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# Home Medical Device for Tinnitus Treatment

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## 1. Introduction

### 1.1 A tinnitus definition

Tinnitus is almost exclusively defined as ringing in the ear(s); more common in the popular than the professional literature since the turn of the century. It is now well recognized that tinnitus is chiefly neural, that is a perception being in one or both ears. This is not to deny cochlear tinnitus or the role of the cochlea in the tinnitus process. It is also typical to define tinnitus as a phantom sound with no external stimulus; also suggesting tinnitus arises in the central nervous system. The phantom descriptor is somewhat problematic (Shulman, 1995); however external sound can and does influence the perception of tinnitus and is a common therapeutic treatment in the form of masking. Further, that means the perception of tinnitus is interactive with external ambient sound. If sound levels are dramatically reduced as in echo free space (anechoic) normal hearing young individuals will generally report tinnitus like perceptions without sensations. The first in a series of studies Heller and Bergmann, (1952) reported almost 94% of normal hearing subjects experienced hearing sounds in a sound attenuated chamber (ambient level of 15-18 dB SPL) after just a few minutes. This finding was repeated but to a lesser degree in three studies (Del Bo et al., 2008; Knobel and Sanchez, 2008; Tucker et al., 2005) in which a 64-68 % of the subjects reported tinnitus. Most interestingly, if attention was redirected away from the auditory modality, the percent responding was less than half (45%). If the subjects were engaged in a cognitive task the percent report tinnitus was <20%. It is not surprising that attention or top down processing plays a role in tinnitus with normal hearing individuals since it is a major factor in segregating those who are bothered or not by their tinnitus (Erlandsson et al., 1992). For those that are not bothered by their tinnitus, the typical response is I do not pay attention to it.

There are no published reports of tinnitus being induced in the almost absolute silence, in human terms, in anechoic space. The room in the Del Bo et al., (2008) study is termed a sound proof chamber and also an anechoic chamber; it may have been anechoic with sound attenuation below minimal audible fields. Anechoic space is valuable component in an assessment of silence induced tinnitus since the sound levels are generally less than the air reference of 0.0002 dynes/cm$^2$. While antidotal in nature, I have a vivid memory of my first experience in an anechoic chamber as a graduate student at Florida State University. I walked out on a wire mesh since there were Fiberglas sound wedges below as above and around me. Once the doors were shut I immediately heard my physiological noise of respiration etc. I spoke and it appeared to me that my words were sucked away from my

mouth, then, I heard a high frequency hissing seemingly in the middle of my head which I now identify as tinnitus. Upon exiting the chamber all such perceptions ceased. Re-entering the hissing returned as did my sense of bodily noises. The three other graduate students in the lab had the same experience as did other visiting students. We thought this was a common experience not worthy of a formal report. My hearing was at 0 dB HL up to 8 kHz (highest measured) and my minimal audible angle at 2 kHz was < $4^0$. A few years later my high frequency hearing was measured and it too was normal up to 20 kHz. I had no more than a cursory understanding of tinnitus and concluded at the time the critical factor in its appearance was the lowered ambient noise of the chamber. With this experience in mind, I must conclude that tinnitus is naturally induced by silence. I have never experience the same tinnitus perception is single or double walled acoustic enclosures with less attenuation.

Absolute silence can also be achieved with eight nerve section. Tinnitus is generally not eliminated, but can be increased by this procedure (Cope et al, 2011) although the effect was found to vary from increased to decreased tinnitus or no effect (Mollar et al., 1993). Tinnitus can be associated with severe deafness and can generally be ameliorated to degree with the electrical stimulation of a cochlear implant (Amoodi et al., 2011; Arndt et al., 2011; Pan et al., 2009).

What then is the mechanism that produces tinnitus with just being in silence or immediately having an eight nerve sectioning, this cannot be the result of complex neural plastic changes in the brain, it is most likely a release from neural inhibition in the peripheral neural structures, probably acting the spiral ganglia by the central auditory system. This would account for the rapid turn on/off when stepping out of anechoic space and back in.

In addition there may be an unmasking of non-lemniscal pathways, again under the influence of the central nervous system. Moller et al., (1992) reported tinnitus patients summed somatosensory stimulation (mild shock to the medial nerve) with an auditory tone which resulted in increased loudness perception. This multimodal effect is seen in young children but not adults. The non-lemniscal pathway is multimodal and the likely candidate for this effect in tinnitus patients. That pathway has a subcortical input into the limbic system and direct input into the auditory association cortex. Whether the non-lemniscal pathway can be activated by just silence has not been studied. This pathway is involved in orientation and would certainly respond to abrupt silence.

