cala kIQ™

Patient Guide

Caution: Federal law restricts this device to sale by or on the order of a physician

LBL-5191 Rev 16 DRAFT

cala®

Manufactured by Cala Health, Inc.

1800 Gateway Drive, Suite 300
San Mateo, CA 94404

888-699-1009

www.CalaHealth.com

Sign Up for MyCala.com (Optional)

To view insights on your usage and tremor patterns and to get additional help with setup and therapy, you can access guidance for Cala kIQ™ therapy online.

NOTE: You do not have to sign up in order to setup and use Cala kIQ therapy.

Step 1: Check the email address you shared with Cala. You will receive an email, titled "*Welcome to Cala kIQ therapy*". If you do not see it, check your spam folder or call us at 888-699-1009. In the email, click on Sign Up.

Step 2: Your web browser will open. Enter your Date of Birth and Zip Code.

View instructional videos at MyCala.com

Step 3: Once authenticated, create a password.

Step 4: After creating your password, check your email to complete sign up.

When you sign in you will first be invited to set up therapy. You can also:

- Learn more about Cala kIQ Therapy
- View instructional videos
- View insights on your usage and tremor patterns

Know that Customer Care is here for you, 888-699-1009 and CustomerCare@CalaHealth.com.

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1.1 Guide to Symbols on Box

	Caution		Type BF Applied Part(s) • Cala kIQ™ Stimulator • Cala kIQ Band
	Refer to instructions for use		Sold by prescription only. Caution: Federal law restricts this device to sale by or on the order of a physician.
	Contains electronic equipment. Properly dispose of in accordance with local regulations.		Date of manufacture
MEE	Medical Electrical Equipment		Use by date
	Manufacturer		

IP22	Protected against intrusion from fingers and small objects, and from water drops vertically falling on the Cala kIQ™ device when it is tilted up to 15˚from vertical. Do not immerse in a bathtub or use while swimming.
	The Cala kIQ device is rated for these temperature limits. For more information on environmental parameters, refer to the Technical Specifications in this User Guide.
	The Cala kIQ device is rated for these humidity limits. For more information on environmental parameters, refer to the Technical Specifications in this User Guide.
	The Cala kIQ device is rated for these atmospheric pressure limits. For more information on environmental parameters, refer to the Technical Specifications in this User Guide.
SN	Serial number
REF	Catalog number
LOT	Batch code
	Class II Equipment

1.2 Introducing Cala kIQ™ Therapy

For more information, view instructional videos at MyCala.com.

1.3 Indications for Use

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

Cala kIQ is indicated to aid in the temporary relief of postural and kinetic hand tremor symptoms that impact some activities of daily living in the treated hand following stimulation in adults with Parkinson's disease (PD).

- Cala kIQ therapy is a non-invasive, wrist-worn device for adults with essential tremor or Parkinson's disease.
- Meaningful relief is usually observed after use.
- Electrodes embedded in a band (Cala kIQ band), deliver therapy to nerves in the wrist.
- Cala kIQ therapy is delivered during 40-minute stimulation sessions, which can be started and stopped on demand.
- Cala kIQ therapy should be applied when temporary relief of hand tremor is desired (i.e. before activities involving your hands such as meals or writing).
- The device has been evaluated in subjects diagnosed with essential tremor or Parkinson's disease, and the effectiveness of the device has not been evaluated for tremor associated with other conditions.
- In a clinical study of the device, many participants were also taking medication for their tremor and it was difficult to assess the effect of the device compared to medication.

1.4 Cala kIQ™ System Components

Your Cala kIQ therapy system contains the following:

Cala kIQ Stimulator

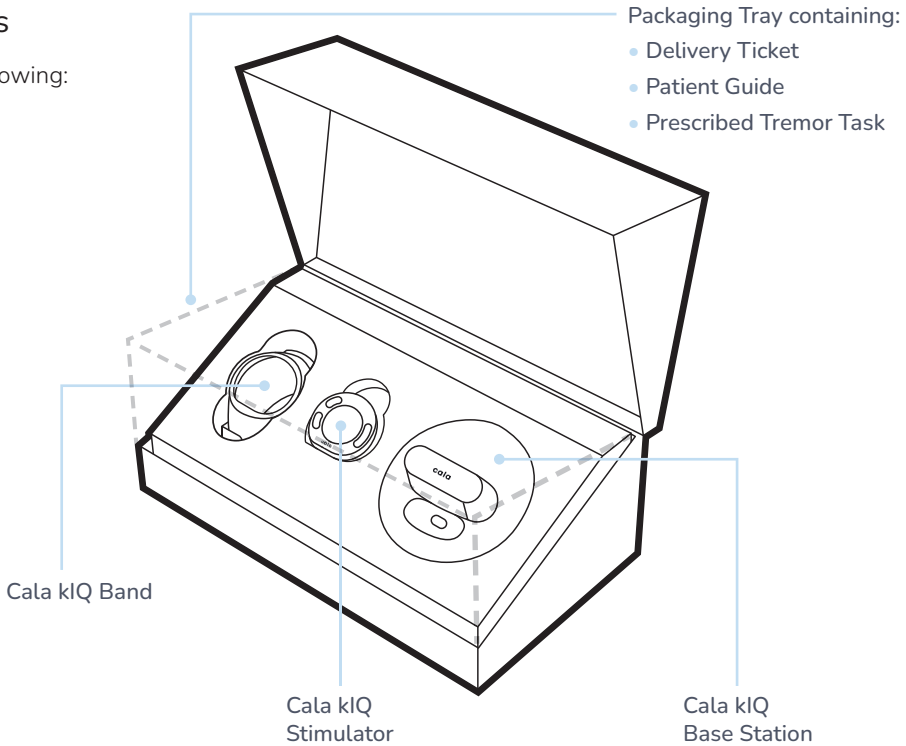
- Snaps into the Cala kIQ band.

Cala kIQ Band

- Delivers therapy to nerves in your wrist through electrodes.

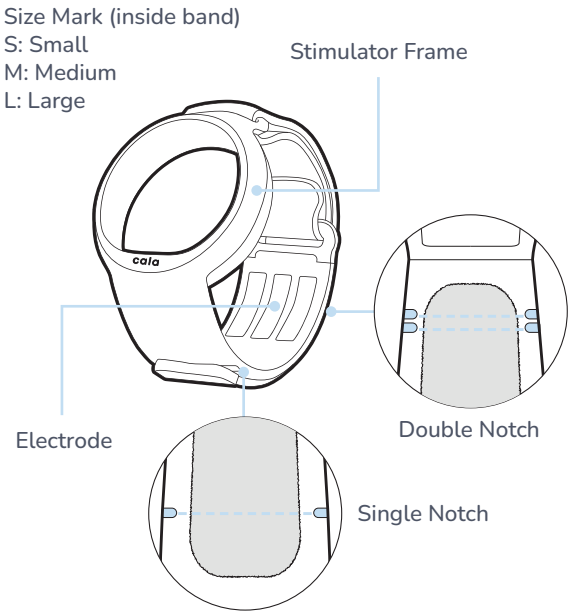
Cala kIQ Base Station

- AC-powered base station in which the Cala kIQ System sits for recharging.

