Resound Live™ TS: An Innovative Tinnitus Sound Generator Device to Assist in Tinnitus Management

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Tinnitus is a concern for many people, and affects approximately 10% of the overall population, with approximately 3-5% of the population suffering from clinically treatable tinnitus (McFadden, 1982). As hearing loss is increasingly identified and diagnosed, this trend is most likely to continue and grow (Vernon, 1998). Many tinnitus sufferers, and clinicians, have struggled finding flexible tinnitus treatment devices that are suitable components of a tinnitus treatment and counseling support program. ReSound Live™TS is an advanced combination hearing instrument and Tinnitus Sound Generator (TSG) device that provides fitting flexibility for clinicians, and an innovative TSG solution for users. It can be used as a combination device to address both hearing loss and tinnitus, as well as a TSG only, for those individuals struggling with tinnitus only.

What is tinnitus, and what causes it?

Tinnitus is an involuntary perception of sound that originates in the head (McFadden, 1982). It is most commonly referred to as 'ringing in the ears', but can take on a number of perceptual characteristics, such as clicking, chirping or pulsing. It can be constant and steady, or it can be intermittent. The perception of tinnitus can greatly vary from person to person.

Outside of known medical complications that may lead to tinnitus, it is important to note that the exact mechanism of tinnitus causation is not exactly known, but there are different theories and models that have been examined. It is also important to remember that psychological factors play a large role in tinnitus perception. One of the more studied, and well-accepted, neurophysiological models of tinnitus discusses the role of cochlear damage in regards to tinnitus causation (it is a very in-depth model, and this paper will only address some of the main points). It is believed that when the outer hair cells (OHC) are damaged, they are no longer able to carry out an important role, which is to inhibit the neuronal firings of the inner hair cells (IHC) in the absence of auditory input. When the OHC are no longer able to perform this function, the IHC spontaneously fire neurons to the brain, which are processed, amplified and recognized as noise, even in the absence of auditory input. This noise is recognized as tinnitus (Figure 1).

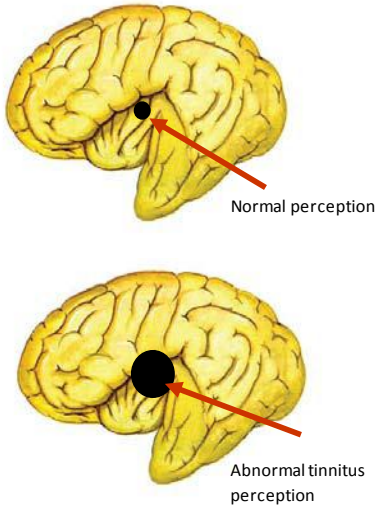

Figure 1. Abnormal tinnitus perception due to outer hair cell damage.

Tinnitus does not seem to be limited to OHC damage alone, as it seems IHC damage can also play a role in the generation of tinnitus. This suggests that there are additional mechanisms that are also responsible in tinnitus generation beyond OHC damage (Jastreboff & Hazell, 1993). There are other theories as to the mechanisms that may be causing tinnitus, but it is not the intention of this paper to discuss all of them.

The strength of a person's tinnitus is not only due to cochlear damage, but to the focus that one puts on the tinnitus. This is called 'prioritization'. The more focus, or priority, a person puts on the their tinnitus, the more audible it will be, and the more easily the brain will be able to detect the neuronal patterns that characterize the tinnitus, even in the presence of other auditory input, such as background noise or speech. For most people, they can ignore and habituate to the tinnitus quite easily, and the tinnitus blends into the background without much further notice. But, for some individuals, this is not the case.