Could this pathway be switch on and off with just stepping in and out of anechoic space? Perhaps this is but one element in a cascade of effects inducing the perception of tinnitus. The artificial nature of anechoic space must activate the limbic system and in particular the amygdala. Input to the amygdala is both subcortical (non-lemniscal pathways) and cortical via the classical auditory pathways. These pathways are termed the low and high road respectively by LeDoux (1990). The amygdala is active in severe disabling tinnitus and plays a notable role in contributing to tinnitus annoyance first postulated by Shulman and Goldstein (1996).

Tinnitus is thus a perception without a sensation, that is nonetheless interactive with external sound conditions, generated by the brain.` It is the brain component (both auditory and non-auditory) that appears to be implicated much more so than the ear in the perception of tinnitus in normal hearing individuals and likely those suffering long term hearing loss. It should be apparent, then, that treatment strategies must involve neural mechanisms to be effective and masking meets that criterion in that it has central neural effects (Goldstein et al., 2001).

### 1.2 Neuroscience of treatment

Tinnitus can be present in individuals with normal hearing; however normal hearing measurement does not always indicate fully intact hair cells (Bredgerg, 1967) or a spinal ganglia free of deaffrination or even cochlea free of dead regions (Weisz et al., 2006). High frequency audiometery on tinnitus patients revealed 12 of 18 had threshold elevation in the high frequency region (10, 12, 14, 16 kHz) in one study (Shim et al., 2009). Goldstein et al., (2006) reported high hearing loss common in severe disabling tinnitus. Thus tinnitus can exist in individuals even if hearing appears unremarkable in the conventional audiometric range and some hearing loss in the very high frequencies may be more commonly present than previously believed (Goldstein et al., 2005). Further, there may be neuroplastic changes in the brain regions that code these very high frequencies, which may contribute to the tinnitus percept. Very high frequency hearing loss (>10 kHz) might benefit from very high frequency sound therapy (Goldstein et al., 2006) including ultrasonic masking Meikle et al., 1999; Lenhardt, 2003).

Overwhelmingly, hearing loss is often associated with tinnitus and it appears to be the key factor triggering the events that lead to tinnitus in humans and animals. The most frequent cause of hearing loss is intense noise which is often characterized as a high frequency loss of hearing behaviorally and a loss of hair cells and changes in the nerve and auditory synapses in the brain. Spontaneous firing rates tend to increase in the first auditory brain synapse (dorsal and ventral cochlear nucleus) as well as in the midbrain (inferior colliculus) and auditory cortex (primary and secondary)[Wienbruch et al., 2006; Eggermont and Roberts 2004]. Tinnitus neural induced changes are not limited to the classical pathways but also present in the non-classical or non-lemnsical pathways (Mollar et al., 1992) Both pathway have input into the limbic system (LeDoux, 1990) and it is the involvement of this system that form the final common pathway in tinnitus (Shulman 1995; Shulman and Goldstein 2006; Shulman et al., 2009).

The change in neurons' spontaneous firing rates along the neuraxis is also accompanied by changes in the neural tuning properties of neurons representing the peripheral region of the hearing loss (Schaetta and Kempter, 2009). The neuromechanisms that give rise to neuro hyperactivity have not been identified but some form of increased gain in the central nervous system is likely, which suggests that additional stimulation covering the effect frequency region might form the basis of sound therapy.

Norena and Eggermont (2005) reported that cats exposed to a traumatizing noise and immediately placed in a 40 dB high frequency sound environment had much less hearing loss compared with similarly exposed cats placed in a quiet environment. The hearing loss in the quiet reared cats ranged from 6 to 32 kHz with the loss, on average, 40 dB. In contrast, the hearing loss in the high frequency environment cats was restricted to 6-8 kHz at a level near 35 dB. Despite the restricted hearing loss for the high frequency stimulated cats in the 6-8 kHz range, no auditory cortical reprogramming was found, suggesting that the high frequency stimulation prevented the expected reorganization. It would seem then an effective treatment for tinnitus in humans would be very high frequency stimulation at a moderate level covering the tinnitus pitch match and the tinnitus spectrum (Schaette et al., 2010)

Encouraged by the Norena and Eggermont's (2005) study high frequency stimulation was applied with tinnitus patients and matched controls with similar sensorineural hearing loss and no history of tinnitus (Goldstein et al., 2005. The results revealed that high frequency stimulation for 5-8 weeks dramatically reduced the level of sound needed to mask tinnitus

and thresholds of hearing improved by 5-25 dB suggesting plastic changes had occurred in the central nervous system. The animal study (Norena and Eggermont; 2005) demonstrated that sound therapy can prevent brain reprogramming as a result of one intense noise exposure; thus preserving hearing that would likely have been lost. The human data with people having long term hearing loss and some with severe tinnitus, suggest that the brain can reprogram back, modifying the neural state again, and as a result, making masking more effective at lower levels and improving hearing. Hearing improvement due solely to listening to high frequencies via the UltraQuiet system could generate skepticism; nonetheless, the limited data is very suggestive of threshold improvement due to reverse neuroplasticity in the high frequencies which did not exceed 25 dB. Further the concept is consistent with conventional auditory theory; however sampling variability is clearly a concern, resolvable with an expanded data base.

