Neuromonics
Tinnitus Treatment

Oasis Workbook

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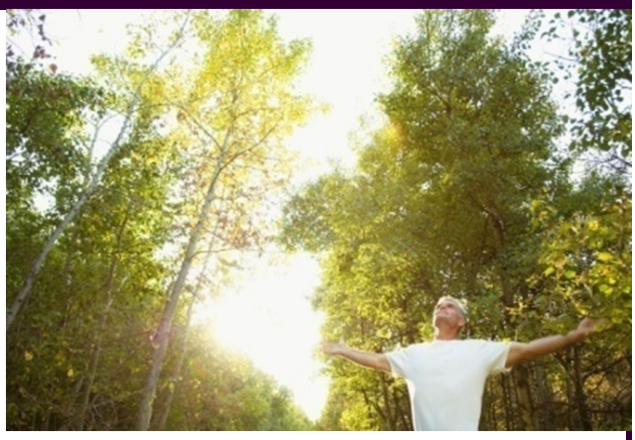


Welcome

Congratulations

Congratulations on your decision to begin the Neuromonics Tinnitus Treatment. This guide is designed to give you the help you need to get the greatest benefit from your treatment program.

The Neuromonics Oasis Device is a medical device that is small and lightweight - approximately the same size and weight as a mobile phone, and used with specifically selected earphones. The Oasis delivers prescriptive music signals at a comfortable listening level that stimulate a wide range of the auditory system. This stimulation is much wider than you would receive from listening to normal music, MP3 players, hearing aids or other sound devices. Since the signal is pleasant to listen to, it helps to promote positive changes in relaxation, concentration, stress, anxiety and sleep, which help decrease tinnitus disturbance during treatment. The appearance of the Neuromonics Device is designed to be compact and discreet, so that you can easily and comfortably use your treatment.

Common Goals Achieved with Neuromonics Tinnitus Treatment

Outcomes from the Third Clinical Trial:

91% of people who used the Neuromonics Tinnitus Treatment reported a significant reduction in the tinnitus disturbance

86% had a significant reduction in the tinnitus awareness

70% had a significant reduction in the tinnitus volume

78% had a significant improvement in their tolerance to loud sounds

97% would recommend the treatment to others

(Davis, Paki and Hanley; Ear and Hearing, 2007)

Upon completion of the Neuromonics Tinnitus Treatment, we ask people for their comments. Commonly, people report the following:

"I noticed an improvement in falling sleep as well as an improvement in the quality of sleep"

"I felt a reduction in the need to have ambient sound around"

"I find it easier to concentrate and work"

"I find that treatment has taken the edge off the tinnitus"

"I generally only hear the tinnitus when I stop and think about it"

"If I do hear the tinnitus now I no longer worry about it"

"I am able to go out without worrying about being exposed to loud sounds"

"I enjoy socializing"

Although tinnitus is an internal phenomenon, its impact can affect family members. This occurs because people with tinnitus often have to use their energy dealing with the tinnitus so that they have little tolerance or energy for other things. Therefore, we ask family members if they have noticed anything different in their family member since completing treatment. Here are some common responses:

"No longer grumpy"

"No longer talks about the tinnitus"

"Appears to be more energetic"

"Appears happier and more relaxed"

How to Use This Workbook

This booklet is designed to help maximize your Neuromonics Tinnitus Treatment. The following pages will guide you step by step through the treatment process over the next 6-8 months.

The goal of your treatment is to reduce the amount of time you are bothered by and aware of your tinnitus. The end result will be long-term improvement in these areas. The Neuromonics Tinnitus Treatment is clinically proven to provide significant reductions in awareness and disturbance.

This booklet also contains *helpful resources* such as:

- Tips to maximize the results you will see using this treatment
- Assignments to help maximize your treatment
- Device Troubleshooting Tips providing instructions on how to address various device questions or issues
- Frequently Asked Questions (FAQ's) and answers

Assignments:
There are different assignments during the course of your treatment. A treatment calendar is provided on the next page to help you track your progress.

Each week you will have a different section to read about various topics including information on sleep, diet and medication and environmental noises. **It is ok if you want to read ahead to a specific section that discusses one of your problem areas. If you do not have any issues with a particular topic, feel free to skip that section.**

You will also return to the clinic for follow-up appointments during your treatment. Please make sure to review the calendar with your clinician so these are scheduled at the correct times.

Again, please make sure to read the all the information provided.

You can find further resources by visiting our website at www.neuromonics.com or contacting your clinic.

Neuromonics Oasis Assignment Calendar

Remember….if there is a particular topic that you need help with, you can read that section before the scheduled week. If there is a topic that is not problematic for you, you can skip that section.

Treatment Schedule	Assignment	Date Completed
Week #1 *Begin Treatment*	**Beginning Treatment Device Information**	
Week #3	**Sleep**	
Week #4	**Stress and Relaxation**	
Week #5	**Relaxation Exercises**	
Week #6	**Thinking Differently about Your Tinnitus**	
Week #7	**Environmental Noises**	
Week #8	**Diet and Medication**	

NOTES:

Weekly Treatment Lessons

Neuromonics
Tinnitus Treatment

Lesson for Week #1
BEGINNING TREATMENT

BEGINNING TREATMENT

A good first exercise before beginning your treatment is to ask yourself: "What specifically do I want out of this treatment?" Do I want the treatment to help me sleep better? To improve my concentration? To make my tinnitus less bothersome? Ask yourself these questions and write down your goals below.

1. _____
2. _____
3. _____
4. _____
5. _____

Keeping track of your goals is an important way to measure progress throughout your treatment.

When should you wear your Neuromonics Device?

- Your device should be worn when your **tinnitus is most bothersome.** It's much more about using the device at the "right times" rather than when it is most convenient.
- Think about using the device in the same sense you would use aspirin for a headache (in other words, put the device on when your tinnitus bothers you most; use it to provide relief from your tinnitus). Identify specific situations that are impacted by your tinnitus and focus your use of the device at those times. You may feel that your tinnitus is bothersome at ALL times. Try to think of your tinnitus on a scale of one to ten. There are usually times during the day that are maybe lower on the scale and times when it may be off the charts! Focus your use on the situations where you would rate your tinnitus on the higher end of the scale.
- Situations when the tinnitus is bothersome and other appropriate times to use your treatment (i.e. working on the computer, reading a book, going to sleep):

1. _____
2. _____
3. _____

- The **recommended dose is 2-4 hours daily**. You can use it more if you find it helpful, however usage of greater than four hours per day will not shorten the treatment period.
- Keep in mind this time does not have to be consecutive, for example you can wear it 1/2 hour at breakfast, another 1/2 hour at lunch, and an hour before bed and you'll complete your two hours of required usage. You can use the treatment in 15 minute intervals if you like, and you will be surprised at how quickly the time adds up! The treatment was designed to fit into your lifestyle easily, but you must remember to use the treatment at those times when your tinnitus is most bothersome.
- Try to use your device if possible as soon as your tinnitus becomes bothersome. The longer you wait, the more your tinnitus can escalate.
- Occasionally, if you don't need more than 2 hours on a particular day, don't struggle to get it in. The reason being, this treatment should not add stress to your day. It should be a source of relief and pleasant to use.

When *not* to wear your Neuromonics Device:

- While exercising
- When straining to hear
- While driving
- While watching television
- When your device may get wet

The idea is to not wear your device when you are doing things which will elevate your heart rate or when you are in a situation where you are straining to hear something else. Using the device during these times will make it difficult to get the most out of your treatment.

Volume Setting

- At the beginning of your treatment process, set the volume at a **comfortable listening level** that provides as much blending between the music and your tinnitus as possible.
- *Always be sure that the volume level is comfortable*.

How long will my treatment take?

The length of the treatment will vary from person to person; depending on your tinnitus and how committed you are to the treatment process. Patients who use their device consistently will be more likely to see results more quickly. Typically, the treatment is anywhere from six to eight months, but some patients may take longer. Individual factors such as hearing loss, tolerance for loud sounds, stress, personal health and treatment compliance can influence the length of treatment.

The Tinnitus Cycle*:

Understanding what tinnitus is and why it can become bothersome is important. The cycle of tinnitus has three main components that feed one another. In order for a treatment to be effective, each of these areas must be addressed. The Neuromonics Tinnitus Treatment works to ensure that each of these areas are addressed , thereby providing long-term relief for your tinnitus.

*P**lease see Appendix E for a more in-depth discussion on the tinnitus cycle**

There are three components to the tinnitus Cycle: **Auditory, Attentional, and Emotional**.

***Auditory*:** There is an auditory perception of the tinnitus sound. This perception is generally triggered by changes in hearing or damage at some level in the patient's auditory system. The lack of auditory signals sometimes also can result in an increased sensitivity for sounds stemming from the same lack of auditory stimulation. This is sometimes referred to as *hyperacusis* or *decreased sound tolerance*.

