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Sanctuary™

Fitting the Sanctuary Device: A New Tinnitus Management Tool

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Relief



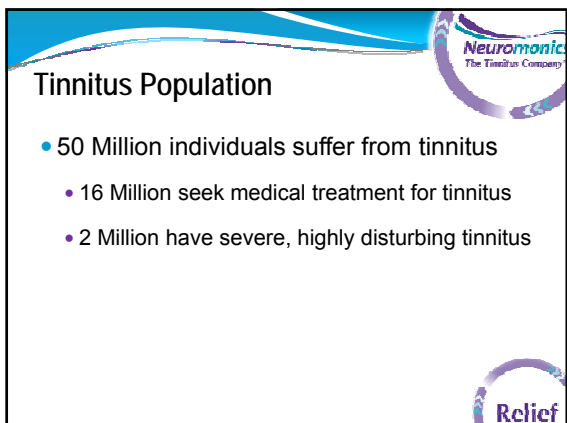
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- Situational relief on demand for the mild to moderate tinnitus sufferer
- Customized acoustic signal
 - Spectral modification
 - Wide frequency stimulation
- Three hearing profiles
 - Covers about 75% of patients
- User friendly setup
 - Ready to go in minutes
- Engineered for maximum relief



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Tinnitus Population

- 50 Million individuals suffer from tinnitus
 - 16 Million seek medical treatment for tinnitus
 - 2 Million have severe, highly disturbing tinnitus

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Sanctuary Fitting Training Format

- Candidacy considerations
- Getting to know the Sanctuary
- Fitting Profile Selection
- Counseling topics
- Device Usage Guidelines
- Follow-up Considerations
- Q & A



Sanctuary
Candidacy Considerations



Symmetrical hearing
Thresholds ≤ 20 dBHL between ears

No indication of reactive tinnitus
Patient history or Residual Inhibition test

No significant psychological history associated with tinnitus
Depression/anxiety/disturbance

Lower end of disturbance scale
TRQ score below 35
Score of zero on TRQ question #24

No indication of Hyperacusis





Reactive Tinnitus

Reactive tinnitus is an extreme and rare condition whereby a person's tinnitus is worsened after exposure to mild –moderate levels of sound and this increase tends to last for more than a day



Indicators which raise the possibility of Reactive Tinnitus:

- After RI testing, tinnitus is reported as exacerbated
- Suspected in people who a report of history of:
 - over-use of hearing protection when not indicated
 - have found that nothing reduces their awareness of tinnitus
 - have had trials with other acoustic based treatments that clearly aggravated their tinnitus




Residual Inhibition Testing

- Standard Procedure:
 - Binaural presentation
 - Select NBN at Tinnitus Pitch Matched frequency
 - Presentation level: 65-75 dB HL. Must be at least 10 dBSL
 - Present NBN for 1 minute
- Additional presentation level procedure:
 - Presentation level: 10 dB HL above NBN MML





Neurophysiology

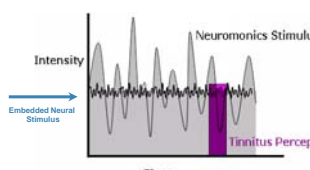
Auditory
• High Frequency Stimulation





Emotional
• Calming music
• Targets the limbic system



Customized Acoustic Signal



- High level of interaction
- Maximum neural stimulation
- Relief and reduced awareness during listening sessions
- 4 Musical Tracks
- Wide Frequency Stimulation to 12.5K



Getting to Know the Sanctuary™

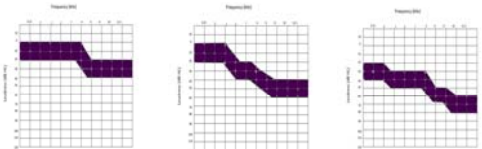
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- Relief on demand



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Fitting Profile Selections

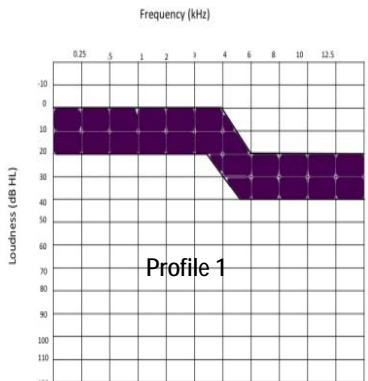


Profile 1 Profile 2 Profile 3

- Selection based on the patient's audiogram
- 10k and 12.5 k are included in the prescriptions, but not required
- 75% of audiometric thresholds should fall within fitting range