Only a few decades ago most neural scientists believed that the adult brain was hard wired, now it is well accepted the adult brain is plastic and capable of reprogramming after sensory or motor loss or with learning (Syka et al., 2003). Neural maps change with experience. Hearing loss triggers a reprogramming in the auditory cortex which results in a change in frequency response. With noise induced hearing loss, cortical neurons sensitive to the loss reprogram lower in frequency. Somehow the high frequency stimulation therapy maintains or re-establishes the original neural map. Reduced inhibition is likely the active factor in the cortical affecting the periphery to achieve enhanced hearing.

High frequency sound therapy can restore or even improve hearing by preventing auditory cortical reorganization, that is to say, the auditory cortex contributes to sound sensitivity at the ear. If the auditory cortex is ablated, the audiogram is about 25 dB poorer (see Heffner and Heffner, 1986; 1995 for reviews). The assumption is that the cortex, or its actions (efferent control), exerts an influence on hearing level at the neural periphery. Changes in hearing threshold indirectly implied central changes have taken place as a result of therapy.

## 2. Medical masking devices for tinnitus

There exist a number of devices for the treatment of tinnitus, however the US Food and Drug Administration (FDA) identified only two, hearing aids and maskers. Combination devices are a merge of a hearing aid and a masker.

### 2.1 Limitations

Hearing aids are designed to amplify speech sounds and are generally limited in high frequency (<10 kHz) fidelity. Hearing aid use has been reported to be of benefit in adjusting to tinnitus particularly when combined with counseling, since tinnitus evokes a variety of emotional reactions and quality of life issues. Thus a device designed to maximize speech perception as a result of hearing loss is used to treat tinnitus. Increasing the stimulation to the brain appears to be the principal mechanism that induces suppression and or accommodation to tinnitus. Relief from the effects of tinnitus is possible for some, but long term use of hearing aids does not appear to be efficacious for most tinnitus patients. The lack of high frequency energy in hearing aids may limit their success as maskers (Schaette et al., 2010). Combination devices may have more utility (Sweetow and Sabes, 2010) and flexibility in fitting individuals with tinnitus. The use of music in a wearable combination device may be relaxing, but unless the upper frequency limit covers the tinnitus spectrum, the effectiveness may be reduced unless the music is customized (Starackle et al., 2010; Wilson et al., 2010).

Maskers are wearable devices that produce a sound band to mask the tinnitus and through use, produce some measure of tinnitus inhibition. Wearable maskers have been available for the last forty years (Vernon and Meikle, 2000; 2003) and produce about 70% complete masking. Only 10% achieve no masking while the remainder exhibit diminished tinnitus perception. Maskers only cover the tinnitus and do not treat the cause. Maskers can aid in tinnitus habituation but generally they are used at a low volume for that purpose. In the table below, the experience at the Tinnitus Clinic at the Oregon Health and Science University (Vernon and Meikle, 2003) reveals that most patients can get partial or complete masking. The masking efficiency of a commercial high frequency product, UltraQuiet, has comparable efficiency and is an end element in the new technology presented herein (see Table I). Masking alone is not sufficient; the sound must also interact with the brain to reduce the effects of tinnitus.

masking by wearable devices

| | Vernon Meikle survey | UltraQuiet |
|---|---|---|
| • complete masking | 70.5 | 75 |
| • partial masking | 19.6 | 15 |
| • no masking | 9.9 | 10 |

Table 1. The wearable masking devices (maskers, hearing aids and combination devices) yielded some degree of masking to 90% of the tinnitus patients in the Oregon survey. UltraQuiet, the end component in the new home based tinnitus system present here had the same level of effectiveness in masking. Long term compliance is a problem for all such devices.

### 2.2 Economics

Hearing aids and custom maskers are expensive which can limit their utilization in the tinnitus population. Even when purchased, if these devices may be less successful over time, and if so, the patient will possibly become discouraged and abandon the approach that once was successful. It is most important for devices to be part of a structure tinnitus therapy program. Tinnitus devices are also expensive to design, achieve regulatory approval, manufacture, distribute and support.

### 2.3 Patient preferences

Since tinnitus has no known cure, a variety of treatments from pharmaceuticals to psychotherapy have be suggested; some health care providers still only offer the advice to live with it, thus tinnitus patients in the age of worldwide interaction through the web, are

often weary of new treatment approaches, especially expensive ones. Effective tinnitus approaches require patience, perseverance, commitment and discipline. Nonetheless, the typical patient is looking for a cure not a long term treatment. The tinnitus device should be considered only a tool not a solution in and of itself. The tool must be used regularly for full benefit (Del Bo and Ambrosetti 2007).