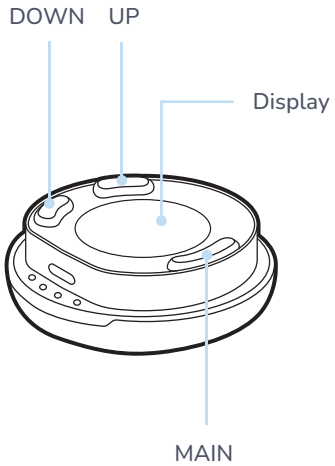


Turn page to learn more about System Components

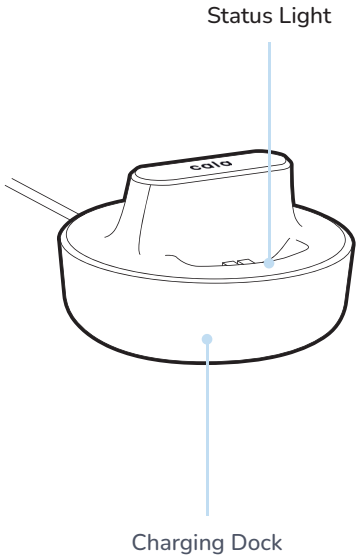
Cala kIQ™ Band



Cala kIQ Stimulator



Cala kIQ Base Station



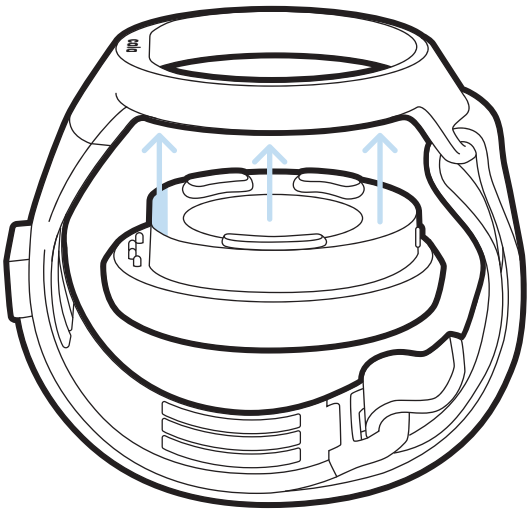
1.5 Assembly

Before assembling, check that your Cala kIQ™ band size, printed on the inside of the band, matches your prescribed size printed on the delivery ticket. If you have received the wrong band size, please contact Cala Health at 888-699-1009 or CustomerCare@CalaHealth.com.

Step 1: To assemble the Cala kIQ system, hold the stimulator underneath the frame of the band.

Step 2: Position the flat edge of the stimulator with the embossed Cala logo on the band and press the stimulator into the band as shown until the face of the stimulator is flush with the frame of the band.

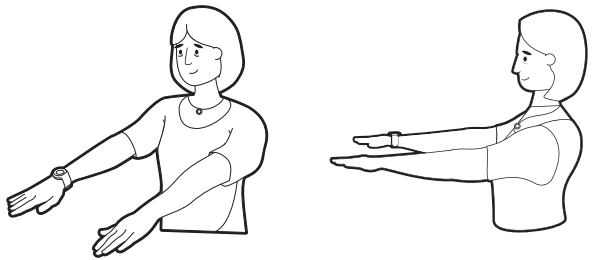
- If the stimulator is not securely connected to the band, the Cala kIQ system will not function.
- The Cala kIQ system must be assembled with the band attached to the stimulator in order to charge.



1.6 About Your Tremor Task

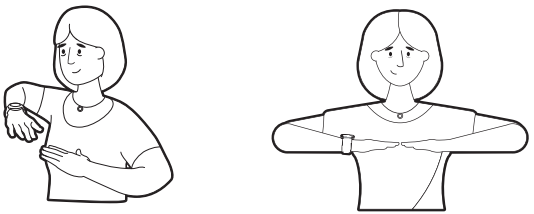
- Your tremor task is ONE of the tasks pictured to the right, prescribed by your doctor to help elicit your tremor. You may not tremor every time you perform your task.
- During your set up, the Cala kIQ™ system uses your tremor task to calibrate therapy over the course of three measurements.
- Minimize movements unrelated to your tremor while performing the tremor task. For instance, avoid walking or talking during the task.
- During the first weeks of using therapy, you will perform your tremor task before and after every session. After this initial period, the system will only prompt you periodically.
- It is important to complete your tremor task correctly every time you are prompted in order to see your response to therapy over time.

Determine your tremor task by checking your Prescription Information Card in the Cala kIQ box.



Outstretched postural hold

OR



Wing-beating postural hold

Cala kIQ™ Therapy Guide Roadmap

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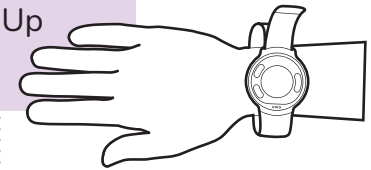

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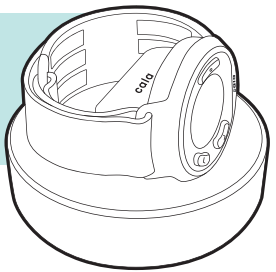


2. SAFETY INFORMATION

This section lists general Warnings and Cautions related to using Cala kIQ™ therapy.

Please read all safety information before using the Cala kIQ therapy.

Should any technical problem occur that is not covered in the Patient Guide, please contact Cala Health at 888-699-1009 or CustomerCare@CalaHealth.com.

2.1 Contraindications

- The device should NOT be used:
  - By people with an implanted electrical medical device, such as a pacemaker, defibrillator, or deep brain stimulator.
  - By people that have suspected or diagnosed epilepsy or other seizure disorder.
  - By people who are pregnant.
  - On swollen, infected, inflamed areas, or skin eruptions, open wounds, or cancerous lesions.

2.2 Warnings

- To avoid the risk of electric shock, burns electrical interference, or death, do not use Cala kIQ™ therapy if you have:
  - A pacemaker
  - An implanted defibrillator
  - Other implanted electronic devices, or implanted metal in the wrist
- Do not use Cala kIQ therapy 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 kIQ therapy:
  - 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 kIQ therapy on the neck.
  - Doing so can cause a severe muscle spasm, resulting in the closure of the airway, difficulty with breathing, or adverse effects on heart rhythm.
- Do not use Cala kIQ therapy **on** the chest.
  - Introduction of an electric current into the chest may cause rhythm disturbances to the heart, which could cause death.
- Do not apply Cala kIQ therapy **near** the chest.
  - This may increase the risk of abnormal heart rhythm (arrhythmia).
- Do not apply Cala kIQ therapy 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 kIQ™ therapy over – or in proximity to – cancerous lesions.
- To prevent electrical shock, do not immerse the Cala kIQ device in water.
- Do not wear the Cala kIQ device while performing activities where the Cala kIQ device is underwater (e.g., swimming or bathing).
- Do not use the Cala kIQ device simultaneously with:
  - High-frequency surgical equipment, as this may result in electrical burns and/or possible damage to the Cala kIQ device.
  - Electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the Cala kIQ device is in use.
- To prevent an explosion hazard and possible injury, stop Cala kIQ therapy when at a refueling place (e.g., gas station).
- Do not use the Cala kIQ device near flammable fuel, fumes, or chemicals.
- Physician approval should be obtained by your prescribing physician before using Cala kIQ therapy if you have any implanted devices at the site of stimulation.
- Cala kIQ therapy 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 putting on the Cala kIQ device.
- 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 the Cala kIQ device from your wrist during therapy.
- To charge the Cala kIQ device, use only the Cala kIQ Base Station with power cord, BW100PA.
- The cord on the charger may present a choking hazard. Keep away from children.

