Treatment of tinnitus with a customized, dynamic acoustic neural stimulus: underlying principles and clinical efficacy

Objectives: The purpose of this article was to:
1. Describe the underlying principles behind the Neuromonics Tinnitus Treatment approach.
2. Summarize the evidence for clinical efficacy based on data obtained from controlled clinical studies and a private practice clinical setting.

Overview of tinnitus pathogenesis: Tinnitus is heterogeneous in nature, making it difficult to understand its initial causes, progression, symptoms, and effects on different patients. However, development of the condition typically involves neuroplastic changes in the auditory, attentional and emotional processes within the brain. See Figure 1 for an overview of the processes involved in the development of clinically significant tinnitus.

Auditory processes. Functional studies have shown that auditory deprivation causes the auditory system to become more active and more sensitive to sound. Following peripheral hearing loss or damage, changes take place in the activity levels of auditory nerves. The auditory cortex subsequently receives more and/or different neural input, which it may then interpret as ringing or buzzing sounds.

Attentional processes. In patients with clinically significant tinnitus, perceptual filters that work on all the senses determine that attention should be applied to the specific patterns of neural activity associated with the tinnitus. This brings the tinnitus constantly to the patient’s conscious attention.

Emotional processes. The limbic system and the autonomic nervous system are involved in the control and expression of emotional states. In patients with clinically significant tinnitus, these systems become engaged in response to the awareness of tinnitus. This can lead to a stressful state of high arousal and anxiety in response to the tinnitus awareness, and have a significant effect on the patient’s quality of life and general well-being.

Neuromonics Tinnitus Treatment: The Neuromonics Tinnitus Treatment was designed to simultaneously address the auditory, attentional, and emotional aspects that contribute to clinically significant tinnitus. The Neuromonics Tinnitus Treatment combines the use of an acoustic stimulus with a structured program of counseling and support by a clinician trained in tinnitus management.

A key component of the approach is the use of an individually customized acoustic stimulus designed to provide stimulation to auditory pathways deprived by hearing loss; to engage positively with the limbic system; and to allow intermittent, momentary tinnitus perception within a pleasant and relaxing auditory sensation, thereby facilitating desensitization to the tinnitus perception. The stimulus is provided via a proprietary, purpose-built medical device. Patients typically use their customized treatment for 2 or more hours per day, especially at those times of the day (or night) when their tinnitus is most disturbing. In addition, treatment involves a structured rehabilitation program, typically provided over a 6-month period by a clinician specifically trained in tinnitus treatment. Figure 1 provides a schematic overview of key processes addressed by the Neuromonics Tinnitus Treatment. Overall, this approach serves to ensure that the treatment is focused as much as possible on the unique situation and needs of each individual patient.

Auditory stimulation. Recent studies have shown that neuronal changes that result from hearing damage can be prevented by feeding sound to the auditory system in a manner that is specific to the frequencies of hearing loss. In the Neuromonics Tinnitus Treatment, this is achieved through the use of a wide frequency stimulus that is customized to account for each patient’s audiometric profile. The acoustic stimulus is created by combining licensed music recordings with a specially designed broad frequency noise component at a predetermined signal-to-noise ratio. The customization process boosts intensity in areas where an individual has relatively poorer hearing, and reduces the intensity in areas of relatively stronger hearing. This ensures that an appropriate amount of stimulation is provided regardless of the nature and degree of each patient’s individual hearing loss profile.

Relaxation and relief. The use of relaxing music as part of the Neuromonics Tinnitus Treatment acoustic stimulus reduces the engagement of the limbic system/amygdala and autonomic nervous system, which are major contributors to tinnitus-related disturbance. The use of music also facilitates a sense of relief from the tinnitus perception. These effects are reinforced and complemented by treatment-facilitated improvements in sleep, and by benefits arising from counseling and support programs.

To facilitate relaxation, the music selected has a tempo that is similar to that of a relaxed heart beat (i.e. 50 to 70 beats per minute) with few distractions. To avoid evoking the brain’s linguistic areas, no recognizable lyrics are used. Patients are instructed to use the treatment mainly at times of the day when their tinnitus is most disturbing. Ironically, the worst times for tinnitus are quiet times—when others usually relax. The relaxing music also makes therapy pleasant to use, potentially contributing to better compliance, earlier results, and more consistent benefits.

Desensitization to reduce attention to tinnitus. The use of an acoustic stimulus can help the brain become habituated to the tinnitus perception by providing partial perception while simultaneously reducing its significance, especially when reinforced by counseling. The Neuromonics Tinnitus Treatment approach applies this approach in a novel fashion by also drawing on the principles of systematic desensitization. A common behavior therapy technique, systematic desensitization exposes subjects to increasing hierarchies of anxiety-provoking situations during a state of deep relaxation, thus desensitizing the subject to the anxiety-provoking stimulus.

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![Figure 1. Overview of Tinnitus Development and Treatment](Image 325x80 to 552x250)

Figure 1. Overview of Tinnitus Development and Treatment
Schematic overview of key processes involved in the development of clinically significant tinnitus and how they are addressed by the Neuromonics Tinnitus Treatment.
Although the course of treatment, patients typically report that they become progressively less generally aware of their tinnitus and less disturbed by it, even when not actually listening to the stimulus. These sustained treatment benefits suggest that treatment is effecting change at a neuronal level.