### 2.4 Innovation based on best practices and science

Treatment of tinnitus with high frequency signals that cover the tinnitus pitch frequencies (areas of hearing loss) and higher has been shown to be effective using behavioral and imaging studies(Goldstein et al., 2001;2005;Shulman et al., 2004). Nonetheless, the compliance of patients has been less than expected (~75% improvement) outside the research laboratory environment. There is a need for a home based unit that will provide the needed time of treatment to insure success. It is hypothesized that a stand-alone home unit will lead to a greater success rate in treating tinnitus, especially in environments lacking audiological infrastructure and /or professional supervision. Tinnitus devices, dissimilar to hearing aids, are more strictly regulated. The UltraQuiet device is the interface to the patient in a new home unit to be described and that interface has received regulatory clearance.

### 2.5 UltraQuiet

UltraQuiet is a tinnitus therapy product that provides patterned auditory stimulation in the high audio and into ultrasonic ranges (10-22 kHz) using a bone conduction transducer; and is based on the work of Lenhardt (2003), demonstrating ultrasonic perception by humans. UltraQuiet therapy differs from conventional maskers by providing very high frequency (5-22 kHz) sound therapy. In UltraQuiet therapy, the auditory stimulation is processed music that has been pre-filtered and up shifted in pitch using amplitude modulation (upper sideband). Music was selected as the core of the stimulus since it was found to be more effective tinnitus masker than noise (see Wilson et al., 2010 for review) since music engages more central and cognitive processes. The tinnitus treatment stimulus was produced using Kyma Version 5 software with a Capybara 320 Sound Computation Engine (Symbolic Sound Corporation, Champaign, IL) and stored on a compact disk (CD). The CD signal was fed into a custom-made amplifier delivered to the skin off the head in the mastoid region using a piezoelectric bone conduction transducer. The transducer was held in place by a plastic headband found to have comparable force as a standard metal audiometric bone conduction headband. Although the stimulus is presented on only one side of the head, it is heard binaurally through bone conduction, although it is about 5 dB sensation level (SL) more intense on the fitted side. In UltraQuiet therapy, the processed and frequency shifted music is presented at 12 dB SL for minimum periods of 1 hour twice weekly with daily use encouraged. The goal is to effect changes in the central nervous system mechanisms of tinnitus, resulting in long-term inhibition (Goldstein et al., 2001; 2005).

### 2.6 Regulatory issues

The US FDA (www.fda.gov/MedicalDevices/default.htm) recognizes two types of tinnitus treatment devices, hearing aids and tinnitus masker devices (TMD). The later can be used in a variety of forms as wearable devices and appliques for temporary relief. The use of personal music devices for relaxation, as long as no medical claims are made, is unregulated. The FDA defines “a tinnitus masker is an electronic device intended to

generate noise of sufficient intensity and bandwidth to mask ringing in the ears or internal head noises. Because the device is able to mask internal noises, it is also used an aid in hearing external noises and speech. TMDs include "in-the-ear" and "behind-the-ear" air conduction configurations. The device type also includes ultrasound TMDs." The FDA treats tinnitus masker devices as Class II with special controls (code KLW) such that the device must meet the FDA recommendations and provide assurances of safety and effectiveness. Specifically there must be a premarket notification that addresses any associated health risks to health and the manufacturer must obtain a substantial equivalence determination from FDA prior to marketing the device. That is what devices on the market are similar to the new device.

The manufacturer may submit a traditional 510(k) or an abbreviated 510(k). An abbreviated 510(k) provides the least burdensome means of demonstrating substantial equivalence for a new device. The abbreviated 510(k) submission must include the proposed labeling for the new device specifying device description, intended use, and directions. Furthermore, information on device development, performance specifications, testing methods, test data and description of the risk analysis used must be furnished. A labeled drawing, similar to that used in a patent and a discussion of the device characteristics related to the risks in a class II special controls device is needed as well as a declaration of conformity to any standard selected adhering to the testing described in the standard.

A traditional 510(k) must meet all of the informational and data requirements of an abbreviated 510(k) including methods, data, acceptance criteria, and conclusions; however the device description is more formal including:

- "a description of the components of the device and its assembly,
- a description of any accessories used with the device,
- the range of dimensions, shapes, and device designs,
- engineering drawings, if applicable,
- a description of the principle of operation (i.e., the scientific principles behind how the device achieves its intended use).

For ultrasound TMDs, engineering drawings should show:

- detailed dimensions of the circular tip area of the transducer that will contact the mastoid area,
- associated static force necessary to achieve output levels, and
- how the static force is achieved."

