

JUN - 7 2001

K 011364

510(K) Summary for the Siemens Custom TCI

1. **Applicant's Name & Address:** Siemens Hearing Instruments
10 Constitution Ave.
PO Box 1397
Piscataway, NJ 08855

2. **Contact Person, Telephone and e-mail Address:** Dave Slavin
732-562-6658
dslavin@siemens-hearing.com

3. **Device Trade or Proprietary Name:** Custom TCI (Tinnitus Control Instrument)

4. **Device Common Name / Classification Name:** **Tinnitus Masker**

Product Code: **KLW**

5. **Establishment Registration Number:** 2217809

6. **Address of Manufacturing Site:** Siemens Hearing Instruments
10 Constitution Ave.
PO Box 1397
Piscataway, NJ 08855

7. **Classification of Device:** Class II

8. **Marketed Devices to which the claim of substantial equivalence is made:** K974751
General Hearing Instruments
Tranquil Tri-OE

9. **Compliance with Section 514, Performance Standards:** Not Applicable

10. **Indications for Use:**

The TCI is a custom in-the-ear style electronic, air conduction broad-band noise generator intended to output noise of sufficient intensity and bandwidth to be used for tinnitus habituation therapy and is also suitable for tinnitus masking therapy. Custom TCI is intended to be used by those individuals who experience tinnitus, and do not need or desire amplification. This device is fit by a qualified audiologist or other hearing healthcare professional familiar with the diagnosis of tinnitus and subsequent rehabilitation therapy.

The target population is primarily the adult population over 18 years of age. The target group for this product includes individuals reporting tinnitus who do not desire or need amplification. This product may also be used with children 5 years of age or older.

11. **Description of Device:**

Custom TCI is a fully digital, low-level noise generator that was developed to be used along with appropriate counseling and/or tinnitus therapy. This product is available in a full in-the-ear, half shell, in-the-canal, or helix shell. It is programmable, with selectable noise and output levels. The output noise can be custom-tailored to the user's individual requirements.

12. **Comparison Information to Predicate Device:**

The Custom TCI is substantially equivalent to the General Hearing Instruments Tranquil Tri-OE (K974751). The Tranquil is also a noiser for tinnitus, with no amplification characteristics. The Siemens Custom TCI differs from the Tranquil, in that the Custom TCI is a digital product and is fully programmable, which increases the flexibility of the device.

The following table compares the Siemens Hearing Instruments Custom TCI device and General Hearing Instruments Tranquil Tri-OE.

	Siemens Hearing Instrument Custom TCI Device	General Hearing Instruments Tranquil Tri-OE
Intended Use	Mask tinnitus as part of tinnitus management	Mask tinnitus as part of tinnitus management

	program	program
Target Population	Adults and children (≥ 5 years) with tinnitus that are participating in a tinnitus management program	Adults with tinnitus that are participating in a tinnitus management program
Operation Circuit type Programmable Available noises Volume control	Digital Yes Four Yes	Analog No One Yes
Physical Description	Custom product, available as helix, in-the-ear, half shell, and in-the-canal	Custom product, available as in-the-ear and mini-canal
RMS Output Characteristics White noise Pink noise Speech noise High-tone noise	86 dB SPL 75 dB SPL 71 dB SPL 81 dB SPL	75 dB SPL
Volume control range	Programmable: OFF, 8 dB, 16 dB, 32 dB	40 dB

Custom TCI Comparison with Predicate Device

13. Information required under Title 21, Section 874.3400, and not already provided above.

Risks

The maximum output for Custom TCI is 86 dB measured with an A-weighted filter. As the noise may be on continuously and as the noise level does fall into the range which can cause hearing loss (OSHA Regulations (Standard – 29 CFR 1910.95 Occupational Noise Exposure)), warnings are included in the Technical Information for the Hearing Health Professional and in the User’s Manual for the consumer.

Hearing Healthcare Professional Diagnosis:

The sale and fitting of the Siemens Custom TCI will only be conducted through a Hearing Healthcare Professional, such as an audiologist or otolaryngologist.

Benefits:

Relief of tinnitus symptoms may be provided by this device when utilized with appropriate counseling and/or tinnitus therapy.

Warnings for Safe Use

As the noise may be on continuously and as the noise level does fall into the range which can cause hearing loss (OSHA Regulations (Standard – 29 CFR 1910.95 Occupational Noise Exposure)), warnings are included in the Technical Information for the Hearing Health Professional and in the User's Manual for the consumer.



JUN - 7 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Siemens Hearing Instruments
c/o Dave Slavin
10 Constitution Avenue
P.O. Box 1397
Piscataway, NJ 08855-1397

Re: K011364
Trade Name: Custom TCI
Regulation Number: 874.3400
Regulatory Class: II
Product Code: 77 KLW
Dated: May 14, 2001
Received: May 15, 2001

Dear Mr. Slavin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - c/o Dave Slavin

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(K) NUMBER (IF KNOWN): **K011364**

DEVICE NAME: **CUSTOM TCI**

INDICATIONS FOR USE:

Tinnitus is a noise (buzzing, ringing, or roaring) perceived by an individual where there is no external acoustic stimulus (Mueller and Hall, 1998). The device is intended for use by people who experience tinnitus as a part of a tinnitus management program. Patients should receive medical evaluations to rule out medically or surgically treatable diseases for which tinnitus is a symptom before proceeding with non-medical tinnitus management. Tinnitus management programs include a complete audiologic assessment, tinnitus evaluation, directive counseling, and extended use of a low-level noise generator to facilitate habituation of the tinnitus. While not specifically endorsed by Siemens Hearing Instruments, the TRT (Tinnitus Retraining Therapy) method is one example of a tinnitus management program (Jasterboff, 1993).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Karen Boden
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K011364



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2001

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c/o Dave Slavin
10 Constitution Avenue
P.O. Box 1397
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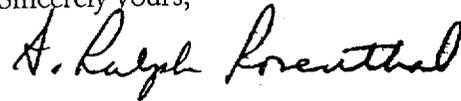
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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Sincerely yours,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
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510(K) NUMBER (IF KNOWN): **K011364**

DEVICE NAME: **CUSTOM TCI**

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use *js*
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____
(Optional Format 1-2-96)

Karen Bohm

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K011364

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Karen Baker

Subject: 510(k) Number K011364

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
 - Requires additional information (other than refuse to accept).
 - Is substantially equivalent to marketed devices.
 - NOT substantially equivalent to marketed devices.
- De Novo Classification Candidate? YES NO

- Other (e.g., exempt by regulation, not a device, duplicate, etc.) YES NO
- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

This 510(k) contains:

- Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices N/A
- The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class:

Additional Product Code(s) with panel (optional):