When the tinnitus becomes a focal point, it can lead to negative emotions that are associated with the tinnitus, such as frustration, anxiety and helplessness. These negative emotions, which involve the limbic system, can lead to physical changes and reactions in the body, such as stress, which includes the autonomic nervous system (Henry et al, 2002). When a person is stressed by the situation, the tinnitus remains, or at times can get worse, which prompts the cycle to repeat itself. This is often referred to as the 'Vicious Cycle of Tinnitus' (Figure 2). Apart from tinnitus that is caused by a known medical complication, most agree the goal of tinnitus treatment is to break the vicious cycle, and have a person in control of their reactions to the tinnitus, ultimately learning to habituate to their tinnitus. Habituation is the process in which one becomes 'used to' the stimulus. A good example of this is air conditioner noise. Most normal hearing people will hear the air conditioning noise when they walk into a room, since the air conditioning stimulus is new to the brain, but quickly learn to put the noise in the back of their mind, and focus on more important stimuli. When the air conditioning noise is no longer recognized by the individual, habituation to it has occurred.

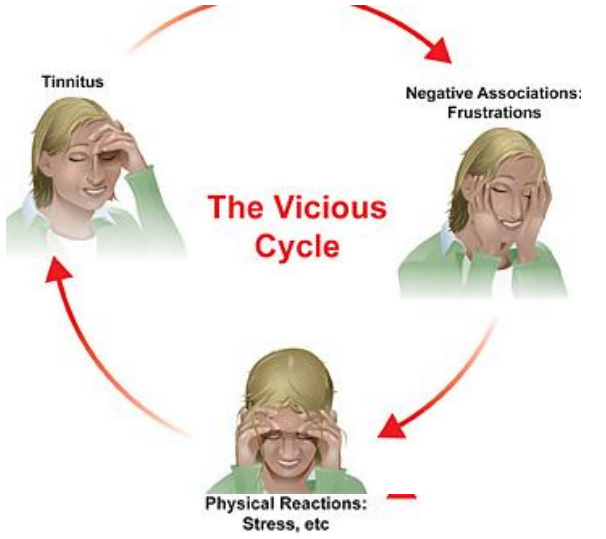

Figure 2. The vicious cycle of tinnitus

By breaking the vicious cycle, we still enable the individual to attend to their tinnitus, but rather than react negatively to it, they are aware and accepting of the tinnitus. This can result in more control of how one reacts to their tinnitus. Ultimately, the goal over time is to habituate to the tinnitus altogether, although complete habituation may not occur in many individuals.

Tinnitus treatments and counseling methods

There are many different types of tinnitus treatments, resulting in a number of methods to choose from. We will discuss some of the more common treatments. One of the most common treatments is sound therapy, also known as acoustic therapy. Sound therapy is simply the introduction of an external sound, to help reduce the contrast of the tinnitus against the background. By increasing the level of external sounds in the patient's environment, we aim to decrease the perception of the tinnitus. A common example to illustrate sound therapy is the "candle on the table" analogy. A candle lit on a table in a dark room becomes the focal point, as it is very easy to detect the light against the dark background. In contrast, the same candle on a table in a lit room with dinnerware and a busy restaurant environment becomes less noticeable against the background (Figure 3).

Figure 3. Sound therapy analogy – the candle intensity is decreased at a busy dinner table as opposed to being isolated in the dark.

There are many different tools that can be used in sound therapy. ReSound Live™TS is a combination unit which has both hearing instrument features, as well as a tinnitus sound generator (TSG) feature to help address tinnitus. The TSG can be used in sound therapy to help increase the level of background noise, which can help decrease the contrast of the tinnitus. ReSound Live™TS also contains other unique features, such as frequency shaping of the white noise, amplitude modulation and environmental steering, which can help personalize the TSG and provide more comfort for the individual. In addition, with the introduction of open fit hearing instruments, we are able to allow more natural sound through the ear canal. For some individuals, simply providing amplification through the open fit hearing instrument is enough sound therapy to help them habituate to their tinnitus, even without the TSG.