The safety risks and the mitigations are summarized in Table II. Note that the mitigations are labeling and testing

Generally three predicate devices are selected to show how the new device is both similar to and different from the FDA submitted device. The manufacturers, predicate device names, and 510(k) numbers should accompany the comparative performance comparisons.

Preclinical and clinical studies for traditional 510(k) application can be submitted if needed. FDA recommends a preclinical to evaluate the biocompatibility of device materials contacting patients if it is not already approved. For ultrasound TMDs, a risk analysis of potential ultrasonic energy adverse effects, as tissue heating of tissue or changes in auditory threshold, must be submitted. Maximum output intensity must be measured and reported to avoid cavitation.

Clinical studies are not usually required, but if needed, the following specifications are recommended:

| risks | mitigation |
|---|---|
| • worsening of tinnitus | labeling; clinical testing |
| • change in hearing | preclinical testing; labeling; clinical testing |
| • adverse tissue reaction | preclinical testing |
| • electrical hazards | preclinical testing |
| • tissue heating (ultrasonics) | preclinical testing |
| • improper use | labeling |

Table 2. The safety risks and the suggest FDA mitigation

- "design, i.e., masking pattern, peak intensity or duration, etc. dissimilar from any design previously cleared under a premarket notification;
- new technology, i.e., technology different from that used in legally marketed TMDs;
- Indications for use dissimilar from TMDs of the same type.'

If a clinical study is carried out it should address issues related to changes in auditory thresholds, pre- and post-exposure to ultrasonic masking stimuli, possible negative side effects of fatigue, headaches, nausea, irritability, and "fullness" in the ear. If a clinical study is needed to demonstrate substantial equivalence, i.e., conducted prior to obtaining 510(k) clearance of the device, the study must be conducted under the Investigational Device Exemptions (IDE) and have institutional review board (IRB) approval with signed and understood, informed consent.

The European Union (EU) assigns medical devices to four groups according to their level of perceived risk before they are approved. Class I is low risk, IIa (tinnitus maskers), IIb (which includes diagnostic radiology equipment) and Class III is high risk (implantable devices). Compliance with the EU guideline leads to CE (conformance mark) certification for medical devices. The method of device development includes specifying performance to specifications, hazard analysis, frequency measurement, function assessment, safety and sustainability must be documentation before applying for the CE mark.

### 2.7 Innovation in sound therapy

The animal work of (Norena and Eggermont, 2005) indicates that moderate levels of high frequency noise stimulation post noise exposure mitigated the neuroreprograming in the auditory cortex characteristically associated with tinnitus. This is direct substantiation that external sound or masking can alter the neural substrate of tinnitus. Moffat et al., (2009) applied these concepts to humans by fitting tinnitus patients with either standard hearing aids or aids with a broad frequency response to 8 kHz. Neither amplification scheme altered the tinnitus spectrum or its loudness. The most obvious conclusion is there was insufficient high frequency stimulation to alter the tinnitus spectrum. The same conclusion was reached

by Schaette et al., (2010) is a similar but not identical study. The issue is not masking since most individuals can experience tinnitus masking.
The critical elements in tinnitus maskers for the purpose of brain therapy are very high frequency stimulation, beyond standard hearing aids, individual adjustability for custom fitting and the ability to affect tinnitus loudness through dedicated use. Treatment of tinnitus with high frequency signals that cover the tinnitus pitch frequencies (areas of hearing loss) and higher has been shown to be effective using behavioral and imaging studies (Shulman et al., 2004; Lanting et al., 2009 for review). The use of the UltraQuiet device with a pass band of 6-20 kHz not only masked the tinnitus but also reduced minimal masking levels by an average of 10 dB (5-25 dB), increased hearing in the tinnitus spectrum by 10 dB and reduced tinnitus severity by questionnaire over a period of eight weeks (Goldstein et al., 2005). Nonetheless, the compliance of patients has been less than expected outside the research laboratory environment unless the device is used in context of counseling and support. There is a need for a home based unit that will provide the time needed to insure therapeutic success, especially in environments lacking audiological infrastructure and /or professional supervision.