2.3 Cautions

- Use Cala kIQ™ therapy only as directed by this Patient Guide or your physician.
- Do not use Cala kIQ therapy if you have suspected or diagnosed epilepsy or other seizure disorder.
- Do not use Cala kIQ therapy if you are pregnant.
- Higher stimulation levels may be associated with potential for an increase in skin irritation, including electrical stimulation burns of the skin, which may cause focal pinpoint edema, erosion, and crusting.
- Store the Cala kIQ device to prevent exposure to dust and pests It is recommended to store the device in the original packaging when not in use or being charged.
- To prevent damage and/or performance issues to the Cala kIQ device:
  - Keep the Cala kIQ device dry. The Cala kIQ device can withstand some splashing.
  - Do not use in places with high humidity (e.g., the bathroom).
  - Do not store or transport the Cala kIQ 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 in temperatures that exceed the recommended operating 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 Cala kIQ device.
  - Do not use the Cala kIQ device **within 3 ½ feet** of shortwave or microwave equipment.
- To prevent damage, performance issues, increased emissions, or decreased immunity of the Cala kIQ device, only use the accessories recommended by Cala Health with the device.
- Use Cala kIQ therapy 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 kIQ™ therapy 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 kIQ therapy during X-ray examinations.
- To prevent Cala kIQ 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 CustomerCare@CalaHealth.com

2.4 Adverse Reactions

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

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

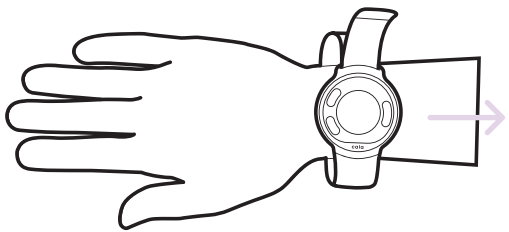
In the unlikely event that any of the following more significant issues happen, immediately stop using Cala kIQ therapy and contact your physician.

- 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.

3.1 Putting On

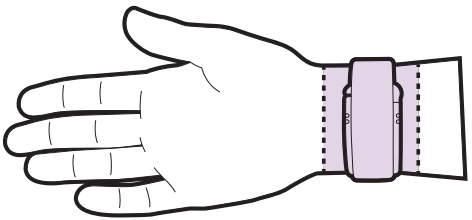
Step 1: Wet your wrist before setting up the Cala kIQ system to prevent uncomfortable therapy, skin irritation, and/or shock. For example, you can wet your wrist using a water bottle or by placing your wrist under running water. If there is any excess oil or lotion on your wrist, wash with soap and water and rinse well before wearing the Cala kIQ system.

Step 2: Insert your prescribed hand through the band making sure the embossed Cala logo at the flat edge of the stimulator is right-side up.



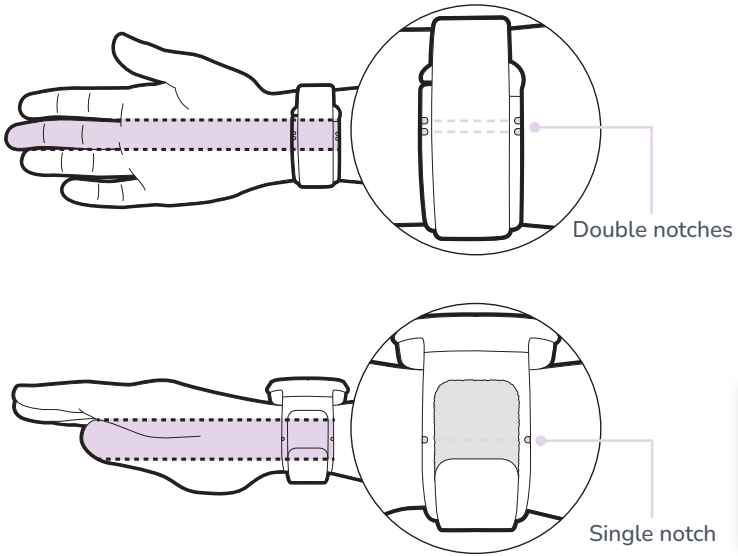
Right hand view

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



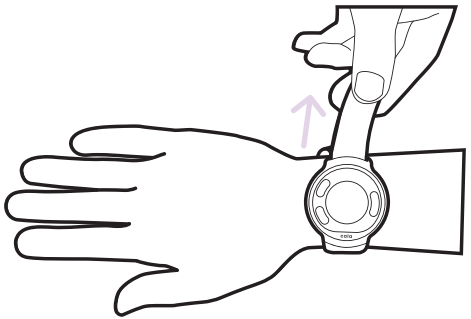
For more information, view instructional videos at MyCala.com

Step 4: Ensure that the double notches on the band are approximately aligned with the center of the inside of your wrist and that the single notch is in line with your thumb. Reposition if necessary.



Step 5: Pull the end of the Cala kIQ™ band to tighten and then fasten the band securely and tightly.

- The band should be comfortable but snug enough so it does not slide along or around the wrist.
- The electrodes should be flush with the skin.



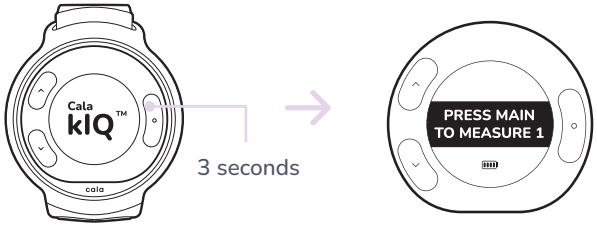
NOTE: If you feel your band is too large or too small, such that the single and double notches do not approximately align as shown to the left, please contact Cala Health at 888-699-1009 or CustomerCare@CalaHealth.com.

3.2 Calibrating

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

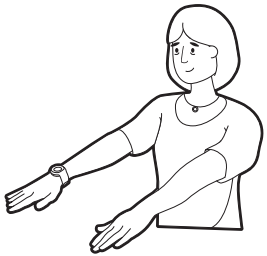
MAIN button

Step 2: Press and hold the MAIN button for 3 seconds to start setup. You will see *"PRESS MAIN TO MEASURE 1"*.



NOTE: The Cala kIQ system goes into SLEEP mode and fades to white if you are not actively pressing any buttons. You can press any button to wake it up.

Step 3: Get in position to do your tremor task (see below). You can find your prescribed tremor task on your Prescription Information Card in the Cala kIQ box.



Outstretched postural hold

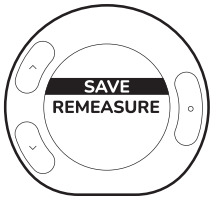
or

Wing-beating postural hold

Step 4: Press the MAIN button to start the measurement.

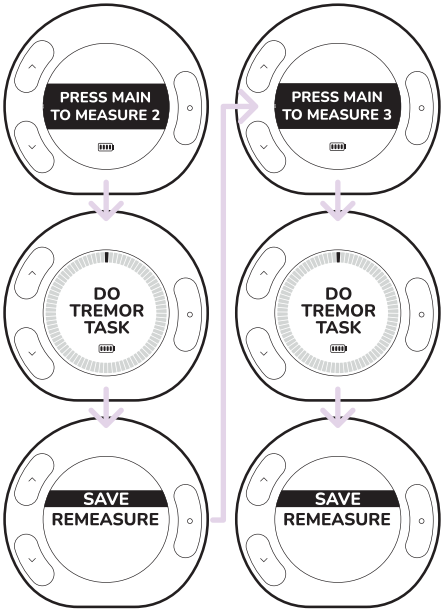
Step 5: Perform your tremor task until “DO TREMOR TASK” disappears (~20 seconds). Avoid unrelated movement during your tremor task (e.g. walking or talking). The Cala kIQ™ system will vibrate when the tremor task is complete.

Step 6: Press the MAIN button to save the measurement if you performed your tremor task for the full 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, the Cala kIQ system will prompt you for Measures 2 and 3. Repeat Steps 4-6 to perform and save Measures 2 and 3.

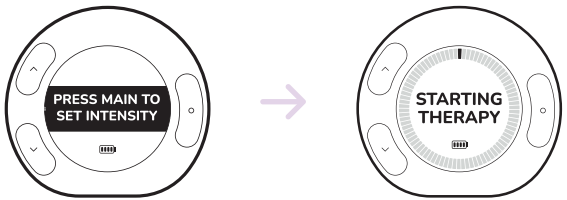


3.3 Setting Stimulation Intensity

After calibrating the Cala kIQ system to your tremor, you will set your default stimulation intensity for therapy.