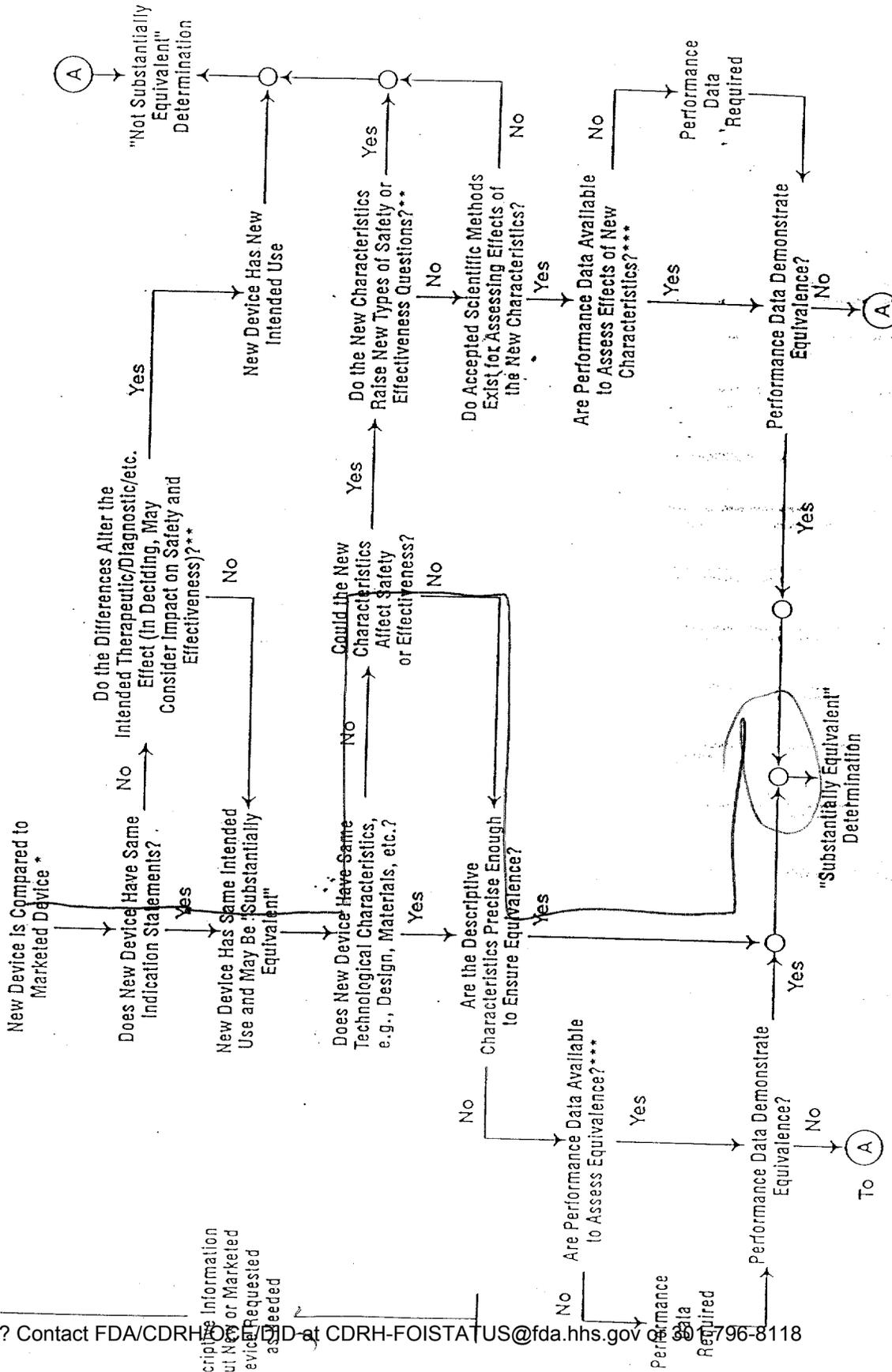
874.3400 77KLW

Review: [Signature] 573101
(Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 6/4/01
(Division Director) (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



Questions? Contact FDA/CDRH HQ or CDRH-FOI STATUS@fda.hhs.gov or 1-800-796-8118

* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information to Clarify the Relationship Between Marketed and "Predicate" (Pre-Amendments or Classifications Post-Amendments) Devices Is Unclear.
 ** This Decision is Based on Descriptive Information Alone, But Limited Testing Information Is Sometimes Required.
 *** Data May Be in 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

Document # K011364

Company Name: Siemens Hearing Instruments
10 Constitution Ave.
Piscataway, New Jersey 08855

Contact Person: Dave Slavin
Director of Quality Assurance and Regulatory Affairs

Device Name: Custom TCI (Tinnitus Control Masker)

CLASSIFICATION NAME: Tinnitus Masker

COMMON NAME: Tinnitus Masker

PRODUCT TO WHICH COMPARED: (510(k) NUMBER IF KNOWN)

K974751 General Hearing Instruments Tranquil Tri-OE

INTENDED USE STATEMENT: Tinnitus is a noise (buzzing, ringing, or roaring) perceived by an individual where there is no external acoustic stimulus (Mueller and Hall, 1998). The device is intended for use by people who experience tinnitus as a part of a tinnitus management program. Patients should receive medical evaluations to rule out medically or surgically treatable diseases for which tinnitus is a symptom before proceeding with non- medical tinnitus management. Tinnitus management programs include a complete audiological assessment, tinnitus evaluation, directive counseling, and extended use of a low-level noise generator to facilitate habituation of the tinnitus. While not specifically endorsed by Siemens Hearing Instruments, the TRT (Tinnitus Retraining Therapy) method is one example of a tinnitus management program (Jasterboff, 1993).

Submission Provides:

Comparative Specifications:	yes
Comparative Lab Data:	no
Summary of Animal Testing:	no
Summary of Clinical Testing:	no
510(K) Summary:	yes

GENERAL INFORMATION SUMMARY

Life-Supporting or Life-Sustaining:	no
Is it an Implant?	no
Software Driven: (programmable)	yes
Sterility: (sterilized by user)	no
Single Use:	no
Home or prescription use:	yes
Drug or Biologic product:	no
Device a kit:	no

b

	YES	NO
1. IS PRODUCT A DEVICE?	x	- IF NO STOP
2. DEVICE SUBJECT TO 510(k)?	x	- IF NO STOP
3. SAME INDICATION STATEMENT?	x	- IF YES GO TO 5
4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?		- IF YES STOP, NE
5. SAME TECHNOLOGICAL CHARACTERISTICS?		x - IF YES GO TO 7
6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?		x - IF YES GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?		- IF NO GO TO 10 - IF YES STOP
8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?		x - IF YES STOP, NE
9. ACCEPTED SCIENTIFIC METHODS EXIST?		- IF NO STOP, NE - IF NO, REQUEST DATA
10. PERFORMANCE DATA AVAILABLE?		
11. DATA DEMONSTRATE EQUIVALENCE?	x	

Questions numbers 5 and 6 are answered as no as the subject device is technologically different. The device is digital, programmable and is indicated for adults and children of at least 5 years. In addition the RMS Output characteristics are different. The device has a While Noise output of 86 dB, Pink Noise output of 75 dB, Speech Noise of 71 dB, and High-tone output of 81 dB. The predicate device has only a Speech Noise output of 75 dB. In addition, the volume control range of the predicate tinnitus masker is 40dB and the subject volume control range is Off, 8, 16, or 32 dB.

A. Device Description:

The Custom TCI is a fully digital, low-level noise generator that was developed to be used along with appropriate counseling and/or tinnitus therapy. The device is available in a full in-the-ear, half shell, in-the-canal, or helix shell. It is programmable with selectable noise and output levels.