### 2.8 Tinnitus masker for in home use

Bone conduction delivery is employed to provide a comfortable high frequency listening experience. The transducer is a custom-made aluminum ceramic bimorph with a high-frequency limit of 50 kHz. The transducer is coupled to the skin and held in place with a band, much as are traditional clinical bone-conduction transducers. Rather than using synthetic recorded stimuli the sound from a television is the source which is encode by a directional microphone (or direct out port), high passed filtered (4kHz) and amplitude modulated by a variable carrier(s). The carrier can be tuned by the patient (that is selected from ~4 to 20+ kHz) to match their tinnitus and compensate for their skull acoustics by adjusting to "confortable (a mixture of the carrier frequency and idiopathic skull resonances). The carrier can be set to sweep if adjustment is not desired. In the frequency sweep mode the modulated audio sound retains it pitch qualities but varies in loudness as brain/skull resonances are passed by the sweep. The wideband multiplication and a summing analog modulator circuit have easy to use dial-in carrier frequencies. This module outputs to an amplifier and bone conduction transducer (UltraQuiet). All the processing is preengineered in the module (Vicari et al., 2008).
In the first example a sibilant sound /s/ (Figure 1) is modulated by two carriers at 6 and 12 kHz. The amplitude of the 12 kHz carrier is higher by 10 dB to increase salience. An example of speech prior to being filtered and modulated is depicted in the upper panel (A) of Figure 2. After the speech signal is modulated (multiplied) by twin carriers (19 and 22 kHz) the resulting full amplitude modulated signal has an effective band width of 16-24 kHz (panel B). The use of this system will enhance intelligibility (Vicari et al., 2008) but the rationale is to use television as an engaging source for high frequency therapy as well as conventional listening and viewing.
The details of the system are presented in Figure 3. The anticipated source is a television to maintain interest, but it could be a radio, computer or any media device, the signal is fed into a modulator (modified Analog Devices ADL 5319). The carrier(s) is supplied by a modified oscillator chip (Analog Devices AD 5932 generator) with a programmable frequency profile. The carrier can be swept in frequency over the tinnitus spectrum and higher. Alternatively two carriers can be used that are fixed or sweep over more constrained ranges over the same tinnitus spectrum. The carrier frequency shift is not perceived as changes in pitch as much as loudness fluctuations as the carrier interact with head resonances. When the modulating

frequency (filtered television signal with a 2-8 kHz pass band) is multiplied by a carrier the result is the carrier plus and minus the modulator. So if the carrier is 12 kHz the resulting signal is 12 +/- 2-8 kHz. The carrier is present in full amplitude Modulation (AM) absent in carrier suppressed modulation (CSM) and absent along with lower sideband in upper sideband modulation (USM). Going forward with the example

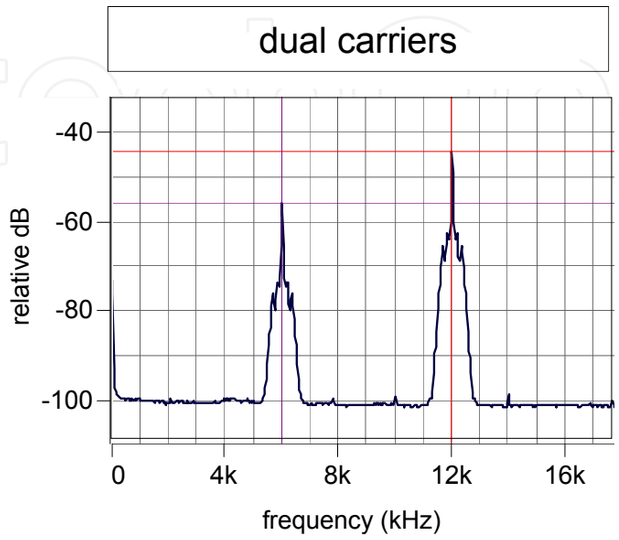


Fig. 1. The double carrier modulation of /s/ is depicted.

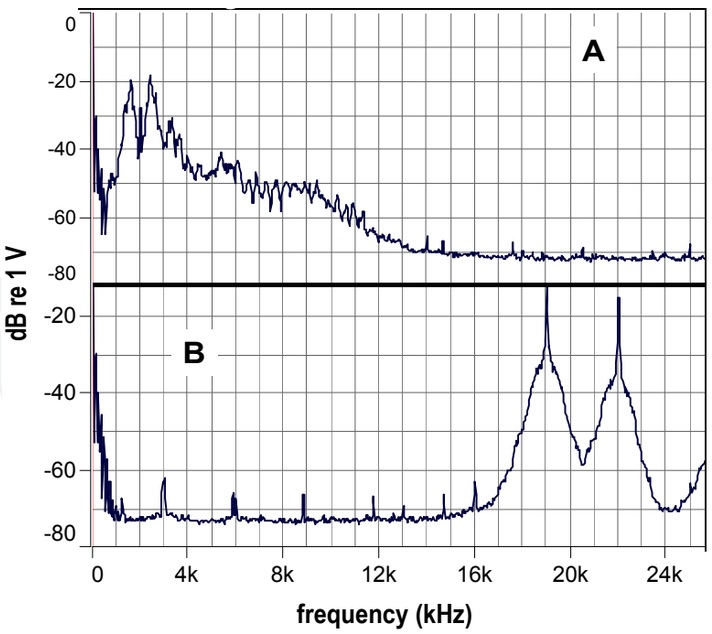


Fig. 2. The speech segment to be modulated is depicted in panel A, and the dual carrier modulation is depicted in panel B. By selecting the appropriate carrier or carriers the high frequency stimulation can be shifted and customized to the patient to treat the tinnitus pitch, spectrum and higher frequency areas as indicated by high frequency audiometry.

