Clinically proven: Spectral notching of amplification as a treatment for tinnitus

Jennifer Gehlen, AuD
Sr. Clinical Education Specialist
Tinnitus therapy options

Tune out tinnitus.
Unique therapies for lasting relief.
Treatments for Tinnitus

Amplification

Static signal  Modulated  Notch therapy
Benefits of amplification for tinnitus

#1 treatment for Tinnitus
• “The sounds amplified by the hearing aids produce neural activity by the auditory system, which interferes with the representation of tinnitus in the central auditory system”

• Amplification helps to reduce the contrast between the tinnitus and the background by enriching the sound environment

• The most effective hearing aid settings for communication are not necessarily the best for reducing tinnitus audibility

Anderson, 2002; Searchfield, 2006
Habituation Therapy

What if amplification isn’t enough?

Static signals: Soft and gentle sounds that take away the annoyance of tinnitus.
Habituation

• "It is the reduction or elimination of CNS activity in response to repetitive stimuli” (Encyclopedia of Neuroscience, 1987)

• It is a natural process of the CNS and crucial to brain function due to its limitations when performing many tasks simultaneously
Therapy signals options

- Tinnitus Therapy
  - Signal: White Noise
  - Modulated: Ocean Waves
  - Static: White Noise, Pink Noise, Speech Noise, High Tone, Brownian Noise
  - Mix with microphone
  - Handles: 1 - 10
  - Master Volume: 15.00 dB
Modulated sound options

Ocean Waves: What could be more relaxing than the sound of a seashore?
Ocean wave therapy signals mimic the sound of the sea to provide a Positive, Soothing and Stress Relieving listening experience
Treatments for tinnitus
Notch Therapy

Relief without adding a masking sound
A joint comprehensive tinnitus study conducted by the Kresge Hearing Research Laboratory and the University of Oregon Health Sciences Center Tinnitus Clinic revealed:

Tinnitus pitch falls largely into two broad categories: tonal and noise

- 59%, reported tonal tinnitus
- 25% reported noise-type tinnitus
- 16% presented with a combination

The subjects were further classified based on frequency of the tinnitus

- 63%, indicated perceiving tinnitus between 2000 and 7000 Hz.
- 21% had low-tone tinnitus below 2000 Hz
- 16% above 7000 Hz
In post-synaptic neural activity, an excitatory and inhibitory imbalance due to damaged inner hair cells leads to:

- Reduction in the inhibitory capacity of neurons that are deprived of input
- Neural hyperactivity (increased spontaneous activity) also occurs
- This leads to increased neural synchrony
- This can also cause changes in the tonotopic map – i.e. spatial arrangement of where sounds of different frequency are processed in the brain
Neurophysiological model of tinnitus

• Tonal Tinnitus, with hearing loss, is thought to be caused by the maladaptive (undesirable) reorganization of neurons in the brain

• Reorganization is possible because the neurons in the brain have the ability to change or adapt (neural plasticity)
Neurophysiological model of tinnitus
Dr. Jastreboff

Why do individuals have different reactions to tinnitus?
Different areas of the brain have different roles

The limbic system is responsible for motivation, mood and emotion

Tinnitus-related complaints such as insomnia, anxiety, depression, fear are indicative of the association of the limbic system

Dalgleish, 2004; Jastreboff, 1990
Neurophysiological model of tinnitus
Dr. Jastreboff

Disabling: 5% of patients
Intervention is essential

15% of patients
Candidate for intervention
Neurophysiological model of Tinnitus

Objective Quantification of the Tinnitus Decompensation by Synchronization Measures of Auditory Evoked Single Sweeps

Daniel J. Strauss, Member, IEEE, Wolfgang Delb, Roberto D'Amelio, Yin Fen Low, and Peter Falkai

N=29 patients
Separated into 2 groups
  18-Degree 1 tinnitus (compensated group)
  11-Degree 3 and 4 tinnitus (decompensated group)

• Objective quantification of the tinnitus decompensation using the synchronization stability of ALR sequences. Introduction of the \textit{l-hab} factor (long-term habituation factor).

