Cala TAPS® Therapy for essential tremor

TAPS therapy, delivered through the Cala kIQ® Plus device, is the first and only FDA-cleared, non-invasive treatment that delivers personalized stimulation at the wrist to provide tremor relief throughout the day for people with essential tremor (ET) and Parkinson's disease (PD).

The Cala kIQ Plus device is physician-prescribed and clinically proven to safely and effectively reduce action hand tremors.

The Cala kIQ Plus, the latest advancement in TAPS therapy, is the first and only wearable to offer multiple stimulation waveform modes, which users can choose and change at any time, and adaptive calibration to personalize therapy.

Nine out of 10 patients experience tremor reduction with a complete 40-minute therapy session.[3]

With each TAPS therapy session, patients experience a boost of tremor relief during and in the hours after use.[3,4]

TAPS therapy outperforms standard of care alone (e.g., medication) over one month of home use.[5]

With continued daily use of TAPS therapy, many patients experience gradual improvement in their underlying tremor.[3,6]

Patients have used TAPS therapy successfully for multiple years (3 years+) without habituation.[7]

How Cala TAPS Therapy Works

The brain is the control center for action hand tremors. The Cala device senses each patient's unique tremor signature and personalizes stimulation. TAPS therapy is delivered noninvasively through the nerves on the wrist to the brain to counteract tremor.

The mechanism of action of TAPS therapy is proven to directly act on the VIM (ventral intermediate nucleus) of thalamus and brain's tremor circuitry, the same location as deep brain stimulation (DBS),[1,2] as demonstrated through direct microelectrode recording and PET imaging studies

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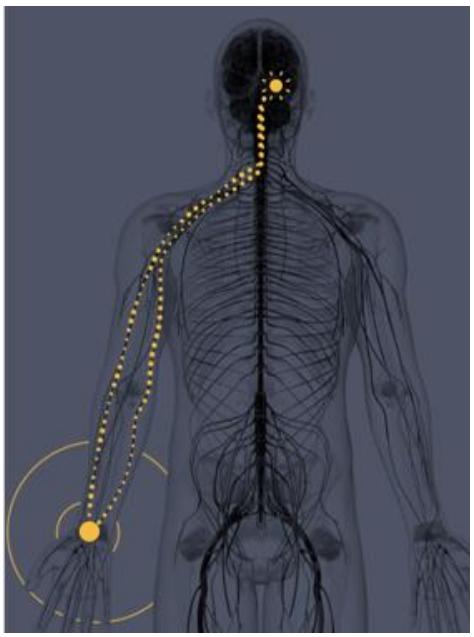
Addressing an Unmet Need for Action Hand Tremor

Action tremor of the hand occurs when the hand shakes uncontrollably during activities – such as eating, drinking, or writing. Hand tremor can deeply impact day-to-day life, making everyday activities difficult and isolating. Most people with action hand tremor have ET. Some people with PD may also have action hand tremor, although most often associated with PD is resting hand tremor. Tremors can also impact mental health, with nearly doubling in the rates of depression and anxiety in ET patients compared to non-ET patients (depression: 25.6% vs 15.3%; anxiety: 27.7% vs 15.5%).[9] Clinical studies also estimate that roughly 1/3 of ET patients suffer from social phobia.[10]

Many Americans struggle with action hand tremor and have insufficient treatment options that are non-specific for their condition and often cause unwanted side effects. Drugs most used to treat ET include beta-blockers such as propranolol and an epilepsy drug called primidone. Many patients cannot tolerate these drugs because they can cause a range of undesirable side effects such as fatigue, nausea and depression. Patients may also be unable to use these medications due to contraindications with comorbidity. More than 2/3 of patients discontinue propranolol due to side effects or lack of benefit, and 41% of patients discontinue primidone for these reasons.[8]

There are surgical options like DBS or MR guided focused ultrasound (ablation), which can be effective, but are invasive and irreversible procedures.



Cala TAPS therapy fills the treatment gap between medications and invasive surgical procedures, with a non-invasive wrist-worn wearable device that is clinically proven to reduce tremors.

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The Cala kIQ® Plus Device is comprised of the following:

Stimulator
Controls and feedback are on the device. No app required

Band
Comfortable to wear all day.

Base Station
Convenient base station for charging.

Patient Portal
Users see insights and track progress.

The Cala kIQ Plus device features the most advanced TAPS® technology, designed to optimize tremor relief and provide on-demand, comfortable, and personalized therapy.

Designed with patients in mind, the Cala kIQ Plus includes:

- **Multiple therapy modes:** Three stimulation modes: A, B, and C. Users can easily select or switch modes at any time to discover what works best for them. In a clinical study, allowing patients to choose their preferred waveform significantly increased overall treatment efficacy compared to using the traditional waveform alone.
- **Adaptive calibration:** Personalizes therapy by calibrating before each session when the user initiates therapy, capturing and adjusting to their unique tremor fluctuations throughout the day.
- **Dynamic intensity:** Remembers the user's last-used intensity and sets subsequent therapy sessions to adjust to changing preference and needs.
- **More intuitive experience:** To enhance accessibility and ease of use, the device comes fully assembled in easy-to-open packaging, and on-device controls simplify getting started on therapy. No app is required.
- **Designed for all-day comfort:** A high-contrast, E-ink screen in a discreet design gives users flexibility to wear the device all day and use it as a watch. No sticky gel adhesives are required, and therapy sessions can be performed as many times a day as needed.
- **Easy management:** The MyCala patient portal provides users insights into their usage, making it easy to share information with their healthcare provider.