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

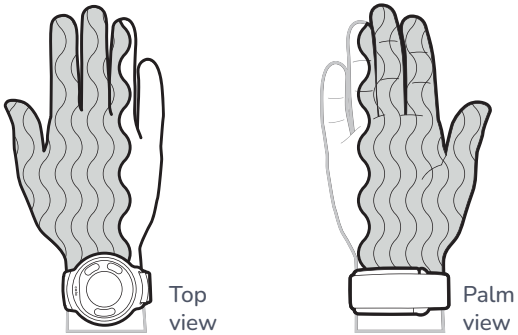
Step 1: Press the MAIN button from *"PRESS MAIN TO SET INTENSITY"*. The Cala kIQ system will start stimulation.



Step 2: Press the UP button to slowly increase the intensity until you start to feel sensation in the highlighted areas to the right. You may not feel the sensation right away.

NOTE: The intensity starts at 0.50 milliampere (mA) and goes up to 8 mA. Each time you press the UP button, the intensity will increase a small amount.

Step 3: Continue to press the UP button, until you find an intensity level that will be comfortable for a 40-minute therapy session while doing light daily activities (i.e. eating, drinking, etc.) If you do not feel the tingling sensation within the area highlighted below, move to Step 4.



NOTE: Tingling sensation varies depending on the positioning of the Cala kIQ™ system, position and movement of your wrist, and the moisture on your wrist. **You should not feel the tingling sensation in your pinky.**

Step 4 (optional): To reposition the Cala kIQ system if the sensation is not in the correct area:

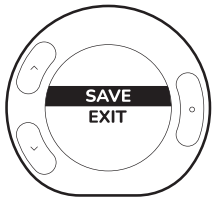
- Press the MAIN button and wait for therapy to stop.
- Press the DOWN button to highlight *"RESET INTENSITY"* and the MAIN button to select.
- Dampen your wrist if desired, and adjust the placement of the band (see page 20).
- Repeat steps 1-3 when you are ready to set your intensity again (see page 24).

NOTE: If you feel your band is too large or too small, such that the single and double notches do not approximately align as shown on page 21, please contact Cala Health at 888-699-1009 or CustomerCare@CalaHealth.com.

Turn page to continue to Step 5 →

Step 5: Press the MAIN button to stop stimulation when you find an intensity level that will be comfortable for a 40-minute therapy session while doing light daily activities (i.e. eating, drinking, etc.).

Step 6: Press the MAIN button again to save your stimulation level.



NOTE: This will be your default stimulation intensity for therapy. You can always adjust the intensity up or down during a session.

Your Cala kIQ system is set up and ready for use!

NOTE: Only use Cala kIQ therapy for the prescribed hand.

Turn to Page 28
to Start Therapy

4.1 Therapy with the Cala kIQ System

- A therapy session is set to be 40 minutes long, and delivers electrical stimulation to treat your tremor. Most people experience tremor relief after a session.

Step 1: Wet your wrist before a session to prevent uncomfortable therapy, skin irritation, and/or shock. For example, you can wet your wrist using a water bottle or by placing your wrist under running water. If there is any excess oil or lotion on your wrist, wash with soap and water and rinse well before wearing the Cala kIQ system. Put Cala kIQ system on the prescribed hand as described in 3.1 Putting On.

NOTE: If the display is white, it is in SLEEP mode.
Press any button to wake it up.

Step 2: Press the MAIN button to start a therapy session from the time display. You will now see *"START SESSION"*.

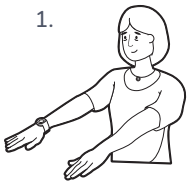
Step 3: Press the MAIN button again to start a session.

Step 4: Press the MAIN button to do your prescribed tremor task. If you would like to skip and are given the option, press the DOWN button and then MAIN to skip until the next session.

For more information, view instructional videos at MyCala.com

NOTE: Tremor task measurements will be prompted periodically before and after therapy sessions. If prompted, it is important to complete your tremor task to see your response to therapy over time.

1.



2.

1. Outstretched postural hold
2. Wing-beating postural hold

Step 5: To complete your tremor task:

- Find your tremor task on your Prescription Information Card (see page 12 for more information).
- Get in a position to do your prescribed tremor task.
- Perform tremor task until “DO TREMOR TASK” disappears (~20 seconds).

Step 6: Press the MAIN button to start therapy after collecting your tremor task.

NOTE: Once therapy starts, it automatically ramps to your default intensity while displaying “*STARTING THERAPY A*”. Therapy is then 40 minutes of stimulation.

Turn page to continue to Step 7

Step 7: The 40-minute timer will begin the countdown.

Step 8 (optional): You can adjust therapy intensity as needed to maintain a comfortable and consistent sensation during sessions. During your session:

- To stop the increasing therapy intensity ramping up to your preset, press any button.
- Press the UP button to increase the intensity.
- Press the DOWN button to decrease the intensity.

4.2 Stopping Therapy

After 40 minutes, your Cala kIQ therapy will automatically stop when the countdown timer reaches zero minutes and the Cala kIQ system displays *"THERAPY COMPLETE"*.

Step 1: To stop your session early, press and hold the MAIN button until you see *"THERAPY STOPPED"*.

- When your session stops, the Cala kIQ system 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 (see page 12).

NOTE: Tremor task measurements will be prompted periodically before and after therapy sessions. If prompted, it is important to complete your tremor task to see your response to therapy over time.

(Optional) In addition to your pre and post tremor task, you can draw a pre and post Archimedes spiral to see how the Cala therapy is working for you.

Spiral Drawing[1]

Pre-therapy

Post-therapy

1. Lin PT, *et al.* Mov Discord. 2018 Jul;33(7):1182-1183. doi:10.1002/mds.27350.

4.3 Rating Your Tremor

During the first weeks of using therapy, you will rate your tremor after every session. After this initial period, the system will only prompt you periodically. 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 the UP button or the DOWN button to highlight the rating you want.

Step 3: Press the MAIN button to save your rating.

You have successfully completed a therapy session with the Cala kIQ™ system!

4.4 Removing the Cala kIQ System

Avoid removing the Cala kIQ system during therapy.

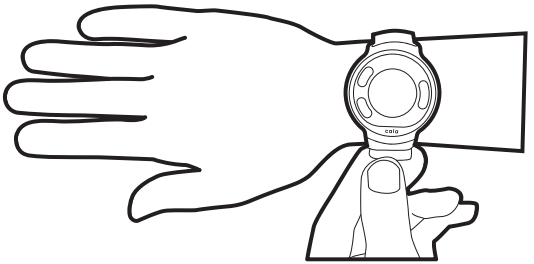
Between sessions, you can remove the Cala kIQ system.

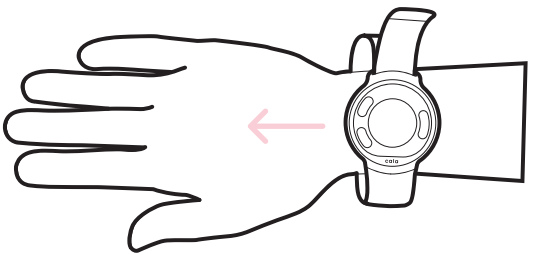
Step 1: Make sure therapy has stopped. If you are in the middle of a session, press and hold the MAIN button until you see *"THERAPY STOPPED"* (see page 30).

Step 2: Unfasten the band to release the connection.

Step 3: Remove the Cala kIQ system from the wrist.

NOTE: Leave the stimulator and band attached until you are prompted to replace the band. The Cala kIQ system will display *"REPLACE BAND"* in order to maintain effective therapy (see page 35).





4.5 Viewing Your Therapy Information

After a session, you can learn more about your Cala kIQ™ therapy at MyCala.com. See page 3 to sign up.