• This synchronization stability was significantly different in a group of compensated and decompensated tinnitus patients.

• It is concluded that the synchronization stability of ALR sequences might be used in the objective quantification of the tinnitus decompensation.
Okamoto 2010 discussed neurophysiological studies showing tinnitus may be caused by maladaptive reorganization of the auditory cortex

- Magnetoencephalography (MEG) studies showed auditory cortical map regions corresponding to tinnitus frequency were distorted
- + correlation between amount of distortion and perceived tinnitus strength
- Enhanced aud cortex activity corresponding to the tinnitus frequency
- Related to tinnitus intrusiveness

---

**Magnetoencephalography** (MEG) is a functional neuroimaging technique for mapping brain activity by recording magnetic fields produced by electrical currents occurring naturally in the brain, using very sensitive magnetometers.

**Magnetoencephalography - Wikipedia**
https://en.wikipedia.org/wiki/Magnetoencephalography
• 10 normal hearing subjects listen to music with a spectral notch at 1kHz, for ~3h/day for 3 days
  • In effect, a *functional* deafferentation
  • The spectral notch abolished afferent input to cortical neurons tuned to 1kHz region

• MEG recordings showed a significant decrease in evoked activity for a test stimulus centered on the notch and non-significant decrease for a control stimulus

• All neurons have the capacity to excite or inhibit and a balance between these two is important for the proper perception of sound, as well as other senses

• It’s possible to counteract this spontaneous and excessive neural firing (excitation) and reduce the perception of tinnitus by creating the opposite/inhibitory response
Tailor-made notched music treatment as an approach to tinnitus intervention

We can decreased brain activity in a notched region; possibly through lateral inhibition

Auditory system demonstrates plasticity

Could spectrally notched music reduce aberrant brain activity related to tinnitus?

And reduce subjectively reported tinnitus loudness?
Clinical study sites & publications for TMNMT

University Hospital Munster, Germany
8 clinical studies, each with 9-100 subjects, resulting in 11 papers published in

- Proceedings of the National Academy of Sciences, 2010
- Communicative and Integrative Biology, 2010
- Music Perception, 2010
- PloS ONE, 2011
- Frontiers in Systems Neuroscience, 2012
- PloS One, 2014
- Neural Plasticity, 2014

University Clinic Parma, Italy
1 clinical study, 43 patients, resulting in 1 paper published in

- Clinical Neurophysiology, 2015
- PloS One, 2015
- PloS One, 2015
- BMC Neurology
- International Tinnitus Journal, 2009
Listening to tailor-made notched music reduces tinnitus loudness and tinnitus-related auditory cortex activity

Hidehiko Okamoto a,1, Henning Stracke a,1, Wolfgang Stoll a,2, and Christo Pantev a,3

aInstitute for Biomagnetism and Biosignalanalysis, Westfalian Wilhelms-University, Maldenweg 15, Muenster, Germany; and bDepartment of Otohinolaryngology, Head and Neck Surgery, Muenster University Hospital, Kardinal-von-Galen-Ring 10, 48149 Muenster, Germany

Edited by Michael M. Merzenich, University of California at San Francisco, San Francisco, CA, and approved December 3, 2009 (received for review September 30, 2009)
Objective outcomes

After 12 months of regular listening, the target patient group exhibited reduced evoked activity in auditory cortex areas corresponding to the tinnitus frequency.
Subjective outcomes

After 12 months of regular listening, the target patient group showed significantly reduced subjective tinnitus loudness.

Fig. 3. Normalized tinnitus loudness change after 6 and 12 months of treatment (or monitoring) relative to baseline (0) for the three patient groups (target, placebo, and monitoring). Positive change values reflect improvement, negative change values reflect impairment. The bars indicate group averages, each x indicates an individual data point. The error bars denote confidence intervals. The data were normalized as following: [(tinnitus loudness_Average months 1–6 or months 7–12/tinnitus loudness baseline – 1) × 100]. As indicated by the confidence interval bars, only the changes in the target group were statistically significant.
Notch therapy is designed to induce neural plasticity-based changes in the auditory system (auditory cortex) with the purpose of reducing the perceived loudness of tinnitus.