Access and Coverage

Cala TAPS Therapy is available by the Veterans Affairs (VA) Health System at no cost to eligible VA beneficiaries and has Medicare coverage for those who meet Local Coverage Criteria.

Please refer to the Medicare Local Coverage Determination (LCD) criteria (L39591) for specific documentation requirements.
https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=39591&ver=11

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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 durable medical equipment (DME) platform is reshaping the delivery of prescription therapies.

Clinical Evidence Supporting Use of TAPS in Patients with Essential Tremor

TAPS therapy is the most researched wearable treatment for essential tremor, with over 2,000 patients studied across multiple publications.

RECENT CLINICAL PUBLICATIONS

With continued daily use of Cala TAPS™ therapy, many patients experience gradual improvement in their underlying tremor (without needing all-day stimulation)[6]

This was a retrospective analysis of the PROSPECT study, evaluating underlying tremor improvement with twice-daily TAPS using pre-stimulation tremor assessments at enrollment versus month 1 and 3 (N = 192).[3] Pre-stimulation BF-ADL (Bain & Findley Activities of Daily Living) significantly improved by 2.0 points at month 1 and 2.7 points at month 3. Over 80% of patients showed underlying tremor improvement at months 1 and 3, based on a 1-point improvement in a BF-ADL task rated ≥3 at baseline.

https://doi.org/10.5334/tohm.1091

TAPS mechanism of action is proven to directly act on the VIM of thalamus and brain's tremor circuitry, the same location as deep brain stimulation, as demonstrated through direct microelectrode recording[2]

The magnitude of TAPS-related tremor reduction was positively correlated with modulation of alpha and beta-band Local Field Potentials (LFP) in the VIM.

https://doi.org/10.1016/j.brs.2025.06.004

A large real-world evidence (RWE) analysis published in 2023 found that patients using TAPS therapy achieved consistent relief over multiple years of use.[7] This study, which expanded on an earlier RWE analysis,[11] examined the real-world application of TAPS therapy by analyzing usage (N=1,223) and effectiveness data (N=808 of 1,223) collected from device logs and voluntary patient survey. Consistent with previous findings, the study found TAPS therapy effectively reduced tremor showing an average reduction in tremor power of 64%. Further, the study suggested no habituation over long-term use (up to 3.4 years). https://www.doi.org/10.5334/tohm.775

A randomized pragmatic trial published by CVS Health in 2023 found that adding TAPS therapy to standard of care (SOC) improved tremor and functional burden over SOC alone.[5] This study enrolled 310 patients recruited from the database of a large health insurer (AETNA) and is the largest prospective study run in essential tremor to-date. The study demonstrated significant improvements over one month in tremor power and Bain & Findley Activities of Daily Living (BF-ADL) scores for TAPS over SOC alone. https://www.doi.org/10.5334/tohm.798

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A secondary analysis of previously published studies assessed TAPS response in patients with high unmet need and patients who observed benefit from TAPS therapy during their first month of use.[12] The study found significant improvement over sham in the high unmet need subgroup of a randomized controlled study (N= 47) and significant improvements over multiple months of use in the high unmet need (N = 138) and early responder cohort (N = 51). https://doi.org/10.1080/17434440.2023.2274604

SELECT HIGHLIGHTS OF PRIOR PUBLICATIONS

Two acute randomized clinical trials demonstrated that TAPS improved tremor significantly more than sham.[13,14] These studies enrolled 23 and 93 patients, respectively.
https://doi.org/10.1002/mds.27350

https://doi.org/10.1111/ner.12930

A longitudinal study ('PROSPECT') assessed the safety and efficacy of twice-daily, home-use TAPS in 263 patients seen at 26 sites.[3] At the time, this was the largest study ever run in essential tremor. Significant improvements in tremor were observed across clinician-rated, patient-rated, and motion sensor-based measurements. https://www.doi.org/10.5334/tohm.59

A follow-on study validated patients' observation that tremor relief last for more than an hour after TAPS.[4] Patients reported this in PROSPECT (see above), and it was validated with an in-clinic study evaluating increments of tremor relief in 15 patients. https://doi.org/10.3389/fnins.2020.530300

A follow-on mechanism-of-action study of TAPS evaluated metabolic changes in the brain using Positron Emission Tomography (PET) imaging.[1] Similar to PROSPECT, patients used therapy twice-daily for 3 months. The study demonstrated metabolic changes in the tremor network that were correlated to clinical ratings of tremor improvement. https://www.doi.org/10.5334/tohm.565

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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.

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