



VA Consult for Ordering the Cala kIQ System

Thank you for your interest in Cala kIQ™, a TAPS (Transcutaneous Afferent Patterned Stimulation) next generation FDA-cleared wearable neuromodulation therapy for action hand tremors. To order the Cala kIQ System for your patient, a consult to prosthetics and a patient intake form are required.

The Cala kIQ System is for people with action hand tremors, a diagnosis of either essential tremor or Parkinson's disease and have tried or cannot tolerate pharmacological interventions.

Refer to the VA SOP Topic: Non-invasive Nerve Stimulation for Management of Tremor for more information.

1. Patient Intake and Agreement Form - Signed by Patient

- Include name of prescribing provider
- Include last 4 digits of patient SSN
- Send to Cala at time of consult through one of the following channels:
 - Fax: 1-833-230-9251
 - Encrypted Email: VA@CalaHealth.com
 - Secure Upload: CalaRx.com

2. Consult - Include the following information when submitting for a prosthetics consult. If prescribing for both hands, two devices are needed - one dedicated to each hand.

- Prescribed hand (left and/or right)
- Tremor task (outstretched or wing beating postural hold)
- Wrist measurement in centimeters
- Name of prescribing provider
- Number of bands included in order*
 - 1 Band = 3 Months of Therapy
 - 4 Bands = 12 Months of Therapy

*Number of bands in consult determines when the next consult is required for the patient to continue therapy.

If you or your staff have any questions or concerns about your patient's Cala kIQ order, please do not hesitate to contact our Customer Care team at 888-699-1009 or CustomerCare@CalaHealth.com.

We look forward to working together to provide the best possible care for your patient.

Cala kIQ is indicated to aid in the temporary relief of hand tremors in the treated hand following stimulation in adults with essential tremor. Cala kIQ is indicated to aid in the temporary relief of postural and kinetic hand tremor symptoms that impact some activities of daily living the treated hand following stimulation in adults with Parkinson's Disease. Caution: Federal law restricts this device to sale by or on the order of a physician. Before use, refer to the product labeling for complete product instructions for use, contraindications, warnings, and precautions at CalaHealth.com/Safety. SD-20011 Rev A

Health Care Professional Line: 888-585-7101 | Cala Customer Care: 888-699-1009 | 1800 Gateway Drive | Suite 300 | San Mateo, CA | 94404

Copyright © 2019-2023, Cala Health, Inc. All Rights Reserved. Cala Health, Cala, and Cala kIQ are trademarks of Cala Health, Inc., registered or pending in the U.S. and other countries.

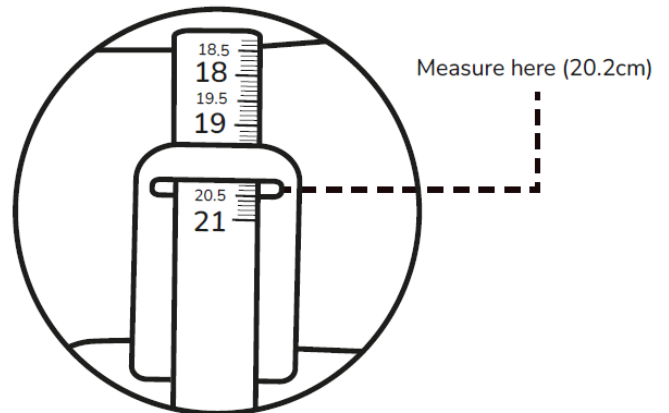
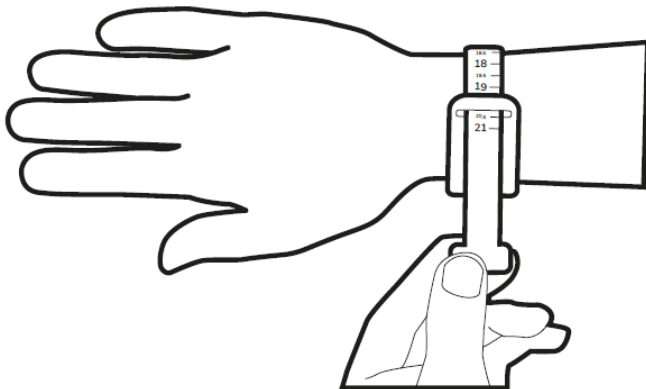
Measuring Wrist Size

Capturing an accurate measure of your patient’s wrist is important to ensure proper fit of the Cala kIQ™ band for nerve targeting and therapy delivery. Cala provides a tool to help measure the patient’s wrist size to input onto the prescription form (cm). A soft tape measure (tailor’s tape, sewing tape, or paper measuring tape) may also be used. Please see the suggested approach below:



