Available by Rx only

Now, a pioneering neuromodulation therapy for pediatric ADHD that works at night

INTRODUCING

Monarch eTNS® System

by NeuroSigma

external Trigeminal Nerve Stimulation for Attention Deficit Hyperactivity Disorder

www.monarch-etns.com

A safe and effective non-medication treatment for children ages 7 to 12 years[1,2]

The symptoms of Attention Deficit Hyperactivity Disorder (ADHD) take a toll on family life, and a diagnosis can be unwelcome for many parents of children with ADHD. Aside from perceived stigmas associated with the condition, parents may balk at the idea of psychotropic medication for their children.

Now there's another choice you can offer parents: a noninvasive neuromodulation treatment device based on research funded by the National Institute of Mental Health (NIMH).

Monarch eTNS® System: Proven effective

The Monarch eTNS System is the first FDA-cleared device for ADHD with proven efficacy in alleviating ADHD symptoms. This non-medication, minimal-risk monotherapy is used by parents or caregivers for at-home treatment of children ages 7 to 12 years old who are not currently taking prescription medication for ADHD.

Indications and Important Safety Information

The Monarch external Trigeminal Nerve Stimulation (eTNS) System is indicated for treatment of pediatric Attention Deficit Hyperactivity Disorder (ADHD) as a monotherapy in patients ages 7 through 12 years old who are not currently taking prescription ADHD medications. The device is to be used for patient treatment by prescription only and is intended to be used in the home under the supervision of a caregiver during periods of sleep.

Contraindications: The Monarch eTNS System should not be used by patients with implanted cardiac and/or neurostimulation systems, or an implanted metallic or electronic device in their head. Please refer to the instructions for use for the full list of contraindications, warnings, precautions and other safety information, which is available at **www.monarch-eTNS.com/safety**.

A neuromodulation device to improve ADHD symptoms in children aged 7-12 years

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Therapy backed by neuroscience

The Monarch eTNS® System targets the neurologic underpinnings that lead to ADHD, helping to regulate brain areas linked to ADHD symptoms via the trigeminal nerve. This high bandwidth pathway to the brain stem and prefrontal cortex is tied to a key brain region associated with attention, mood, anxiety, and executive control of behavior. By using mild stimulating pulses delivered to nerve branches through the skin of the forehead, the Monarch eTNS System increases neuronal activity in these brain areas and decreases excitability. Neuroimaging and EEG studies have documented these effects.

A non-medication prescription monotherapy designed for bedtime use overnight

The Monarch eTNS System:

- A cell phone-sized device that connects to a disposable adhesive patch that is placed on the child's forehead at bedtime
- The device sends low stimulating pulses to the trigeminal nerve through the patch overnight
- The pulsing effects are mild and typically not intrusive, and children have described the stimulation as a tingling sensation on the skin
- The device is intended to be used under the supervision of a caregiver during periods of sleep
- In the morning, when the child wakes up, the patch is removed

The Monarch eTNS System is convenient and easy for parents to use. Because it is a non-medication option, the device meets the needs of parents and caregivers who have fears about jumping right to psychotropic medications. Clinical trials suggest that a response to eTNS may take up to 4 weeks to become noticeable.

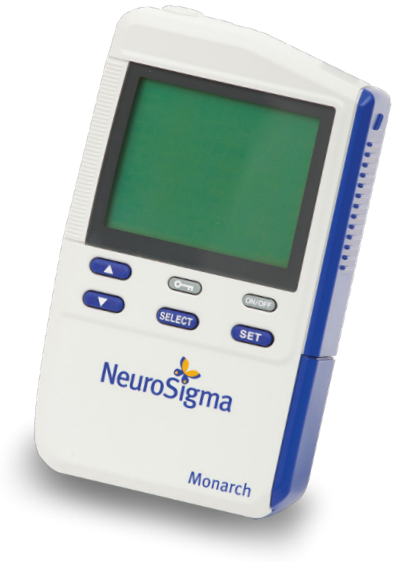
Important Safety Information (continued)

Warnings: Children 7 to 12 years receiving eTNS treatment should be closely supervised by an adult who has read the user manual and is familiar with the Monarch eTNS System.

