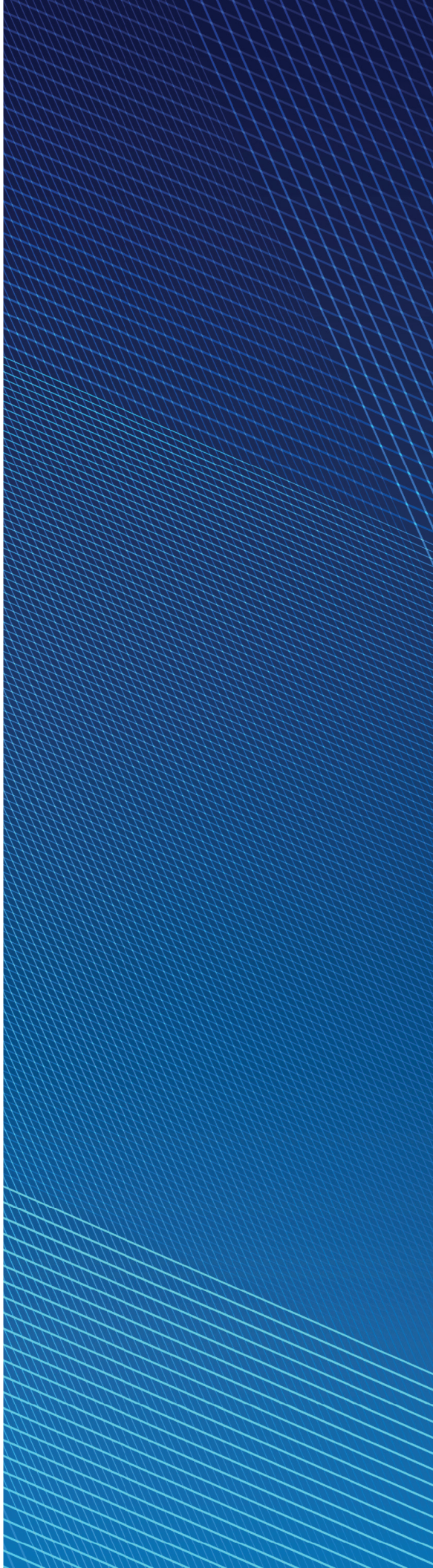
FROST & SULLIVAN

NEUROMOD DEVICES RECEIVES THE 2023 NEW PRODUCT INNOVATION AWARD

Identified as best in class in the North American neuromodulation devices for tinnitus industry



Best Practices Criteria for World-Class Performance

Frost & Sullivan applies a rigorous analytical process to evaluate multiple nominees for each Award category before determining the final Award recipient. The process involves a detailed evaluation of best practices criteria across two dimensions for each nominated company. Neuromod Devices excels in many of the criteria in the neuromodulation devices for tinnitus space.

The Silent Burden of Tinnitus

Tinnitus is a complex neurological condition characterized by the perception of sound in the absence of external stimuli. It affects nearly 300 million individuals globally, with 25 million cases recorded in the United States (US) alone[1]. Tinnitus is the most prevalent and rapidly expanding service-related disability in the US, for which the US Veterans Administration compensated 2.7 million veterans in 2022[2]. Treatment options include pharmacotherapy, education, counseling, and cognitive behavioral and sound therapy.

According to the World Health Organization, neurological conditions contribute to 6.3% of the global disease burden[3]. In the US, for clinic sessions alone, tinnitus treatment costs $660 per patient per year[4]. Consequently, there is a growing recognition of the necessity for sustainable solutions that improve treatment efficacy and alleviate symptoms over the long term. Within this framework, Neuromod Devices uniquely leverages its technology to meet tinnitus patients' needs, positioning itself to capitalize on new growth opportunities and cementing its pioneering leadership.

[1] "Tinnitus," National Institute on Deafness and Other Communication Disorders (NIH, February 2017)
[2] Ibid.
[3] *Global Deep Brain Stimulation Growth Opportunities* (Frost & Sullivan, April 2022)
[4] Goldstein E., Ho C.X., Hanna R., Elinger C., Yaremchuk K.L., Seidman M.D., Jesse M.T. Cost of care for subjective tinnitus in relation to patient satisfaction. Otolaryngol. Head Neck Surg. 2015;152:518–523. doi: 10.1177/0194599814566179

Neuromod Devices: A Game-changing Solution

Founded in 2010 and headquartered in Dublin, Ireland, Neuromod Devices (Neuromod) is a medical technology company specializing in designing and developing bimodal neuromodulation technologies to cater to the clinical requirements of patients with persistent tinnitus.

