Introducing Multiflex Tinnitus Pro

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Tinnitus: A Common but Not Fully Understood Problem

Tinnitus refers to the perception of phantom sounds, which do not have a corresponding acoustic source in the environment. These sounds are commonly described by those who experience them as ringing, buzzing, or roaring in one ear, both ears or in the head. Depending on how tinnitus is defined and assessed, estimates of its prevalence range from 5% to 43% (McCormack et al. 2016). Importantly, prevalence increases with age, and is higher among individuals with hearing impairment compared to individuals of the same age without a hearing loss (Lewis et al., 2020; Nondahl et al., 2011). Other risk factors or comorbidities of tinnitus may include a history of otosclerosis, ear surgery, cardiovascular disease, and noise exposure (Nondahl et al., 2011). Tinnitus has been a top disability claim among military veterans in the United States (Maynard et al., 2018). Chronic tinnitus can interfere with the ability to fall asleep or concentrate, and may promote stress, anxiety and depressive feelings, thus increasing distress and reducing quality of life (Weidt et al., 2016).

While the biological mechanisms of tinnitus remain not fully understood, several modern neuroscientific models emphasize an initial mismatch between sensory inputs and central processing (Roberts & Salvi, 2019). In some of these models, tinnitus is explained as a result of cascading effects, whereby cochlear damage reduces peripheral neural input at some frequencies, which then leads to an increase in neural "gain" in corresponding tonotopic regions of the central auditory system—a form of compensatory plasticity. In the absence of typical sound input, increased central gain leads to the over-amplification of spontaneous neural activity, thus mimicking acoustic input and creating an illusory percept of sound (Noreña, 2011; Roberts & Salvi, 2019). These models may explain why tinnitus is frequently associated with hearing loss and why, when tinnitus is matched to an external sound, the frequency of that matching sound often falls within a frequency range where hearing thresholds are elevated (Norena et al., 2002).

Despite these advances, many unknowns remain regarding the neurophysiological underpinning of tinnitus, and it is likely that a single model cannot explain all tinnitus cases. In some individuals, tinnitus may be unrelated to cochlear damage, may involve the middle ear (e.g., Job et al., 2016), or have a non-auditory origin (Langguth et al., 2013).

Current Approaches to Tinnitus Management

One of the first comprehensive clinical approaches to tinnitus management is Tinnitus Retraining Therapy (TRT) (Jastreboff, 1990). TRT takes a two-pronged approach, combining the use of acoustic therapy and directed counseling. Defined broadly, acoustic therapy refers to the use of acoustic stimulation, which can be achieved through amplifying ambient sounds and/or generating an independent tinnitus "masker" with a hearing aid. A tinnitus masker is an acoustic stimulus generated by the device, which is designed to partially or completely mask the tinnitus. In a typical TRT protocol, a tinnitus masker is used in combination with counseling to promote tinnitus "habituation", a decrease in tinnitus severity or intrusiveness over time. A premise of TRT is that, for "habituation" to occur, the level of the acoustic stimulus should remain below the level at which it completely masks tinnitus (Jastreboff, 2000), also known as the minimum masking level (MML). However, some studies have reported significant benefits even when the tinnitus stimulus was at or slightly above the MML (Henry et al., 2016; Tyler et al., 2012).

A more recent approach to tinnitus management, which has garnered increasing support based on clinical studies over the past 15 years, is Progressive Tinnitus Management (PTM) (Henry et al., 2005). PTM recognizes that not all tinnitus patients require the same level of management and is organized into successive levels of care. PTM Level 1 is the triage process by which individuals with tinnitus are referred by non-audiologist health-service providers for audiological care. PTM Level 2 involves a thorough audiological evaluation, during which the characteristics of tinnitus, including its severity and impact, are evaluated in greater depth. In addition to a thorough case history, this evaluation may take advantage of questionnaires, such as the Tinnitus Handicap Inventory (THI) or the Tinnitus Handicap Survey (THS), which were designed specifically to help hearing professionals and/or patients assess tinnitus. Based on the assessment of the patient-specific hearing loss and tinnitus severity, the professional may opt to provide the patient with information on hearing loss and/or tinnitus, and on management strategies for either or both. Fitting with hearing aids is usually performed at this stage, often utilizing tinnitus maskers to provide additional acoustic therapy. Subsequent PTM levels involve group education (Level 3), interdisciplinary evaluation (Level 4) and finally, individualized support (Level 5). The latter two levels, being more time consuming and requiring additional resources, are usually reserved for individuals with particularly bothersome tinnitus, or those with associated (e.g., psychological) difficulties.