The output noise can be custom-tailored to the user's individual requirements. The maximum output for the device is 86 dB measured with an A-weighted filter. As the noise may be on continuously and as the noise level does fall into the range which can cause hearing loss (OSHA Regulations (Standard- 29 CFR 1910/95 Occupational Noise Exposure)), warnings are included in the Technical Information for the Hearing Health Professional and in the User's Manual for the consumer.

B. Device Materials and Toxicity

The materials of construction are equivalent to other hearing devices currently marketed.

C. Comparative Specifications

Comparisons are made between the subject and each of the cited predicate devices. These comparisons include intended use, target population, operation, physical description, RMS Output Characteristics and volume control range.

D. Physical Properties and Performance Testing

The physical properties are described in terms of output characteristics and method of operation. No performance testing is provided

E. Clinical Testing

No clinical testing is provided.

F. Sterilization

N/A

G. Device Labeling

Sample labeling is provided. Included in the labeling is a warning statement that the maximum output for Custom TCI is 86 dB measured with an A-weighted filter. As the noise may be on continuously and as the noise level does fall into the range which can cause hearing loss (OSHA Regulations (Standard- 29 CFR 1910/95 Occupational Noise Exposure)), warnings are included in the Technical Information for the Hearing Health Professional and in the User's Manual for the consumer.

H. 510(k) Summary or Statement

A 510(k) Summary is provided.

SUMMARY: The Siemens' Custom TCI is a tinnitus masking device that is intended to be used in conjunction with a tinnitus retraining system. It is used by patients who have normal to near normal hearing. The output characteristics are high enough to potentially cause hearing damage if improperly used. A warning is included in the professional literature as well as in the patient's literature.

This reviewer asked Teri Cygnarowicz to comment on the technical characteristics and indications for use. Ms. Cygnarowicz stated that the indications for use and the technical specifications are consistent with other tinnitus masking devices that have been cleared. Dr. Kane, DOED audiologist agreed with Ms. Cygnarowicz.

Based on the above, this review has no questions regarding the safety or effectiveness of the subject device.

8

RECOMMENDATION:

The Seimen's Custom TCI is substantially equivalent to the cited predicate tinnitus masker.

CFR# 874.3400
Product Code 77-KLW
CLASS II



Karen H. Baker, MSN, RN
Nurse Consultant/ENTB

Baker, Karen

From: Cygnarowicz, Teresa
Sent: Thursday, May 24, 2001 10:16 AM
To: Baker, Karen
Cc: Cygnarowicz, Teresa
Subject: K011364 and K011366

I have carefully read through the above referenced 510(k)'s, with particular attention to the labeling including the technical specifications. In addition, I showed the documents to Jim Kane, who had recently reviewed submissions from Siemens for similar products (tinnitus maskers). Dr. Kane indicated that the indications for use and the technical specifications, including the "Maximum Allowable Instrument Use" graph were consistent with information he has previously reviewed/cleared for the predicate device.

I have no questions for the sponsor. It is recommended that the devices be substantially equivalent.

Teri Cygnarowicz, M.A., CCC-A
Clinical Audiologist
ENTB/DOED/ODE/CDRH
(301)594-2080 ext. 185
(301) 480- 4201 (fax)

Screening Checklist

For all Premarket Notification 510(k) Submissions

3-30-01

Device Name: <i>Custom TCI</i>	<i>KD11364</i>				
Submitter (Company): <i>Seiners Hearing Instruments</i>					
Items which should be included (circle missing & needed information)	SPECIAL	ABBREVIATED	TRADITIONAL	✓ IF ITEM IS NEEDED AND IS MISSING	
	YES NO	YES NO	YES NO		
1. Cover Letter clearly identifies Submission as: a) "Special 510(k): Device Modification" b) "Abbreviated 510(k)" c) <u>Traditional 510(k)</u>		GO TO # 2,3	GO TO # 2,4,5	GO TO #2, 5	

2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS							✓ IF ITEM IS NEEDED
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i) including forms 3454 and/or 3455	NA		YES		NO		AND IS MISSING
	SPECIALS		ABBREVIATED		TRADITIONAL		
	YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, device class					✓		
b) OR a statement that the device is not yet classified	FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device	NA				✓		
d) compliance with Section 514 - performance standards	NA				✓		
e) address of manufacturer					✓		
f) Truthful and Accurate Statement					✓		
g) Indications for Use enclosure					✓		
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)					✓		
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)					✓		
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals					✓		
k) Proposed Labeling:					✓		
i) package labeling (user info)					✓		
ii) statement of intended use					✓		
iii) advertisements or promotional materials					✓		
i) MRI compatibility (if claimed)					✓		
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:					✓		
i) Labeling					✓		
ii) intended use					✓		
iii) physical characteristics					✓		
iv) anatomical sites of use					✓		
v) performance (bench, animal, clinical) testing	NA				✓		
vi) safety characteristics	NA				✓		
m) If kit, kit certification					✓		

3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE			
a) Name & 510(k) number of legally marketed (unmodified) predicate device			
b) STATEMENT - INTENDED USE AND INDICATIONS FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS			* If no - STOP not a special

LABELING HAVE NOT CHANGED*				
c)	STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*			* If no - STOP not a special
d)	Design Control Activities Summary			
i)	Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis			
ii)	Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied			
iii)	A declaration of conformity with design controls. The declaration of conformity should include:			
	1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met			
	2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.			

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING	
	YES	NO	YES	NO	YES	NO		
	4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE							
a)	For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b)	If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c)	For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i)	An identification of the applicable recognized consensus standards that were met							
ii)	A specification, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below							
iii)	An identification, for each consensus standard, of							

any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed			
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device			
v) A specification of any deviations from each applicable standard that were applied			
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference			
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations			
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards			

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							NA
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:							
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							✓
vi) radiation dose							✓
c) Software validation & verification:							
i) hazard analysis							✓
ii) level of concern							✓
iii) development documentation							✓
iv) certification							✓

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening Yes No
 Date: 5/21/01

Reviewer: Karen Baker
 Concurrence by Review Branch: J. Senola

13

K 011364/A'

SIEMENS

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Control Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

May 14, 2001

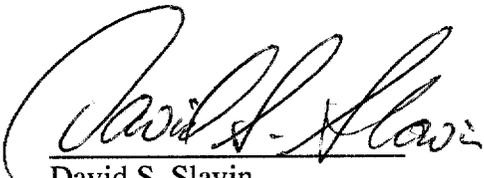
Attn: Document Mail Clerk

Re: 510(K) Submissions K011364 and K011366, Indications for Use Request

Enclosed please find the separate page "Indications for Use" as requested in your correspondence dated May 4, 2001 for the above referenced 510 (K)'s.

If there should be anything else that you need, please let me know.

RECEIVED
MAY 15 11 09 AM '01
FDA/CDRH/OCF/DIR



David S. Slavin
Director of Quality Assurance and Regulatory Affairs

5/14/01

Date

SK10 14

510(K) NUMBER (IF KNOWN): **K011364**

DEVICE NAME: **CUSTOM TCI**

INDICATIONS FOR USE:

Tinnitus is a noise (buzzing, ringing, or roaring) perceived by an individual where there is no external acoustic stimulus (Mueller and Hall, 1998). The device is intended for use by people who experience tinnitus as a part of a tinnitus management program. Patients should receive medical evaluations to rule out medically or surgically treatable diseases for which tinnitus is a symptom before proceeding with non-medical tinnitus management. Tinnitus management programs include a complete audiologic assessment, tinnitus evaluation, directive counseling, and extended use of a low-level noise generator to facilitate habituation of the tinnitus. While not specifically endorsed by Siemens Hearing Instruments, the TRT (Tinnitus Retraining Therapy) method is one example of a tinnitus management program (Jasterboff, 1993).

