

The Cala kIQ™ System Transcutaneous Afferent Patterned Stimulation (TAPS) Therapy

About the Cala kIQ™ System with TAPS Therapy

The Cala kIQ System with TAPS (Transcutaneous Afferent Patterned Stimulation) therapy is the only FDA-cleared, wearable device that delivers effective therapy for action hand tremor relief in people with essential tremor and Parkinson's disease. The TAPS device is physician-prescribed and clinically proven to safely and effectively reduce action hand tremors.



Nine out of 10 patients experience tremor reduction with a complete 40-minute session.¹

Some patients may begin to experience relief during their therapy session.²

Most maintain relief for over an hour after therapy.¹

How does Cala kIQ with TAPS Therapy work?

The brain is the control center for action hand tremors. The Cala kIQ device senses each patient's unique tremor signature and individualizes stimulation. TAPS therapy is delivered non-invasively through the nerves on the wrist to the brain to counteract tremor. Responses to therapy can be accessed securely at MyCala.com patient portal.

About Action Hand Tremors

The Cala kIQ System is for people with action tremor of the hand. Action tremor of the hand occurs when the hand shakes uncontrollably during activities – such as writing or drinking. It can also happen while your hands are holding a posture – such as outstretched in front of your body. It can deeply impact day-to-day life, making everyday activities difficult. Most people with action tremor of the hand have essential tremor (ET). Some people with Parkinson's disease (PD) may also have action tremor of the hand – although it is less common.

Often associated with PD, resting hand tremor is different from action hand tremor. In resting hand tremor, shaking occurs when hands are relaxed – resting on the lap for instance – not when moving or holding a posture.

An Unmet Need

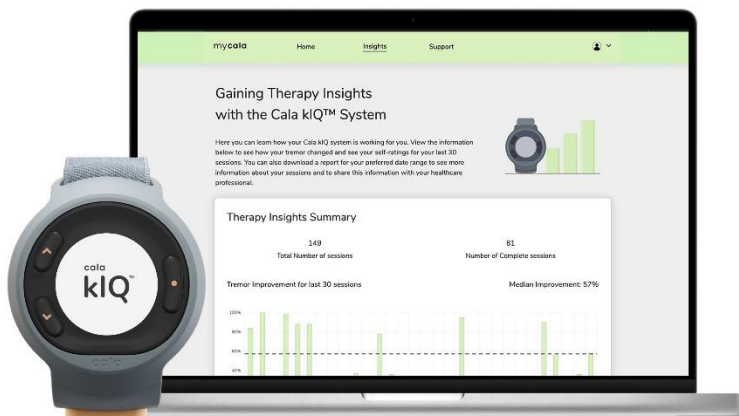
Over 7 million Americans struggle with action hand tremor. Drugs most used to treat ET include beta-blockers such as propranolol and an epilepsy drug called primidone. These help some people, but they can cause a range of undesirable side effects such as fatigue, nausea and depression. Some patients may be unable to use these medications due to contraindications with comorbidity. One study shows that 35% of people discontinue using drugs due to side effects or a lack of benefit.³ There are surgical options like Deep Brain Stimulation (DBS) or ablation, which can be effective, but are invasive procedures. Only 1 in 10 essential tremor patients are satisfied with their current treatment.⁴



Tremors can also impact mental health. They can discourage people from doing what they love. Clinical studies estimate 50% of ET patients suffer from social phobia, and 80% of ET patients suffer from depression that can severely impact quality of life.⁵

Cala kIQ System Features

The Cala kIQ System empowers clinicians and patients by providing an on-demand, comfortable, at-home therapy for ease of use and ease of management with objective data. Designed with patients in mind, the Cala kIQ System provides:



- A discreet wearable device
- An easy-to-read screen
- Comfortable dry electrode bands
- Simple magnetic charging base station
- Up to five therapy sessions daily on a full charge
- Access to the MyCala.com Patient Portal to see therapy results over time

Medicare may provide coverage for the Cala kIQ System if all eligibility requirements and documentation are satisfied. The Cala kIQ System is covered by the Veterans Affairs (VA) Health System at no cost to VA beneficiaries. Cala is working to secure additional coverage and reimbursement for the new breakthrough designated Parkinson's disease indication for the Cala kIQ System.

Indications for Use. The Cala kIQ device is indicated to aid in the temporary relief of hand tremors in the treated hand following stimulation in adults with essential tremor. The Cala kIQ device 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. Prior to use, refer to the product labeling for complete product instructions for use, contraindications, warnings, and precautions at <https://calahealth.com>.

1. Isaacson SH, et al. Prospective Home-use Study on Non-Invasive Neuromodulation Therapy for Essential Tremor. Tremor J. 2020;10:29. SD 138min; median 60min. As measured by Cala device following three months of repeated home use in 205 patients with essential tremor who completed the study. Many participants were also taking medication for their tremor and it was difficult to assess the effect of the device compared to medication.
2. Yu, J.Y., et al. Transcutaneous afferent patterned stimulation therapy reduces hand tremor for one hour in essential tremor patients. Frontiers in Neuroscience, 14. 2020.
3. Elias WJ, et al. N Engl J Med. 2016 Aug 25;375(8):730-9. doi: 10.1056/NEJMoa1600159
4. Louis ED, Rohl B, Rice C. Defining the Treatment Gap: What Essential Tremor Patients Want That They Are Not Getting. Tremor Other Hyperkinet Mov (N Y). 2015 Aug 14;5:331. doi: 10.7916/D87080M9. PMID: 26317044; PMCID: PMC4548969.
5. Smeltere L, Kuznetsov V, Erts R. Depression and social phobia in essential tremor and Parkinson's disease. Brain and Behavior, 2017



About Cala®

Cala Health is a bioelectronic medicine company transforming the standard of care for chronic disease. The company's wearable neuromodulation therapies merge innovations in neuroscience and technology to deliver individualized peripheral nerve stimulation, and its direct-to-home digital DME platform is reshaping the delivery of prescription therapies. Cala Health's products are the only FDA-cleared, clinically validated non-invasive devices for the relief of hand tremors so patients with essential tremor can return to the moments that matter. New therapies are under development in neurology, cardiology, and psychiatry. Founded in 2014, the company is headquartered in the San Francisco Bay Area and backed by leading investors in both healthcare and technology.

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