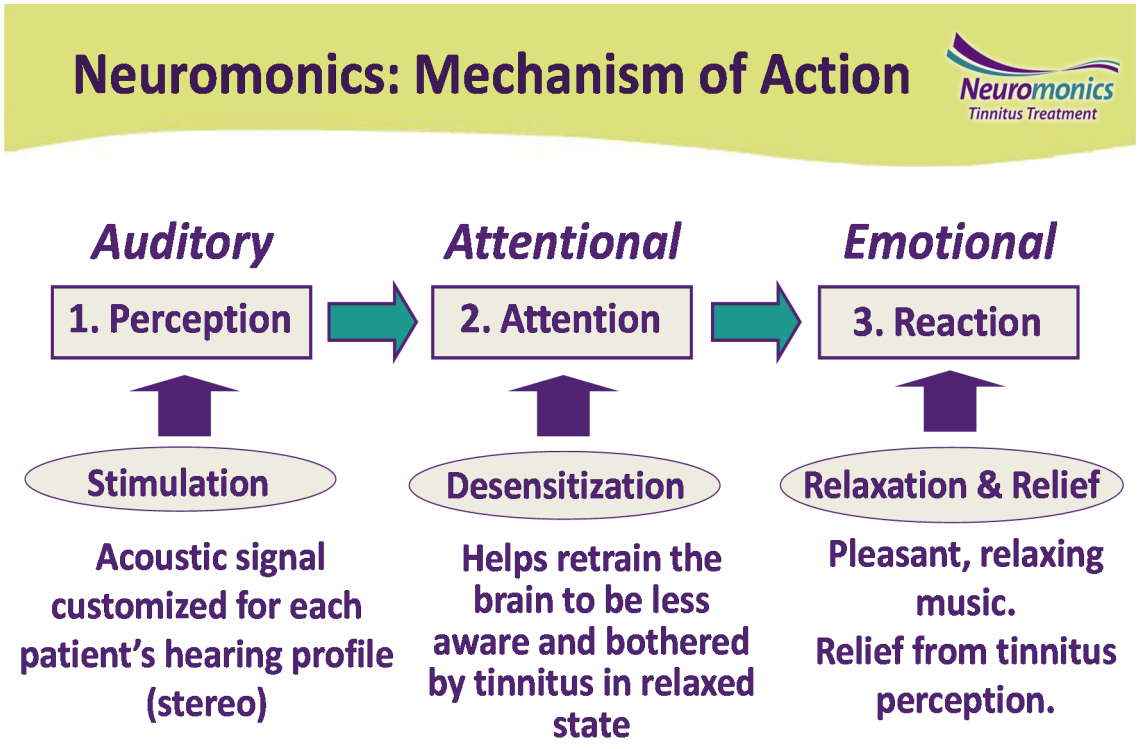
***Attentional*:** After perceiving the tinnitus sound, the brain then determines it to be something important to listen to and labels it as a significant signal. In some cases the brain has labeled the tinnitus sound as harmful or threatening to the body. As a result, this causes the brain to pay closer attention and continuously monitor this sound.

***Emotional*:** The heightened attention from the brain leads you to develop an emotional response to the tinnitus signal. This emotional response may include *anxiety, fear, a sense of a loss of control, annoyance, frustration, sleep/concentration problems, etc*. These negative emotions can increase your stress level, which will only make your tinnitus seem louder. These components can develop into a vicious cycle that keeps repeating itself with each one feeding the other.

How does the treatment work?

The Neuromonics Tinnitus Treatment is designed to treat all 3 components of tinnitus:

- ***Auditory:*** wide frequency stimulation of the auditory centers of the brain. In other words, the device provides auditory stimulation to all frequencies, from the very low to the ultra high pitched. This allows each area of your auditory system to benefit from the treatment.
- ***Attentional:*** teaches the brain to ignore the tinnitus signal in order to become less aware of the tinnitus using a process of desensitization over the coming months.
- ***Emotional***: provides relief, relaxation, and a sense of control over your tinnitus. With treatment you are working to remove the negative label your brain has assigned to the tinnitus and reassign it to a neutral category. This is achieved by wearing the device during the times when you are most impacted by your tinnitus. By pairing the relaxing aspects of the Neuromonics treatment during these times, you can lose the harmful label your brain has assigned the tinnitus.



Hanley PJ, Davis PB. Treatment of tinnitus with a customized, dynamic acoustic neural stimulus: underlying principles and clinical efficacy. Trends in Amplification. 2008; Sep;12(3):210-22. Epub 2008 Jul 9.

Decreased Sound Tolerance (DST) and Hyperacusis:

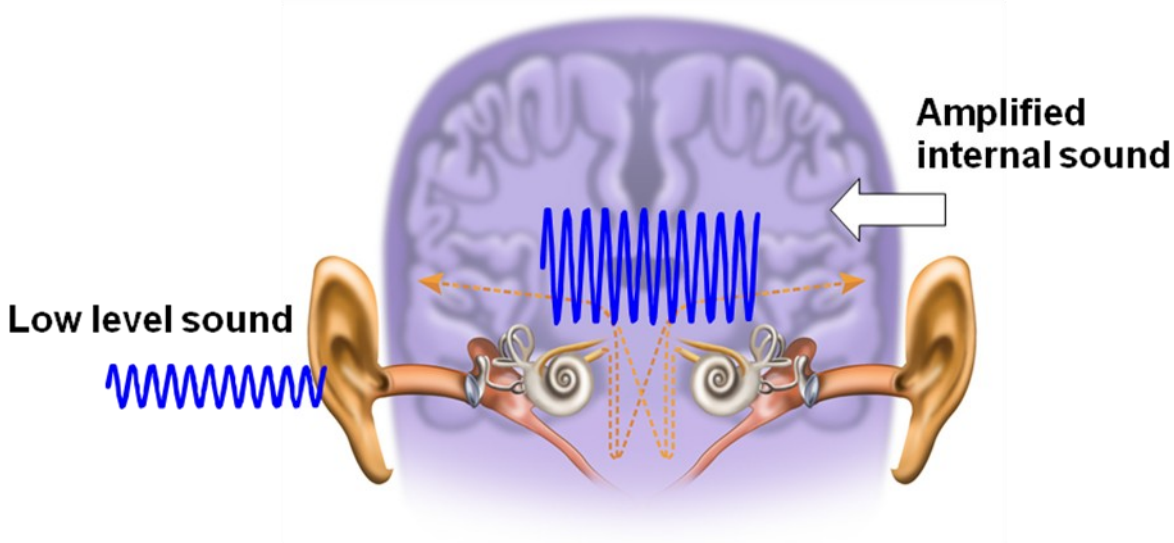
What is DST and Hyperacusis ?

- Decreased Sound Tolerance (DST) is discomfort from sounds at a level which most people would not find uncomfortable.
- Hyperacusis is extreme where soft everyday sounds are uncomfortable.
- Approximately 66% of tinnitus patients suffer from some degree of Decreased Sound Tolerance.

How is loudness tolerance measured?

- Your clinician performs a test called a Loudness Discomfort Level (LDL). This is where different tones are presented to you while you point to a chart that determines how loud you perceive the sound. When you point to the "Uncomfortable Loudness Level" on the chart, the tone is stopped immediately. Depending upon your measurements, it can be determined whether you are considered to have "Normal" loudness tolerance, "Decreased Sound Tolerance" or "Hyperacusis".

- **Central Gain** helps to explain how hypersensitivity to sound occurs. Whenever we have a lack of auditory or sound information going to the brain, such as with hearing loss, or the inappropriate use of earplugs, the brain attempts to "strain to hear". This straining to hear causes a compensatory activity in the brain due to this lack of auditory or sound input and neurological changes take place. Much like an antennae searching for a signal, the brain's internal amplifiers are on high alert searching for sound. So when sounds occur, they are "internally amplified" so to speak appearing much louder than they are.



How does Neuromonics help Hyperacusis or DST?

- The great news for patients with DST or hyperacusis is that there is help!
- Neuromonics works extremely well to treat either of these conditions.
- Your Sound Sensitivity will be addressed before we actively work on treating your tinnitus
- You will utilize the same Neuromonics treatment device for both the sound sensitivity and the tinnitus treatment
- Remember, you always have control over the volume and it should be always set for comfort. Gradually, over time, your comfort levels will increase.
- Always avoid the inappropriate or overuse of earplugs. They should be used to protect your ears from loud noise exposure but not from everyday environmental sounds.

What to expect during your treatment

Congratulations on beginning Neuromonics Tinnitus Treatment. The goal of this workbook is to give you the help you need to get the greatest benefit from your treatment program.

We want to make sure you are successful with your tinnitus treatment. To assist you, we have outlined what to expect from treatment.

Neuromonics Tinnitus Treatment should be used for 2-4 hours per day when your tinnitus is most disturbing.

The length of time that treatment will take will vary from person to person. The minimum period for treatment is six to eight months.

There are two stages during treatment:

- **Stage 1 –** Is designed to help you get relief from the tinnitus while using the treatment and also to help you relax. The goal of phase one is to move the brain's label of the tinnitus from a negative one to neutral. Also, by feeding the brain specific sounds, there are neurological changes that take place within the central auditory nervous system, which act to reduce your tinnitus perception.
- **Stage 2** – The purpose of the second stage of treatment is to retrain your brain to be less aware and bothered by the tinnitus. In other words, to desensitize the brain to the tinnitus.