*Need to
define
amplification*

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FDA/CDRH/OCE/DMD

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____
(Optional Format 1-2-96)

15

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

May 04, 2001

SIEMENS HEARING INSTRUMENTS, INC. 510(k) Number: K011364
10 CONSTITUTION AVE. Received: 04-MAY-2001
P.O. BOX 1397 Product: CUSTOM TCI (TINNITUS
PISCATAWAY, NJ 08855 CONTROL INSTRUMENT)
ATTN: DAVE SLAVIN

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff

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SIEMENS

K011364

(510K) PREMARKET NOTIFICATION COVER LETTER

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Control Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

May 3, 2001

Attn: Document Mail Clerk

Re: 510(K) Submission - Siemens Hearing Instruments TCI Device (In-the-Ear Version)

Attached please find all required information pertaining to the 510(K) submission for the Siemens Hearing Instruments TCI Device.

Truthful and Accurate Statement:

I certify that, in my capacity as the Director of Quality Assurance and Regulatory Affairs of Siemens Hearing Instruments, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.



David S. Slavin
Director of Quality Assurance and Regulatory Affairs

May 3, 2001

Date

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EN
SK10 17

Siemens Hearing Instruments, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH.FDOSTB@FDA.HHS.GOV or 1-800-561-8118
10 Constitution Avenue P.O. Box 1357 Piscataway, New Jersey 08854-1357

Custom TCI Siemens Hearing Instruments, Inc.

Section Label	
	Table of Contents
1	Summary
2	Product Description
3	Technical Specifications
4	Risks
5	Labeling
6	Software Validation
7	Comparison to Predicate Device
	Appendices
8	A. Technical Specifications
9	B. User's Manual
10	C. Software Validation
11	D. Technical Information for Predicate Device
12	Bibliography

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510(K) Summary for the Siemens Custom TCI

1. **Applicant's Name & Address:** Siemens Hearing Instruments
10 Constitution Ave.
PO Box 1397
Piscataway, NJ 08855

2. **Contact Person, Telephone and e-mail Address:** Dave Slavin
732-562-6658
dslavin@siemens-hearing.com

3. **Device Trade or Proprietary Name:** Custom TCI (Tinnitus Control Instrument)

4. **Device Common Name / Classification Name:** **Tinnitus Masker**

Product Code: **KLW**

5. **Establishment Registration Number:** 2217809

6. **Address of Manufacturing Site:** Siemens Hearing Instruments
10 Constitution Ave.
PO Box 1397
Piscataway, NJ 08855

7. **Classification of Device:** Class II

8. **Marketed Devices to which the claim of substantial equivalence is made:** K974751
General Hearing Instruments
Tranquil Tri-OE

9. **Compliance with Section 514, Performance Standards:** Not Applicable

10. **Indications for Use:**

The TCI is a custom in-the-ear style electronic, air conduction broad-band noise generator intended to output noise of sufficient intensity and bandwidth to be used for tinnitus habituation therapy and is also suitable for tinnitus masking therapy. Custom TCI is intended to be used by those individuals who experience tinnitus, and do not need or desire amplification. This device is fit by a qualified audiologist or other hearing healthcare professional familiar with the diagnosis of tinnitus and subsequent rehabilitation therapy.

The target population is primarily the adult population over 18 years of age. The target group for this product includes individuals reporting tinnitus who do not desire or need amplification. This product may also be used with children 5 years of age or older.

11. **Description of Device:**

Custom TCI is a fully digital, low-level noise generator that was developed to be used along with appropriate counseling and/or tinnitus therapy. This product is available in a full in-the-ear, half shell, in-the-canal, or helix shell. It is programmable, with selectable noise and output levels. The output noise can be custom-tailored to the user's individual requirements.

12. **Comparison Information to Predicate Device:**

The Custom TCI is substantially equivalent to the General Hearing Instruments Tranquil Tri-OE (K974751). The Tranquil is also a noiser for tinnitus, with no amplification characteristics. The Siemens Custom TCI differs from the Tranquil, in that the Custom TCI is a digital product and is fully programmable, which increases the flexibility of the device.

The following table compares the Siemens Hearing Instruments Custom TCI device and General Hearing Instruments Tranquil Tri-OE.

	Siemens Hearing Instrument Custom TCI Device	General Hearing Instruments Tranquil Tri-OE
Intended Use	Mask tinnitus as part of tinnitus management	Mask tinnitus as part of tinnitus management

	program	program
Target Population	Adults and children (≥ 5 years) with tinnitus that are participating in a tinnitus management program	Adults with tinnitus that are participating in a tinnitus management program
Operation Circuit type Programmable Available noises Volume control	Digital Yes Four Yes	Analog No One Yes
Physical Description	Custom product, available as helix, in-the-ear, half shell, and in-the-canal	Custom product, available as in-the-ear and mini-canal
RMS Output Characteristics White noise Pink noise Speech noise High-tone noise	86 dB SPL 75 dB SPL 71 dB SPL 81 dB SPL	75 dB SPL
Volume control range	Programmable: OFF, 8 dB, 16 dB, 32 dB	40 dB

Custom TCI Comparison with Predicate Device

13. Information required under Title 21, Section 874.3400, and not already provided above.

Risks

The maximum output for Custom TCI is 86 dB measured with an A-weighted filter. As the noise may be on continuously and as the noise level does fall into the range which can cause hearing loss (OSHA Regulations (Standard – 29 CFR 1910.95 Occupational Noise Exposure)), warnings are included in the Technical Information for the Hearing Health Professional and in the User’s Manual for the consumer.

Hearing Healthcare Professional Diagnosis:

The sale and fitting of the Siemens Custom TCI will only be conducted through a Hearing Healthcare Professional, such as an audiologist or otolaryngologist.

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Benefits:

Relief of tinnitus symptoms may be provided by this device when utilized with appropriate counseling and/or tinnitus therapy.

Warnings for Safe Use

As the noise may be on continuously and as the noise level does fall into the range which can cause hearing loss (OSHA Regulations (Standard – 29 CFR 1910.95 Occupational Noise Exposure)), warnings are included in the Technical Information for the Hearing Health Professional and in the User's Manual for the consumer.

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Product Description

Indications for Use

Tinnitus is a noise (buzzing, ringing, or roaring) perceived by an individual where there is no external acoustic stimulus (Mueller and Hall, 1998). The device is intended for use by people who experience tinnitus as a part of a tinnitus management program. Patients should receive medical evaluations to rule out medically or surgically treatable diseases for which tinnitus is a symptom before proceeding with non-medical tinnitus management. Tinnitus management programs include a complete audiologic assessment, tinnitus evaluation, directive counseling, and extended use of a low-level noise generator to facilitate habituation of the tinnitus. While not specifically endorsed by Siemens Hearing Instruments, the TRT (Tinnitus Retraining Therapy) method is one example of a tinnitus management program (Jasterboff, 1993).