Other tools that can be used are sound pillows, which generate noise and can be useful for people

who have difficulty sleeping. Other, more common everyday sounds, such as TVs, radios, fans, or even opening a window to hear environmental sounds from outside can also be useful. In addition, music can be a very helpful form of sound therapy. In its simplest form, sound therapy is the introduction of an external sound to help 'drown out' the tinnitus, and allow the individual to habituate to their tinnitus.

Another well-known and heavily practiced tinnitus treatment approach is tinnitus retraining therapy (TRT). TRT has a well-defined protocol, where emphasis is placed on educating the patient on the neurophysiologic foundations of tinnitus. TRT aims to provide the patient with a better understanding of where tinnitus comes from, as well as understanding the reactions produced by the limbic system and autonomic nervous system in response to the tinnitus. The goal is, through knowledge and understanding, for the patient to have more control over their emotions and reactions to the tinnitus, allowing them to more efficiently cope, and ultimately habituate to their tinnitus (Henry et al, 2002). Sound therapy (not necessarily a TSG device) is an integrated part of TRT.

There are also other treatment plans including different psychological and psychiatric models for more severe cases of tinnitus, that have also proven effective. It is not the intention of this paper to explore these models, but information can be found explaining these methods in greater detail. Many times, a combined approach to tinnitus treatment, involving multiple disciplines and treatments can occur according to the individual's needs. Regardless of what treatment plan is used, the goal is to have a person in control of their tinnitus and how they react to it, as this will help break the vicious cycle (Figure 4) and allow for habituation.

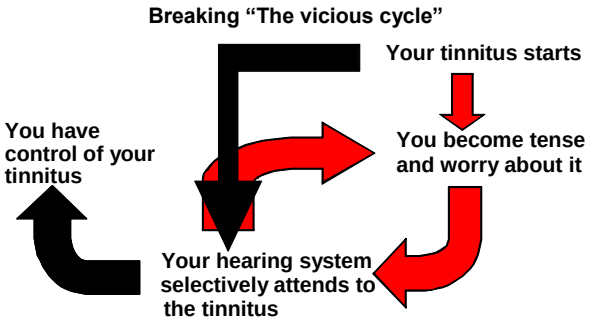

Figure 4. Breaking the vicious cycle - the red arrows indicate the path of the vicious cycle prior to tinnitus treatment, and the black arrows indicate the goal of tinnitus treatment – being in control.

Regardless of what method you choose to use, monitoring the status of any treatment plan is very important. It is suggested that both subjective and objective measurements be taken through treatment. Objective measures are often carried out by common tinnitus questionnaires, such as the Tinnitus Handicap Inventory (THI), Tinnitus Handicap Questionnaire (THQ), or Tinnitus Reaction Questionnaire (TRQ). Questionnaires try to look at varying aspects of the tinnitus and how it is affecting the person. Questionnaires can be given as baseline measures, and again later on in treatment for post-treatment measures. Subjective measures are typically in the form of patient feedback. Letting the patient discuss how the treatment is working for them and how it is affecting their tinnitus can lead to important insights on the part of the clinician as well as the patient. Both measures are important to fully understand the effects a tinnitus treatment plan is having on the patient. It is important to note that post-treatment measures should be considered carefully, as early results can be due more to the placebo effect rather than the treatment itself. Lastly, creating realistic expectations from the start is often helpful. As full habituation may not take place for all, and that tinnitus treatment can take an extended period of time (6mos – 2yrs, or longer for some), it is important that one's expectations are in line with the treatment objective.

ReSound Live™TS

ReSound Live™TS is a fully functional and flexible combination hearing loss and tinnitus solution to assist in your treatment of tinnitus/hearing loss sufferers. For your patients, it offers a cosmetic and customizable solution to help treat their tinnitus, helping to provide more relief and a better quality of life. The hearing instrument portion of ReSound Live™TS offers all the advanced digital technology of our ReSound Live™ hearing instruments, but also offers unique TSG features such as frequency shaping of the white noise signal, amplitude modulation and Environmental Steering.