STAGE ONE EXPECTATIONS

Sound Quality:

- An additional signal is added to highly customized music, commonly referred to as the “shower sound”. This is added to help get as much blending of your tinnitus and the music as possible. Some people hear the shower sound and some do not. The signal is effective regardless of whether you hear it or not.
- Your may find some of the programs to be “high-pitched or tinny”. This is because there are high pitched sounds that have been added that you may have not heard for a while because of hearing loss, or because of the limitations of most music. Most people say they get used to this over a few weeks.
- The treatment will sound equally loud in both ears because it is specially programmed to your hearing levels in each ear. If it does not sound equal, adjust the placement of your earphones to achieve a more balanced sound. Also, check the placement of your earphone jack so that it fits snugly into the device.

Volume:

- Set the volume to a comfortable level that provides as much blending of the music and the tinnitus as possible. The main goal with volume is to always make sure it is comfortable. This is more important than trying to cover the tinnitus with an uncomfortably loud volume.
- Most people are able to hear others speaking to them while using the treatment.

Usage:

- It is recommended that you use it at those times when your tinnitus is most disturbing.
- Consistent usage is recommended of at least 2-4 hours per day
- You will be able to use your treatment while carrying out most normal activities such as reading, working on the computer or walking.
- When NOT to use treatment:
    - Driving
    - Exercising enough to raise your heart rate
    - Listening to television and situations in which you are straining to hear
    - Getting device wet

Results:

- The most important thing to remember early on is that the benefits of treatment in the beginning are *limited to treatment times only*. Most people will be aware of the tinnitus at other times.
- Treatment is comfortable and pleasant to use.
- Treatment assists with relaxation, which may carry over after a treatment session has ended.
- Improved ability to go to sleep if the tinnitus is disturbing at this time.
- Improved ability to concentrate if tinnitus disturbs concentration.
- Treatment is enjoyable and easy to fit into one's lifestyle.

*Occasionally people report increased awareness of their tinnitus just after listening to the device; this is referred to as **"relief contrast"**. This happens because the tinnitus appears louder in comparison to the relief experienced while using the device. This relief contrast perception typically only lasts for a short period of time. If you experience relief contrast, try turning down the volume for a few minutes prior to removing the device, taking the device off in an environment that is not completely quiet, or use it for shorter periods of time, to reduce this perception*.

Expectations Later in Treatment

STAGE TWO EXPECTATIONS

Sound Quality:

- The signal is changed in Stage Two to help with retraining the brain to be less aware of the tinnitus. You will not hear the "shower" sound once this change has happened, however the music will remain the same.

Volume:

- Set the volume comfortably. The goal is to hear the music about 50% of the time and the tinnitus about 50% of the time.

Usage:

- Continue to use the treatment for 2-4 hours daily at the times when your tinnitus is most disturbing.

Results:

- You will begin to slowly see benefits carry over to times when you are not wearing the device.
- At first, you may find you are not getting quite the same relief while listening as you did in Stage One. Do not worry because this is common and should improve quickly. If your tinnitus is worse than average on a particular day, you can use more volume to achieve relief. Remember, the volume should never be uncomfortably loud. You should adjust your volume so that you hear your tinnitus 50% of the time on most days during this phase of treatment for optimum results.
- You should see results during this stage that include decreased awareness and disturbance from the tinnitus even when not using the treatment.
- You may also see an improved ability to tolerate certain sounds that were not comfortable before you began treatment.

Additional information and helpful hints

- This treatment is not a treatment for hearing loss and we do not expect any change in your hearing levels.
- There is no need for you to monitor or check-in with your tinnitus on a daily or weekly basis. Your clinician will do the monitoring at appointment times when you are in the office so you can sit back, relax and enjoy the treatment.
- During treatment, you may find that the time of the day when you are most disturbed by your tinnitus may change. If this happens, we recommend you adjust the time you use the treatment so that you are using the treatment when the tinnitus is most bothersome.
- When anyone starts on a long-term treatment, whether it is losing weight, getting fit or treating tinnitus, it is natural to look for immediate results. With all of these long term lifestyle changes, results are gradual and happen in small steps. There are often ups and downs along the way. There are individual differences and people will respond to the same treatment at different rates.

Device Mechanics

This workbook is designed to provide step–by-step instructions for using the Neuromonics Tinnitus Treatment. By carefully following each of the steps within this treatment plan, you will begin to see a reduction in the awareness of your tinnitus, along with long term relief from your symptoms.

How to use the Neuromonics Oasis Device

This summary is not intended to replace the information located in your Neuromonics Oasis Device User Manual. Please read the entire User Manual prior to operating your device.

A brief review is provided here.

Earphone Information:

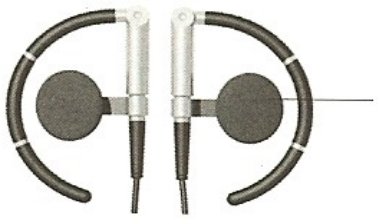


Figure 1

Figure 2

Figure 3

Figure 4

To insert your earphones:

1. Arrange the earphones on a table in front of you. Ensure the foam covers on the earphones are facing towards you. The earphone on the right is to be placed in your right ear. (Figure 1)
2. Pick up the right earphone and swing the hook outwards so you can hook it around your ear. (Figure 2)
3. Place the right earphone in your right ear. The top of the support arm should lie next to the join between the top of your ear and your head. Adjust the length and support arm so the earphone fits firmly in the bowl of your ear. (Figure 3)
4. Adjust the hook so that it fits snugly and comfortably behind your ear. (Figure 4)
5. Repeat steps 2 to 4 when positioning the left earphone.

Additional Earphone Information:

- The earphones are designed to be ear specific and the device is programmed according to your hearing profile.
- Due to this fact, it is important you insert the correct earphone into each ear.
- Use only headphones provided by Neuromonics.
- Do not remove your earphones from the device when not using your treatment. This lessens the wear-and-tear on the earphone jack.
- The earphones that are included with the device have been specifically chosen to allow for the greatest impact on your tinnitus. They are high quality earphones that have the capability to reach the higher frequencies necessary as part of the treatment process.
- If you experience any discomfort from the earphones, contact your clinician.
- Small adjustments in placement of the earphones will impact sound quality and comfort.

Smart Wrap:

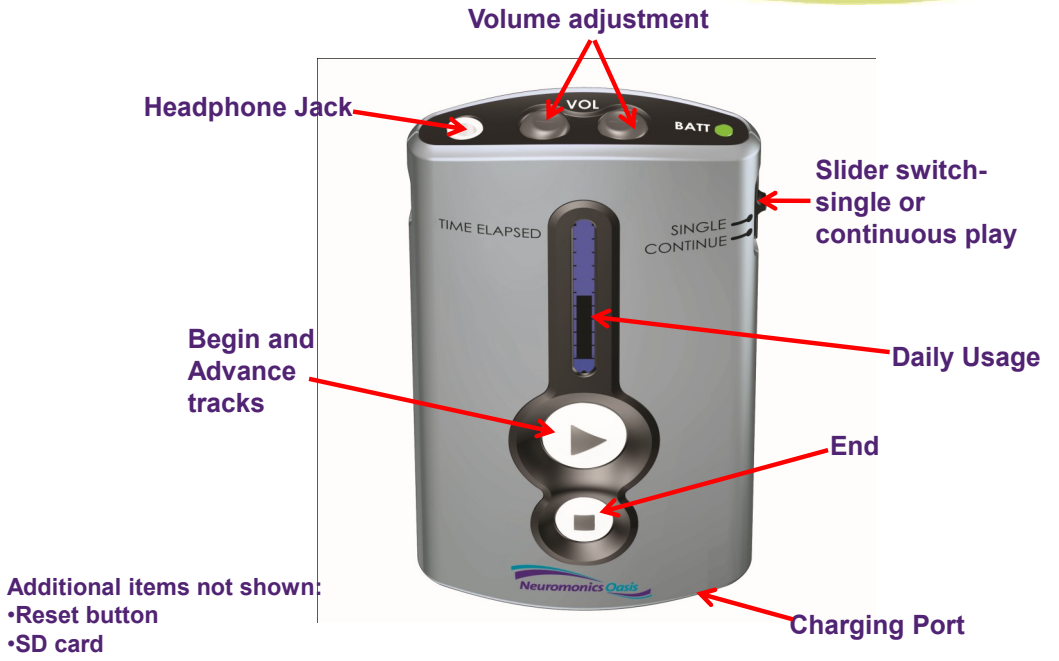
- Included with your earphones is a Smart-Wrap that allows you to wrap up the cord of the earphones in order to prevent any damage from occurring during use.
- It is recommended that you select the desired length and then wrap up the rest of the cord to prevent it from becoming tangled. This is to be done at the 'Y' of the cord. Use the slots at either end to thread the cord through. (Please see the instruction sheet inserted in the Smart-Wrap package).

Battery*:*

Please refer to your Device User Manual for important safety information and specific instructions on charging your device.