The goal is to lessen neural hyperactivity by strengthening the weakened inhibitory networks in the frequency band for an individual’s tinnitus.
Signia Notch Therapy

- Signia Notch Therapy is designed to target those neurons in the brain that are contributing to the tinnitus, specifically tonal tinnitus, and create a counteractive inhibitory response.
- When this balance is restored, the perception of tinnitus decreases.
- It’s possible to create this counteractive response through lateral inhibition.
- With Signia Notch Therapy, a .5 octave notched filter is applied to the amplified signal centered at the frequency of the perceived tinnitus.
The notch is placed at the center frequency of the tinnitus in an area of audibility.

This causes the brain to send lateral inhibitory responses because there is no stimulus there.

Over time, the brain is trained to provide more lateral inhibition which will decrease the perception of tinnitus.
“We have shown that this approach indeed improves the therapeutic result in a 3 weeks pre-/post therapy analysis using subjective and objective means.”
Clinical study

Six-month Evaluation of a Hearing Aid Supported Tinnitus Treatment using Notched Environmental Sounds

Haab et al., in Submission

Purpose –
The purpose of the study was to examine the long-term performance of a hearing-aid assisted tinnitus intervention

Subjects –
• 34 subjects (10 female; 24 male); mean age 56 years
• All reported subjective, chronic, tonal tinnitus
• Mild-to-moderate hearing loss
• Tinnitus frequency identified using a “standard” frequency-matching procedure
• Subjects randomly placed in one of two groups
• Group 1 – fit with commercially available, digital BTEs
• Group 2 – fit with the same instruments, but spectrally notched at their tinnitus frequency (bandwidth = .5 octave)
Clinical study

Objective evaluation –
• EEG in conjunction with the collection of auditory late responses (ALR) were obtained at the beginning of the study, after 3 months and after 6 months. Stimuli were presented using pure tone bursts set to the subject’s MCL

Objective assessment –
• Neural long-term habituation (l-hab) in ALR responses have been used to quantify tinnitus distress
• It is believed that individuals who cannot habituate to their tinnitus have a habituation deficit or the loss of automatic to consecutively presented uniform sounds at a comfortable loudness level
• This loss is shown as a decline of the (instantaneous) wavelet phase stability (WPS) in the ALR sequence

Subjective evaluation –
• Subjects completed the TQ52 at the beginning of the study, after 3 months and after 6 months
Clinical study objective results

- Mean objective habituation marker development for 3- and 6-months post therapy.
- Bars indicate the average habituation factor as measured with EEG.
- Data on the y-axis is expressed as long-term habituation gain, with 0.0 representing no habituation ability and 4.0 indicating the ability to habituate to the presented tone.
- Group 1 (control with traditional amplification) is represented by the grey bars and Group 2 (Notch Therapy), is represented by the black bars.
Clinical study subjective results

Group 1 –
• Group data was analyzed and results indicated an improvement for Group 1 in the first three months of TQ52 score improvement of 3.75 score points
• At 6 months, the net improvement for Group 1 was 3.8 points

Group 2 -
• Group 2 showed a stronger improvement at 3 months and was able to maintain a significantly reduced tinnitus distress level during the entire duration of the study for a net improvement in the TQ52 score of 12.65.
• The subjects in Group 2 (notch therapy) showed overall larger and persistent therapeutic effects in terms of the TQ52 score
Tinnitus Notch Therapy
Patented and clinically proven

- Candidates for Notch Therapy
  - Tonal Tinnitus- pure-tone, whistling, ringing or humming sound
  - Any type and degree of hearing loss

- Tinnitus pitch assessment via Connexx 8.2
  - Easy step-by-step process
  - No additional tools required
Signia Tinnitus therapies
Notch Therapy - Guided Matching

Guided Matching:
Play tone A and B and select the most similar to the tinnitus.