Most literature suggests that using a broadband stimulus activates the most neurons, and is most effective for sound therapy. Based on this knowledge, the default noise setting for Live™TS is set to a broadband filtering setting, but has the flexibility of low and high cut controls to provide more individualized comfort. The low cut filter's range is 250Hz-2kHz, while the high cut filter's range is 2kHz-6kHz.

Another feature, which can be personalized for patient comfort, is amplitude modulation. Amplitude modulation (AM) is a fluctuation in the level of the noise signal while all other spectral components remain uniform. AM attenuation in Live™TS is non-deterministic (randomized) to avoid audible periodicity, meaning that the amount of attenuation will not always be the same. AM in ReSound's fitting software, Aventa, can be configured to a maximum attenuation of 3 options:

- Mild (-4 dB)
- Moderate (-8 dB)
- Strong (-12 dB)

This means that if a 'Moderate' AM setting is chosen, the white noise energy can fluctuate up to -8dB from the programmed volume of the tinnitus sound generator (TSG). For example, if the programmed volume of the TSG is 65dBSPL, and a 'Moderate' AM setting is chosen, the TSG volume can fluctuate between 65dBSPL and 57dBSPL, keeping in mind that the fluctuations will be randomized. Once the AM is activated, you have the option of controlling the speed at which the AM fluctuations occur. You can select between three options.

- Slow (2secs)
- Medium (4secs)
- Fast (8secs)

The time represents how often a fluctuation will occur in the white noise energy. Amplitude modulation and amplitude modulation speed are strictly comfort features, and should be considered on a case-by-case basis.

A truly unique feature to Live™TS that can be beneficial in tinnitus treatment is Environmental Steering. Environmental Steering acts as an automatic volume control that adjusts the level of the white noise signal, according to the listening environment. It uses a classifier that assigns the input into one of seven listening environments (Quiet, Soft Speech, Loud Speech, Soft Speech in Noise, Loud Speech in Noise, Moderate Noise and Loud Noise).

Since typically people report their tinnitus being worse in quiet situations, when the user is in a 'Quiet' environment, the TSG volume will be at the programmed setting. When the user is in a more speech-heavy environment, or a noisy environment, less noise is needed to decrease the contrast of the tinnitus, since there is more environmental stimuli present, and thus the TSG volume will decrease (Figure 5).

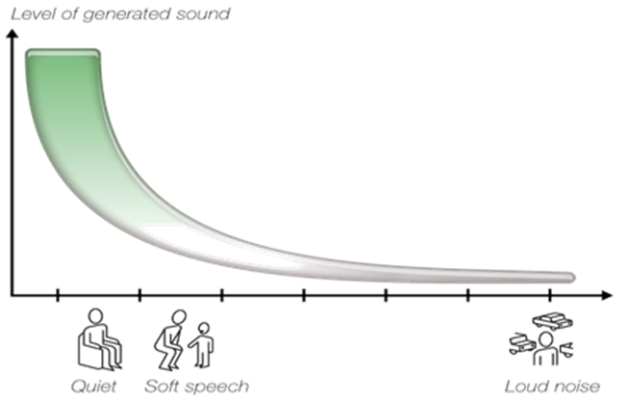

Figure 5. Environmental Steering - The tinnitus sound generator volume will automatically adjust according to listening environment.

Environmental Steering serves a number of purposes. First, for users who are not familiar with a manual volume control, or do not fully understand the aim of sound therapy (or tinnitus treatment), Environmental Steering can help avoid the potential risk of completely masking the tinnitus. Completely masking the tinnitus does not allow for habituation, as one cannot habituate to what is not audible, and this can be detrimental in the tinnitus treatment.