Neuromod's corporate culture revolves around using purpose to drive innovation. Its device roadmap, i.e., planning, development, and implementation strategies, incorporates customer feedback, ensuring that its offerings clearly align with patients' dynamic needs. As a result, Frost & Sullivan recognizes how the company's device, Lenire®, takes tinnitus treatment one step further than any competing solution.

Setting New Standards: A Breakthrough Treatment Device For Tinnitus

Neuromod's flagship product, the Lenire® Tinnitus Treatment Device, uses neuromodulation to modify nerve activity by providing a stimulus to ease chronic symptoms of this disease. Additionally, the company has conducted extensive clinical trials to validate the non-invasive bimodal neuromodulation device effectiveness. Lenire® received De Novo clearance from the US Food and Drug Administration (FDA) for treating tinnitus and has European CE-mark certification. It is accessible across Europe, the US, and Ireland.

Lenire® combines acoustic and electrical intraoral stimulation. Researchers found that the bimodal neuromodulation technology induces positive neuroplasticity more effectively than the stimulation of a single input. This is crucial in mitigating tinnitus symptoms, as the mechanism counters the deleterious neuroplasticity that gives rise to tinnitus in the first instance.

Lenire® Tinnitus Treatment Device

Courtesy of Neuromod Devices

Lenire® comprises Bluetooth headphones playing custom sounds to the ear to activate the auditory nerve and a Tonguetip®, a proprietary intraoral device triggering nerves via mild electrical stimulation to the tongue's surface[5]. Playing custom treatment sounds and performing smooth tongue stimulation reduces patients' tinnitus severity in a non-invasive way. Overall, Lenire® has three main components:

- **The Controller:** A lightweight handheld device that enables users to manage the timing and intensity of the treatment. It allows initiating, pausing, and resuming treatment sessions, along with regulating sound volume and tongue stimulation levels.
- **The Tonguetip®:** The ergonomically designed proprietary intra-oral device sits comfortably in the closed mouth and delivers mild and safe energy pulses to the surface of the tip of the tongue via tiny electrodes.
- **Bluetooth Headphones:** These headphones pair with the controller and deliver personalized sounds that activate the auditory nerve, transmitting signals to the brain.

[5] FDA Grants Lenire® Tinnitus Treatment Device De Novo Approval (Lenire press release, March 2023)

As an ISO 13485-accredited medical device manufacturer,[6] Neuromod consistently demonstrates its ability to provide medical devices and related services that meet customer and applicable regulatory requirements.

Steps Taken to Ensure Quality and Reliability

Neuromod collaborates with opinion-leading scientists to conduct large-scale exploratory and confirmatory trials, building clinical evidence for its interventions at internationally recognized sites. For example, the FDA approved Lenire® based on its robust results in the 112-patient pivotal TENT-A3 clinical trial and confirmatory real-world evidence (RWE) from 204 patients[7].

TENT-A3's primary endpoint analysis revealed that moderate, severe, and catastrophic tinnitus patients (as defined by the Tinnitus Handicap Inventory) achieved meaningful improvement following the bimodal treatment phase of the trial. Neuromod's analysis showed that this patient group was more likely to significantly improve clinically using Lenire's bimodal sound and tongue stimulation than sound therapy alone - all with zero adverse events linked to Lenire®. Moreover, these efficacy, compliance, and safety findings were consistent with the RWE from 204 patients in its De Novo submission.

> *"After the treatment ended, 91% of trial participants who used Lenire® as directed reported a sustained reduction in symptoms for 12 months. Furthermore, 95% of trial participants sensed improved tinnitus symptom severity after 12 weeks of treatment. Lenire® was more effective overall than sound therapy, one of the current clinical treatment standards."*
>
> ***- Manuel Albornoz***
> ***Best Practices Research Analyst***

After the treatment ended, 91% of trial participants who used Lenire® as directed reported a sustained reduction in symptoms for 12 months. Furthermore, 95% of TENT-A2 trial participants sensed improved tinnitus symptom severity after 12 weeks of treatment. The majority of TENT-A3 participants with moderate or worse tinnitus had significant relief using Lenire when audio-only had no meaningful impact[8]. Lenire® was more effective overall than sound therapy, one of the current clinical treatment standards.

The FDA's recent approval is a significant milestone for the company and represents a breakthrough for the millions of Americans currently suffering from tinnitus. It underscores Neuromod's unwavering commitment to investing in cutting-edge research and development over the past decade. The new and purpose-built Lenire® clearly sets it apart, with superior design, reliability, and quality as its central pillars.