Step 1:
- Tone A (75/70 dB HL, 4000 Hz): [Select]
- Tone B (68/63 dB HL, 5333 Hz): [Select]

Selected tinnitus frequency: [Blank]
Frequency Check:
The tinnitus frequency will be validated with the Frequency Check.

[Activate Notch]
[1 Universal]
Signia Notch Therapy
Activate Notch

Guided Matching  Manual Matching  Direct Entry

Play tone A and B and select the most similar to the tinnitus.

Step 1
Tone A (75 / 70 dB HL, 4000 Hz):  Select
Tone B (68 / 63 dB HL, 5333 Hz):  Keep button pressed to play tone A

Restart
Signia Tinnitus therapies
Notch Therapy - Frequency Check

**Frequency Check**

The tinnitus frequency will be validated with the Frequency Check.

- **Step 1**
  - Tone A (75 / 70 dB HL, 4000 Hz) [Select]
  - Tone B (58 / 63 dB HL, 5333 Hz) [Select]

- **Activate Notch**
  - [ ] 1 Universal
Signia Notch Therapy
Activate Notch

Completed
Frequency 4000 Hz has been taken over as tonal tinnitus.

Selected tonal tinnitus frequency: 4000 Hz

Frequency Check
Which tone sounds most similar to your perceived tinnitus?

- Tone A (65/70 dB HL, 2000 Hz):
  - Select

- Tone B (75/70 dB HL, 4000 Hz):
  - Select

- Tone C (70/65 dB HL, 8000 Hz):
  - Select

Activate Notch

Universal
- Recorded Music
- Outdoor Sports
- Tinnitus Sound T...

Restart
Signia Tinnitus therapies
Notch Therapy - Activate Notch

Activate Notch
1. Universal
2. Recorded Music
3. Outdoor Spots
4. Tinnitus Sound Therapy
Activate Notch

1. Universal
2. Reverberant Room...
3. Tinnitus Signal
Signia Notch Therapy
Activate Notch
• We recommend that the notch be placed in all programs.

• The width of the notch is only 0.5 octave and therefore should not interfere with normal conversation.

• However, the option of choosing to active specific programs “notch free” is provided for flexible, individualized therapy.

• The data suggests that longer wearing times are better than shorter; especially if the prescribed gain is mild and therefore, the notch depth is shallower.
New with Nx platform
CROS/BiCROS compatible

• Notch therapy may be applied in a CROS or BiCROS fitting.
New with Nx platform

A notch may be applied to a sound therapy signal, either ocean wave or static signal
Case Studies

Patient presented tonal tinnitus
- Pitch matched in software to 4K Hz
- Results at 6 m FU: significantly reduced tinnitus “less intrusive and easier to ignore”
**Description:** Pt. complains of constant bilateral tinnitus that interferes with speech understanding. Tinnitus described as gradual in onset, constant in nature, and tonal (teakettle “weeeeee”) in manner.

**Audiogram:** Normal 250 – 2K sloping to mild SNHL 3K – 8K, Au.

**Pitch match:** 4K Hz

**Outcome:** Pt. reports improved speech understanding and decreased awareness of tinnitus, which was initially indicated on the TCHQ as having an awareness of more than 50% of awake hours.
Case Studies

**Description:** Pt. complains of constant, high-pitched bilateral tinnitus following chemotherapy treatments and the use of fluorouracil to treat colon cancer.

**Audiogram:** normal 250 – 2K dropping to moderate SNHL through 8K, Au.

**Pitch match:** 4K Hz

**Outcome:** Pt. reported subtle decrease over 45-day adjustment period with notch therapy and required a sound generator applied to the Universal program to achieve “quiet”.
Case Studies

Description: Pt. complains of tinnitus with fluctuating severity. Reports it was triggered by ear cleaning (flushing) for cerumen impaction.

Audiogram: normal 250 – 2K, dropping to mild SNHL through 8K, Au.

