

# aurex

## AUREX – A NEW PARADIGM IN THE TREATMENT OF TINNITUS

Dr Mark Brenner, CEO, Aurex International Corp

The Aurex-3® is a new treatment and management system for chronic tinnitus

Aurex International Corporation (AIC), an ADM Tronics subsidiary, has developed an innovative mobile based tele-audiology tinnitus therapy incorporating cloud based interaction via smart phone or tablet for patient applicator settings and monitoring through an international network of audiologists.

The underlying principles used in the Aurex-3 have evolved over the last 20 years in using beat harmonics to specifically act on the areas of a patient's Tinnitus sound derived from neurophysiological and psychological dysfunction. This is a unique and patented aspect of the Aurex-3 modality.

The beat harmonic excitation is applied conductively to the cochlea and counterintuitively creates a consonant and often relaxing effect. This offers respite to the patient and encourages continued use.

Regular and continued use of the Aurex-3 matched to a patient's Tinnitus sound acts to reverse the 'repetitive memory function' of Tinnitus.

The team at AIC have used advanced firmware and software solutions to produce a wearable device with wireless operation and control through a smartphone app. This enables direct control and monitoring of the patient's treatment by their audiologist and 'big data' capture for population statistics.

This disruptive technology will lead to a breakthrough in affordable and accessible Tinnitus treatment.

### Background

I first met and worked with the late Dr Alfonso DiMino in New Jersey at the end of the 90's. Having completed a lifetime of cutting edge inventions, Dr DiMino had developed a severe form of tinnitus that he had tried to control using all treatments available to no avail. Having exhausted all medical avenues, he was struck by the lack of understanding and the passive nature of dealing with his serious and often distressing condition, being told to 'learn to live with it'.

He wasn't prepared to accept that there was nothing that could be done to alleviate his tinnitus but instead began to apply his significant knowledge of medical sound physics with a highly creative engineering mind to firstly rationalize what was going on in scientific terms, and then provide a platform for an engineered solution.

Dr DiMino considered hearing as a repetitive memory function. Describing tinnitus, he focused on the effect of damaged hearing hair cells in the cochlea 'imprinting' sounds in the brain through memory repetition. He proposed that by stimulating the damaged nerve endings in a broad band surrounding the tinnitus sound, the brains repetitive memory attribute may deviate to repeat the sound injected. Eventual inability to reproduce the original tinnitus sound will alleviate the intensity.

Using these principles, the first Aurex-3 was developed for DiMino's own use only, and employed a central vibratory and audio frequency excitation tuned to a broad band surrounding his tinnitus. Through frequent use of the device, long-term masking and reduction in intensity was achieved, providing the treatment and management of his tinnitus.

The Aurex-3 generates a complex range of frequency spectra from the interactions of three fundamental frequencies (hence 'Aurex-3') together with sideband frequencies. The resulting harmonic frequencies span

the audible range from 200 to 20,000 Hz (for reference middle C on a piano has a frequency of 256 Hz, human

speech tends to be around 300 – 1,000 Hz, sounds above 5,000 Hz are high pitched squeals or screeches). These frequency spectra are tuned to complement the user's tinnitus and applied via an applicator to the mastoid bone behind the ear, and then transmitted by bone conduction to the inner ear.

To provide user adjustable setting of the device Di Mino employed extremely innovative application of harmonic beat theory to derive consonant frequencies between the sound delivered and the tinnitus sound.

Early user experiences in the USA and UK with the FDA-cleared Aurex-3 showed some remarkable results and was being regarded as a major new development in the treatment of tinnitus. However, the device was difficult to use needing patience, practice and a little encouragement.

Thus, a blueprint was created for an easier to use, more accessible and less costly version of the original Aurex-3. The disruptive approach to a technological solution to tinnitus has led to fresh thinking and a holistic view of tinnitus treatment and management. The new generation Aurex-3 has been developed in the laboratories of ADMT in Northvale, NJ and will begin clinical evaluation in September with availability scheduled for 2019.

The Aurex psychophysics model

Many therapeutic options have been considered in the management of Tinnitus, including surgical treatments, drug treatments, psychological techniques and physical therapies. Many are still practiced though often the evidence base is weak or completely lacking.

Sound therapy for the relief of Tinnitus is not new, dating back as far as ancient Babylon in 650 BC. The use of Tinnitus maskers was pioneered by Vernon in the 1970's (Vernon, J., Attempts to relieve tinnitus, *Journal of the American Audiology Society*, 2, 1977).

