THE MACLEAN GROUP LLC
Email: cala_orders@macleanhealth.com
Phone: (800) 683-4923 (option 8)
Fax: (916) 270-2142
FSS 65 II A: 36F78723D0201
UEI: DAM9QJJ7FTL4
CAGE CODE: 857V9
EIN: 83-1385452

VA Consult for Ordering Cala Products

Thank you for your interest in Cala TAPS® Therapy, a FDA-cleared wearable neuromodulation therapy for action hand tremors. Cala therapy 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.

To order Cala products for your patient, a consult to prosthetics and a patient intake form are required. Cala products are exclusively distributed by The Maclean Health Group LLC and are available on the Federal Supply Schedule (FSS).

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 Maclean Health at time of consult through one of the following channels:
  - Fax: 916-270-2142
  - Email: cala_orders@macleanhealth.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.

Unsure of product or size? Copy this line into the PO and we can help adjust the order as needed:
"Please order the most appropriate size and/or product based on the Veterans' previous orders and send written confirmation of any changes to the email referenced in the PO"

Prosthetics Agents - Contact Maclean Health: 800-683-4923 (option 8) or cala_orders@macleanhealth.com

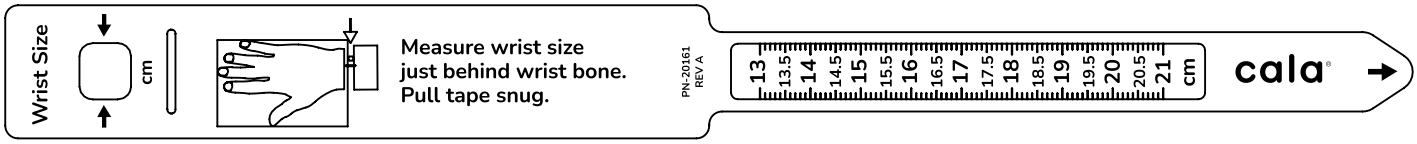
Health Care Professionals - Contact Cala Customer Care: 888-699-1009 or customercare@calahealth.com

Indications for Use: Cala kIQ Plus is indicated to aid in the temporary relief of hand tremors in the treated hand following stimulation in adults with essential tremor. Cala kIQ Plus 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.

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.

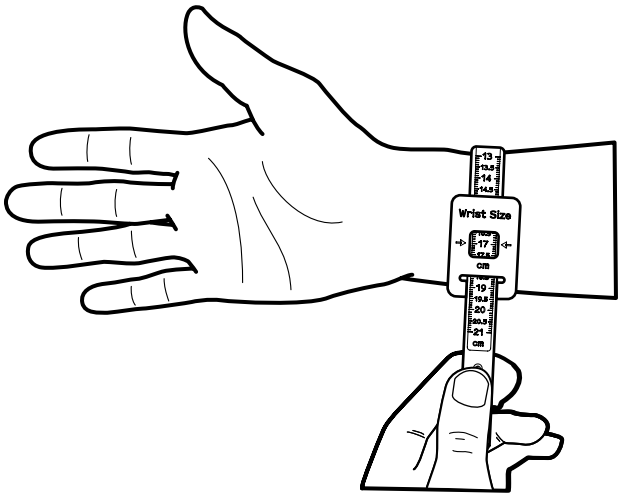
Measuring Wrist Size

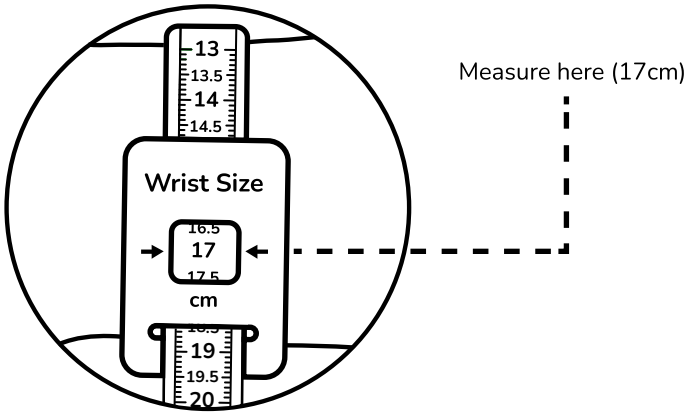
Capturing an accurate measure of your patient's wrist is important to ensure proper fit of the Cala band for nerve targeting and therapy delivery. Cala provides a tool to help measure the patient's wrist size to input onto the prescription form (cm). A soft tape measure (tailor's tape, sewing tape, or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