Pitch match:
- Initial match 6 kHz (patient matched on his own with online assessment 12 kHz).
- At follow-up, patient reported tinnitus pitch changed but, loudness is reduced.
- New pitch report from patient 8K Hz; pitch matched by HCP at 4 kHz.
- Replaced notch at 4 kHz and discussed octave confusion as well as possible reasons for change of pitch.
- Added program with a notched ocean wave tinnitus therapy signal for patient to try.
**Patient history:** Hearing loss, aural fullness, and constant, high-pitched, tinnitus; reported that her tinnitus is worse at night. She describes it as a ringing. Patient has a strong history of occupational noise exposure (factory).

**Pitch match:** 8000 Hz; Notch applied.

**Outcome:** THI pre-therapy score 64 on 12/22/17

THI post-therapy score 24 on 1/19/17
Case Studies
Tinnitus Handicap Inventory

Tinnitus Handicap Inventory (THI)

Instructions: The purpose of this questionnaire is to identify how much the patient is affected by tinnitus. Please answer all the questions, add up your total score, and discuss your results with your doctor.

Name: ____________________________  Date: ____________________________

Instructions: The purpose of this questionnaire is to identify how much the patient is affected by tinnitus. Please answer all the questions, add up your total score, and discuss your results with your doctor.

1. Because of your tinnitus, is it difficult for you to concentrate? ________
2. Does the loudness of your tinnitus make it difficult for you to hear people? ________
3. Does your tinnitus make you irritable? ________
4. Does your tinnitus make you feel embarrassed? ________
5. Because of your tinnitus, do you feel depressed? ________
6. Does your tinnitus make you feel anxious? ________
7. Because of your tinnitus, do you feel tired? ________
8. Are you able to accept the situation you're in? ________
9. Can you sleep through the night? ________
10. Can you hear the sounds around you? ________
11. Do you feel that your tinnitus makes you feel tired? ________
12. Do you feel that your tinnitus makes you feel irritable? ________
13. Do you feel that your tinnitus makes you feel depressed? ________
14. Do you feel that your tinnitus makes you feel anxious? ________
15. Do you feel that your tinnitus makes you feel angry? ________
16. Do you feel that your tinnitus makes you feel sad? ________
17. Do you feel that your tinnitus makes you feel worried? ________
18. Do you feel that your tinnitus makes you feel frustrated? ________
19. Do you feel that your tinnitus makes you feel lonely? ________
20. Do you feel that your tinnitus makes you feel isolated? ________
21. Do you feel that your tinnitus makes you feel depressed? ________
22. Do you feel that your tinnitus makes you feel anxious? ________
23. Do you feel that your tinnitus makes you feel angry? ________
24. Do you feel that your tinnitus makes you feel sad? ________
25. Do you feel that your tinnitus makes you feel worried? ________
26. Do you feel that your tinnitus makes you feel frustrated? ________
27. Do you feel that your tinnitus makes you feel lonely? ________
28. Do you feel that your tinnitus makes you feel isolated? ________
29. Do you feel that your tinnitus makes you feel depressed? ________
30. Do you feel that your tinnitus makes you feel anxious? ________
31. Do you feel that your tinnitus makes you feel angry? ________
32. Do you feel that your tinnitus makes you feel sad? ________
33. Do you feel that your tinnitus makes you feel worried? ________
34. Do you feel that your tinnitus makes you feel frustrated? ________
35. Do you feel that your tinnitus makes you feel lonely? ________
36. Do you feel that your tinnitus makes you feel isolated? ________
37. Do you feel that your tinnitus makes you feel depressed? ________
38. Do you feel that your tinnitus makes you feel anxious? ________
39. Do you feel that your tinnitus makes you feel angry? ________
40. Do you feel that your tinnitus makes you feel sad? ________
41. Do you feel that your tinnitus makes you feel worried? ________
42. Do you feel that your tinnitus makes you feel frustrated? ________
43. Do you feel that your tinnitus makes you feel lonely? ________
44. Do you feel that your tinnitus makes you feel isolated? ________
45. Do you feel that your tinnitus makes you feel depressed? ________
46. Do you feel that your tinnitus makes you feel anxious? ________
47. Do you feel that your tinnitus makes you feel angry? ________
48. Do you feel that your tinnitus makes you feel sad? ________
49. Do you feel that your tinnitus makes you feel worried? ________
50. Do you feel that your tinnitus makes you feel frustrated? ________
51. Do you feel that your tinnitus makes you feel lonely? ________
52. Do you feel that your tinnitus makes you feel isolated? ________
53. Do you feel that your tinnitus makes you feel depressed? ________
54. Do you feel that your tinnitus makes you feel anxious? ________
55. Do you feel that your tinnitus makes you feel angry? ________
56. Do you feel that your tinnitus makes you feel sad? ________
57. Do you feel that your tinnitus makes you feel worried? ________
58. Do you feel that your tinnitus makes you feel frustrated? ________
59. Do you feel that your tinnitus makes you feel lonely? ________
60. Do you feel that your tinnitus makes you feel isolated? ________