You can access the following information:

- Guidance in your journey of learning and using Cala kIQ therapy.
- Data insights on how the therapy is working for you.
- A summary of your therapy including system information and band life remaining until a new one is needed.
- Searchable knowledge database for frequently asked questions, access instructional videos and guides, and contact Customer Care.
- Downloadable PDF reports to share your therapy insights with your health care provider.
- A summary of your device usage patterns.

5.1 Charging

Step 1: Plug the base station into the wall outlet using the power cord.

Step 2: Place the stimulator with the band attached into the base station. The stimulator will show battery charging and battery charge level.

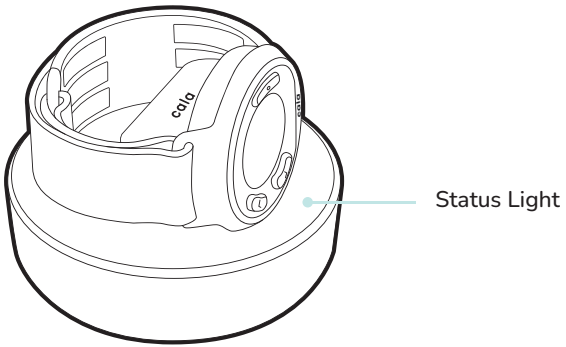
- The base station status lights indicate:

white light	– flashing - system is connecting to Cala Cloud – constant - system is connected to Cala Cloud
green light	charging
yellow light	system updating, do not remove from the base station
red light	replace the Cala kIQ band

Charge the Cala kIQ system...

- Overnight
- With band attached to the stimulator

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



To power down the base station, unplug the power cord from the wall outlet.

5.2 Replacing the Band

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

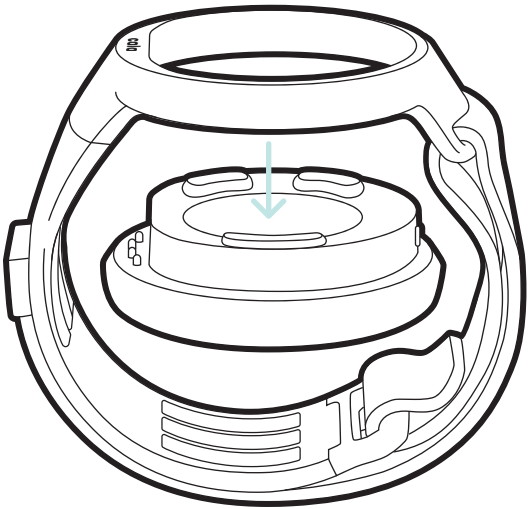
Step 2: Press the stimulator through the used band to replace it.

Step 3: With the new band, hold the stimulator underneath the frame of the band. Position the flat edge of the stimulator with the embossed Cala logo on the band.

Step 4: Press the stimulator into the band until the face of the stimulator is flush with the frame of the band.

Step 5: Place the stimulator attached to the new band in the base station for 15 seconds in order to clear the *"REPLACE BAND"* message.

NOTE: Your band will need to be replaced every 90 days. You can see when your band needs to be replaced by visiting MyCala.com



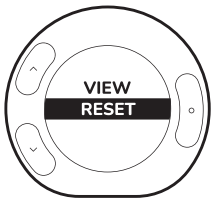
5.3 Changing the Default Stimulation Intensity

Change the default setting if you would prefer a different stimulation intensity for therapy.

> Note: The default setting cannot be changed during a session, you must stop therapy first or change your setting before or after therapy.

Step 1: From the time display, press the UP or DOWN buttons until you see *"INTENSITY SETTING"*. Press the MAIN button to select.

Step 2: Press the DOWN button to highlight *"RESET"*. Then press the MAIN button.



Step 3: Use the UP or DOWN buttons to adjust the intensity to an appropriate level. See pages 24-25 for more detail on choosing an intensity level for therapy.

Step 4: Press the MAIN button to stop the therapy. Then press MAIN button again to save the intensity.

5.4 Resetting the Cala kIQ™ System

If the Cala kIQ System is performing in a way that you do not expect, you may perform a reset. Your settings will not be erased if you perform a reset.

Step 1: Press and hold the MAIN and UP buttons at the same time for a few seconds until the Cala kIQ system displays *"POWERING DOWN"*.

Step 2: Release the buttons and the Cala kIQ system will automatically restart displaying the Cala kIQ logo.

5.5 Cleaning and Storing

Cleaning the Cala kIQ band can help maintain a good connection between the band and your skin. To clean the Cala kIQ band, use a disinfecting wipe on the inside of the band to wipe the six rectangular, black electrodes. All other Cala kIQ components can also be cleaned by using a disinfecting wipe as often as once per week.

When not using therapy, charge the Cala kIQ system overnight on the base station with the stimulator attached to the band.

6.1 Frequently Asked Questions

Q1: Can I wear a watch or other metal jewelry on my arm when using the Cala kIQ™ system?

Do not wear any metallic items on the same wrist as the Cala kIQ system during therapy.

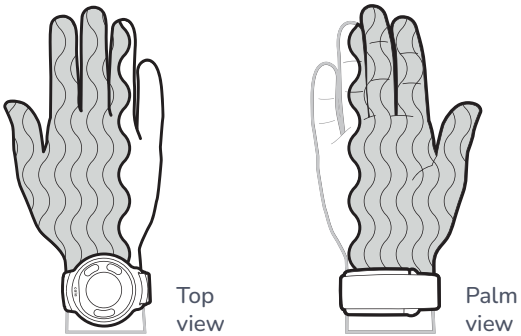
Q2: Why does the Cala kIQ system display turn off?

By design the Cala kIQ system is always on, but in order to conserve battery, the Cala kIQ system goes into sleep mode and fades to white if you are not actively pressing any buttons. Press any button to wake it up.

Q3: How do I know I've placed the Cala kIQ system on my wrist correctly?

Only use Cala kIQ therapy for the prescribed hand. In a therapy session, you should feel a tingling sensation in your hand and fingers but not your pinky. If you aren't feeling this in any part of the hand or fi ngers, consider adjusting the band.

If you feel it is only some part of the wrist, hand, or fingers as highlighted below, it's a good start and may be how therapy will work for you. It is important that you feel this tingling in some part of the wrist, hand, or fingers, not necessarily all of the highlighted area.



Top view

Palm view

Q4: My band doesn't fit. It is too tight or too loose. What should I do?

Pull the end of the Cala kIQ™ band to tighten—fasten it securely and tightly. It should be snug enough so it does not slide along or around the wrist. If the electrodes are not flush to the skin, simply reach out to our Customer Care team at 888-699-1009 or CustomerCare@CalaHealth.com for help.

Q5: If I use it at a higher stimulation intensity setting, will I see greater benefit?

Higher intensity does not necessarily mean better efficacy. Stimulate at an intensity that you can feel in your hand and fingers, without causing discomfort or muscle contraction.

Q6: Can I wear the Cala kIQ system all-day?

It is recommended that the Cala kIQ system be worn when using therapy.

Q7: How long does the battery last?

When the battery is fully charged, it will last about 5 sessions depending on your stimulation intensity.

Q8: How do I properly dispose of the Cala kIQ band?

There are no special instructions to dispose of the band. It does not contain a battery and can be disposed of as such.

If you need help, simply reach out to our Customer Care team at 888-699-1009 or CustomerCare@CalaHealth.com.

6.2 Troubleshooting

The Cala kIQ™ base station securely transfers data to the Cala Cloud. You can view your data on MyCala.com, and this is used by Cala Health to assist you with system support. The data provides Customer Care with information on band expiration dates and system function, such as the occurrence of error messages. In addition, system usage data, including dates and duration of sessions and tremor tasks, rated session data and intensity settings, is transferred for any needed system support and is available on MyCala.com.