of the 12 kHz carrier the USB signal would have a pass band from 14-20 kHz. AM mode is not used for speech perception since the carrier is the strongest signal, usually very audible; resulting in hearing a steady pitch plus the modulated speech. For tinnitus masking, this is not such a problem because the goal is high frequency stimulation. As depicted in Figure 3 (upper panel A) there is an attenuator to adjust the level of high frequency stimulation which should be 12 dB above sensation level (SL). Low level stimulation is important because hyperacusis is always a concern in severe tinnitus. Returning to Figure 3 (B panel) the output of the modulator, appropriately attenuated is amplified and fed into a custom aluminum ceramic transducer. The transducer should be placed on the skin of the head near the ear, the mastoid region is recommended. Alternatively, the transducer can be placed on the skin of the skull in front of the ear, on the so called "ultrasonic window". The maximum output for the FDA approved amplified/transducer is < 76 dB SPL equivalent (maximum force is 100 dB re 1 μN), thus this would be unsuitable for those (ager 18+) with more than a 60 dB HL hearing loss. A newer amplifier has 20 dB more output. The frequency sweep mode may be best if limited audiometric infrastructure is available.

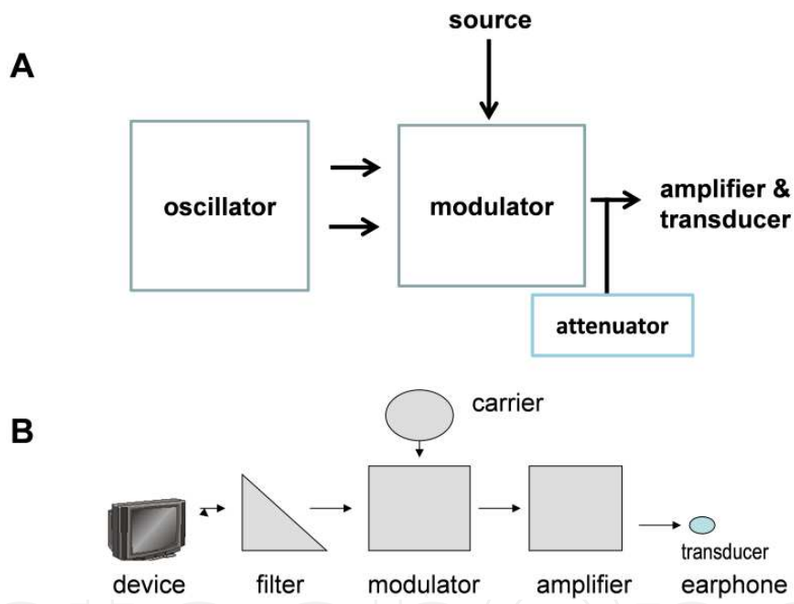


Fig. 3. The home medical device for tinnitus is depicted. The essential elements, oscillator, modulator and amplifier are fed into an UltraQuiet amplifier and transducer after preprocessing a television signal (panel A). The entire system is depicted in panel B.

In reference to the UltraQuiet amplifier and transducer's FDA compliance, the force exerted by bone conduction vibrators in audiometry and its relation to hearing level is normally measured according to standard ANSI S3.43-1992, for frequencies up to 4 kHz. There is no standard for calibration of bone conduction force in the UltraQuiet™ range from 6 kHz to 20 kHz. There are also no artificial mastoids with impedance calibrated in this range. The following measurements use a frequency of 6 kHz, and extrapolate the results to the higher frequencies. Although the standard is given in force, measurements are often made in acceleration for practical reasons, and converted to force (Hakansson et al., 1985). Hakansson et al., in their calibration of direct bone conduction, faced a similar need to extrapolate from existing standards.