In the USA, Henry and colleagues (Henry, J.A, et al Using therapeutic sound with progressive audiologic tinnitus management, *Trends in Amplification*, 12, 2010) introduced a framework for the management of troublesome Tinnitus to the USA Veterans Administration, Progressive Tinnitus Management, in which sound therapy is an essential component derived from combinations of sound and types of sound to manage Tinnitus.

The underlying principle used in the Aurex-3 considers the extent to which amplitude modulation of a stimulus will increase the acceptability and efficacy of sound therapy for a patient. The synthesis of a complex sound signal from the intermodulation of two variable frequency generators and their combined amplitude modulation is used to generate a complex harmonic spectrum that is user controlled to match the patient's Tinnitus sound. Crucially, the introduction of beat harmonics is used to specifically excite the areas of a patient's Tinnitus sound derived from neurophysiological and psychological dysfunction.

The beat harmonic excitation is applied conductively to the cochlea and counterintuitively creates a consonant and hence relaxing effect. The resultant relaxation to create a soporific effect offers respite to the patient and encourages continued use. Relaxation has often been included as an element of other treatment approaches (Dineen, R. et al Managing tinnitus: a comparison of different approaches to tinnitus management training, *Brit. Journal of Audiology*, 31, 1997).

Regular and continued use of the Aurex-3 matched to a patient's Tinnitus sound in this way acts to reverse the psychological 'repetitive memory function' of Tinnitus by neuronal plasticity together with cognitive reprocessing.

The 'Aurex' effect

Central to the Aurex-3 approach is the application of beat harmonics.

Traditionally, dissonance has been widely believed to be the product of "beating": interference between frequency components in the cochlea that has been believed to be more pronounced in dissonant than consonant sounds. However, harmonic frequency relations, a higher-order sound attribute closely related to pitch perception, has also been proposed to account for consonance. Some combinations of musical notes sound pleasing and are termed "consonant," but others sound unpleasant and are termed "dissonant." The distinction between consonance and dissonance plays a central role in Western music, and its origins have

posed one of the oldest and most debated problems in perception.

Contemporary thinking on consonance is instead rooted in acoustics, beginning with the fact that musical instrument and voice sounds are composed of multiple discrete frequencies. These frequencies are termed “harmonics” because they are typically integer multiples of the fundamental frequency of the sound. Harmonics are combined in a single waveform when traveling in the air but are partly segregated by the cochlea, because different auditory nerve fibers respond to different frequencies (Plomp, R. The ear as a frequency analyzer, J Acoustic Society America, 36, 1964).

When several notes are combined, the resulting sound waveform that enters the ear contains all the individual frequencies of each note. Auditory scientists have long noted that aspects of the pattern of component frequencies differ between consonant and dissonant chords. Prevailing theories ascribe consonance to the fact that dissonant chords contain frequency components that are too closely spaced to be resolved by the cochlea. Two such components shift in and out of phase over time, producing an interaction that oscillates between constructive and destructive interference. The amplitude of the combined physical waveform thus alternately waxes and wanes. If the components are close enough to excite the same set of auditory fibers, amplitude modulations are directly observable in the response of the auditory nerve. These amplitude modulations are called “beats,” and result in an unpleasant sensation known as “roughness,” analogous to the tactile roughness felt when touching a corrugated surface [in practice, the perception of roughness is dependent on the depth and rate of amplitude modulation, as well as the center frequency of the tones involved. Theories of dissonance based on beating have been dominant in the last century and are now a regular presence in textbooks (Deutsch, D., The psychology of music, Academic, San Diego, 2009).

However, a second acoustic property also differentiates consonance and dissonance: the component frequencies of the notes of consonant chords combine to produce an aggregate spectrum that is typically harmonic, resembling the spectrum of a single sound with a lower pitch. In contrast, dissonant chords produce an inharmonic spectrum. Such observations led to a series of analyses and models of consonance based on harmonicity (Ebeling, M. Neuronal periodicity detection as a basis for the perception of consonance, J Acoustic Society America, 12, 2008) Although beating-based theories are widely accepted as the standard account of consonance, harmonicity has remained a plausible alternative. Mc Dermott et al (Mc Dermott, JH, et al, Individual differences reveal the basis of consonance, Curr Biol, 20, 2010) argues that harmonicity is more closely related to consonance than is beating.

This disassociation of harmonicity from beating in the Aurex-3 and its unique matching to a person's Tinnitus sound presents a unique and differentiated model and modality for Tinnitus treatment.