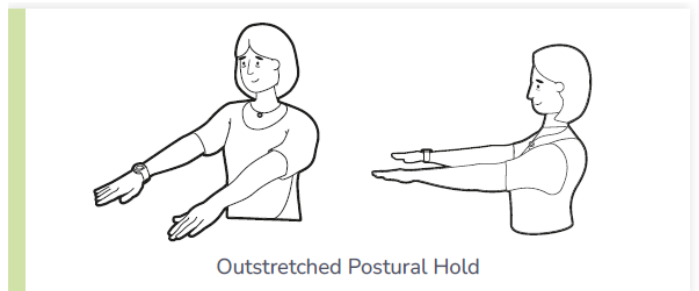
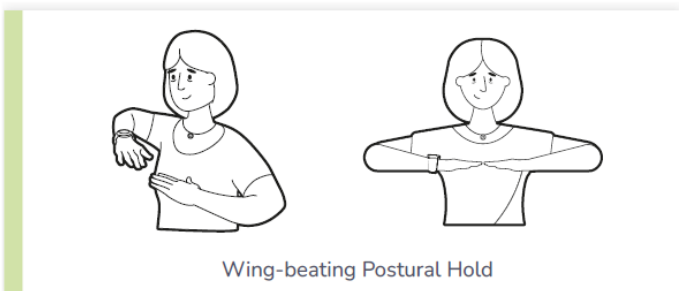
Position the measuring tool on the wrist as close to the hand as possible without impeding wrist movement. Should the patient have a prominent or protruding wrist bone, avoid measuring over it but rather measure proximal to the wrist bone.

Hold the measuring tool tight to the skin, but do not squeeze wrist. Measure where the top of the slit sits on the tool markings, (not where the end of the tool sits on the markings). Note the size in cm on the patient’s prescription form. Cala will use this to ship the correct size band to your patient.



Selecting a Tremor Task

The Cala kIQ System calibrates therapy to each patient’s unique tremor physiology based on a postural hold called a “tremor task”. It is important for the prescribing clinician to indicate on the prescription form which tremor task (**wing-beating or outstretched hold**) predominantly elicits the hand tremor.





VA Cala kIQ™ System Ordering Process for Prosthetics Department

Cala kIQ is a TAPS (Transcutaneous Afferent Patterned Stimulation) next generation FDA-cleared wearable neuromodulation therapy for action hand tremors.



1. VA Facility Set-Up as New Vendor



2. Provider sends consult to Prosthetics



3. Prosthetics Submits PO to Cala



4. Cala ships device to VA or Patient (*varies by VA)

1. New Vendor Set-Up. To be completed by Prosthetics department.

- Complete Form W-9 Cala and VA New Vendor Form with pre-filled Cala info.
- Refer to VA SOP Topic: *Non-Invasive Nerve Stimulation for Management of Tremor.*

2. Consult. Provider (neurologist, occupational therapist, etc) sends consult to Prosthetics.

- Consult includes prescribed hand, tremor task, and wrist measurement to be included with purchase order (PO).

3. Send Purchase Order to Cala. To be completed by Prosthetics department, and must include the following:

Patient Information:

- Name
- Address
- Date of Birth
- Phone Number
- Last 4 Digits of SSN
- Email

Diagnosis & Device Information:

- Patient Diagnosis
- Prescribed Hand
- Tremor Task
- Wrist Size
- Quantity

VA Information:

- Consulting Provider Name
- HCP Email
- VA Institution Name
- VA Credit Card

4. Product Shipment & Patient Training. Process varies by VA.

- VA indicates on PO if Cala should ship directly to the patient or to the VA.
- Cala Customer Care offers training to all patients.

For questions about pricing and POs, please call Cala Customer Care at (888-699-1009) Monday through Friday, 8 am – 7 pm Eastern, 5 am – 4 pm Pacific, or send an encrypted email: VA@CalaHealth.com.

We look forward to working together to provide the best possible care for your patient.

Cala kIQ is indicated to aid in the temporary relief of hand tremors in the treated hand following stimulation in adults with essential tremor. Cala kIQ is indicated to aid in the temporary relief of postural and kinetic hand tremor symptoms that impact some activities of daily living the treated hand following stimulation in adults with Parkinson’s Disease. Caution: Federal law restricts this device to sale by or on the order of a physician. Before use, refer to the product labeling for complete product instructions for use, contraindications, warnings, and precautions at CalaHealth.com/Safety.