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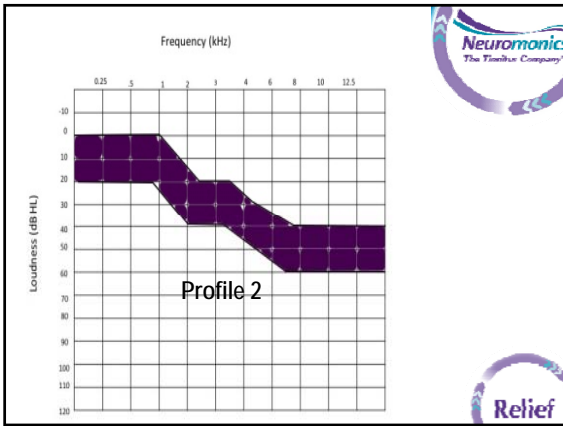
Frequency (kHz)

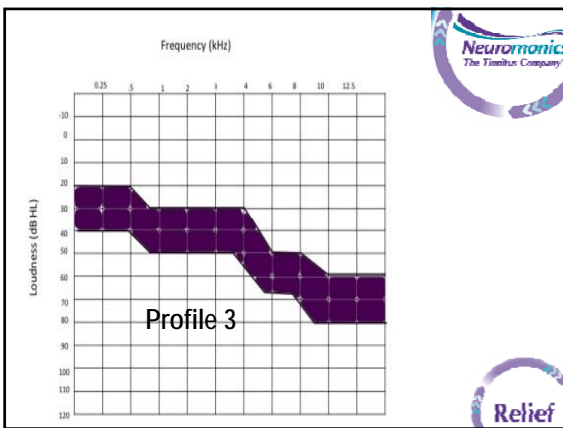
Loudness (dB HL)

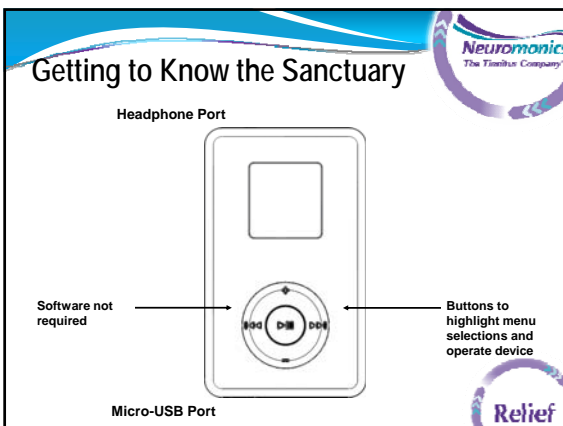
Profile 1

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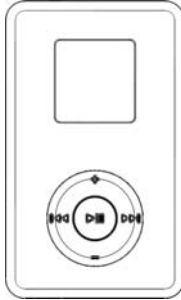
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Getting to know the Sanctuary

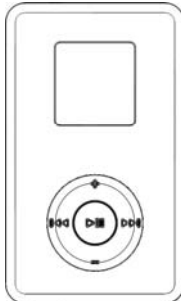


- Center Button
 - Power on
 - Play/Pause Tracks
 - Access Set-up Menu
 - Access Clinician Menu

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Getting to know the Sanctuary



- << or >> to:
 - select Tracks
 - Select desired time for sleep timer
- +/- to :
 - adjust volume incrementally
 - Select headphone
 - Select fitting profile

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Accessory Options

- **Headphone Options**
 - Sony
 - Sanctuary ships with this option
 - Bose IE2's
 - Can be ordered
 - If there are fit concerns
- **Auxiliary Speaker**
 - JBL
 - Bedside for sleep
 - Desk for concentration




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Headphones

Standard Sony MDR-ED12LP Headphones



Optional Bose IE2 Headphone Upgrade



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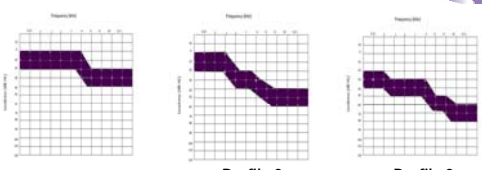
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Fitting Profile Selection Guidelines

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Fitting Profile Selections



Profile 1 Profile 2 Profile 3

- Selection based on the patient's audiogram
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Fitting Profile Selection

	0.25	0.50	1.0	2.0	3.0	4.0	6.0	8.0	10.0*	12.5*
Left										
Right										
Fitting #1	0-20	0-20	0-20	0-20	0-20	0-30	20-40	20-40	20-40	20-40
Fitting #2	0-20	0-20	0-20	15-40	20-40	25-45	35-55	40-60	40-60	40-60
Fitting #3	20-40	20-40	30-50	30-50	30-50	30-55	50-65	50-70	60-80	60-80

For each frequency, circle the appropriate fitting range(s)

- Thresholds must be symmetrical, ≤ 20 dB HL between ears at any frequency
- Choose the Fitting profile with the most circles selected
- ≥ 6 out of 8 frequencies if 250-8k are assessed
- ≥ 7 out of 10 frequencies if 10 k and 12.5 k are assessed