While there exist other approaches to tinnitus management, TRT and PTM are, arguably, the two most widely used and supported approaches today. Since there is no widely accepted consensus among tinnitus-research experts regarding the biological mechanisms underlying tinnitus, and the mechanisms may differ across individuals, tinnitus treatments that invoke a single biological theory as the main basis for their efficacy should be regarded with caution. Moreover, outcomes of tinnitus interventions can vary across individuals (Frederick, 2014). As such, an approach to tinnitus management that is guided by empirical evidence seems most prudent.

Multiflex Tinnitus

In 2012, Starkey introduced Multiflex Tinnitus, enabling hearing professionals to efficiently and effectively manage tinnitus with hearing aids that generate highly customizable tinnitus masker stimuli (Galster, 2012, 2013). At first fit, the hearing professional can quickly generate a broad-band noise with a nominally flat spectrum, akin to the "white noise" stimulus commonly used in TRT. The overall level (volume) of the noise is automatically fit based on the patient's three-frequency (500, 1000, 2000 Hz) pure-tone threshold average. From this starting point, the volume and spectrum of the masker can be adjusted by the professional (through the fitting software), if desired to create a variety of maskers. For example, hearing professionals who desire to fit a narrow-band noise or a noise with a spectral notch in it (known as "notched noise") instead of a broad-band masker, can do so, simply, by selectively turning off some of the frequency bands (Figure 1).

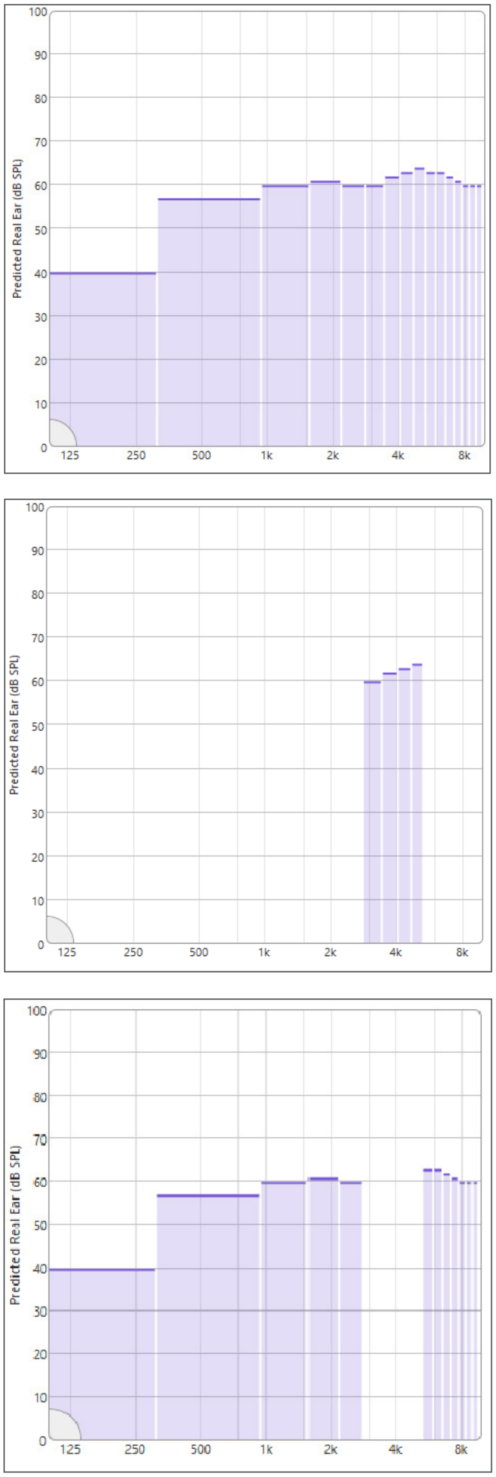


Figure 1. An illustration of masker spectra produced using Starkey's Multiflex Tinnitus feature, a flexible tinnitus-stimulus spectral-shaping tool that lets the hearing-care professional fit a flat-spectrum ("white-noise") tinnitus stimulus (top), or almost any other desired spectral shape, such as narrow-band noise (middle) and "notched" noise (bottom).