Environmental Steering also ensures that the TSG signal does not interfere with important information, such as speech. Lastly, taking away the need for a manual volume control can put less emphasis on the instrument, and for some, may help reduce the attention that is paid to the tinnitus. This can occur if one is constantly adjusting the volume control. If Environmental Steering is not preferred, a manual volume control can be activated. For some tinnitus patients, this provides a greater sense of control. Environmental Steering or the manual volume control can be selected in the 'Sound Level Adjustment' drop-down option in the Aventa fitting software.

Note:

- *Within any individual program the manual volume control can either be off, designated to the hearing instrument or designated to the TSG. It cannot be active for both the hearing instrument and TSG in the same program.*
- *By default, amplitude modulation and Environmental Steering are deactivated.*

Another flexible feature in ReSound Live™TS is the option of having up to four customizable programs. Live™TS can be fit as a combination device, where the hearing instrument is active as well as the TSG, or the hearing instrument portion can be

deactivated, and it can act as a tinnitus sound generator only. It can also be fit as a hearing instrument only, should you want to start tinnitus treatment using only amplification, rather than activating the TSG from the start. Having the flexibility to control how you want to program the instrument, and having four programs allows you to truly personalize the device however you feel is most appropriate for your patient.

Research Studies using ReSound Live™TS (Study A & B)

Study A and B were multi-facility external trials conducted at multiple well-established tinnitus clinics worldwide, to evaluate the benefit of the ReSound Live™TS combination instrument in regards to tinnitus treatment. The studies also focused on finding mixing point information, Environmental Steering and amplitude modulation preferences, all important functions of the Live™TS instrument. It is important to note that both trials used some form of counseling and treatment (e.g. TRT) in combination with using Live™TS.

Trial design for Study A:

This study involved 30 tinnitus patients falling within Jastreboff's tinnitus category 1 and 2 (Henry et al. 2002). Subjects presented with mild and moderate bilateral hearing losses. All had suffered from tinnitus at least 6 months and patients with Menière's disease and middle or external ear disease were excluded.

After fitting the Live™TS receiver-in-the-ear instruments, Tinnitus Retraining Therapy (TRT) was administered for 6 months, and the effect of the treatment was evaluated using the Structured Interview (Jastreboff & Jastreboff 2000), TRI Tinnitus Patient Assessment and Outcome Measurement (Langguth et. al 2007), and THI self-administered questionnaire (Newmann et al. 1996).

Trial design for Study B:

Twenty four subjects with varying perceptions of tinnitus were recruited for this trial. Thirteen of the test subjects had varying degrees of sensorineural hearing loss with thresholds falling within the mild to moderate range, and eleven of them had no significant hearing loss. The subjects were fit with Live™TS receiver-in-the-ear devices. Twenty two subjects were fit binaurally and two subjects were fit monaurally. They were seen over a period of approximately six months for five visits. The Tinnitus Handicap Inventory (THI) and Tinnitus Handicap Questionnaire (THQ) were administered at the initial, mid and final visits to evaluate how the subjects perceived their tinnitus following the fitting. Half the test subjects were fitted with the Environmental Steering enabled at the first visit, and the other half with the volume control enabled. Approximately four weeks after visit one, the sound level adjustment (i.e. Environmental Steering and manual VC) was switched to the opposite of what they were initially fitted with. The test subjects then rated their preferences on a take-home questionnaire. Amplitude modulation was evaluated by initially giving all subjects two programs - one with modulation and one without. Approximately two weeks after visit one, all subjects were asked how they perceived the modulation and then chose one TSG program, either with or without modulation. This TSG program was adjusted based on their preferences.

Results for Trial A:

Assessment results were collected at the initial fitting, and again after 3 months and 6 months. Figure 6 shows the development in the 6 months' time frame of THI scores, and Figure 7 shows the structured Interview VAS scores regarding 'annoyance', 'intensity' and 'tinnitus effects on patients' life'. After 6 months all differences are significant (THI: p=0.001; annoyance and intensity: p<0.001; life effect: p=0.002), (Carraba et. al 2008).