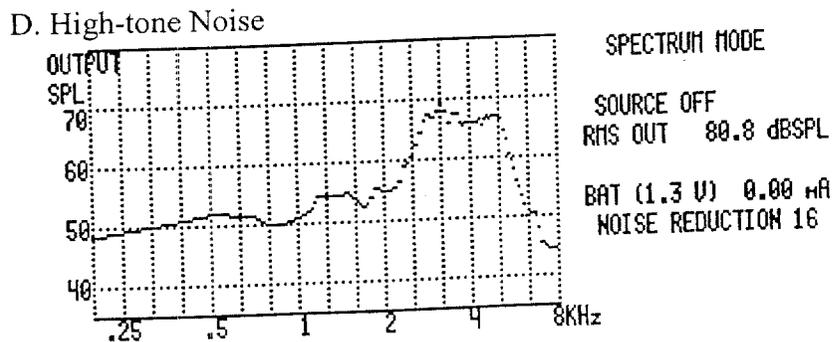
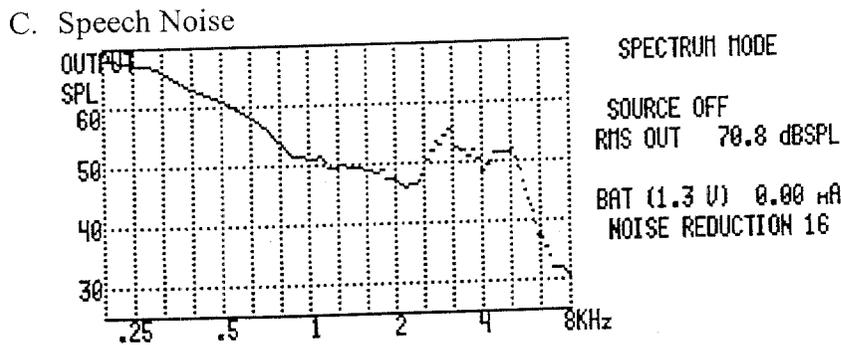
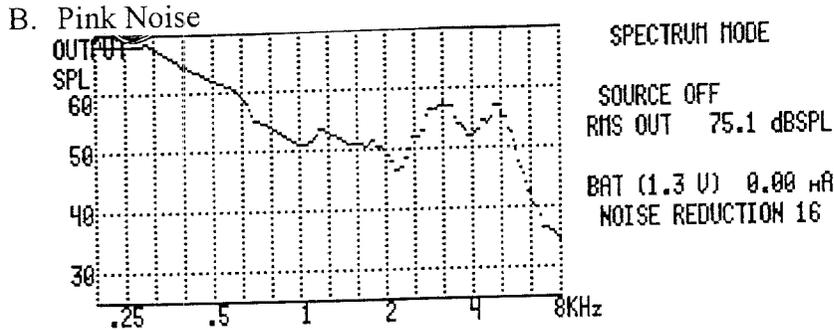
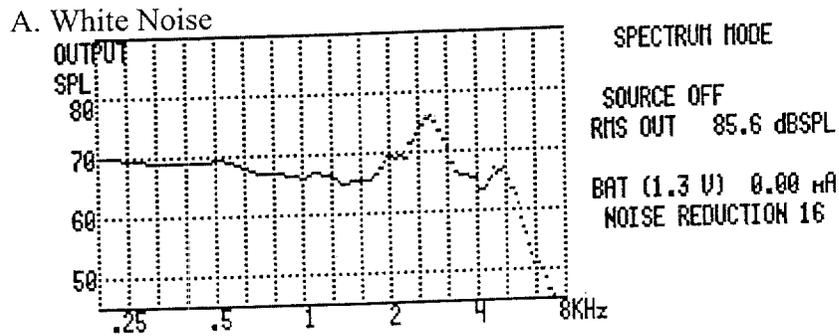
Target Population

The target population is primarily the adult population over 18 years of age. It has been estimated 17 percent of the adult population reports tinnitus, including 33 percent of the population over 60 reporting some degree of tinnitus (Bauman, 1998). The target group for this product includes individuals reporting tinnitus who do not desire or need amplification. This product may also be used with children 5 years of age or older. Tinnitus has been reported in children (Baguley and McFerran, 1999) with hearing loss. This group has been shown to respond to counseling/tinnitus therapy programs, similar to adult programs. While some Hearing Health Professionals recommend use of this type of device with children 5 years of age or older, the clinical efficacy of this device with children is based on subjective reports.

Principles of Operation

The device is a programmable digital tinnitus masker, allowing the programming of the noise characteristics through the use of software installed on a personal computer. Four types of noise spectra are pre-programmed as noisers – white noise, pink noise, speech noise, and high-tone noise. Figure 1 displays the four types of noise. These standard noise spectra can be adjusted to fit the individual tinnitus patient's requirements. The output level of the device is programmable and can be adjusted further with a volume control. The output range of the volume control can be programmed to four levels.

Figure 1 – Noise Types

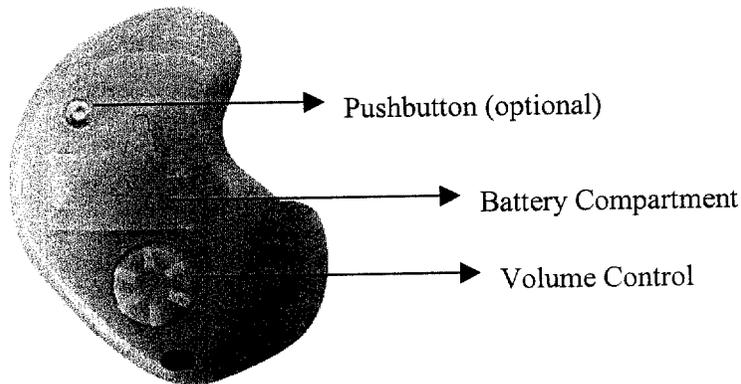


24

Physical Description

The product is housed in a standard in-the-ear casing. The material and composition of this case is identical to custom hearing aids in use by Siemens. Figure 2 displays the Custom TCI in-the-ear device. Helix, half shell, and in-the-canal TCI devices have the same features.

Figure 2 – Custom TCI In-the-Ear Device



Technical Specifications

Output Characteristics

Figure 1 in the previous section shows the maximum output for the four noise types. As shown in the figure, the output at any one frequency of the pink noise, speech noise, and high-tone noise does not exceed 70 dB SPL. The maximum output at 2700 Hz of the white noise is 76 dB SPL. Table 1 displays the overall RMS output of the four noises.

Noise Type	RMS Output
White Noise	86 dB SPL
Pink Noise	75 dB SPL
Speech Noise	71 dB SPL
High-tone Noise	81 dB SPL

Table 1- RMS Output of Custom TCI Noises

Programming

The programming of the noise level is accomplished using Siemens CONNEX software. The hearing professional selects the most appropriate noise type and level based on their assessment of the patient's tinnitus. The output level is set equal to or slightly lower than the perceived level of the tinnitus. The sensation level (dB level above the individual's threshold of sensitivity) of tinnitus is estimated to be between 3 and 15 dB in 95% of persons with tinnitus. The volume control range is also programmable using Siemens software. The hearing professional can choose among OFF and three output ranges of 8 dB, 16 dB and 32 dB. When the volume control range is programmed to OFF, the output intensity is fixed and rotation of the volume control does not change the output. When the volume control range is set to 8 dB (or 16 dB or 32 dB), and the volume control is set to the mid-point, rotation of the volume wheel will increase or decrease the output intensity of the noise up to 4 dB (or 8 dB or 16 dB respectively). Figure 3 shows a noise sample, 30 dB SPL overall output, and volume control range of 16 dB. This is an example of a device programmed for anticipated use. The output of this example instrument, as programmed, will never exceed the dashed line.

