



# A Sound Therapy System While You Sleep

Summary by John A. Coverstone, AuD

## Many devices are marketed as tools

for decreasing the severity of tinnitus. However, few have been subjected to independent research to study their effectiveness. Otoharmonics approached the Department of Veterans Affairs Rehabilitation Research & Development (RR&D) National Center for Rehabilitative Auditory Research in Portland, Oregon, to do just that with the Levo System™. The Levo System uses software on an iPad Air to deliver customized sound therapy during sleep.

Sixty participants were recruited for this study.<sup>1</sup> Candidates had to have tinnitus for at least six months, score at least 25/100 on the *Tinnitus Functional Index* (TFI), pass a screening test for dementia, have sufficient hearing to enable perception of the sound therapy stimulus, and speak English. Individuals were excluded if they had intermittent tinnitus; had conductive hearing loss (a medical problem of the outer portion of the ear); were unable to respond properly to instructions on a computer screen; had a history of loud noise exposure, behavioral problems, mental conditions, or emotional disorders; or had previously used a tinnitus treatment system.

While controlling for demographics, participants were randomly assigned to one of three groups: One group was given the Levo System with

tinnitus-matched stimulus; another group was provided with the Levo System using a noise stimulus (white noise and/or band noise – but not the stimulus intended for this system); the third group was given a bedside sound generator device and allowed to choose a stimulus comfortable to them. All participants received the same counseling and used their assigned devices for three months. Participants were clinically tested and given a series of measures at the beginning of the study, during all follow-up visits, and at the end of the study. Measures included the TFI, NRS (numeric rating scale for tinnitus loudness), *Tinnitus and Hearing Survey* (THS), and tinnitus loudness match (LM).

As measured by the TFI, all three groups exhibited overall improvement in tinnitus reaction. Those using the Levo System versus the bedside sound generator showed slightly more improvement, although it did not matter whether participants used the Levo System's tinnitus-matched stimulus or a generic noise stimulus. The Levo System using tinnitus-matched stimulus led to a greater reduction in tinnitus loudness (as measured by the NRS) compared to the system using noise or the bedside sound generator. There was no clear difference for LM measurements between the three groups.

Overall, this study shows a greater reduction in tinnitus reaction when using the Levo System (regardless of stimulus) and a greater reduction in tinnitus loudness perception when using the tinnitus-matched stimulus. The authors acknowledged that a fully blinded study was not possible and that participants knew that some would be receiving a device with custom ear molds, as is used by the Levo System, and some would be receiving a bedside sound generator. Therefore, potential psychological effects cannot be ignored. It was also not possible to account for the effects of placebo, and those effects are likely present in all tinnitus treatment.

These results should be replicated to ensure reliability. Other factors also need to be studied, such as who is a good candidate for the system versus other therapies. However, based on these results, the Levo System appears to hold promise for improvement in tinnitus perception. 🌈

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*This study is presented as independent research. No compensation has been provided to the American Tinnitus Association and this article is not an endorsement of the Levo System™ or Otoharmonics by the ATA, the Veterans Administration, or any part of the U.S. government.*

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<sup>1</sup> Theodoroff S.M., McMillan G.P., Zaugg T., Cheslock M., Roberts C., Henry J.A. (2017). Randomized controlled trial of a novel device for tinnitus sound therapy during sleep. *American Journal of Audiology*, 26, 543–554.