A Customer-centric Approach Delivering Targeted Therapies

Neuromod goes beyond its extensive expertise and best-in-class capabilities, with customer value as a strategic imperative. The company earns a sterling reputation by working closely with patients to create breakthrough treatments for under-served chronic conditions.

Within its monthly grand rounds, Neuromod speaks to its partners about unique cases and best practices, actively listening to their demands and needs. Over 600 tinnitus volunteers have participated in three

[6] Neuromod's Quality System Certificate ISO 13485: 2016 (Neuromod Devices webpage: https://www.neuromoddevices.com/quality)
[7] FDA Grants Lenire® Tinnitus Treatment Device De Novo Approval (Lenire press release, March 2023)
[8] "TENT-A1 and TENT-A2 Clinical Trials were not included in Lenire's De Novo FDA Approval Grant process" (Neuromod Devices webpage: https://www.neuromoddevices.com/tenta2)

clinical trials using its non-invasive bimodal neuromodulation treatment device for tinnitus, and the results are nothing short of remarkable.

For instance, 79.4% of patients experienced a clinically significant improvement, 82.4% were compliant with the bimodal treatment, and 88.6% would recommend Lenire® over other treatment options[9]. Additionally, the company successfully replicated these results in the RWE field, where over 80% of clinical trial participants recommended Lenire® as an effective treatment for tinnitus[10].

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European citizens can access Lenire through Neuromod Device's tinnitus care clinic, Òtologie, or Neuromod Device's expansive Partner Provider Clinics across Europe. Patients can book online tinnitus assessments where audiologists will learn more about the nature and severity of their tinnitus. After evaluation, these experts formulate a personalized treatment plan for the patients.

Through a dedicated team of client success experts, the company provides exceptional customer service and works towards gathering several data points through its partners and clinic in Dublin. It destines these efforts to obtain direct and indirect product performance and quality feedback, striving to address needs as they arise. Neuromod will soon launch additional communication channels for in-depth clinical feedback[11].

On top of the clinical trial result data, the company fills its website with video testimonials, written testimonials, and case studies that signify the real benefits of the solution in patients' lives. It created an unparalleled offer by intelligently combining the high quantitative effectiveness element of the device with its individual and subjective success:

"Before the trial started on a tinnitus pain scale of 1-10, I was a 10-10. After the sixth week of the trial, I was down to around 3-10. Lenire® Tinnitus Treatment Device made a huge impact on my life. [12]*"*

-Niall, Clinical Trial Participant

"I woke up on a Sunday morning and realized my tinnitus was gone, and it never came back. [13]*"*

-Patricia, Clinical Trial Participant

[9] FDA Grants Lenire® Tinnitus Treatment Device De Novo Approval (Lenire press release, March 2023)
[10] Frost & Sullivan Interview with Neuromod Devices (Frost & Sullivan, March 2023)
[11] Ibid.
[12] Patient Stories (Neuromod Devices webpage: www.neuromoddevices.com/stories)
[13] Ibid.

A Promising Outlook for 2023 and Beyond

Since the release of the FDA approval and its latest clinical trial results to the press, Neuromod has generated a steady demand in the US, as its Lenire® Tinnitus Treatment Device addresses an unmet need that affects millions of Americans. Hence, the company is partnering with first-class audiologists to grow its best practices and capabilities in the country. Ensuring top-notch support, it will organically develop from its starting 20 to 30 high-quality locations[14].

The American veteran community is a vital point of contact for Neuromod to engage and learn the best ways to treat specific populations and target audiences inside the tinnitus community. By leveraging these insights, Lenire® can enter solidly into its intensive technological development phase, ensuring the highest standard of care and improving the lives of those suffering from this debilitating condition.

With its CE marking across European countries and the coveted FDA approval, the company has solidified its position as a global leader in tinnitus treatment. The award of an FDA De Novo Grant has caused a surge in demand in the United States and has further underlined the credibility and reputation of Neuromod Devices and Lenire in Europe. Over and above, Neuromod will strengthen its collaboration with groups supporting tinnitus to lessen the silent burden it places on those who experience it and destigmatize it in the conversation. The company is also working on copayments and reimbursement options (especially in Europe).

In 2023, Neuromod Devices secured a financing round of €30 million ($33m), spearheaded by Panakès Partners and including the European Investment Bank and existing investor Fountain Healthcare Partners[15]. This sizable investment demonstrates the confidence in Neuromod Device's revolutionary tinnitus treatment device.