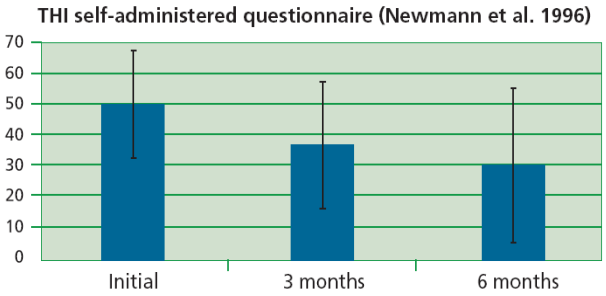

Figure 6. Pre- and post THI questionnaire results

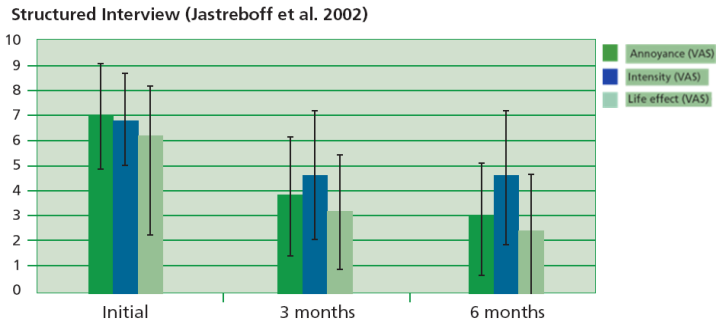

Figure 7. Pre- and post Structured Interview results.

Results for Trial B:

Twenty of the twenty four subjects answered the THQ and sixteen answered the THI. The subjects revealed a significant improvement in their tinnitus questionnaire scores over a period of six months, which was documented by an improvement in their THQ and THI scores. On an average, their THQ scores dropped significantly from 50.8 at the beginning of the trial to 33.0 at the end of six months ($P<0.05$), and the THI scores also dropped significantly from 58.4 at the start to 29.9 at the end of six months ($P<0.05$).

As far as the features of the TSG, 68% of the subjects preferred the volume control over Environmental Steering and 73% preferred continuous noise over modulated noise. Approximately 82% of the subjects preferred the filter settings to allow broadband noise (i.e 500-6kHz), while 18% preferred more narrow-band filter settings.

In conclusion, the trials revealed ReSound Live™TS to provide significant benefit in improving the patient's perception of their tinnitus. The various feature options make Live™TS a very flexible tinnitus solution, allowing the professional to personalize the fit according to patient preference.

Other notable conclusions:

- No subjects wearing the TSG reported a worsening in tinnitus (or hearing) at the conclusion of the 6 month trial.
- 7 of 10 subjects that responded reported the TSG was 'very helpful', and 3 of 10 reported the TSG was 'helpful.'
- The average pitch match for all subjects was 9kHz.
- 22 subjects fit binaurally; 2 subjects fit monaurally.
- Initial broadband frequency filter settings (i.e. 500Hz-6kHz) were maintained for 15/22 subjects.
- The sound quality of the hearing instrument received an average rating of 8.28 out of a possible 10 (1 = poor sound quality, 10 = excellent)

Fitting ReSound Live™TS

To program ReSound Live™TS, you must use the Aventa fitting software (the correct version is needed). Within this software you have access to not only the hearing instrument features, but the ability to adjust all the features in the TSG that have been previously discussed. By default, we set the frequency response of the TSG to broadband and shut off all the additional features, such as amplitude modulation and Environmental Steering (Figure 8).

