatment and sham groups for both tremor severity and ADLs.

Safety was assessed using adverse event data collected during the study. Three percent (3/93) of enrolled patients experienced four non-serious adverse events (one patient reported two adverse events). The four 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).

The limitations of the study were that:

- The device was only evaluated in patients diagnosed with essential tremor, and the effectiveness of the device has not been evaluated for tremor associated with other conditions;
- Effectiveness was only evaluated within one clinic visit immediately after a 40-minute stimulation session, and it is unknown if repeated treatment will provide better, worse or similar benefit;
- The active device provided stimulation that could be felt by the patient, while the sham device was inactive; it is therefore possible that some patients could have correctly identified the treatment group they were in, which could have biased study results; and
- Many patients in the study were also taking medication for their tremor, and it was difficult to assess the effect of the device compared to medication.

9.0

TECHNICAL SPECIFICATIONS

THERAPY SESSION

Time	40 min per session
Start Therapy	Press MAIN button on therapy display
Stop Therapy	Press and hold MAIN button
Manual Intensity Increase/Decrease	≤ 0.5 mA per step

CONDITIONS THAT WILL TERMINATE OUTPUT

Time	40 min per session
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OUTPUT

Waveform	Biphasic symmetric, rectangular
Regulated Current or Voltage	Constant Current
D. C. Component	None, zero net current
Maximum Output Voltage (+/-20%)	200 V
Maximum Output Current (+/-20%)	8 mA at 10 k Ω
Pulse Duration (+/- 20%)	300 μ sec (<i>Fixed</i>)
Pulse Repetition Frequency (+/-20%)	150 Hz (<i>Fixed</i>)
Pulse Pattern	Continuous, bursts tuned to tremor frequency between 4-12 Hz

POWER	
Battery Type	Permanent rechargeable battery, not serviceable or replaceable
Power Source	AC 50/60 Hz Rated Voltage: 100-240V Max Current: 0.5 A
Duration	Fully charged battery lasts 5 therapy sessions

ELECTRODES	
Type	Cala Trio Band with multiuse electrodes embedded
Number of Electrodes	3
Dimensions	22mm x 22mm

MEASUREMENT ACCURACY	
Frequency	+/- 20% in the 4-12 Hz range

ENVIRONMENTAL	
Operating Parameters:	
Temperature Range	5-40°C (41-104°F)
Relative Humidity Range	15-90%
Atmospheric Pressure Range	700-1060 hPa
Transport and Storage Parameters (Cala Trio):	
Temperature Range	-20-45°C (-4-113°F)
Relative Humidity Range	<= 90%, non-condensing
Atmospheric Pressure Range	700-1060 hPa
Shelf-life and Storage Parameters (Electrodes):	
Temperature Range	20-27°C (68-81°F)
Relative Humidity Range	<= 90%
Atmospheric Pressure Range	700-1060 hPa

Expected Service Life of Stimulator and Base Station: 3 years

10.0

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.

GENERAL RADIO COMPLIANCE

ITEM	SPECIFICATION
Stimulator Bluetooth	Module FCC ID: 2AA9B05
Radio Frequency (RF) Range	2402 MHz to 2480 MHz
Base Station	FCC ID: 2AT2D-BASE0017
Radio Frequency (RF) Range	13.56 MHz 2402 MHz to 2480 MHz
LTE Module	FCC ID: XPY2AGQN4NNN
Radio Frequency (RF) Range	Device operates within approved frequencies overlapping with the following cellular bands: LTE 2,1900 PCS UP LTE 25,1900+ UP LTE 35,TD PCS Lower DOWN UMTS CH 2 UP UMTS CH 25 UP UMTS CH 35 DOWN

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.

EMISSIONS TESTS	COMPLIANCE	
RF emissions CISPR 11	Group 1	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.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker emissions	Complies	

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.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
(50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage Dips 30% reduction, 25/30 periods At 0°	Voltage Dips 30% reduction, 25/30 periods At 0°	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.
	Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	
	Voltage Dips > 95% reduction, 1 period At 0°	Voltage Dips > 95% reduction, 1 period At 0°	
	Voltage Interruptions > 95% reduction, 250/300 periods	Voltage Interruptions > 95% reduction, 250/300 periods	

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz (6 Vrms in ISM and amateur radio Bands within 150kHz – 80MHz)	3 Vrms	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 $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range. ^b

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. ^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter M		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

Test Frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 – 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0.3	28
870						
930						
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse	2	0.3	28
1845						
1970						

IMMUNITY TO RF WIRELESS COMMUNICATIONS EQUIPMENT

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

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) 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.

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