Frost & Sullivan believes Neuromod is well-positioned to drive the tinnitus treatment space into its next growth phase, capturing market share and sustaining its leadership in the coming years.

[14] Frost & Sullivan Interview with Neuromod Devices (Frost & Sullivan, March 2023)
[15] "Neuromod closes €30m financing for tinnitus treatment device" (Neuromod Press release)

Conclusion

To create a new solution, a company needs to understand the market's needs and deliver a solid solution designed and embedded with high-quality and reliable performance. Frost & Sullivan finds that Neuromod Devices (Neuromod) embodies this concept.

Neuromod's flagship product, the Lenire® Tinnitus Treatment Device, offers a non-invasive solution for reducing tinnitus severity. Lenire® combines custom treatment sounds and smooth tongue stimulation to relieve patients without invasive procedures or adverse events. Neuromod Devices is certified to ISO 13485. Its non-invasive bimodal neuromodulation device, Lenre, has shown efficacy and a high success rate. Approximately 91% of Neuromod's compliant TENT-A2 trial participants reported a sustained reduction in tinnitus up to 12 months after the treatment ended.

Additionally, 95% of complaint TENT-A2 trial participants experienced an improvement in tinnitus severity after 12 weeks of treatment. The majority of TENT-A3 participants with moderate or worse tinnitus had significant relief using Lenire when audio-only had no meaningful impact. Above and beyond, besides our belief that Neuromod Device's Lenire sets a new standard of care for tinnitus patients, the company integrates a customer-centric approach to ensure that its offering addresses the wants and needs of users. With its strong overall performance, Neuromod earns the 2023 Frost & Sullivan New Product Innovation Award.

What You Need to Know about the New Product Innovation Recognition

Frost & Sullivan's New Product Innovation Award recognizes the company that offers a new product or solution that uniquely addresses key customer challenges.

Best Practices Award Analysis

For the New Product Innovation Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

New Product Attributes

Match to Needs: Customer needs directly influence and inspire product design and positioning

Reliability: Product consistently meets or exceeds customer performance expectations

Quality: Product offers best-in-class quality with a full complement of features and functionality

Positioning: Product serves a unique, unmet need that competitors cannot easily replicate

Design: Product features an innovative design that enhances both visual appeal and ease of use

Customer Impact

Price/Performance Value: Products or services provide the best value for the price compared to similar market offerings

Customer Purchase Experience: Quality of the purchase experience assures customers that they are buying the optimal solution for addressing their unique needs and constraints

Customer Ownership Experience: Customers proudly own the company's product or service and have a positive experience throughout the life of the product or service

Customer Service Experience: Customer service is accessible, fast, stress-free, and high quality

Brand Equity: Customers perceive the brand positively and exhibit high brand loyalty

About Frost & Sullivan

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The Growth Pipeline Engine™

Frost & Sullivan's proprietary model to systematically create ongoing growth opportunities and strategies for our clients is fuelled by the Innovation Generator™.
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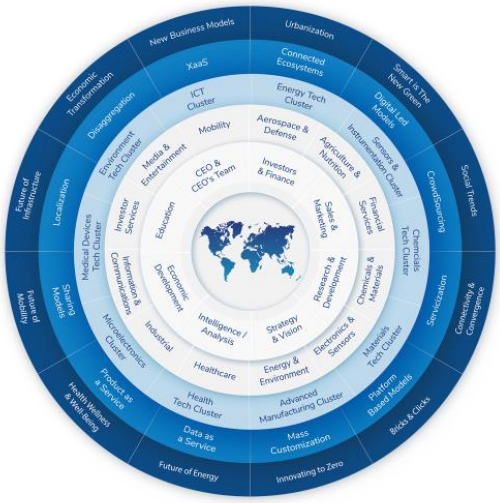
Key Impacts:

- **Growth Pipeline:** *Continuous Flow of Growth Opportunities*
- **Growth Strategies:** *Proven Best Practices*
- **Innovation Culture:** *Optimized Customer Experience*
- **ROI & Margin:** *Implementation Excellence*
- **Transformational Growth:** *Industry Leadership*

The Innovation Generator™

Our 6 analytical perspectives are crucial in capturing the broadest range of innovative growth opportunities, most of which occur at the points of these perspectives.



Analytical Perspectives:

- **Mega Trend (MT)**
- **Business Model (BM)**
- **Technology (TE)**
- **Industries (IN)**
- **Customer (CU)**
- **Geographies (GE)**