If you have any issues using Cala kIQ therapy 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 CustomerCare@CalaHealth.com.

Band Not Connected

Step 1: Press the MAIN button to exit the warning.

Step 2: If prompted, complete the post therapy tremor task and rating.

Step 3: Remove the Cala kIQ™ system from your wrist.

Step 4: Clean the Cala kIQ band using a disinfecting wipe on the inside of the band to wipe the six rectangular, black electrodes.

Step 5: Ensure the stimulator is securely and correctly assembled by pressing the stimulator into the band until the face of the stimulator is flush with the frame of the band (see page 35).

Step 6: Dampen your wrist with water.

Step 7: Tightly secure the Cala kIQ system on your wrist. Ensure the electrodes are flush with the skin.

Step 8: Restart therapy.

Step 9: If the error re-occurs, reset the system as in section 5.4.

Step 10: If the warning persists, stop using the Cala kIQ system and contact Customer Care at 888-699-1009 or CustomerCare@CalaHealth.com.

Adjust Band on Wrist

Step 1: Press the MAIN button to exit the warning.

Step 2: If prompted, complete the post therapy tremor task and rating.

Step 3: Remove the Cala kIQ™ system from your wrist.

Step 4: Clean the Cala kIQ band using a disinfecting wipe on the inside of the band to wipe the six rectangular, black electrodes.

Step 5: Ensure the stimulator is securely and correctly assembled by pressing the stimulator into the band until the face of the stimulator is flush with the frame of the band (see page 35).

Step 6: Dampen your wrist with water.

Step 7: Tightly secure the Cala kIQ system on your wrist. Ensure the electrodes are flush with the skin.

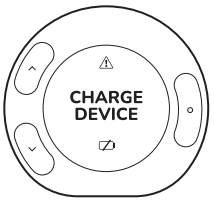
Step 8: Restart therapy.

Step 9: If the error re-occurs, reset the system as in section 5.4.

Step 10: If the warning persists, stop using the Cala kIQ system and contact Customer Care at 888-699-1009 or CustomerCare@CalaHealth.com.

Charge Device

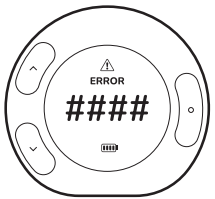
The Cala kIQ system needs to be charged. Place the system, with the band attached, into the base station. Note the band must be attached in order for the system to charge.



Error

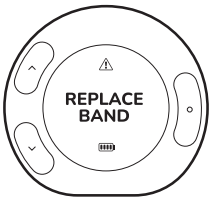
The Cala kIQ™ system has stopped functioning due to an internal error. Press and hold the MAIN button for a few seconds to reset it. Use the system as instructed.

If the error persists, contact Cala Health at 888-699-1009 or CustomerCare@CalaHealth.com



Replace Band

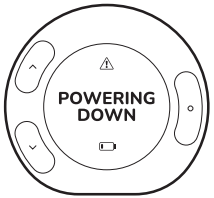
Replace the band as soon as possible. Therapy will be available for ten days after the first appearance of this message. See page 35 for directions on disconnecting and connecting the stimulator and band.



Replace the band as soon as possible. Therapy will not be available until a new band is attached. See page 35 for directions on disconnecting and connecting the stimulator and band.

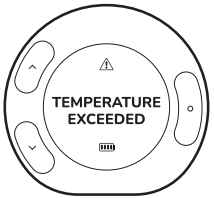
Powering Down

Appears when the system resets.



Temperature Exceeded

The Cala kIQ™ system has stopped working because the temperature is too high inside the stimulator. To prevent damage to the system, remove it from your wrist and allow the stimulator to cool down.



6.3 Clinical Study Summary

6.3.1 ET-22 Study Clinical Summary

The objective of this study was to evaluate the safety and efficacy of symptomatic action tremor relief in the treated hand following stimulation with the Cala Trio System using the Cala kIQ™ bands as compared to the Trio bands in adults with essential tremors and Parkinson's disease. The single-center, two-arm, unblinded, nonsignificant risk crossover study with no sham group included two study visits with study clinicians and a 2-week home use period of during which subjects were instructed to complete TAPS therapy sessions twice daily. Assessment performed during study visits were completed while subjects were off medication, home-use sessions completed with subjects on medication per their standard of care.

Study Design

Study evaluations included:

- Unvalidated subset of Movement Disorder Society Unified PD Rating Scale Modified Part III (MDS-UPDRS), The Essential Tremor Rating Assessment Scale (TETRAS) - clinician ratings of patients' abilities to perform tasks such as a finger-to-nose movement or holding arms outstretched
- Unvalidated subset of BF-ADL - patient ratings of their own ability to perform activities of daily living such as eating, drinking, or writing.
- Device sensor measurements of tremor power.

Subjects participated in both arms of the study with a wash-out period (>24 hours) between arms:

- Arm 1: Subjects received TAPS therapy using Cala Trio for two weeks.
- Arm 2: Subjects received TAPS therapy using Cala kIQ for two weeks.

The study included five telemedicine visits conducted over four weeks. Within each arm, patients completed two study visits that included a TAPS therapy session and clinician and subject-rated assessments. Between the study visits within each arm, subjects were instructed to complete TAPS therapy sessions twice a day for a two-week home-use period.

Results

A total of 19 subjects completed the study, 13 with essential tremor and 6 with Parkinson's Disease.

There were no reports of device-related serious adverse events. Patients reported a total of five device-related adverse events with one adverse event reported for Cala kIQ™. The most common adverse event reported was persistent skin irritation. The study investigator assessed all device-related adverse events as mild in nature. All adverse events were resolved with minimal intervention.

In an unvalidated subset of clinician-rated tremor assessments (TETRAS and MDS-UPDRS) and subject-rated assessments (BF- ADLs), Cala kIQ and Cala Trio demonstrated similar safety and effectiveness outcomes.

Study data demonstrated Cala kIQ and Cala Trio deliver TAPS therapy with similar safety and effectiveness.

6.3.2 ET-22 Study Limitations

The following study limitations should be noted:

The studies only evaluated therapy in patients diagnosed with essential tremor and Parkinson's Disease, and these study findings may not extend to tremor associated with other conditions.

The longitudinal at-home study was run open-label, unblinded, and without a randomized controlled sham-stimulation arm, so contribution of placebo effect cannot be ruled out. Prior sham-controlled studies of TAPS therapy suggest that the observed longitudinal therapy effects are greater than placebo.

Many patients in these studies were also taking medication for their tremor. While therapy was shown to be effective for patients on and off medication, it is unknown how patients tied timing of Cala home-use therapy sessions to their medication.

The study used unvalidated clinical and patient assessments, therefore results are exploratory in nature.

Turn to Page 48 to read about the study summary

6.3.3 PD-02 Study Summary

The PD-02 study evaluated the safety and effectiveness of TAPS therapy in patients with Parkinson's Disease. The single-arm, non-blinded, non-significant risk study included a 4-week home use period of during which subjects were instructed to complete TAPS therapy sessions twice daily.

Study Design

Study evaluations included:

- Unvalidated subset of MDS-UPDRS - clinician rating of patients' abilities to perform tasks such as a finger-to-nose movement or holding arms outstretched
- Unvalidated subset of BF-ADL - patient self-rating their ability to perform activities of daily living such as eating, drinking, or writing
- Motion sensors measuring the amount of tremor-related movement

The study included telemedicine visits and a four-week home use period as follows:

- Visit 1 – Subjects were screened for eligibility and enrolled in the study.
- Visit 2 – Subjects underwent device training and calibration. Subjects then completed the first TAPS therapy session and clinician and subject-rated assessments. Subjects withheld medication use prior to this visit so that therapy sessions and assessments were completed in the medication "off" state.
- Home Use – Subjects underwent a period of home-use during which they were instructed to complete TAPS therapy sessions twice a day for four weeks. Subjects completed home-use therapy sessions while in the medication "on" state as per their standard of care.
- Visit 3 – Subjects completed the final TAPS therapy session and clinician and subject-rated assessments. Subjects withheld medication use prior to this visit so that therapy sessions and assessments were completed in the medication "off" state.