26

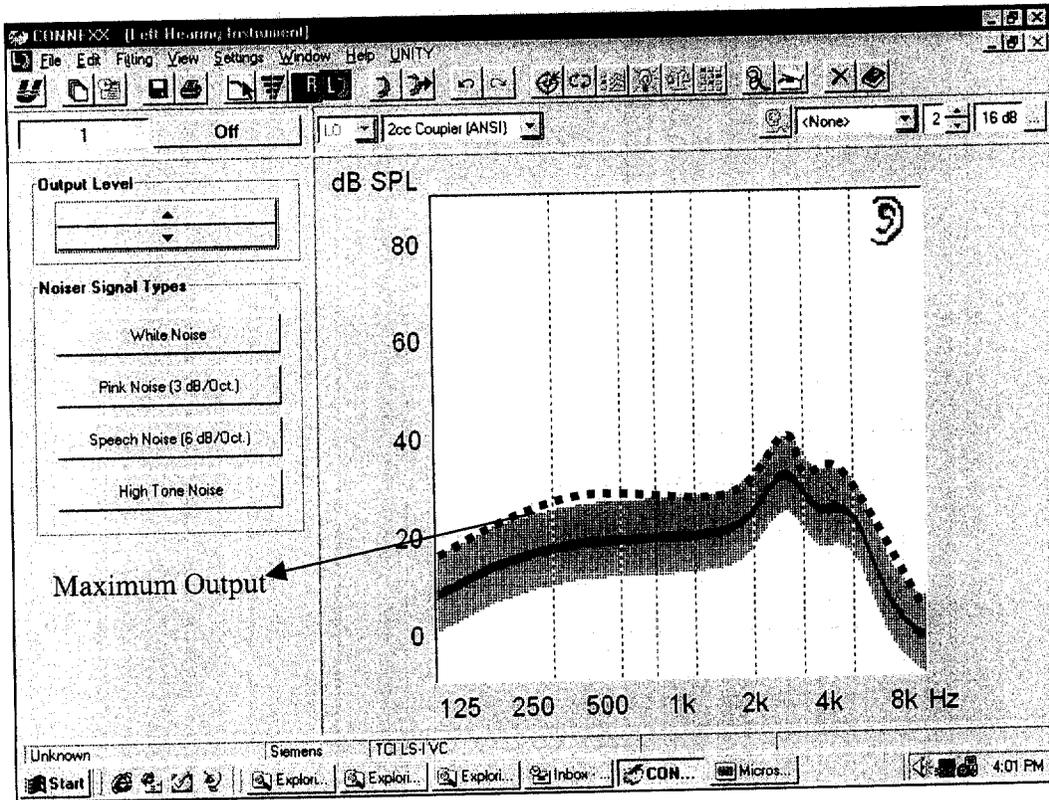


Figure 3 – Sample of noise, overall output of 30 dB SPL and volume control range of 16 dB.

Power Consumption

A standard 1.3 Volt battery is used with a current drain of 0.6 mA.

Standards

Output characteristics of the Custom TCI are measured in a standard 2-cc coupler. This coupler is used to measure output characteristics of custom in-the-ear devices that deliver acoustic energy to the ear canal. The most common example of such a device is a hearing aid. There is currently no standard for measurement of the noise output of a tinnitus masker device.

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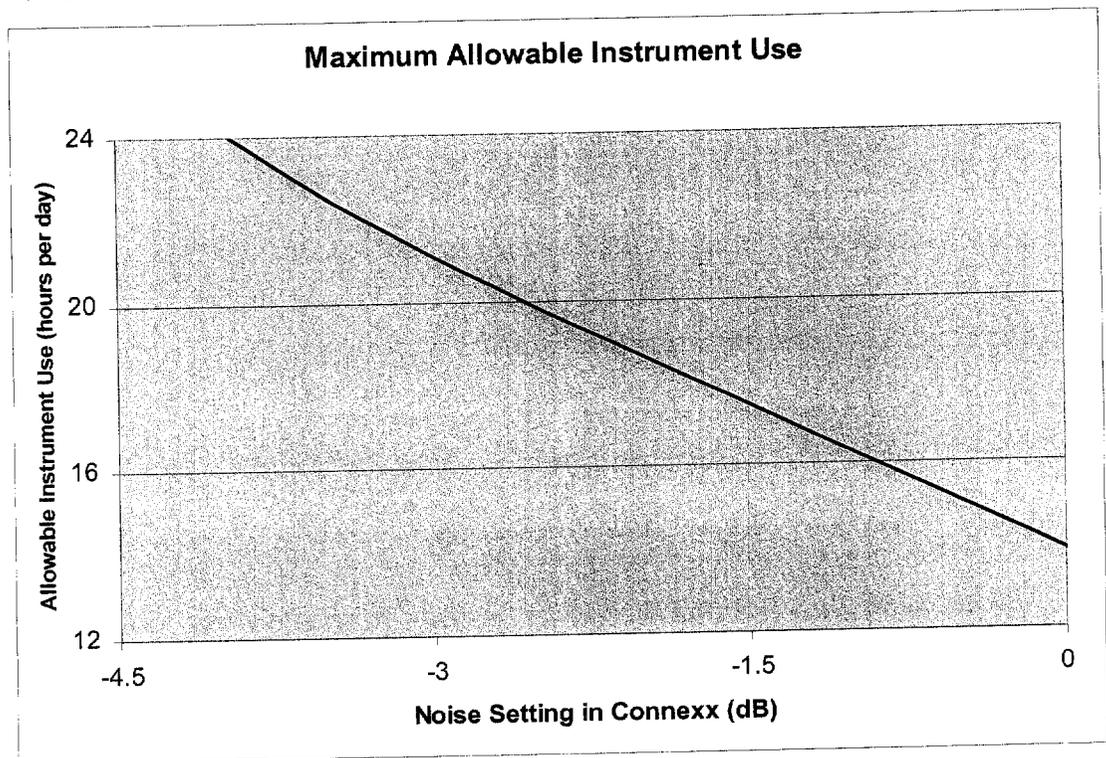
Risks

Output

The nominal maximum output of the Custom TCI is 85 dB (86 dB in the sample device in Figure 1A). The maximum output of the masker noise measured with an A-weighted filter is 86 dBA. The result of the noise measured in the two methods being similar reflects the high-frequency emphasis of the noise. As the noise may be on continuously and as the noise level does fall into the range which can cause hearing loss (OSHA Regulations (Standard – 29 CFR 1910.95 Occupational Noise Exposure)), warnings are included in the Technical Information for the Hearing Health Professional and in the User's Manual for the consumer.