- Only the charger supplied with your device should be used.
- The device contains a rechargeable Lithium-Ion Battery that gets approximately 25 hours of usage per charge. It is recommended you charge the device daily. You cannot listen to the treatment while the device is charging so plan accordingly. Charge time is approximately two hours for a fully discharged device.
- The battery indicator light will begin to flash when the battery charge is low. This generally happens when there is about 4 hours of usage left.
- In order to prevent damage when recharging, be sure to plug the charger in to the correct port which is located on the bottom of the device.

Getting to know the device



Buttons:

- The buttons on the front of the device have been designed for ease of use.
- When the **"Begin"** button is pressed, the device will power on and begin playing the treatment.
- When the **"End"** button is pressed, the device will discontinue playing and turn off the power.
- Volume buttons **(+) and (-)** will adjust the volume of your device. Each time you press a button the volume will increase or decrease. The buttons are designed so that it is not possible to get a sudden increase in volume. Repeatedly press the buttons until you reach the correct volume for that treatment session.
- The volume will reset to its programmed minimum setting after five minutes of non-use. You will need to re-adjust the volume control if you have not used the device in the last five minutes.
- There is no visual display of where you are setting the volume. Remember to set the volume according to the level that provides blending with your tinnitus and is comfortable. Your volume setting may vary from day to day. This is normal. Try to

only adjust the volume when you initially switch on the Neuromonics device. Do not adjust again unless is becomes uncomfortably loud. Set it and forget it!

Single/Continuous Switch:

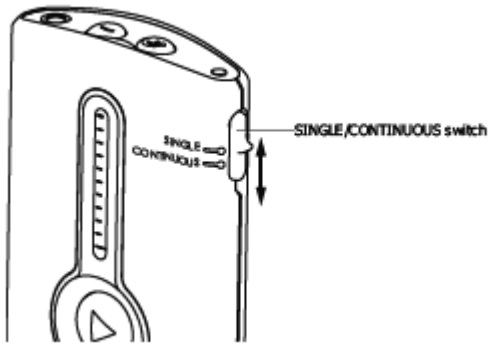


Figure 5

- Use the single track when falling off to sleep. This will turn off the device after one track (approximately 50-60 minutes of listening).
- Use the continuous switch for continuous play. When used in continuous mode, the device will cycle through all available tracks until the "End" button is pressed.

Time Usage Display:

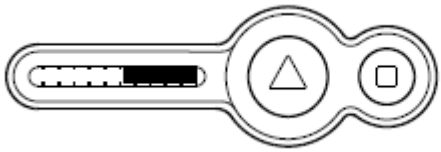


Figure 6

- Figure 6 shows the Neuromonics LCD window displaying daily usage hours.
- This will allow you to quickly determine how many hours you have used the device on that particular day.
- The window is a 4 hour block so when it is half full, you know you have reached your necessary two hour minimum for the day.
- This Time Usage will reset automatically and clear itself everyday at 3AM.
- This feature makes it easy to track your 2-4 hours of use each day.

Listening Tracks:

- Your device has been pre-programmed with 4 musical tracks. These tracks have been chosen to help stimulate your auditory system. It is recommended you listen to all four tracks.
- Tracks 1 and 2 are classical selections. These may be preferred during concentration tasks such as working on the computer.
- Tracks 3 and 4 are contemporary/relaxation tracks. These may be preferred during relaxation activities such as falling off to sleep.

  Remember, this music is designed to eventually be something that is in the "background". You do not need to pay attention to the music. It is to your benefit to eventually learn to tune it out. This will help with re-training the brain to ignore the tinnitus.

FREQUENTLY ASKED QUESTIONS

Q: Will my tinnitus get worse using this device?

A: No, there isn't anything contained within the device that will make your tinnitus worse. While initially wearing the device, you may have immediate relief and relaxation from your tinnitus and once the device is removed your tinnitus may seem louder for a brief time, but will gradually begin to decrease. This is similar to individuals who wear eyeglasses; there is a contrast effect that occurs once they remove their glasses, until their eyes adjust. It is also common that your tinnitus changes pitch during the treatment. If you have any concerns about your tinnitus perception while using treatment, contact your clinician.

Q: If someone else in my family has tinnitus, can they use my device?

A: Since the Neuromonics device is individually prescribed and contoured to your hearing profile and being classified as a FDA Cleared Medical Device, it cannot be shared with someone else (The FDA mandates that it is a one patient, one use device).

Q: If I fall asleep with my device on, does it count towards my 2-4 hours a day?

A: The 2-4 hours per day only includes waking hours. Due to the relaxation provided by the device, it is an excellent way to help fall asleep at night. And it is safe to use while sleeping. However, keep in mind that it is important to wear your device throughout the day when your tinnitus is most bothersome (for a minimum of 2 hours total usage per day).

Q: **Can I have different musical tracks for my device?**

A: No additional or alternate musical tracks can be programmed on the device. The musical tracks contained in the Neuromonics device are very specific and have been chosen to help counteract your tinnitus. In order to retrain your brain to ignore your tinnitus, the music needs to be redundant in nature. The sooner you can put the music into the background, the more quickly you will be able to put your tinnitus there as well.

Q: **I use hearing aids and Neuromonics, when should I use Neuromonics vs. hearing aids?**

A: If you use hearing aids, make sure that they are used for communication purposes and not while wearing your Neuromonics device. The Neuromonics device may be used during quieter times when there is nothing for the hearing aids to amplify. ***You will need to remove your hearing aids while using the Neuromonics device. Remember to reach for the device when the tinnitus is most bothersome.***

Q: Can I use my own earphones?

A: No. Due to limitations of the frequency response, other earphones will not be calibrated to provide the full prescription of your treatment. If you have problems with the prescribed earphones, please contact your provider.

Q: What if the treatment is not completely covering my tinnitus?

A: It is not necessary for the treatment to cover your tinnitus in order to be effective. The goal of the treatment is to provide some degree of relief from your tinnitus, while also providing relaxation. Factors that influence how much the treatment will blend with your tinnitus include your hearing loss, the perceived volume of your tinnitus and how well you can tolerate sounds.

Q: What if my earphones don't sound balanced?

A: For more balanced loudness perception, first adjust the earphone placement. Due to the size and shape of each patient's ear canal; loudness perception can vary. You can experiment with earphone placement in order to balance the loudness. Also be sure to check that the earphone jack is securely connected and inserted completely. For further tips on troubleshooting earphone issues, please see the "Device Troubleshooting" section of this workbook.

Q: How loud should I play my device?

A: Your first goal should always be to **listen at a comfortable volume level**. If the device is too loud it can take away from the relaxation you should experience from the music. Be sure to turn up the volume if you feel you need more relief, ***but be certain it is a comfortable level.***

Q: Will I have to use the device forever?

A: At the completion of your 6-8 month treatment plan, we recommend that you continue to stimulate your auditory system by using the device from 2-4 hours per week. This additional period is called the maintenance phase and will vary from patient to patient.

Q: When am I done with treatment?

A: Completion of the treatment process varies from patient to patient. This will depend upon a number of factors including how you have progressed through the treatment process and whether or not you have accomplished the goals you set out to achieve. Your clinician will be able to help you determine when this has been accomplished.

Congratulations! You have completed this week's lesson.
CONTINUE WITH LESSON #2 NEXT WEEK.

Tips for Success

- **Put the earphones on & press "Begin"**
- **Use at a comfortable volume that provides relief to the tinnitus**
- **Use when the tinnitus is most bothersome**
- **These items can trigger tinnitus. Try to limit them.**
    - **Caffeine**
    - **Alcohol**
    - **Nicotine**
    - **Exposure to loud sounds without using ear protection**

LESSON WEEK #2
Sleep

COMPLETE THIS LESSON IF YOU HAVE PROBLEMS SLEEPING DUE TO YOUR TINNITUS

If you are consistently missing out on sleep, this can impact your health more than your tinnitus.

Many people suspect that their tinnitus is loudest when they are in bed, trying to get to sleep. However, several studies have shown that actual loudness of tinnitus usually does not vary much during the day, but there are times when tinnitus appears more noticeable. At bedtime there is generally little environmental noise around to cover the tinnitus and little else to occupy your attention, so the tinnitus can be more bothersome at this time.

Using the Neuromonics Tinnitus Treatment at bedtime may help you get to sleep. The **"single"** function on your device will automatically switch off the treatment after one track, allowing you to sleep without worrying about switching it off.

General habits that promote a good night sleep:

- Go to bed at around the same time every night.
- Reduce the silence prior to falling asleep through the use of your Neuromonics device.
- Avoid excessive caffeine (e.g., coffee, tea, cola drinks, and many chocolates) more than 12 hours before bedtime.
- Avoid smoking at least a few hours before bedtime.
- Avoid drinking alcohol at least 4 hours before bedtime. Substitute with a hot non-alcoholic or non-caffeinated drink before bedtime.
- Exercise regularly early in the day to promote sleep and improve relaxation.
- Enjoy relaxing activities before bedtime, such as meditation or listening to your Neuromonics device.
- Keep the bedroom cool and use natural fibers for your bedding.
- Gradually dim the lights from sundown as you get ready for bed.
- Take a warm shower or bath 2 hours prior to bedtime.