Results

There were no reports of device-related serious adverse events. Patients reported a total of seven device-related adverse events which included skin irritation or sores and discomfort or pain with stimulation. The study investigator assessed all device-related adverse events as mild or moderate in nature. All adverse events were resolved with minimal intervention

Across visits, TAPS therapy improved by 0.5±0.5 points on an unvalidated subset of MDS-UPDRS dominant hand tasks listed below:

- Rest Tremor Amplitude
- Postural Tremor
- Kinetic Tremor
- Pronation-Supination
- Finger Tapping
- Hand Movements

Also, across visits, TAPS therapy improved the ability to perform some activities of daily living by 0.4±0.5 points, based on an unvalidated subset of BF-ADL tasks listed below:

- 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
- Write a letter

Pre-stimulation to post-stimulation change was evaluated for each of the MDS-UPDRS Part III dominant hand tasks and the Bain and Findley ADL tasks at both Visits 2 and 3. The MDS-UPDRS and BF-ADL scales are assessed at 1-point increments and improvement was calculated for the average scores as well as for each individual task.

The responder rate, defined as the percent of subjects that had a ≥ 0.5-point average per-task improvement, was calculated for the average scores as well as for each individual task.

Table 2 below provides study data for all enrolled subjects and includes responder rates for assessment averages and individual tasks. Of note, the CGI-I and PGI-I were used as secondary endpoints in the study:

Table 2. PD-02 Responder Rates for All Enrolled Subjects

	Visit 2					Visit 3				
	N	Pre Mean ±SD	Post Mean ± SD	Change Mean ± SD	Responder Rate (%)	N	Pre Mean ±SD	Post Mean ± SD	Change Mean ± SD	Responder Rate (%)
MDS-UPDRS										
Average across 6 tasks*	40	1.63 ± 0.55	1.20 ± 0.69	-0.44 ± 0.44	40%	36	1.51 ± 0.50	1.11 ± 0.57	-0.40 ± 0.37	44%
Rest Tremor	40	1.85 ± 1.10	1.33 ± 1.07	-0.53 ± 0.82	45%	36	1.94 ± 0.95	1.44 ± 1.05	-0.50 ± 0.94	39%
Postural Tremor	40	2.30 ± 0.88	1.35 ± 1.08	-0.95 ± 0.88	70%	36	2.14 ± 0.96	1.31 ± 1.06	-0.83 ± 0.88	61%

* For averaged scores, a Responder was defined as subjects that had a ≥ 0.5-point average per-task improvement

Table 2. PD-02 Responder Rates for All Enrolled Subjects (Continued)

	Visit 2					Visit 3				
	N	Pre Mean ±SD	Post Mean ± SD	Change Mean ± SD	Responder Rate (%)	N	Pre Mean ±SD	Post Mean ± SD	Change Mean ± SD	Responder Rate (%)
MDS-UPDRS										
Kinetic Tremor	40	1.08 ± 0.92	0.75 ± 0.81	-0.33 ± 0.53	35%	36	1.06 ± 0.92	0.83 ± 0.74	-0.22 ± 0.42	22%
Pronation-Supination	40	1.50 ± 0.91	1.23 ± 0.95	-0.28 ± 0.72	33%	36	1.31 ± 0.95	1.17 ± 1.00	-0.14 ± 0.76	28%
Finger Tapping	40	1.75 ± 0.87	1.45 ± 0.96	-0.30 ± 0.76	28%	36	1.47 ± 0.84	1.03 ± 0.77	-0.44 ± 0.56	42%
Hand Movements	40	1.30 ± 0.82	1.10 ± 0.87	-0.20 ± 0.79	35%	36	1.14 ± 0.80	0.89 ± 0.67	-0.25 ± 0.69	28%

Table 2. PD-02 Responder Rates for All Enrolled Subjects (Continued)										
	Visit 2					Visit 3				
	N	Pre Mean ±SD	Post Mean ± SD	Change Mean ± SD	Responder Rate (%)	N	Pre Mean ±SD	Post Mean ± SD	Change Mean ± SD	Responder Rate (%)
BF-ADLs										
Average ADL Rating (8 Tasks, 8-32)*	40	1.93 ± 0.50	1.48 ± 0.43	-0.44 ± 0.43	43%	36	1.76 ± 0.48	1.44 ± 0.37	-0.32 ± 0.39	25%
Use a spoon to drink soup	40	2.23 ± 0.97	1.60 ± 0.74	-0.63 ± 0.74	55%	36	2.19 ± 0.92	1.78 ± 0.76	-0.42 ± 0.77	33%
Hold a cup of tea	40	2.13 ± 0.94	1.75 ± 0.84	-0.38 ± 0.84	40%	36	2.03 ± 1.00	1.69 ± 0.79	-0.33 ± 0.68	25%

* For averaged scores, a Responder was defined as subjects that had a ≥ 0.5-point average per-task improvement

Table 2. PD-02 Responder Rates for All Enrolled Subjects (Continued)

	Visit 2					Visit 3				
	N	Pre Mean ±SD	Post Mean ± SD	Change Mean ± SD	Responder Rate (%)	N	Pre Mean ±SD	Post Mean ± SD	Change Mean ± SD	Responder Rate (%)
BF-ADLs										
Pour milk from a bottle or carton	40	2.00 ± 0.72	1.48 ± 0.68	-0.53 ± 0.78	45%	36	1.89 ± 0.67	1.56 ± 0.73	-0.33 ± 0.68	42%
Dial a telephone	40	1.75 ± 0.74	1.23 ± 0.58	-0.53 ± 0.72	45%	36	1.53 ± 0.61	1.17 ± 0.38	-0.36 ± 0.54	33%
Pick up your change in a shop	40	1.60 ± 0.71	1.33 ± 0.53	-0.28 ± 0.64	23%	36	1.42 ± 0.60	1.31 ± 0.52	-0.11 ± 0.52	19%

Table 2. PD-02 Responder Rates for All Enrolled Subjects (Continued)

	Visit 2					Visit 3				
	N	Pre Mean ±SD	Post Mean ± SD	Change Mean ± SD	Responder Rate (%)	N	Pre Mean ±SD	Post Mean ± SD	Change Mean ± SD	Responder Rate (%)
BF-ADLs										
Insert an electric plug into a socket	40	1.65 ± 0.70	1.30 ± 0.52	-0.35 ± 0.70	38%	36	1.42 ± 0.65	1.14 ± 0.42	-0.28 ± 0.61	25%
Unlock your front door with a key	40	1.59 ± 0.72	1.33 ± 0.53	-0.26 ± 0.59	23%	36	1.44 ± 0.61	1.17 ± 0.38	-0.28 ± 0.51	25%
Write a letter	40	2.48 ± 0.78	1.85 ± 0.74	-0.63 ± 0.70	53%	36	2.19 ± 0.86	1.72 ± 0.81	-0.47 ± 0.61	42%

Table 2. PD-02 Responder Rates for All Enrolled Subjects (Continued)

	Visit 2					Visit 3				
	N	Pre Mean ±SD	Post Mean ± SD	Change Mean ± SD	Responder Rate (%)	N	Pre Mean ±SD	Post Mean ± SD	Change Mean ± SD	Responder Rate (%)
Global Impression - Improvement										
Clinical Global Impression – Improvement (CGI-I)	40	N/A			78% (31/40)	36	N/A			83% 30/36)
Patient Global Impression – Improvement (PGI-I)	40	N/A			75% (30/40)	36	N/A			81% (29/36)

Table 3 below provides the responder rates for study subjects with a score of > 2 for a specific task at the applicable visit. The data in **Table 3** are a subset of the results summarized in **Table 2**.