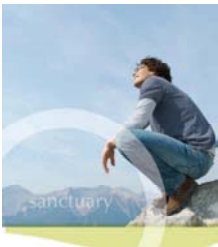
Fitting Profile Selection

	0.25	0.50	1.0	2.0	3.0	4.0	6.0	8.0	10.0*	12.5*
Left	10	15	10	30	40	40	40	60	70	70
Right	5	5	10	20	20	25	40	50	60	60
Fitting #1	0-20	0-20	0-20	0-20	0-20	0-30	20-40	20-40	20-40	20-40
Fitting #2	0-20	0-20	0-20	15-40	20-40	25-45	35-55	40-60	40-60	40-60
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Counseling Topics and Device Usage Guidelines





Topics	Tools to assist
Understanding tinnitus	<ul style="list-style-type: none"> •Patient specific assessment information •Neurophysiology of Tinnitus slide •Tinnitus Management Handbook
Sanctuary Mechanism of Action	<ul style="list-style-type: none"> •Sanctuary User Manual •Tinnitus Management Handbook
Sanctuary tinnitus management goals and expectations	<ul style="list-style-type: none"> •Sanctuary User Manual •Tinnitus Management Handbook •Sanctuary Patient Expectation/Fitting Agreement
General tinnitus management strategies	<ul style="list-style-type: none"> •Tinnitus Management Handbook
Effective Device Usage Guidelines	<ul style="list-style-type: none"> •Tinnitus Management Handbook
Additional Counseling Points: <ul style="list-style-type: none"> • Relief contrast • Contraindicated Activities • Conditions that make tinnitus perception worse 	<ul style="list-style-type: none"> •Sanctuary User Manual •Tinnitus Management Handbook



Sanctuary Tinnitus Management Goals and Expectations


- A tinnitus management tool used to provide relief from tinnitus perception while the device is being worn
- Designed to provide the patient with:
 - a sense of empowerment and control
 - help with relaxation and concentration
 - a listening experience that is comfortable, pleasant, and relaxing
 - a perception of the music in stereo
 - an ability to use the device while carrying out normal tasks including listening to speech





Sanctuary Device Usage Guidelines



- Use in situations that are impacted by bothersome tinnitus to obtain relief.
- Use at a volume level that is **comfortable** while still providing maximum relief from tinnitus.
- Use more volume for relief if needed, **while still using a volume that is comfortable, pleasant, and relaxing.**
- Place the music in the background of awareness and avoid "tuning in" to tinnitus during a listening session.
- Reduce listening volume a few minutes before ending a listening then, remove in an environment that is not completely quiet.



Relief Contrast

A Common Perception



- Tinnitus is more noticeable after listening session due to the "contrast" from experiencing relief with device.
- Perception is short-term
- Strategies to minimize relief contrast
 - Advise patient to decrease volume for 5-10 minutes prior to ending session- think of putting the tinnitus on a dimmer switch with a gradual reintroduction of the tinnitus to help transition from the relief the device provided
 - Advise patient to remove device in an environment that is not completely quiet



Contraindicated Activities

Device cannot not be used:



- When patients are straining to hear
- While exercising strenuously
- While watching TV (with audio)
- While driving
- When the device can get wet



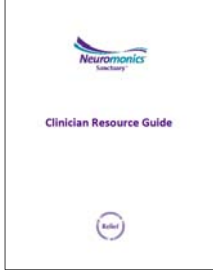

Additional Counselling Points

Conditions that may temporarily make tinnitus perception worse:


- Recent cold, flu, allergy, Eustachian tube dysfunction, excessive ear wax
- New medication, or changed dose of existing medication
- Excessive noise exposure
- Extended periods of straining to hear clearly
- Period of acute stress



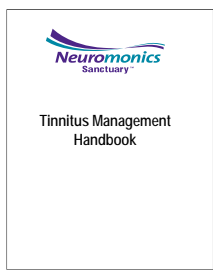

Clinic Resources




- Fitting Criteria
- User Protocol
- Warranty, Loss and Damage
- Terms and Conditions of Sale
- Service and Repair Policy
- Receive an electronic copy
- Hard copy shipped with first order




Patient Supplemental Materials




- Patient Education handbook
- Tips for success



Follow up Considerations



- Suggested follow-up:
 - One week post fit call
 - Four week post fit check
 - Patient needs
 - Clinical judgment
- Follow-up documents
 - TRQ, Patient feedback form
 - Patient goals:
 - Sense of control
 - Relief while wearing the device
 - Comfortable listening experience
- Patient fees
 - Per visit model




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- Tinnitus Management Tool
- Mild-to-moderate tinnitus disturbance TRQ score <35
- Customized stimulus
- Same day fitting

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Thank you for your time and attention!

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