Results regarding the benefits of the Tinnitus Multiflex technology, in combination with hearing-aid use, are reported in earlier publications (Henry, 2016; Henry et al., 2015).

Multiflex Tinnitus Pro

With Multiflex Tinnitus Pro, Starkey extends its offering of flexible tinnitus fitting solutions for hearing professionals by introducing two new tools: audiogram-shaped noise and the tinnitus stimulus personalization. Both tools empower hearing professionals to generate a highly personalized tinnitus masker for their patient, more easily and more rapidly than might be achieved using only manual adjustments of each noise-band level.

Audiogram-shaped Noise

Starkey's new audiogram-shaped noise tool addresses a shortcoming of flat-spectrum broad-band noise (aka, "white noise"). For most individuals with hearing loss, a flat-spectrum stimulus may not be optimal for at least two reasons. Firstly, the sound may not contain enough energy in frequency regions where such energy is needed to most effectively induce a relief from tinnitus. For example, Figure 2 illustrates the case of an individual with steeply sloping high-frequency hearing loss above 2 kHz and a high-pitch tinnitus, resembling a 4 kHz tone. For this individual, using a flat-spectrum ("white") noise 20 dB above the three-frequency (0.5, 1, 2 kHz) pure-tone threshold average, the noise bands closest to the tinnitus frequency (4 kHz) would be well below the hearing threshold and therefore, unlikely to mask tinnitus. Secondly, increasing the masker level to the point where the 4-kHz noise band becomes audible for the patient would result in the 1-kHz band level being more than 40 dB over the 1-kHz pure-tone threshold, such that the masker would likely cover up low-level environmental sounds, and be deemed too loud. The new audiogram-shaped noise feature solves these two issues by automatically adjusting the spectral shape of the noise based on the shape of the patient's audiogram. The algorithm sets the level of each