Table 3. PD-02 Responder Rates for Subjects with Score > 2 per Task

	Visit 2			Visit 3		
	N	Change Mean ± SD	Responder Rate (%)	N	Change Mean ± SD	Responder Rate (%)
MDS-UPDRS						
Action Tremor (Postural and Kinetic)*	18	-0.61 ± 0.58	67%	16	-0.59 ± 0.61	63%
Rest Tremor Amplitude	28	-0.79 ± 0.79	61%	28	-0.57 ± 1.00	39%
Postural Tremor	33	-1.00 ± 0.94	70%	28	-0.93 ± 0.94	64%
Kinetic Tremor	13	-0.54 ± 0.52	54%	12	-0.58 ± 0.51	58%
Pronation-Supination	17	-0.59 ± 0.80	53%	13	-0.23 ± 1.01	38%
Finger Tapping	21	-0.57 ± 0.81	38%	17	-0.65 ± 0.61	59%
Hand Movements	15	-0.47 ± 0.64	40%	10	-0.90 ± 0.74	70%

* For averaged scores, a Responder was defined as subjects that had a ≥ 0.5-point average per-task improvement

Table 3. PD-02 Responder Rates for Subjects with Score > 2 per Task (Continued)

	Visit 2			Visit 3		
	N	Change Mean ± SD	Responder Rate (%)	N	Change Mean ± SD	Responder Rate (%)
BF-ADLs						
Use a spoon to drink soup	30	-0.87 ± 0.68	73%	27	-0.56 ± 0.85	44%
Hold a cup of tea	29	-0.59 ± 0.87	55%	23	-0.52 ± 0.79	39%
Pour milk from a bottle or carton	30	-0.73 ± 0.78	60%	26	-0.46 ± 0.76	58%
Dial a telephone	23	-0.91 ± 0.73	78%	17	-0.76 ± 0.56	71%
Pick up your change in a shop	19	-0.63 ± 0.76	47%	13	-0.54 ± 0.52	54%
Insert an electric plug into a socket	21	-0.81 ± 0.60	71%	12	-0.83 ± 0.83	75%
Unlock your front door with a key	18	-0.61 ± 0.70	50%	14	-0.71 ± 0.61	64%
Write a letter	36	-0.69 ± 0.71	58%	27	-0.63 ± 0.63	56%

6.3.4 PD-02 Study Limitations

A few limitations of these studies of Cala therapy in essential tremor should be noted:

The study only evaluated therapy in patients with Parkinson's disease who had at least mild postural tremor, and these study findings may not extend to patients who do not present with postural tremor. Other upper limb movements, including rest tremor and bradykinesia (slowness of movement), improved for some patients who presented with those symptoms but were not the focus of this study.

The study was run open-label without a randomized controlled sham-stimulation arm and unblinded, and so contribution of placebo effect cannot be ruled out.

Most patients were taking medication for their tremor. While therapy was shown to be effective in clinical and patient assessments completed during the study visits in a medication-off state, the home-use portion was done as "standard-of-care", and it is unknown how patients tied timing of Cala therapy to their medication while at home.

The study used unvalidated clinical and patient reports, therefore results are exploratory in nature.

These results were descriptive in nature, different patients showed improvement in different tasks tested. None of the patients showed improvement in all of the tasks tested and some of the patients showed no improvement in any of the tasks tested.

6.4 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

OUTPUT	
Waveform	Biphasic symmetric, rectangular
Regulated Current or Voltage	Constant Current
D. C. Component	None, zero net current
Maximum Output Voltage (+/-20%)	4 V @ 500 Ω 80 V @ 10 kΩ
Maximum Output Current (+/-20%)	8 mA @ 500 Ω 8 mA @ 10 kΩ
Load Impedance, Expected Range (+/-20% tolerance)	Min: 500 Ω Max: 10 kΩ
Pulse Duration	650 µs
Pulse Repetition Frequency	150 Hz (Fixed)
Pulse Pattern	Continuous, bursts tuned to the tremor frequency between 4-12 Hz

POWER	
Battery Type	Permanent rechargeable battery, not serviceable or replaceable
Power Source	AC 60 Hz Rated Voltage: 120V Max Current: 0.5 A
Duration	Fully charged battery lasts 5 therapy sessions at a stimulation intensity of 8mA

ELECTRODES	
Type	Cala kIQ™ band with embedded electrodes
Number of Electrodes	6
Dimensions	22mm x 6mm
Maximum Current Density $_{RMS}$	1.29 mA/cm^2 @ 500 Ω
Maximum Average Power Density	0.002 W/cm^2 @ 500 Ω

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

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

Expected Service Life of Stimulator and Base Station: 3 years

6.5 Electromagnetic Compatibility Declaration

The Stimulator (FCC ID: 2AT2DS1) and Base Station (FCC ID: 2AT2DB1) comply with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) these devices may not cause harmful interference, and (2) these devices must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy. If this physical equipment is not installed and used in accordance with the instructions, it may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

These devices meet the government's requirements for exposure to radio waves. They are designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission (FCC) of the US Government.

The exposure standard for wireless devices employs a unit of measurement known as the Specific Absorption Rate, or SAR. The Base Station (FCC ID: 2AT2DB1) is compliant with the SAR for Maximum Permissible Exposure (MPE) assessment at 20 cm. Maintain a distance of at least 20 cm from the Base Station when it is in operation.

Electromagnetic Compatibility Warnings:
Use of this equipment adjacent to or stacked with other equipment should be avoided because it could lead to improper operation. If such use is necessary, the equipment should be observed to verify normal operation.

Portable RF communications equipment (including peripherals such as external antennas or cables) should be used no closer than 30 cm (12 inches) to the Stimulator / Base Station. Otherwise, degradation of the performance of this equipment could result.

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

GENERAL RADIO COMPLIANCE	
ITEM	SPECIFICATION
Stimulator Bluetooth	Module FCC ID: 2AT2DS1 To view on display, reset system as in section 5.4 and press UP or DOWN button when the Cala kIQ logo is displayed.
Radio Frequency (RF) Range	2402 MHz to 2480 MHz
Base Station	FCC ID: 2AT2DB1 Contains FCC ID: XPY2AGQN4NNN
Radio Frequency (RF) Range	13.56 MHz 2402 MHz to 2480 MHz
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		
The Cala kIQ™ system is intended for use in the electromagnetic environment specified below. The customer or the user of the Cala kIQ system should assure that it is used in such an environment.		
EMISSIONS TESTS	COMPLIANCE	
RF emissions CISPR 11	Group 1	The Cala kIQ system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Cala kIQ system 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/Flicker emissions	Complies	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The Cala kIQ system is intended for use in the electromagnetic environment specified below. The customer or the user of the Cala kIQ system 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 the Cala kIQ™ system requires continued operation during power mains interruptions, it is recommended that the Cala kIQ system 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 the Cala kIQ™ system, 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 kIQ is used exceeds the applicable RF compliance level above, Cala kIQ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating Cala kIQ. [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 THE CALA kIQ™ SYSTEM

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

Rated maximum output power of transmitter W	Separation distance according to the 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 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 the worst case.						

Conforms to AAMI STD ES60601-1, IEC 60601-2-10, IEC 60601-1-11 Certified to CSA STD C22.2#60601-1

6.6 Warranty Information

Cala Health, Inc. (“Cala®”) warrants, to the original purchaser only, that the Cala kIQ™ system 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 CalaHealth.com/Warranty.

cala®

888-699-1009
www.CalaHealth.com