Total THI Score: ________ (out of 100)

For clinician use only

This questionnaire is reproduced with the kind permission of Dr. Reymers, PhD.

Reference:


(C) Siemens AG, 1993. All rights reserved.

Siemens, Inc. is a trademark of Siemens AG.
Patient history: constant, high-pitched, tinnitus, onset 3 years, worse for the left ear; reported his tinnitus is really affecting his quality of life; history of occupational noise exposure (factory).

Pitch match: 2667 Hz

Outcome: THI pre-therapy score 78 on 8/28/17
THI post-therapy score 26 on 10/23/17
Tinnitus Handicap Inventory (THI)

**Name:**

**Date:**

**Instructions:** The purpose of this questionnaire is to identify, quantify, and evaluate the difficulties that you may be experiencing because of tinnitus. Please do not skip any questions. When you have answered all the questions, total up your total score, based on the values for each response.

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>Sometimes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Because of your tinnitus, is it difficult for you to concentrate?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the loudness of your tinnitus make it difficult for you to hear people?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does your tinnitus make you anxious?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does your tinnitus make you feel embarrassed?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Because of your tinnitus, do you feel depressed?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you often think about your tinnitus?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Because of your tinnitus, do you feel angry?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Because of your tinnitus, do you feel that you have a terrible disease?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does your tinnitus make it difficult for you to enjoy life?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does your tinnitus interfere with your job or household responsibilities?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does your tinnitus make you feel isolated?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does your tinnitus make you feel tired?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you feel that your tinnitus has placed stress on your relationship with members of your family and friends?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you find it difficult to keep your attention away from your tinnitus and its associated symptoms?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you feel that you have no control over your tinnitus?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Because of your tinnitus, do you often feel tired?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Because of your tinnitus, do you feel depressed?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does your tinnitus make you feel anxious?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total THI Score:**

**Interpretation:**

0-50: No handicap

51-60: Mild handicap (Grade 1)

61-80: Moderate handicap (Grade 2)

81-100: Severe handicap (Grade 3)

101-120: Catastrophic handicap (Grade 4)

---

**For Clinician Use Only**

**Decremental Presence of Perceived Tinnitus handicap based on total THI score:**

- **Score:**
  - 0-50: No handicap
  - 51-60: Mild handicap (Grade 1)
  - 61-80: Moderate handicap (Grade 2)
  - 81-100: Severe handicap (Grade 3)
  - 101-120: Catastrophic handicap (Grade 4)

**References:**


---

**Copyright © 2014 Signia, Inc. All rights reserved.**

Signia, Inc. is a trademark licensed by the Asahi Kasei Semiconductor Inc.
Signia Notch Therapy: A Novel Approach Clinically Proven to Reduce the Perception of Tonal Tinnitus

Whitepaper
Gisele Munhoes dos Santos, PhD
Leanne Powers, AuD

How to Use primax Tinnitus Therapy Options

Whitepaper
Vera Wolf, Dipl.-Ing.
Demo of pitch matching procedure
Thank you!