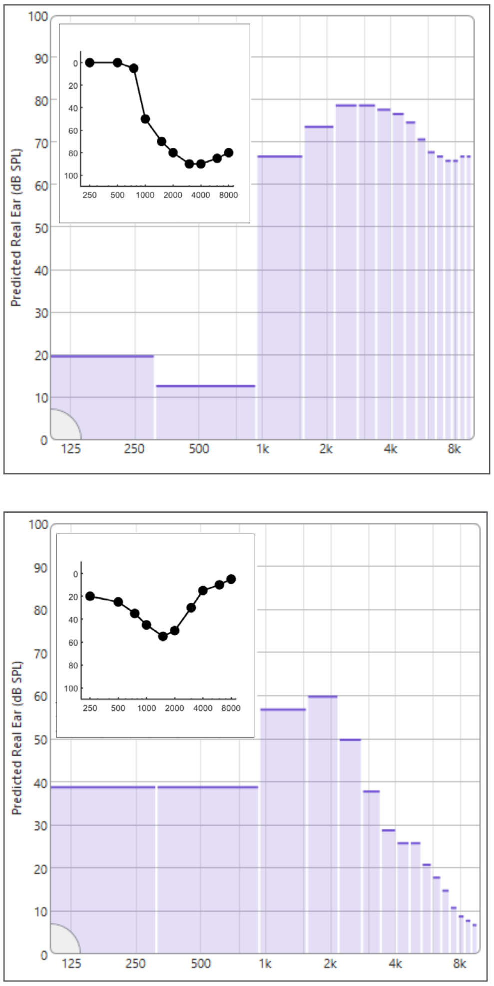
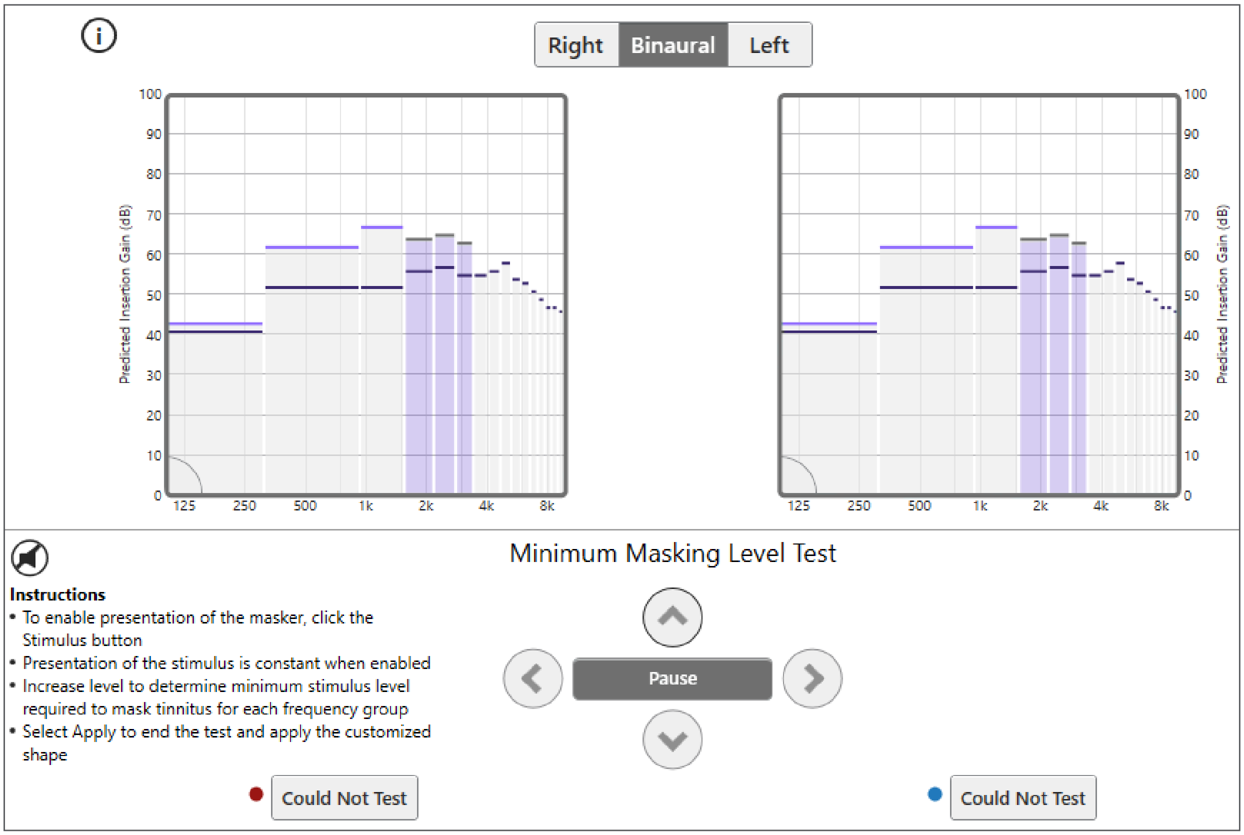


Figure 2. Example of pure-tone audiograms and corresponding audiogram-shaped tinnitus stimuli. Top: High-frequency hearing loss. Bottom: Notched hearing loss.

individual noise band in relation, not to the pure-tone threshold average, but to the hearing-threshold for the corresponding (band-center) frequency. As a result, the spectral shape of the noise mirrors the audiogram, with more sound energy at frequencies where hearing loss is greater than at frequencies where hearing loss is less. An advantageous property of the resulting stimulus is that its frequency bands are all, approximately, equally audible across all frequencies. Thus, regardless of the tinnitus pitch and timbre, and of whether tinnitus is masked by high-frequency sounds, low-frequency sounds, or broad-band sounds, the audiogram-shaped noise stands a greater chance of effectively masking tinnitus than flat-spectrum ("white") noise, even when the sensation level of the former is lower than that of the latter. Moreover, the audiogram noise-shaping process is easy and fast, requiring only from the professional that they select the audiogram-shaped noise option in the fitting software.