The Monarch eTNS System should:

- Only be used by the individual for whom it is intended
- Only be used with the guidance of a licensed physician
- Be used with caution in patients with heart disease or serious medical disorders
- Be kept out of the reach of infants and children under the age of 7 years
- Be used only as directed and be applied to healthy, clean, intact skin
- Not be used with other electronic therapeutic devices
- Not be applied on the neck or chest
- Not be used in the presence of electric monitoring equipment (e.g. cardiac monitors)
- Not be used in the bath or shower
- Not be used while operating machinery

Device performance established in 2 clinical trials[1,2]



Efficacy and tolerability were first described in an **8-week open-label, pilot study** of eTNS treatment of 24 children diagnosed with ADHD aged 7-14 years.[1] Participants were assessed weekly with parent- and physician-completed measures of ADHD symptoms and executive functioning as well as treatment compliance, adverse events, and side effects.

After 4 weeks of nightly use, 64% of the study group were rated "improved" or "very much improved" on the Clinical Global Impression–Improvement scale (CGI-I), and after 8 weeks, 71% had achieved that rating. ADHD Rating Scale IV (ADHD-RS-IV) scores showed a 47% decrease. Compliance was 100%, and no child withdrew from the study due to adverse events.[1] Results were published in the peer-reviewed medical journal *Brain Stimulation* in 2015.

After 4 weeks of nightly use:

64% of the children were rated as "improved" or "improved very much" on the CGI-I rating scale

After 8 weeks of nightly use:

71% were rated as "improved" or "improved very much"

Study 2 was the first **double-blind, randomized, sham-controlled trial** of eTNS as monotherapy for children with ADHD.[2] This was a **4-week trial** of 62 children ages 8-12 years with an open label extension; efficacy was assessed by improvements on the ADHD-RS-IV rating scale. Significant improvements in ADHD-RS scores were seen in the active treatment group at the end of 4 weeks compared to sham. The trial also found significant changes in quantitative electroencephalogram (EEG) recordings among children in the active treatment group compared to those in the sham treatment group. After treatment was stopped, the ADHD-RS scores worsened in both groups, but remained lower in the active treatment group.[2] Results were published in the *Journal of the American Academy of Child and Adolescent Psychiatry* in 2019.

A low-risk treatment option

The most common side effects observed with eTNS use include drowsiness, an increase in appetite, trouble sleeping, teeth clenching, headache, and fatigue. No serious adverse events have been associated with use of the device. For full safety information, please consult the instructions for use.

More information on the Monarch eTNS clinical studies is available on the company's website www.neurosigma.com/journal-articles.html and in the device user manual.

Important Safety Information (continued)

The Monarch electric patches should not be used in patients with dermatitis or sensitive skin, as they are at higher risk of developing irritation, or be removed carelessly as this may damage the skin.

The Monarch lead wires should not be allowed to wrap around the neck.

Do not attach the electric patches:

- Anywhere on the body other than the forehead
- On the neck
- On the chest
- Over a defect in the skull (i.e. post brain surgery)

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external Trigeminal Nerve Stimulation for
Attention Deficit Hyperactivity Disorder

Now, for children ages 7-12 years with ADHD who are not on medication

An FDA-cleared treatment device that works at night

The Monarch eTNS® System is available to physicians and patients through the Monarch Pediatric Care Program

If you have a patient who you think would be appropriate for the Monarch eTNS System, and are interested in participating in the Monarch Pediatric Care Program, scan this convenient QR code to obtain an enrollment form and fill it out. You will be contacted by a representative of the Monarch Pediatric Care Program to discuss next steps.

SCAN TO GET YOUR ORDER FORM

The Monarch Pediatric Care Program will contact the parent's insurance company to determine coverage and work with you on any prior authorizations needed. The Care Program team of patient support advocates will work with parents to navigate the complex insurance environment and assist in finding a fulfillment partner. Care Program team members can also assist in determining the best purchasing options for the family's budget.

For additional assistance, contact the Monarch Pediatric Care Program at 877-765-7660

Find out today about this innovative, low-risk, non-medication option for treating children with ADHD

Learn more at **www.monarch-etns.com**

NeuroSigma

NeuroSigma, Inc.
10960 Wilshire Boulevard
Suite 1910
Los Angeles, CA 90024
Phone: (310) 479-3100

References: 1. McGough JJ, Loo SK, Sturm A, et al. An eight-week, open-label pilot feasibility study of trigeminal nerve stimulation in youth with attention-deficit/hyperactivity disorder. *Brain Stimulation.* 2015;8:299-304. **2.** McGough JJ, Sturm A, Cowen J, et al. Double-blind, sham-controlled, pilot study of trigeminal nerve stimulation for attention-deficit/hyperactivity disorder. *J Am Acad Child Adolesc Psychiatry.* 2019;58(4):403-411.