#### Design Principles

Almost all sounds are complex in nature containing several component parts.

For example, if a single note such as the 'A' immediately above middle 'C' on a piano is played, then the correctly tuned piano string will vibrate at 440Hz. If the sound is analyzed, it will be found to contain harmonics as integer multiples of 440Hz, 2,3,4 times etc. The exact composition of this harmonic series in terms of the amplitude of each harmonic, and the extent in number of harmonics determines the characteristic of the sound, in this case a piano. If a violin were played at the same pitch of 440hz, then the harmonic series of its sound will be correspondingly different.

- The Cochlea is capable of 'decoding and separating' this harmonic series, and transmitting to the brain an analog of this harmonic series through the auditory nerve. The auditory cortex of the brain then, from the process of learning recognition, can reconstruct this sound and recognize it as in this case, a piano or violin.
- Conversely, a sound generated by using a series of oscillators correctly adjusted and added together will produce or 'synthesize' a similar sound of piano or violin, or indeed any other sound desired. It is this sound synthesis technique which is exploited within the Aurex-3 to emulate and hence treat the tinnitus sound perceived.
- Tinnitus is due to the artificial stimulation of particular nerve cells in the parts of the brain responsible for processing sounds, each nerve cell having an assigned frequency. Whilst the cause of this is not known, the patient does know the sonic nature of these sounds, for he hears these sounds.

- Tinnitus sounds are complex comprising a relatively high sonic frequency modulated by a sonic tone of lower frequency. Hence the nerve cells which are artificially stimulated to produce tinnitus sounds are those nerve cells whose assigned frequencies that combine to create the tinnitus sound.
- The function of the Aurex-3 is to generate a sound that matches as closely as possible the tinnitus sounds heard by the patient. This requires that a complex signal can be generated, the component parts of which can be selected by the user to achieve such a matching sound. Most sounds are complex in nature, and are composed of a fundamental frequency and a harmonic series. It follows that a sound can be synthesized by reconstructing the harmonic series, that is by addition of separately generated sounds.
- In the Aurex-3 a complex signal is derived from a high frequency sonic tone modulated by a low frequency sonic tone. This signal actuates a probe to produce vibrations whose repetition rates correspond to the frequencies of the complex signal which frequencies are like those which make up the tinnitus sounds. The vibrations transmitted by the probe to the cochlea act to excite the nerve cells responsible for the tinnitus condition and to restore those cell to a normal state in which the cells are subject to artificial stimulation and therefore cease to produce tinnitus sounds. In general terms, this signal will be created by the intermodulation of 2 audio signals each having a complex nature to create a wide spectrum of beat harmonics. Each audio signal is frequency modulated by a third modulation frequency to generate further sideband pairs of frequencies. The signal resulting from the above processes is then applied to a low pass filter of adjustable cut off frequency so that the degree of harmonic and sideband pair may be controlled. User adjustable settings allow an audio signal capable of matching the tinnitus sound to be generated with a high degree of certainty.

#### Tele audiology – The Aurex app

The term tele audiology was first used in 1999 by Dr Gregg Givens to describe a system being developed at East Carolina University. The first Internet audiological test was accomplished in 2000 by Givens, Balch and Keller.

The first Transatlantic tele-audiology test was performed in April 2009 when Dr James Hall tested a patient in South Africa from Dallas at the AAA conference. Since then interest in tele-audiology has increased significantly.

The Aurex platform uses synchronous tele-audiology whereby a patient can be assessed and device settings chosen in real-time as if the patient is sitting in front of their audiologist. Remote testing where a patient is in a sound booth while the audiologist sits outside the booth is virtually the same as testing the patient over the internet.

The Aurex app provides an easy way for patients to interact with their audiologist via their smartphone. Following a secure sign up/login process, patients can review their treatment plans with their audiologist. The audiologist can match the patient's tinnitus to optimize settings and monitor usage and progress towards improvement targets with the patient. Treatment plans with reminders are used to motivate the user and support compliance with regular news updates informing of the Aurex community experiences together with new research and information on tinnitus.

#### Future Developments

The Aurex-3 technology is patented as a continuation from the original design as 'An electronic stimulation system for treating tinnitus disorders', Di Mino et al US patent # 6,210, 321 B1.

The new wearable device headset, wireless operation and control app is subject to a new patent pending.

Pre- clinical trials are due to commence in Q4 2018 with availability of a CE marked and FDA cleared consumer variant available in 2019.

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