The warning in the Technical Information states:

Note: Anticipated use of the Custom TCI should not reach damaging output levels. However, the output of the noise may be of sufficient intensity level to cause hearing loss if exposure is excessive. If the noise level exceeds 82 dB, which corresponds to a Noise Level of -3.0 dB in Connexx, use of the hearing instrument must be limited according to OSHA Regulations (Standard – 29 CFR 1910.95 Occupational Noise Exposure). Limitations of use as a function of hearing instrument setting are shown in the following graph.



28

The warning in the User's Manual states:

Note: The loudness of the noise should be comfortable for you at all times. High noise levels may harm your hearing. If you have any concerns or questions about the loudness of the noise, contact your Hearing Health Care Professional.

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Labeling

Technical Information

Technical information for the Custom TCI instrument for the hearing health care professional is located in Section 8, Appendix A.

User's Manual

User's manual for the Custom TCI instrument is located in Section 9, Appendix B.

Software Validation

(b)(4)

Comparison of Siemens Hearing Instruments Custom TCI Device and the Predicate Device

Table 2 compares the Siemens Hearing Instruments Custom TCI device and General Hearing Instruments Tranquil Tri-OE. The technical information for the predicate device is taken from its specification sheet in Section 11, Appendix D.

	Siemens Hearing Instrument Custom TCI Device	General Hearing Instruments Tranquil Tri-OE
Intended Use	Mask tinnitus as part of tinnitus management program	Mask tinnitus as part of tinnitus management program
Target Population	Adults and children (≥ 5 years) with tinnitus that are participating in a tinnitus management program	Adults with tinnitus that are participating in a tinnitus management program
Operation Circuit type Programmable Available noises Volume control	Digital Yes Four Yes	Analog No One Yes
Physical Description	Custom product, available as helix, in-the-ear, half shell, and in-the-canal	Custom product, available as in-the-ear and mini-canal
RMS Output Characteristics White noise Pink noise Speech noise High-tone noise	86 dB SPL 75 dB SPL 71 dB SPL 81 dB SPL	75 dB SPL
Volume control range	Programmable: OFF, 8 dB, 16 dB, 32 dB	40 dB

Table 2 – Custom TCI Comparison with Predicate Device

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Discussion

The physical description of the Custom TCI and the predicate device are alike, since both are standard custom models. The intended use of the Custom TCI and predicate device are the same. The RMS output levels between the two devices are comparable. The target population of the Custom TCI is adults and children 5 years of age and older. The target population of the predicate device is adults.

The Custom TCI and the General Hearing Instruments Tranquil Tri-OE differ in terms of the type of signal processing. The Custom TCI is a digital instrument and General Hearing Instruments Tranquil Tri-OE uses analog technology.

The Custom TCI digital circuitry allows greater flexibility in defining the noise output than the predicate device. The acoustic output can be more accurately controlled to ensure patient benefit and comfort. The noise characteristics can also be shaped precisely for maximum benefit. The programmable volume control is another feature to provide patient control and comfort.

Appendix A

Technical Specifications

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SIEMENS

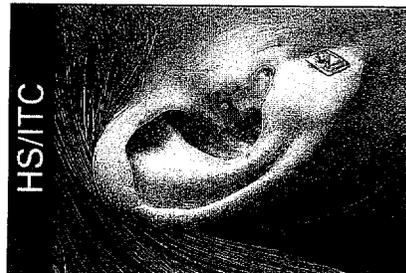
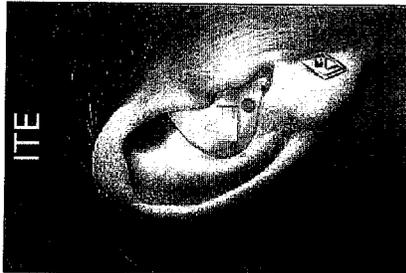
REFUSED

SERENITI™ TCI

Preliminary Technical Information for Custom Tinnitus Control Instruments

35

Quickview



Features:

- Programmable, fully digital 8-channel custom instrument for Tinnitus therapy
- Two individual therapy programs available with manual selection
- Four pre-programmed noise types, with fine-tuning possible in 8 channels
- Volume control with programmable range
- Professional fitting with powerful, easy-to-use CONNEXX™ software fitting system

Option:

- Additional therapy program (includes program button)

Technical Data - 2 cc Coupler

Output Sound Pressure Level (OSPL 90)	
Broadband	85 dB

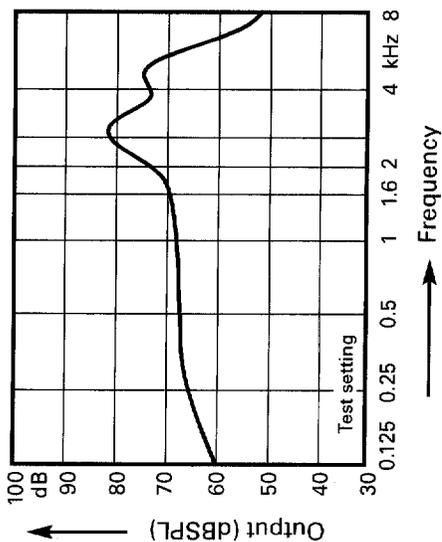
Battery

Type	10A	312	13
Voltage (V)	1.3	1.3	1.3
Current Drain (mA)	0.6	0.6	0.6

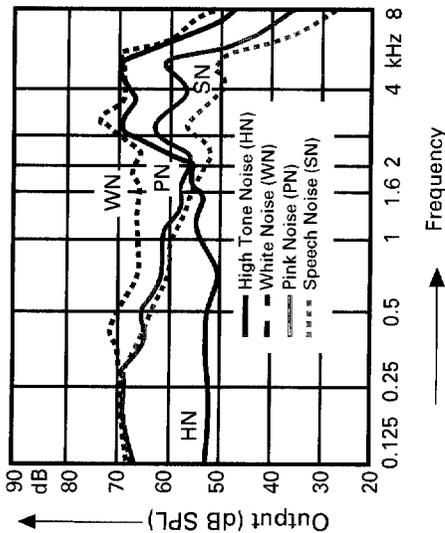
Therapy Noise Characteristics Free Coupler

SERENITY™ TCI

Noise in 1/3 octave bands



Power density spectrum



Fitting Parameters

SERENITY™ TCI

Volume Control Range

off, - 8 dB, - 16 dB, - 32 dB

Master Level Control

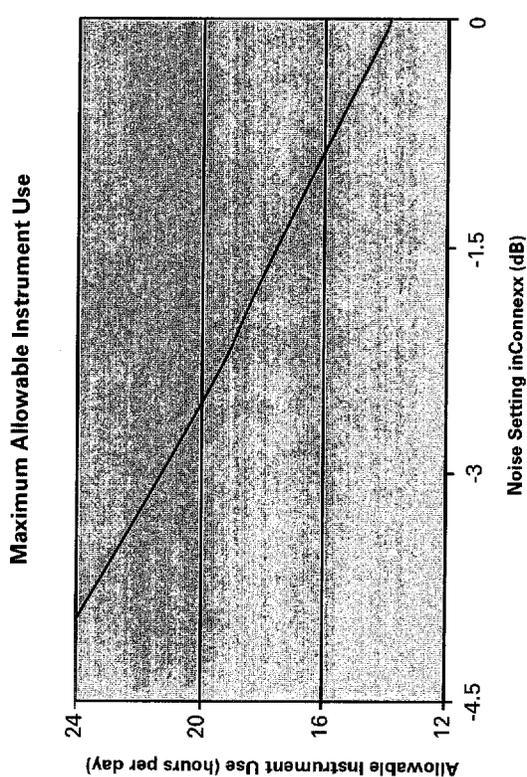
81 dB combined adjustment range (54 x 1.5 dB) from maximum to minimum level - off