- Avoid having a television in the bedroom and do not watch TV just before going to bed.
- Sleep with a low level neutral sound in the room such as a box fan or environmental sound generator.
- Wake up about the same time every day even if you had a late night the night before.

Additional tips for you to consider:

Worry Time:

Problem: Trying to sleep when your mind is filled with all sorts of worrying.

Solution: A few hours before bedtime, put aside time each day dedicated solely to thinking about those issues that worry you. Write down problems and possible solutions.

Clock Watching:

Problem: Glancing at the clock (calculating the time spent in bed so far, how long you were actually sleeping, how many hours to go, etc) promotes more anxiety.

Solution: Turn away the clock face so it cannot be seen from the bed.

Sleeping Pills:

Problem: Sleeping pills are designed for short term use only. If taken for more than 1 month, sleeping pills can lose their effectiveness and become habit forming. Sleeping pills usually only treat the symptoms of a sleeping disorder.

Solution: Use your Neuromonics device to aide you in relaxing and falling to sleep. Consult your physician on how to wean off the sleeping medication while using your Neuromonics device or stop usage of sleeping pills altogether.

Congratulations! You have completed this week's lesson.
Continue with lesson #3 next week.

LESSON WEEK # 3

Stress and Relaxation

COMPLETE THIS LESSON TO LEARN MORE ABOUT MANAGING STRESS

You may not realize how much stress you have until you are able to control it more effectively or reduce it. To aide in reducing stressors in your life, list all areas in your life where there is conflict, excessive worry, uncertainty, or other things that are causing you to feel stressed. Make a list of why each one of these might be causing a stressful feeling.

- _____
- _____
- _____

Concentrate on new or different ways of resolving these problems. Try to share some of your duties to others. For example, a financial guidance counselor could potentially reduce your money worries. Keeping stress levels down can help you:

- Cope better with your tinnitus
- Help you to sleep better
- Reduce any anxiety, tension and depression
- Improve your concentration
- Reduce the likelihood of illness
- Makes life so much more effortless and enjoyable

There are numerous approaches to managing your stress. This skill can be difficult to learn initially since you cannot force relaxation to happen. You will need patience and practice to learn relaxation techniques and apply them successfully.

General practices to manage stress and promote relaxation:

- Plan ahead.
- Prepare for the next days' activities the evening before (i.e., lunches, clothing, work items).
- Fill up your gas tank before it is left with ¼ of a tank.
- Be prepared to wait. (e.g., bring an item you enjoy such as, reading a book while waiting in line or at an office, listening to music or your Neuromonics device).
- Eliminate (or restrict) the amount of caffeine in your diet (e.g., coffee, tea, cola drinks, and many chocolates).
- Relax your standards. A slight change in schedule is okay (e.g., cleaning or changing sheets on Sunday instead of Saturday, mowing lawn next weekend instead of this weekend).
- Say "no" to activities that you do not have the time or energy.
- Learn to delegate tasks to others capable of completing the task.
- Prioritize tasks: put the most important tasks first.
- Try to do the task that you fear or dislike at the beginning of the day instead of at the end.
- Do nothing which requires you to tell a lie.
- Unplug your phone when you want to relax or take time out.
- Take a hot bath (or a cool one in the summer) to relieve tension.
- Exercise at least twice a week.
- Get up and stretch periodically if your work requires you to sit long for hours at a time.
- Try muscle relaxation therapy, yoga, and/or meditation.
- Have a massage!

Congratulations! You have completed this week's lesson.

Continue with lesson #4 next week.

LESSON WEEK #4

Progressive Relaxation Training

COMPLETE THIS LESSON TO LEARN A NEW TECHNIQUE FOR RELAXATION

Exercises that will increase your relaxation can calm your body when you feel anxious. There are two reasons for relaxing. First, when you are suffering from anxiety, tension becomes such a habit that you no longer notice it. Second, by tensing a muscle we also fatigue it; making it easier to relax. The following exercises make you aware of the differences between tension and relaxation.

There are **three stages of exercises**. Relaxation is a physical skill. You must practice it regularly. Once you have learned this technique, you will be able to control anxiety in stressful situations.

Stage 1: Try to do all of the exercises daily for 7 days.

Stage 2: Select exercises that are best for you. Include deep breathing exercises.

Stage 3: When you have reached Stage 2, begin applying relaxation exercises during the day. Do this by deep breathing, tensing your arms briefly, or just by mentally relaxing and allowing your body to follow.

Preparing for Relaxation Exercises:

Choose a quiet time and place to practice.

Try relaxation exercising at the same time as using your Neuromonics device.

Allow 10-15 minutes of relaxation exercise.

Begin by lying on your back or sitting comfortably in an armchair. Do not cross your arms or legs.

Breathe slowly and deeply, and close your eyes.

AVOID tensing up too hard and relaxing suddenly. If anything feels uncomfortable, you may be tensing too much.

Relaxing Hands and Arms:

HANDS: Clench your right fist, keeping the rest of your body relaxed. Notice the tension in your fingers, thumb, palm of your hand, your knuckles and the back of your hand.

Keep your fist clenched; noticing the tension in your wrist and lower part of your arm. Notice how clenching your fist makes your arm tense as well.

Now, let your hand relax and your fingers hang. Notice how the fingers and hand feels warm and relaxed. The arm may feel heavy. Feelings of heaviness and warmth are an important sign that you are succeeding in relaxing.

Continue the relaxation exercise with your left fist.

ARMS: Clench your right arm by bending it up so that your knuckles touch your shoulder, clenching your fist at the same time. Hold for a moment and then let it drop.

Continue the relaxation exercise with your left arm.

Hold your right arm straight in front of you and tense it up. Try to feel as if you are pushing your hand off the end of your arm. Draw your hand back and let your arm drop.

Continue with the left arm.

Relaxing Shoulders and Face:

SHOULDERS: Tense the muscles by hunching up your shoulders. Hold them in an tense position and notice the muscle tension across the top of your shoulders, in your neck, in the top part of your chest and back and in your arms.

Notice how your breathing is affected by the tensing of these muscles.

Now, let your muscles relax and lower your shoulders as low as possible.

NECK: Tense the muscles by pushing your head back against the chair or pillow. Avoid tensing too hard.

Notice the tension in the back of your neck, back of your head, across your shoulders, front of your neck and around your jaw and lower part of your face.

Now, bring your head forward and suddenly let your muscles relax. Allow your head to drop forward; feeling floppy and heavy.

FACE: Begin by frowning and creasing your forehead. Close your eyes as tightly as you can.

Relax

Tense face again, pursing lips and pressing your tongue against the roof of your mouth

Relax your face muscles and breathe slowly.

Let your mouth remain slightly open. Your arms and head should feel heavy, your shoulders are slumped and your face feels soft.

Relaxing your Back and Stomach Muscles

BACK: Concentrate on the muscles in your back.

Arch your back slightly to produce tension.

Hold the tension, then, relax.

STOMACH: Tense your stomach muscles

Pull in your stomach so that you look as thin as possible. Hold and concentrate on the tension.

Gently let your stomach return to normal. Notice how comfortable you feel when the muscles across your stomach are soft and relaxed.

Relaxing your Feet and Legs:

FOOT: Start with your right foot.

Straighten your leg (if sitting on a chair, keep your heel on the floor).

Point your toes down away from you.

Curl your toes under.

Feel the tension in your toes, the sole of your foot, the upper part of the foot, the ankle, lower part of your leg, in the calf muscles, behind your knees, and in the thigh muscles.

Relax your foot.

Repeat procedure with left leg.

The Breathing Exercise:

This is the most important exercise of all. Try to completely relax and "let yourself go" all over, and concentrate on your breathing. Make sure that it is easy and regular. Inhale through your nose and exhale through your mouth. Take four deep breaths, filling your lungs as much as possible and then breathing out slowly.

Finishing a Relaxation Session:

Your breathing should be very slow and gentle. Your arms, legs, and head are heavy. Your face, neck, shoulders, and stomach are soft. Enjoy the changes you have produced. Now think **"CALM"** each time you breathe out.

Congratulations! You have completed this week's lesson.

CONTINUE WITH LESSON #5 NEXT WEEK.

LESSON WEEK #5

Changing How We Think About Tinnitus

COMPLETE THIS LESSON TO LEARN TO CHANGE YOUR PERSPECTIVE ON YOUR TINNITUS

It's certainly understandable to have negative feelings associated with the perception of your tinnitus. The ringing or buzzing in your ears can be very unpleasant and bring about a stress response that you deal with not only in your mind, but your body as well.

It's important to understand that this stress response is not something that you've chosen. It is often a result of how your body reacts to a threatening sound or dangerous environment. In the case of your tinnitus, the moment that you hear your tinnitus, your body chooses to trigger a stress signal in response to the tinnitus sound. During these times, you may experience the following:

- Increased heart rate
- Increased respiration or breathing
- Hot or cold sweats
- Nervousness
- Anxiety
- Irrational thoughts

Fight or Flight

Your body's response to danger is what is known as the fight or flight response. This is a response found within us for protection since the beginning of time. It was to warn us of an approaching danger and was used as a defense mechanism. This is the same mechanism at work when those negative feelings emerge with your tinnitus.