Health Care Professional Line: 888-585-7101 | Cala Customer Care: 888-699-1009 | 1800 Gateway Drive | Suite 300 | San Mateo, CA | 94404

Copyright © 2019-2023, Cala Health, Inc. All Rights Reserved. Cala Health, Cala, and Cala kIQ are trademarks of Cala Health, Inc., registered or pending in the U.S. and other countries.



Cala Customer Care

VA Patient Intake and Agreement Form

Submit completed forms via:

Fax: 1-833-230-9251

Encrypted Email: VA@CalaHealth.com

Secure Upload: CalaRx.com

Cala Customer Care: 1-888-699-1009

1. VA Patient Information

First Name:		
Last Name:		
Date of Birth:	Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female	
Address:		
City:	State:	Zip:
Mobile Phone:	Home Phone:	
Email Address:		
Emergency Contact Name:		
Emergency Contact Phone:	Last 4 Digits Patient SSN:	
Prescribing Provider Name:		

2. VA Patient Authorization & Agreement

I acknowledge that I have been provided with the following notices by accessing the company website or in writing (upon request) and understand notices may be revised from time to time: **Notice of Privacy Practices (HIPAA), Returns and Warranty, and Therapy Terms of Use which include the Patient Bill of Rights and Responsibilities, and Complaint Process.**

I agree to all applicable terms outlined in this document's Patient Acknowledgment and Financial Responsibility sections.

I, or my representative, will promptly notify Cala if I stop using Cala TAPS therapy for any reason or am hospitalized for more than 30 days.

 VA Patient Signature:	Date:
---	-------

Personal representative: If the individual signing this form is not the patient, please print name and specify relationship to the patient; if Power of Attorney, please provide documentation.

Personal Representative:	Date:
--------------------------	-------

3. VA Patient Acknowledgements

- a. I authorize Cala and its staff to provide me with durable medical equipment prescribed by my healthcare professional (HCP). My HCP has explained the nature of this treatment, and I have received sufficient information about the appropriate and safe use of Cala TAPS Therapy to make an informed decision.
- b. I authorize the release to Cala of any medical records for payment purposes, including but not limited to processing insurance claims. I also authorize Cala to share my medical records for healthcare operations and treatment purposes, including but not limited to sharing Cala TAPS therapy data with my prescribing HCP.
- c. My HCP has screened me for the appropriateness of Cala TAPS Therapy. I understand that a full list of contraindications, warnings, and cautions can be found at <https://calahealth.com/terms/indications-for-use/>. I acknowledge either that I do not have any contraindications, or I do have contraindications and have discussed these contraindications with my HCP. I will alert my HCP if my health condition changes such that therapy use becomes contraindicated.
- d. Upon receipt of my device, I understand that training is available to me by a Cala Customer Care Representative. I shall contact Cala Customer Care at 888-699-1009 Monday-Friday from 8 am – 7 pm Eastern, 5 am – 4 pm Pacific to schedule a training appointment.
- e. I take full responsibility for the safe use and care of the Cala TAPS Therapy System (which includes the Cala Stimulator, Base Station, and Band). I will advise my HCP before discontinuing treatment or using the equipment. I shall not hold Cala responsible for any adverse consequences related to any misuse, failure to use, or discontinuation of the treatment. Cala maintains customer support by telephone at 888-699-1009 Monday-Friday from 8 am – 7 pm Eastern, 5 am – 4 pm Pacific. If a treatment reaction occurs when an HCP is absent or outside of Cala business hours, I will stop using the Cala TAPS Therapy System immediately and contact Cala Customer Care or my HCP before resuming use. If a life-threatening medical emergency arises, I will contact my local emergency services number, such as 911, for assistance.
- f. The VA contracts with Cala and the VA agrees to pay 100% of the cost associated with Cala TAPS Therapy. This does not include your healthcare provider's visit.
- g. **Results Not Guaranteed:** My HCP has prescribed Cala TAPS Therapy to deliver electrical stimulation to relieve hand tremor temporarily. I understand that this is not a cure for essential tremor. I also understand that individual patient results may vary, and no warranty or guarantee is made regarding my use of the Cala TAPS Therapy. I understand Cala TAPS therapy is intended for single patient use only and Cala Bands are provided with a minimum of an initial three-month supply that must be replaced.
- h. **Return of Device to Cala:** Within 90 days of receiving Cala TAPS Therapy, I may return all the components for any reason by contacting Cala Customer Care at 1-888-699-1009 Monday-Friday from 8 am - 7 pm Eastern, 5 am - 4 pm Pacific, and returning the equipment. The VA will be refunded on my behalf for returned product that complies with this policy.