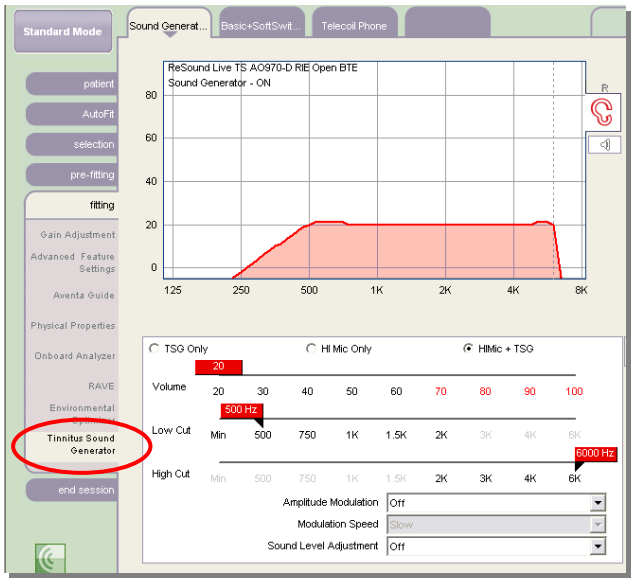

Figure 8. ReSound Live™TS TSG program in Aventa

In regards to setting the device up for a first fit, there are a number of approaches that can result in successful tinnitus treatments. One approach is to only activate the hearing instrument portion, as it has been shown that hearing instrument amplification alone can often times aid in tinnitus treatment (Del Bo et. al 2008). The flexibility of Live™TS gives you the option of activating the TSG later on, should it be the preferred approach for your patient.

Other approaches are using the mixing point, or the threshold of audibility. The mixing point is where the tinnitus and TSG stimulus start to 'blend' together. Often times, as you approach the mixing point, an acoustic change in one's tinnitus can be perceived. This is a very well-known method, and is used by many people in tinnitus treatment. To use this method, we suggest you first establish the threshold of the TSG stimulus, then increase the volume slowly in 1-2dB steps working to find the mixing point level. Once the mixing point is established, turn down the volume of the TSG about 1-4dB from

the mixing point value. The true mixing point value can often be too loud for the tinnitus patient. Instruction is very important when trying to establish the mixing point, as unclear instructions could affect the validity of your mixing point findings.

The threshold of audibility is a different approach, where you can set the level of the TSG stimulus about 5-10dB above the threshold of TSG stimulus. This approach relies less on the instruction given, but may not provide the same quantitative data as the mixing point approach. It can also be useful to establish the minimum masking level (MML). This is where the TSG noise just begins to mask the tinnitus. By using the MML, and the threshold of the TSG noise, you can establish a range, between what is audible, and what is excessive masking for successful tinnitus treatment.

Regardless of the method you choose to use in your tinnitus treatment, always avoid complete masking of the tinnitus, as this will not allow for habituation. When completely masking the tinnitus, the user typically finds immediate relief from the tinnitus, but this will not allow for the brain to adjust and habituate to the tinnitus. When the device is removed, there is a very good chance the tinnitus will still be perceived as it always has, and with the loud volume levels it usually takes to completely mask the tinnitus, could potentially alter the tinnitus negatively.

The methods described are just suggested starting points to help you with your first programming. Questionnaires and subjective comments, as mentioned previously, can be used to monitor the effectiveness of the approach you've chosen.

Individual differences and user comfort should always be considered on a case-by-case basis with regards to tinnitus, as tinnitus can vary greatly between each individual. Please review the ReSound Live™TS fitting guide for more detailed instructions on how to fit the device in Aventa.

In conclusion, ReSound Live™TS is a unique state-of-the-art hearing instrument and tinnitus combination device, that will provide you with the flexibility to address your patient's needs, for both hearing loss and tinnitus treatment.

Programming Notes:

- *You must be in the Natural Directionality program to have Natural Directionality II and the TSG running together.*
- *When using a combination program (i.e. hearing instrument + TSG), the hearing instrument cannot use adaptive directionality - it must use omnidirectionality, fixed directionality or Natural Directionality II. It can have adaptive directionality active in a non-TSG program.*
- *It is recommended to program the TSG before calibrating DFS. In some instances, running the DFS calibration can result in residual inhibition effects, altering the perception of the tinnitus, and TSG programming.*

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