**Clinical outcomes:** Evidence of clinical efficacy in controlled clinical studies, as well as in the private practice clinical setting, has shown that the Neuromonics Tinnitus Treatment approach is clinically effective, efficient, and acceptable to patients, especially those who satisfy various suitability criteria.

**Comparison with other approaches.** In a controlled clinical trial of 50 patients, the effectiveness of the Neuromonics Tinnitus Treatment was compared with two other approaches: a) broadband noise plus counseling and b) counseling only. Treatment was administered over a 6-month period for all groups, with outcomes assessed at 3 and 6 months. The Neuromonics Tinnitus Treatment resulted in greater efficacy (66% mean improvement reported after 6 months) than treatment protocols using counseling alone or with broadband noise (15% and 22% mean improvement, respectively, after 6 months). See Figure 2. Patients receiving the Neuromonics Tinnitus Treatment also reported significantly greater and more consistent improvements in their tolerance of loud sounds than did patients in the other two groups.

**Comparison of stage-based variants.** A recently reported follow-up study compared two variations of the Neuromonics Tinnitus Treatment: a) a one-stage protocol, in which patients received intermittent interaction with their tinnitus perception throughout treatment; and b) a 2-stage protocol, in which an initial 2-month stage involving a high level of interaction was followed by a 4-month stage of intermittent interaction. Both variants yielded consistently positive clinical outcomes. However, there was some evidence for a more consistent benefit within the 2-stage group. Therefore, the 2-stage protocol was adopted for application in the private practice setting.

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**Clinical results in the private practice setting.** A recent study examined clinical outcomes for more than 470 patients undertaking the Neuromonics Tinnitus Treatment in private practice clinics in Australia. Patients were assigned to one of 3 cohorts based on criteria that defined their relative suitability for Neuromonics Tinnitus Treatment. Statistically significant improvements in tinnitus disturbance occurred in all 3 cohorts, although the best outcomes (more than 90% success) were achieved for the most suitable patients. "Success" was defined as the proportion of patients who experienced a reduction in Tinnitus Reaction Questionnaire (TRQ) score of at least 40%. For less suitable patients, success rates and mean improvements were somewhat lower, and discontinuation rates were higher.

**Patient suitability and other considerations:** Based on assessments of more than 2,000 patients in both clinical trial and private practice settings, the best candidates for Neuromonics Tinnitus Treatment are adults with the following characteristics:

1. Clinically significant tinnitus as defined by a score of at least 17 on the TRQ or similar measure of tinnitus disturbance.
2. Normal hearing or some hearing loss, but sufficient residual hearing loss in at least one ear, and an absence of conditions in which hearing thresholds fluctuate.
3. Normal or reduced tolerance of loud sounds.
4. No psychological disturbance that is no worse than mild or moderate.
5. Tinnitus that is not reactive, pulsatile, or multi-tone in nature.
6. Absence of continuing exposure to high levels of noise without adequate protection.
7. No active pursuit of compensation in relation to tinnitus.

Patients whose profiles do not fit the above characteristics may still achieve positive outcomes with treatment. However, modifications in the protocol and patient expectations may be necessary. Some patients may require concurrent psychological interventions or hearing aids.

**Comparison with other treatment programs:** Direct comparisons of the Neuromonics Tinnitus Treatment outcomes with those of other treatment programs are limited by differences in study design. However, greater improvements in tinnitus disturbance and in the proportion of patients reporting significant improvement have been reported for the Neuromonics Tinnitus Treatment when compared with Tinnitus Retraining Therapy, Tinnitus Masking, and Cognitive Behavioral Therapy. High patient acceptance ratings and treatment continuance rates have been observed among patient populations, including those who had previously tried other treatments (e.g., hearing aids, tinnitus maskers) without success. Anecdotal reports have suggested that the Neuromonics Tinnitus Treatment is also more convenient and efficient than counseling-intensive approaches.

**Further directions:** Clinical studies are planned or underway to investigate the relative efficacy of the Neuromonics Tinnitus Treatment for various patient subcategories (e.g., those whose tinnitus is associated with military service or hyperacusis) and to identify neural correlates of treatment responsiveness using brain imaging studies. Product development efforts are addressing the efficacy, efficiency, and user acceptability of treatment.

**Summary:** The Neuromonics Tinnitus Treatment addresses critical auditory, attentional, and emotional aspects of clinically significant tinnitus. Evidence obtained in controlled studies and in private practice settings has demonstrated that the Neuromonics Tinnitus Treatment approach is clinically effective, efficient and acceptable to patients, particularly those who satisfy various suitability criteria.

**References**


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**Figure 2. Clinical outcomes: Neuromonics Tinnitus Treatment vs. control treatments**

Solid bars denote (a) mean improvement in tinnitus disturbance (as measured by a reduction in the Tinnitus Reaction Questionnaire [TRQ] score) or (b) the percentage of patients in each group who reported an improvement in the TRQ score of at least 40% after 6 months of treatment. Changes in TRQ score over time were statistically significant for the Neuromonics Tinnitus Treatment group (p<0.001) but not for the Noise + Counseling or Counseling-Only groups.