Stimulus Personalization Tool

This second new feature goes beyond the audiogram-shaped noise tool, and offers a higher level of custom personalization of the tinnitus-masker spectral shape, based on relevant psychoacoustic measures (Fournier et al., 2018; Henry et al., 2013; Vernon & Meikle, 2003).
The overarching goal is to rapidly design a noise that can effectively and efficiently mask tinnitus. To effectively mask tinnitus, the stimulus must contain energy in frequency bands that produce masking. To efficiently mask tinnitus, only those frequency bands that are effective at masking tinnitus should be included in the stimulus, and the level of the stimulus in these bands should be no greater than needed to achieve masking. Both objectives can be achieved using two simple psychoacoustic measures: the minimum detection level (MDL), which is the lowest stimulus level for which the patient can hear the stimulus, and the minimum masking level (MML), which is the lowest stimulus level for which the stimulus masks the tinnitus. Invariably, the stimulus level needed to mask tinnitus (the MML) is higher than the level at which the stimulus is just detectable (the MDL), so that the difference (in dB) between these two measures (in dB SPL), computed as MML – MDL, is positive. Large differences are indicative of a less efficient masker (a higher sound level above detection threshold needed to mask tinnitus), while smaller differences indicate a more efficient masker. This yields a simple key to designing an effective and efficient customized tinnitus masker: frequency bands for which the measured MML-MDL difference is small support efficient and effective masking, and thus should be retained; frequency bands for which the difference is large do not efficiently mask tinnitus, and can be



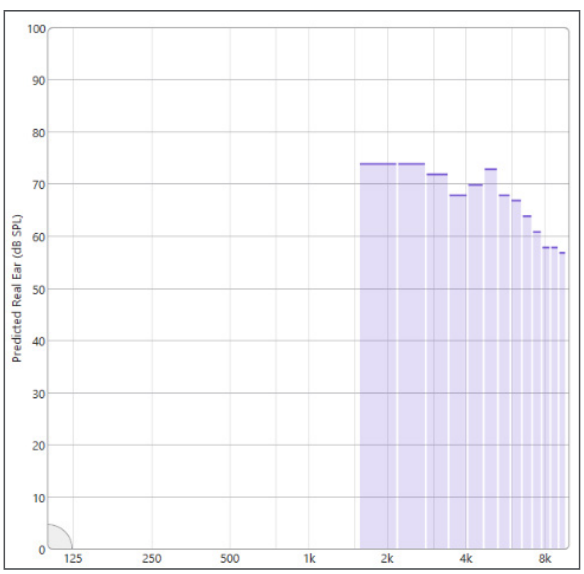


Figure 3. Stimulus personalization tool (top panel). The tool provides detailed instructions for measuring the Minimum Detection Level (MDL) and Minimum Masking Level (MML) of three groups of frequency bands (low, medium, and high). The bottom panel depicts an example custom masker output in which the medium- and high-frequency channels were selected as most efficient at masking tinnitus.

excluded from the final masker spectrum.

The idea of customizing tinnitus masker spectra based on psychoacoustic measures has a long history in audiology. Some authors have suggested using measures of the tinnitus pitch as a basis for personalizing tinnitus maskers, for example, using band-limited noise centered on, or slightly below, the tinnitus-pitch frequency (Schad et al., 2018; Terry et al., 1983). This is consistent with findings indicating more effective masking of tinnitus and, in some cases, greater relief from tinnitus, when the acoustic stimulation bandwidth includes the tinnitus frequency (McNeill et al., 2012). A practical complication with masker-selection strategies based on the tinnitus pitch, is that pitch-matching tinnitus is often a difficult task for the participant and can prove time-consuming. More importantly, the measured tinnitus pitch may not always provide a reliable indication of which stimulus bands most effectively or efficiently mask tinnitus (Fournier et al., 2018). If the audiological goal is to select a masker that can effectively and efficiently mask tinnitus, then this goal can be achieved most rapidly by measuring, directly, MMLs and MDLs; in this context, tinnitus pitch measurement is unnecessary.