Position the measuring tool around the wrist. Measure wrist size just behind wrist bone. Pull tape snug. Hold the measuring tool tight but comfortable to the skin.

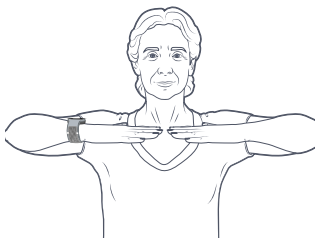
Note the measurement displayed in the window. If in between two measurements, capture the lower measurement. Note the size in cm on the patient's prescription form. Cala will use this to ship the correct size band to your patient.



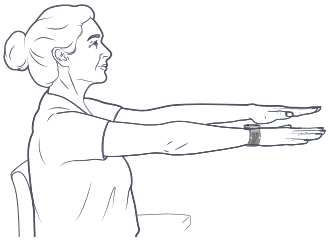


Selecting a Tremor Task

The Cala device 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.



Wing-beating Hold



Outstretched Postural Hold

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Cala Ordering Process for VA Prosthetics Department

Cala products are exclusively distributed by The Maclean Health Group LLC and are available on the Federal Supply Schedule (FSS).

1. Provider sends consult to Prosthetics

2. Prosthetics places order with Maclean Health

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

Order Process

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

- ☐ Consult includes prescribed hand, tremor task, and wrist measurement
- ☐ Patient Intake and Agreement Form

2. Send Order to Maclean Health. 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
  (in centimeters from consult notes)
- ☐ Quantity

VA Information:
- ☐ Consulting Provider Name
- ☐ HCP Email
- ☐ VA Institution Name
- ☐ VA Credit Card

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

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

Unsure of product or size? Copy this line into the PO and we can help adjust the order as needed:
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SD-20022 Rev A

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VA Patient Intake and Agreement Form

1. VA PATIENT INFORMATION

First Name:		
Last Name:		
Date of Birth:	Gender: ☐ Male ☐ 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, Supplier Standards, 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 understand that Maclean Health acts as the VA-authorized supplier of durable medical equipment and that Cala Health, Inc. is the manufacturer of Cala TAPS® Therapy and provides training, product support, and related services. By providing your mobile phone number, you consent to receive autodialed text messages at that number from Cala Health concerning the Cala System. Consent is not required to purchase any goods or services. Text STOP to cancel. Message and data rates may apply.

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 the provision of durable medical equipment prescribed by my healthcare professional (HCP), including the Cala TAPS Therapy manufactured by Cala Health, Inc., through a VA-authorized supplier. My HCP has explained the nature of this treatment, and I have received sufficient information about the Cala TAPS therapy to make an informed decision.

b. I authorize the release to Cala of any medical records for purposes related to Cala TAPS therapy, including treatment coordination, training, product support, quality, business operations, complaint handling, and safety monitoring. 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 contraindications include: having an implanted electrical medical device, such as a pacemaker, defibrillator, or deep brain stimulator; having suspected or diagnosed epilepsy or other seizure disorder; being pregnant; or having swollen, infected, inflamed areas, skin eruptions, open wounds, or cancerous lesions. 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 is becomes contraindicated.

d. My HCP has explained the nature of this treatment, and I have received information about Cala TAPS therapy and its appropriate and safe use. 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 Cala TAPS therapy (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 covers the cost of Cala TAPS therapy when provided in accordance with VA requirements through a VA-authorized supplier. 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.

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