Understanding your Tinnitus

In reading the previous paragraphs, they are not meant to suggest that tinnitus is purely psychological. From many years of clinical research, we know that tinnitus is due to real

changes to the auditory (hearing) system. However, we also understand that negative beliefs about tinnitus can in turn increase the importance the tinnitus has in the brain, making it more of a threat to your system. As a result, there is a greater, more negative, impact on your day to day life. The more negative of an impact your tinnitus has in your life; the more likely you are to pay attention to it. As you can see, this makes for a vicious cycle. In treating tinnitus, it's extremely important to de-emphasize the role of tinnitus in your daily life.

To achieve this, understanding where tinnitus comes from is crucial. Tinnitus is merely a symptom of changes somewhere in the auditory system. Many people with tinnitus think that it will make their hearing worse. In reality, the tinnitus has resulted from hearing loss or changes in the auditory system, not the other way around. Understanding that tinnitus does not contribute to hearing loss can be the first step to removing the importance associated with your tinnitus.

Checking in With Your Tinnitus

This is also known as self monitoring. Remember, in treating tinnitus, we want to de-emphasize the importance your body has placed on the ringing or buzzing. To achieve this, it makes sense that you would discontinue any attempts to monitor or self measure your tinnitus. That is the work of the device and your clinician. The sooner you can stop these practices, the sooner you will be on your way to decreasing your awareness of the tinnitus signal. This also refers to researching tinnitus as well. Once you have met with medical professionals, understanding where tinnitus comes from and committing to treatment**, your research needs to be minimal.** Think about it, the more time you devote to your tinnitus, the greater importance your body will assign to that ringing or buzzing. This doesn't mean not to research tinnitus at all. Understanding is the key to success! It's the continuous research once understanding is achieved that can impede progress and hinder success with therapy.

Congratulations! You have completed this week's lesson.

CONTINUE WITH LESSON #6 NEXT WEEK.

LESSON WEEK #6

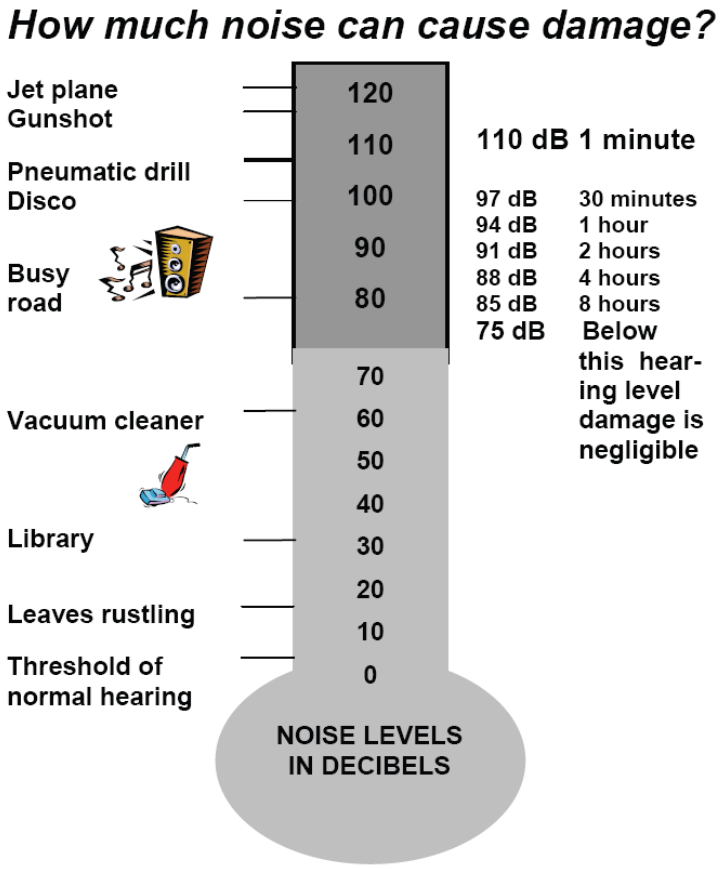
Coping With Environmental Noises

COMPLETE THIS LESSON TO LEARN MORE ABOUT PROPERLY PROTECTING YOUR EARS FROM HARMFUL NOISES

Understanding how environmental sounds can contribute to your tinnitus

Loud Noise

Not only is loud noise the leading cause of tinnitus, but it can also make your existing tinnitus worse. Appropriate ear protection is recommended any time you will be exposed to excessive noise. Examples of noisy activities would be use of fire arms and power tools, attending music concerts or stock car races, and working around jet engines or loud machinery. Use of ear plugs or ear muffs is suitable for hearing protection in any of these scenarios. Talk to your hearing healthcare professional to discuss the best option for you. Take a look at the chart below to ensure that you are protecting your hearing in your daily activities. This chart shows you what activities are appropriate times for using hearing protection.



Excess Quiet

While exposure to loud noise has been found to physically damage the auditory system and make tinnitus louder, long periods of quiet can make your tinnitus seem louder. Think about a lit candle in a brightly lit room. The flame from the candle is hardly noticeable because of the amount of light present in the room. However, if you close the blinds and turn off the lights, that candle will seem much brighter, even though the flame has not changed. What has changed is the environment, making for a far greater contrast between the dark room and the light of the candle. The same can be true of your tinnitus. The more environmental sounds that are present to blend with your tinnitus, the less "bright" your tinnitus will seem.

Congratulations! You have completed this week's lesson.

CONTINUE WITH LESSON #7 NEXT WEEK.

LESSON WEEK #7

Diet and Medication

COMPLETE THIS LESSON TO LEARN MORE ABOUT HOW DIET AND MEDICATION CAN IMPACT YOUR TINNITUS

How your medication or diet could be affecting your tinnitus

Medication and Your Tinnitus

There are times when certain medications can affect your tinnitus, and in some cases make it worse. However, **it is always recommended when considering changes to your medications you consult your physician**. **Any changes to medication should *always* be done under the supervision of a physician.**

It's important to understand that there are many medications on the market today in which tinnitus is listed as a potential side effect. While pharmaceutical side effects should always be taken seriously, it does not mean that every individual taking that medication will experience all side effects listed for that particular drug. Pharmaceutical companies have to be extremely cautious that all potential side effects are listed. However, this does not mean that you will experience tinnitus or an increase in your tinnitus as a result of taking that particular medicine. However, if you notice an immediate cause and effect of increasing tinnitus after taking a prescription, please consult with your physician.

Aspirin

Aspirin, sometimes also referred to as salicylates, have been found to increase tinnitus for some individuals. However, the small amount recommended for heart health and control of blood pressure (baby aspirin 81mg) has rarely been found to be enough to cause any increase in tinnitus. If you are concerned that your use of aspirin is a factor in your significant tinnitus, consult your doctor to find out if there are any viable alternatives for substitution. If taking excessive or frequent aspirin over the counter for pain relief (headaches and mild

muscle or joint pain) you may want to consider other aspirin free over the counter pain relievers to see if there is any effect on your tinnitus.

Antimalarials

These drugs are used for the prevention and treatment of malaria. Quinine is an example of this type of medication, and has been found to have an effect on some individual's tinnitus perception. When considering an antimalarial drug, discuss with your physician any possible alternatives to quinine. Quinine can also be found in some beverages such as tonic water.

Antibiotics

Typical antibiotics usually pose no problem to your auditory system, but there are some antibiotics known to cause damage. However, these are usually only prescribed when absolutely necessary. These cases are typically used when treating a potentially life threatening infection. The ***mycin*** group of antibiotics (gentamycin, erythromycin, lincomycin, etc.) can be particularly damaging to the auditory system. Always consult your physician in weighing out the consequences of these types of drugs.

Alcohol

Research has found that excessive amounts of alcohol can be detrimental to one's health. There are some individuals who feel that alcohol makes their tinnitus worse. Alcohol can also have negative effects on your sleep cycle, which can make tinnitus seem more pronounced. While these effects are highly individualized and it can be difficult to pinpoint specific factors that are influencing your tinnitus, these effects should always be taken into consideration when looking at ways to decrease overall tinnitus perception.

Smoking

The unhealthy aspects of smoking are widely known and accepted. Just like medication and alcohol, the effects of smoking in relation to an individual's tinnitus perception are highly individualized. There are many people who believe that smoking has made their tinnitus worse. With the potential effect of worsening tinnitus, compounded with the adverse health effects, smoking is always discouraged.

Diet

It is no secret that your dietary choices can have a tremendous effect on your overall health. Switching to a well balanced diet can do wonders for your overall sense of well being and your ability to manage your tinnitus.