Starkey's stimulus personalization tool facilitates the above-described process, including the measurement of MDLs, MMLs, and the synthesis of a personalized noise stimulus based on these measurements. It does so by taking the professional and their patient through a short succession of simple steps. In the first step, the MDL is measured for each of three groups of frequency bands (low, medium, and high). In the second step, the MML is measured for each of the same three frequency-band groups. These two steps require the active participation of the professional and of the patient. For MDL measurements, the professional instructs the patient to indicate when they can hear the noise being generated through the hearing aid. The professional determines the MDL by systematically increasing or decreasing the stimulus level, as they do for pure-tone audiometry, except that in this case, the stimulus is a noise band. For MML measurements, the procedure is similar, except that the patient is instructed to indicate when the noise masks their tinnitus. The MDL and MML tests can be conducted in the left ear only, the right ear only, or binaurally, depending on the hearing-loss configuration (e.g., symmetric or asymmetric), and whether tinnitus is lateralized to one ear or not – for strongly asymmetric hearing-loss, or when tinnitus is either lateralized to one ear or different between the left and right ears, individual testing and fitting of the left and/or right ear(s) may be more appropriate; ultimately, whether to test and fit tinnitus maskers monaurally or binaurally should be determined by the professional, on an individual basis, and in accordance with recommendations of the chosen tinnitus-management program. Testing typically takes a few minutes. Once testing is complete, the software uses the results to try to automatically generate an effective and efficient stimulus. The resulting stimulus can be listened to by the patient and, if necessary, adjusted by the hearing-care professional. Obviously, best audiological practices for tinnitus-masker fitting continue to apply; the professional must ensure that the volume of the stimulus is adjusted in a manner consistent with the goals of acoustic therapy (partial masking, mixing point, or complete masking), and that the stimulus is both, effective and acceptable to the patient. PTM guidelines recommend that stimulus use by the patient be discontinued, if adverse effects (such as a worsening in tinnitus) are observed.

In some cases, the results of the MDL and MML tests do not lend themselves to the determination of an effective and efficient custom masker. This may happen in particular, when an MML could not be measured for some frequency groups, due to stimulus band levels reaching the maximum allowed limit before tinnitus could be masked. Tinnitus-stimulus level limitations are imposed by most manufacturers, to limit the risk of noise-induced hearing loss that might be caused by over-use of the tinnitus masker despite professional guidance on proper use. This is assuming no significant sound exposure. Importantly, and as recommended in PTM and TRT, hearing professionals should provide patients with adequate education and guidance regarding proper use of the tinnitus stimulus on a case-by-case basis, taking into account the patient's individual characteristics (age, hearing loss, etiology, tinnitus severity and alleviation needs, tinnitus stimulus settings, lifestyle, etc.), prior to delivering a device equipped with such a capability.

Conclusion

Acoustic therapy is an important component in most comprehensive tinnitus-management programs, such as Tinnitus Retraining Therapy and Progressive Tinnitus Management. While sound amplification alone can already help patients with tinnitus, additional acoustic stimulation with a tinnitus stimulus, or "masker", may provide additional relief, especially in quiet environments (e.g., at home, in evenings). Starkey's innovative Multiflex Tinnitus Pro technology provides hearing professionals with two new tools for efficiently fitting highly personalized tinnitus stimuli: (1) an audiogram-shaped stimulus, spectrum of which is automatically adjusted based on the patient's pure-tone audiogram, and (2) a custom stimulus, spectrum of which is determined based on measured detection and masking thresholds (MDLs and MMLs). These two new tinnitus-stimulus fitting solutions come on top of Starkey's existing "white noise" stimulus feature and the flexible multi-band Multiflex Tinnitus technology which allows hearing professionals to individually adjust stimulus levels in 16 frequency bands. With these new tools, hearing professionals can quickly, and automatically, generate personalized tinnitus stimuli for use in tinnitus-management programs with an 'acoustic therapy' component that calls for the use of such stimuli.

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