The formula for calculation of force is F = |Z| x A/ω, where: F = force in N, A = acceleration in m/s², |Z| = mechanical point impedance in Ns/m, ω = angular frequency (radians/s).
Using the above equation, the following numbers apply to 6 kHz, taken from Table 1 in Hakansson et al. (1985), based on the Reference Equivalent Threshold Force Levels (RETFL) as proposed in ISO/DIS 7566, and the mechanical impedance of the head at the skin surface in the draft revision of IEC publication 373, 1971.

| | |
|---|---|
| Frequency: | 6000 Hz |
| RETFL (dB re 1 mN): | 40.0 dB |
| Mechanical Impedance (dB re: 1 Ns/$_m$): | 34.0 dB |
| RETAL (dB acceleration re: 1 cm/s²): | 17.5 dB (-2.5 dB re 1 m/s²) |

The measurement system consisted of a Brüel & Kjaer 4374 accelerometer with a Brüel & Kjaer Pulse 3560 analysis system. As reference levels for calibration, a Radioear B-71 bone vibrator was used with its standard headband as the static force (measured at 4.4 N) compared to a plastic headband with a static force of 1.5 N and an Madsen Orbiter 922 audiometer, at 0 dB HL and 55 dB HL, on a live human head, since no artificial mastoids are calibrated in the higher frequency range. There was no difference between the two headbands; with complete coupling, the difference in static force made no difference in the measured acceleration. A simple plastic headband was selected for comfort and appearance.
Based on the above table, using an artificial mastoid, at 0 dB HL and 6 kHz, the force should be 40.0 dB and the acceleration should be -2.5 dB. In the experimental arrangement, the acceleration was –12.5 dB re 1 m/s². Thus a correction factor of 10.0 dB must be added to the data to yield measurements comparable to the standard. This is similar to the method used by Hakansson et al. (1985) to arrive at correction factors for direct bone conduction via a screw attached to the skull. In the same experimental arrangement, the 55 dB HL signal from the audiometer produced a 42.0 dB re 1 m/s² acceleration (54.5 dB more than the –12.5 dB acceleration at 0 dB HL), confirming the linearity of the system within 0.5 dB.
The minimum recommended use is one hour daily. Effectiveness can be assessed with tinnitus outcome questionnaires to establish a baseline of functioning; these include the tinnitus intensity index, the annoyance index, and the tinnitus severity index (Goldstein et al.,2001; 2004) which can be filled out by home users.
A stand-alone in home use tinnitus device that employs a recreational source of sound (television) minimizes the need to be in proximity to a hearing health care facility for treatment. Further low cost therapy can be delivered without expensive hospital or practice based facilities; all but eliminating multiple office visits. Compliance will likely improve increasing outcomes. One time purchase eliminated the need for third party carriers to fund on going therapy, particularly in population with a disproportionate access to conventional services. The in home UltraQuiet device will not require special training other than some initial familiarization with the device controls and protocol. There is no need for a medical resource environment for its operation.

Tinnitus and hearing loss are military service-related disabilities for which veteran compensation costs are high and expanding with world-wide theaters of operation (Fausti et al., 2009; Veterans Affairs, 2009). Tinnitus can be induced from blast and noise exposure and a recreational used therapy system can be beneficial in recovery. Rehabilitating injured warfighters can increase readiness as well as be a component in total care. Future plans are to develop a wearable UltraQuiet paired with various types personal listening and multimedia devices for tinnitus therapy.

## 3. Summary

In summary this tinnitus masking system will deliver high frequency bone conduction stimulation without interfering with the television broadcast acoustics, such that patients can watch engaging television programming and receive tinnitus treatment. The innovation is effortless use by embedding the technology into a recreational activity. High frequency bone conduction stimulation was found to be effective in producing residual inhibition (suppression of tinnitus after device is turned off) and reported in 2001 (Goldstein et al.) before the animal studies provided a rational for such treatment. The bioeffect is now known to be more than residual inhibition, but neuroreprogramming in the auditory and limbic systems. There is no effectiveness if the treatment is not carried out. The goal is high frequency treatment that is effective and fully utilized by wedding it to a recreational use, which in turn would translate into improved quality of life for millions globally.

## 4. Acknowledgment

UltraQuiet is now the property of Ceres Biotechnology LLC, Richmond Virginia 23298-0168.

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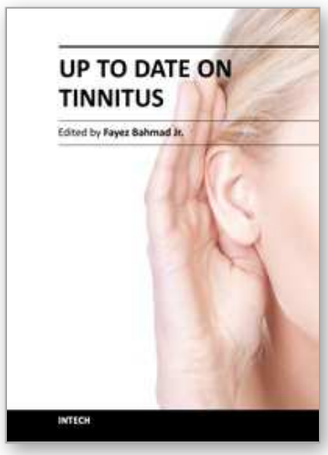


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Up to Date on Tinnitus encompasses both theoretical background on the different forms of tinnitus and a detailed knowledge on state-of-the-art treatment for tinnitus, written for clinicians by clinicians and researchers. Realizing the complexity of tinnitus has highlighted the importance of interdisciplinary research. Therefore, all the authors contributing to the this book were chosen from many specialties of medicine including surgery, psychology, and neuroscience, and came from diverse areas of expertise, such as Neurology, Otolaryngology, Psychiatry, Clinical and Experimental Psychology and Dentistry.



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