> ***Caffeine***: Caffeine is a stimulant and can affect your body negatively in many ways. It can heighten anxiety and nervousness, which can lead to increased tinnitus perception. Cutting down to 8-16 oz of caffeinated beverages per day can help to alleviate your tinnitus symptoms. Don't forget, in addition to coffee, tea, soft drinks, and energy drinks, a significant amount of caffeine can also be found in chocolate.
>
> ***Low Sodium***: Many people also find a decrease in their tinnitus after lowering their sodium or salt intake. A good rule of thumb is not to consume more than 1500 mg per day. Many foods and beverages have high levels of sodium in them, some that would surprise you! Taking a look at the sodium content in the things you eat and drink can not only help to alleviate your tinnitus, but make you more healthy overall.

Vitamin Supplements

There are many over the counter supplements on the market today that claim to treat or cure tinnitus. Always check with your physician before taking any of these supplements, as they can interact with other medications you currently take. There isn't any scientific evidence to support that a supplement will decrease your tinnitus, and many patients have found them to be ineffective. However, there are some patients who report some decrease in their tinnitus after taking these supplements. Always make sure to always consult with your physician when taking any supplements.

Congratulations! You have completed all treatment lessons.

Neuromonics
Tinnitus Treatment

Tips for Success

Stage Two

- Use the device on "single" setting
- Set the volume for 50% mix between and music and tinnitus
- Use the device 2-4 hours per day when your tinnitus is bothersome. If you miss a day or don't get a full two hours occasionally that is fine.

Completing the Program

Are you ready for Maintenance?

Congratulations if you are ready to consider whether or not it is the correct time to enter the maintenance stage of the treatment! This typically takes place at least 26 weeks into your treatment. Remember however, that this decision is made jointly with your clinician. You will need to schedule your final appointment with your clinician in which a questionnaire will be given to you along with some final measurements.

Things to Consider

Consider if you have noticed an improvement in the percent of time that you are aware of the tinnitus _____, and the percent of time you are bothered by the tinnitus _____. Compare with your initial percentages. You may notice a greater decrease the in percent you are bothered by the tinnitus than the awareness change.

- Are there days where you are using the device less than 2 hours per day? Or even days where you are skipping using the device? This indicates not needing to reach for the device as often because your tinnitus is either not noticeable or bothering you as much.

- Consider whether or not you are experiencing periods of silence (without tinnitus) when you are not using the treatment.

- Have you experienced improvement with the treatment goals that you stated at the beginning of your treatment?

The above are excellent signs that desensitization to the tinnitus has occurred.

The next two sections will discuss what to do if the changes are **Satisfactory vs. Unsatisfactory.**

Satisfactory Changes-Desensitization Occurring

If the changes in the above mentioned items are satisfactory, you are ready to begin **The Maintenance Stage of Treatment**. This will be decided by your clinician during your next appointment.

Maintenance

It is now time to begin the maintenance stage of treatment. It is most beneficial to continue a periodic use of the device as opposed to stopping abruptly. Think of it as going to the gym for a period of time and achieving physical results. If you stopped working out altogether, your results may not maintain. However, if you periodically worked out, you can maintain your fitness achievements. Similarly with the treatment, we have found that using your device at least once a week for 2-4 hours is an ideal way to begin your maintenance period. Try to do this for at least several weeks. If you wish to use the treatment more than that, it is ok. Some patients like the relaxation effect of the device. After several weeks of using the device for 2-4 hours a week, it can sit on the shelf and be used as you desire. If anything in your life occurs (illness, excessive noise, major stress etc) and ramps up your tinnitus, you can always initiate your treatment again. Remember, however, that it is always recommended to see your audiologist if tinnitus reoccurs.

Maintenance Recommendations:

Use the treatment 2-4 hours per week

If you experience an increase in your tinnitus, use your device on a more regular, daily schedule. If your tinnitus continues to increase, contact your clinician.

If Changes are not Satisfactory and Desensitization has not yet Occurred

Continue to use your device in the following manner. Reach for the device when you are noticing or bothered by the tinnitus only. Much like you would reach for an aspirin when you have a headache. Remember to set the volume at a level that is covering and exposing your tinnitus about 50/50. Then after you set it, try to forget about it. Get on with doing your activities with it on such as reading, computer work, chores, hobbies, cooking, relaxing etc. Use the device on the single setting to see if you have forgotten that is shut off (desensitization occurring). It should not be disappointing if you are not ready for maintenance at this time as it is not uncommon for many patients to require an additional 1-3 months in active treatment. Revisit this stage and these considerations again in 1-2 months with your clinician.

Appendices

Neuromonics
Tinnitus Treatment

Appendix A: Device Troubleshooting

Technology Issues

The earphones appear to be unbalanced or degraded:

- Check earphone insertion into device, fit and placement on patient. Slight changes in placement can impact sound quality.
- Due to size and shape of the ear canal, loudness perception can vary.
- Clean earphone jack using alcohol or contact cleaner. Small amounts of debris can create an un-balanced sound quality.
- Remove foam earphone cover. Check the screen of the earphone and/or cover for debris. Clean the screen carefully with a small brush, and the earphone cover with soap and water. Replace foam cover once it has completely dried. Earphone covers can also be replaced with spare covers provided in the device kit.
- If a problem still exists, contact your clinic.

The device is not charging:

- Check the green light on the power supply to the charger.
- Try using a different power outlet to make sure it is not a problem with the outlet.
- Verify pins inside charging port have not been damaged by inadvertently plugging the charger into the earphone jack.

The device is “dead”:

- Make sure the device is charged properly.
- Place a paperclip into the reset button on the back of the device (please see User Manual for specific instructions). This will reset your device.
- Contact your clinic if the problem is not resolved.

The LED display reads “No Card”:

- Remove the end cap (using a small screwdriver or paper clip) and reinsert the SD card.
- If the problem is not resolved, contact your clinic.

APPENDIX B: Tinnitus Troubleshooting

Appendix B looks at different factors that can cause increased tinnitus perception. If you are having a problem with your tinnitus increasing, review the following items and contact your clinic for additional assistance.

Life Factors

Have you had a period of acute stress?
A stressful period can increase tinnitus levels despite ongoing treatment. Your device can be used to help at these times, and continual use over the long-term will help you to better deal with other stressful incidents.

Have you had excessive noise exposure lately?
A period of noise exposure to a concert, wedding, machinery, sporting events, etc., can aggravate tinnitus. If the noise is so loud that you need to shout to be heard, then you should consider using hearing protection.

Are you using hearing protection/earplugs appropriately?
Hearing protection should ***not*** be worn at times when there is no significant noise. Conversely, hearing protection ***must*** be worn in the presence of excessive noise levels. Please refer to the section on Environmental Noise for more information about proper hearing protection.

Have you recently had changes in your overall health?
A cold, flu, allergy, or excessive ear wax can enhance tinnitus. Also, changes in medication or dosage may also affect tinnitus. If a change in medication has occurred you should go back to your practitioner.

Have you had extended periods of straining to hear clearly?
Extended periods of straining to hear can exacerbate your tinnitus. Exposure to softly spoken children or adults, a conference or meeting can draw attention to hearing difficulties and problems with the auditory system. Remember that your treatment is not to be used ***during*** situations of straining to hear.

Appendix C: Clinical Data Summary

Neuromonics – Summary of Clinical Efficacy Data and Reference Materials

The initial demonstration of Neuromonics clinical efficacy is documented in four published papers in peer reviewed medical journals demonstrating the results achieved with the Neuromonics treatment.

1) **Davis PB, Wilde RA, Steed LG, Hanley PJ. Treatment of tinnitus with a customized acoustic neural stimulus: A controlled clinical study. *Ear Nose Throat J* 2008;87:330-9.**

   This paper describes the results of a randomized, controlled study where the Neuromonics treatment was randomized against two control groups. We typically refer to this as the "second clinical trial" because it followed a small feasibility trial that has not been published. After 6 months of treatment, 86% of the Neuromonics patients met the minimum criterion for clinical success, defined as an alleviation of tinnitus disturbance of at least 40% (as determined by the Tinnitus Reaction Questionnaire score). By contrast, only 47 and 23% of the patients in the two control groups reported a successful result according to this criterion. Mean improvements in tinnitus disturbance scores in the Neuromonics treatment group was 66% as compared to 22% and 15% in the control groups. The differences between the Neuromonics group and the control groups were statistically significant and significant differences were observed in other clinical outcomes as well.

   We propose that this study is a well-designed and well-conducted investigation showing measurable improvement in the disease condition compared to other available treatments. In addition, not only are the risk for harmful effects extremely low, patient reports of user acceptability were more consistently positive in the Neuromonics group, showing the treatment is not only more efficacious but more tolerable as well.

2) **Davis PB, Paki B, Hanley PJ. The neuromonics tinnitus treatment: third clinical trial. *Ear Hear* 2007;28:242-59.**

   This paper, referring to the "third clinical trial", presents the results of a clinical trial comparing an abbreviated version of the Neuromonics treatment protocol to determine if it is superior to the standard protocol that was studied in the second clinical trial above. The trial concluded that the abbreviated treatment protocol was not statistically superior and, in fact, the results suggest it was inferior to the standard protocol. However, there were a number of extremely important outcomes from the study, particularly the consistency of the benefit compared to the previously described trial. At six months, 91% of all patients showed a clinically significant benefit (defined as an alleviation of tinnitus

disturbance of at least 40%) which is very consistent with the 86% in the previous trial. In addition, the patients were followed to 12 months and the benefit persisted, with 86% showing a clinically significant benefit at that time point. The mean improvement in TRQ at 6 months was 65% as compared to 66% in the previous trial, showing a remarkably consistent benefit.

3) **Hanley PJ, Davis PB, Paki B, Quinn SA, Bellekom SR. Treatment of tinnitus with a customized, dynamic acoustic neural stimulus: clinical outcomes in general private practice. *Ann Otol Rhinol Laryngol* 2008;117:791-9.**

The previous two trials documented the clinical efficacy of the treatment under controlled clinical studies for the most suitable patients. This paper documents the results in real-world clinics across a very diverse patient population with a very large patient base (n=470). The most suitable patients, described as Tier 1 patients (n=237), demonstrated a clinical success rate of 92% with a mean improvement of 72%, value which are extremely consistent with prior studies. Even less suitable Tier 2 patients (n=223) demonstrated a clinical success rate of 60% with a mean improvement of 49%.

4) **Hanley PJ, Davis PB. Treatment of tinnitus with a customized, dynamic acoustic neural stimulus: underlying principles and clinical efficacy. *Trends Amplif* 2008;12:210-22.**

This paper describes the essential underlying scientific principles behind the Neuromonics Tinnitus Treatment as supported by the medical literature. It also summarizes evidence for clinical efficacy from the previous controlled clinical studies and the private practice clinical setting, where it has been shown to provide consistently positive outcomes, particularly among those patients meeting specific criteria. This supports the rationale for the consistent and significant clinical benefit of the treatment.

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Appendix D: Tinnitus Resources

When researching tinnitus, it is important to make sure you are accessing accurate information. We have provided a list of websites known for providing accurate information:

www.neuromonics.com

www.ata.org

www.audiology.org

www.asha.org

Appendix E: In-depth Discussion of the Tinnitus Pathogenesis (Cycle)

The Neuromonics device is distinctive in that it targets the neurological processes underlying tinnitus. There are three discrete but interrelated processes in the development of disturbing tinnitus – all of them involve neuro-plastic changes in the brain.

These processes…

- involve changes within the auditory system which lead to the initial perception of the tinnitus sound
- involve the attentional filters in the brain which cause the patient to pay attention to the tinnitus perception
- involve the emotional response and the autonomic nervous system which cause an aversive reaction to the tinnitus

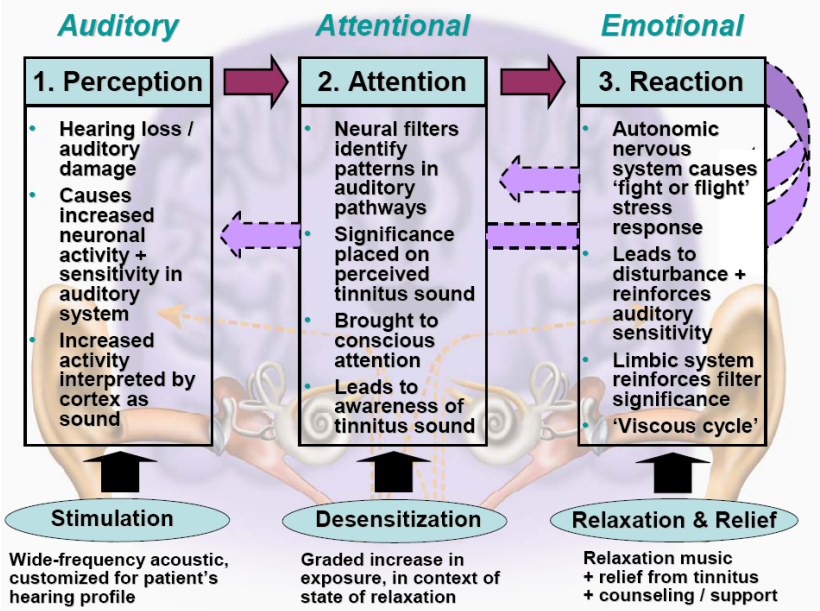
Neural processes that lead to disturbing tinnitus

- **Auditory processes leading to initial tinnitus perception:** studies have shown that auditory deprivation causes the auditory system to become more active[1] and more sensitive to sound[2].Following peripheral hearing damage, for example through noise insult or ototoxic drugs, there are changes in activity levels in the auditory nerves which appear to be centrally mediated[3]. As a consequence, the auditory cortex receives more neural input, which it interprets as sound. Essentially, the cortex detects the amplified background neurological activity, and interprets it as the ringing or buzzing sounds perceived in tinnitus. Changes in the auditory cortex also involve reorganization of the tonotopic map[4].
- **Attentional processes leading to conscious attention to /awareness of the tinnitus:** perceptual filters at work on all of our senses determine which sensory perceptions are brought to our conscious attention and which aren't. These filters play an important function, as they allow the brain to focus on what's important while preventing us from being

overwhelmed by sensory input. The filters recognize specific patterns of neural activity[5], which are constantly being updated and refined through experience. In the case of tinnitus, an importance 'label' is applied to the tinnitus sound, such that it is constantly brought to the patient's attention.

- Emotional (limbic) and autonomic nervous system engagement, leading to aversive reaction to tinnitus: in patients with disturbing tinnitus, the limbic system of the brain, which controls the patient's emotional state, and the autonomic nervous system, responsible for the so-called 'fight or flight' reflex, become engaged in response to the awareness of tinnitus[6]. This causes a stressful state of high arousal and anxiety in response to the tinnitus awareness, which has a significant impact on quality of life and general well being. This reaction also reinforces the other two processes referred to above, i.e. it leads to further increases in the sensitivity of the auditory system, and reinforces the attentional filters. This in turn leads to further increase in tinnitus loudness and awareness, which in turn increases the level of stress, and so on, in a self-perpetuating 'viscous cycle' that makes the tinnitus progressively worse over time.

Overview of tinnitus pathogenesis and mechanism of action of Neuromonics Tinnitus Treatment



Mechanism of action of the Neuromonics Tinnitus Treatment

Discrete aspects of the Neuromonics Tinnitus Treatment address each of the neural processes outlined above.

- **Auditory stimulation to address the effects of auditory deprivation:** Neuromonics delivers a broad frequency stimulus into the system that's been deprived of stimulation and thereby counters the need for increased auditory sensitivity. Studies have shown that neuronal changes that result from hearing damage can be reversed by feeding sound into the auditory system[7]. In the Neuromonics treatment, this is achieved through the use of a wide frequency stimulus that is spectrally modified to account for each patient's hearing loss profile. This modification is performed separately for each ear and the resultant stimuli combined in a way which provides balanced perception across the two ears, and is delivered in stereo to stimulate the integrative pathways of the auditory system. In this way, the treatment stimulates as much of the system as possible as evenly as possible, and thereby reduces the need for the brain to 'turn up' the sensitivity in the auditory system.

- **Relaxation and relief to address the aversive reaction / stress response:** a key part of the Neuromonics stimulus is relaxation music, which addresses the limbic system / autonomic nervous system involvement that causes the aversive reaction to the tinnitus. This aspect of the treatment draws upon studies that have shown that relaxation music is as effective as progressive muscle relaxation in generating a relaxation response8. This benefit is further reinforced by the relief and sense of control that comes from being able to shut out the tinnitus sound (perhaps for the first time in years), as well as by improvements in sleep that commonly result from treatment. The combination of relaxation, relief and improved sleep lead to a reduction in the level of limbic system arousal and the consequential stress response.

- **Systematic desensitization to address the perceptual filters that lead to attention to the tinnitus:** in the context of the relaxation response, Neuromonics addresses the attentional filters using the principles of systematic desensitization. Because of the dynamics of the music, once customized for the patient's profile and delivered in a tightly controlled way, the stimulus allows the patient to cover the tinnitus in the peaks of intensity in the music, while allowing the tinnitus to be momentarily perceived in the intensity troughs. In this way, the brain experiences repeated, momentary perception of the tinnitus whilst in a relaxed state. By gradually increasing the degree of exposure to the tinnitus perception over time, the brain is

'retrained' to perceive the tinnitus sound but not to pay particular attention to it, and not to trigger the stress response in reaction to it.

Clinical outcomes achieved by the Neuromonics Tinnitus Treatment

By addressing in concert all three of the underlying neural processes implicated in disturbing tinnitus, the Neuromonics Tinnitus Treatment is able to achieve consistent, rapid and efficient results for tinnitus patients. In a recently reported clinical study9, 90% of patients with disturbing tinnitus reported a reduction in their tinnitus-related disturbance of 40% or more, with a mean improvement of 65%. Results were reported quickly – with significant benefits after only two months. Also, 80% of subjects at six months reported a level of tinnitus disturbance that was no longer clinically significant. A very high proportion of patients reported sizeable benefits in s sleep, relaxation, and general well being, and over 95% indicated that they found the treatment pleasant to listen to, and would recommend it to others.

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