1	<input type="checkbox"/> MAX	Reduction in 1.5 dB steps	2	<input type="checkbox"/> MAX	Reduction in 1.5 dB steps	3	<input type="checkbox"/> MAX	Reduction in 1.5 dB steps	4	<input type="checkbox"/> MAX	Reduction in 1.5 dB steps	5	<input type="checkbox"/> MAX	Reduction in 1.5 dB steps	6	<input type="checkbox"/> MAX	Reduction in 1.5 dB steps	7	<input type="checkbox"/> MAX	Reduction in 1.5 dB steps	8	<input type="checkbox"/> MAX	Reduction in 1.5 dB steps
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Channel Level Control

Output Level MAX

Test setting



NOTE: Anticipated use of the custom TCI should not reach damaging output levels. However, the output of the noise may be of sufficient intensity level to cause hearing loss if exposure is excessive. If the noise level exceeds 82 dB, which corresponds to a Noise Level of - 3dB in CONNEXX, use of the hearing instrument must be limited according to OSHA Regulations (Standard - 29 CFR 1910.95 Occupational Noise Exposure). Limitations of use as a function of hearing aid setting are shown in the above graph.

Siemens Hearing Instruments, Inc.
Northeast/US HQ: P.O. Box 1397, Piscataway, NJ 08855-1397 • (732) 562-6600 or (800) 766-4500
South: (770) 422-4540 or (800) 922-9998
West: (562) 404-4531 or (800) 998-9787
Midwest/Professional Products: (847) 808-1200 or (800) 333-9083
Southwest/All-Make Repair: (281) 875-8060 or (800) 255-6253
<http://www.siemens-hearing.com>

Siemens Hearing Instruments
A Division of Siemens Canada Limited
 320 Pinebush Road, Cambridge, Ontario, Canada N3C 2V3 • (519) 622-5200 or (800) 663-0620

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Appendix B

User's Manual

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SIEMENS

User's Manual for SERENITI™ Tinnitus Control
Instrument In-the-Ear Models
Helix, Concha and
Canal/Half-Shell



sereniti™

Your Hearing Health Care Professional:

Siemens Hearing Instruments, Inc.

P.O. Box 1397
Piscataway, NJ 08855-1397

Siemens Hearing Instruments

A Division of Siemens Canada Limited

320 Pinebush Road
Cambridge, Ontario
Canada N3C 2V3

<http://www.siemens-hearing.com>

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FILE NAME: 04453•SERENITITCITEUserMan.qxd

LOC: **Administrative**/SHI Jobs/SHI04400-04499/04453

4/27/01

FILE NAME: 04453•SERENITITCITEUserMan.qxd

LOC: **Administrative**/SHI Jobs/SHI04400-04499/04453

4/27/01

41

Introduction

Tinnitus is a noise (buzzing, ringing, and roaring) perceived by the patient/individual where there is no external acoustic stimulus (Mueller & Hall, 1998).

The TCI is not a hearing aid, and on its own does not serve as a treatment or cure for tinnitus. The instrument was designed to be used in conjunction with a tinnitus management program that includes an individualized comprehensive treatment plan. These tinnitus management programs should be operated by a qualified Hearing Health Care Professional.

Most tinnitus therapy programs recommend the volume of noise be set equal to or slightly lower than the perceived level of the tinnitus {5-10 dB Sensation Level (SL)}. This noise level should not interfere with speech understanding. Your Hearing Health Care Professional can instruct you on specific volume control usage.

The loudness of the noise should be comfortable for you at all times. High noise levels may harm your hearing. If you have any concerns or questions about the loudness of the noise, contact your Hearing Health Care Professional.

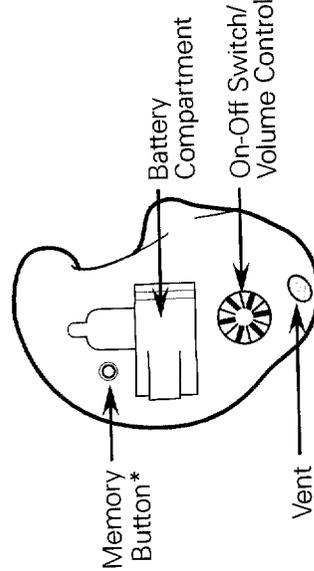
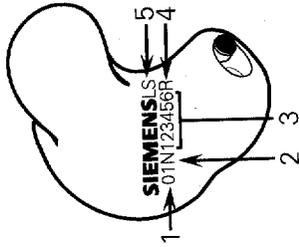
Note: While some Hearing Health Care Professionals recommend use of this type of device with children 5 years of age or older, the clinical efficacy of this device with children is based on subjective reports.

42

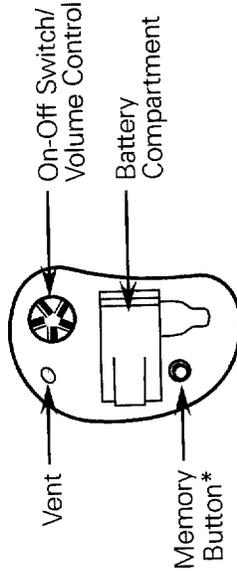
Getting Familiar with Your Instrument

Your tinnitus control instrument is custom-fitted to the contours of your ear. Each instrument can be identified by a serial number found on the outside of the instrument. If the number appears in red, this instrument is for the right ear. If the number appears in blue, this instrument is for the left ear.

- 1 01 – Year manufactured
- 2 N – Facility code where aid was manufactured
- 3 Serial number
- 4 L or R – Left or Right ear aid
- 5 LS – Model type



Example Shown: Right Ear Concha Instrument



Example Shown: Right Ear Canal Instrument

Because your instrument was custom made, its appearance may vary from the ones pictured.

The battery compartment holds the battery that powers the instrument.

The vent hole, which can appear in various locations, provides comfort and pressure release.

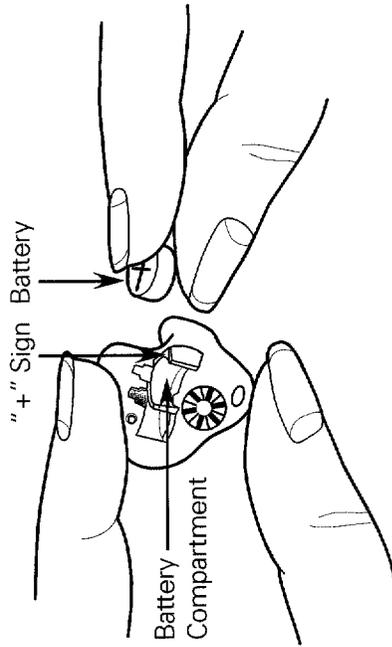
*Note that the diagrams show a Memory Button. Your Hearing Health Care Professional will determine whether to include this control on your instrument. The selection of this option is dependent upon your individual fitting requirements.

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Using Your Instrument

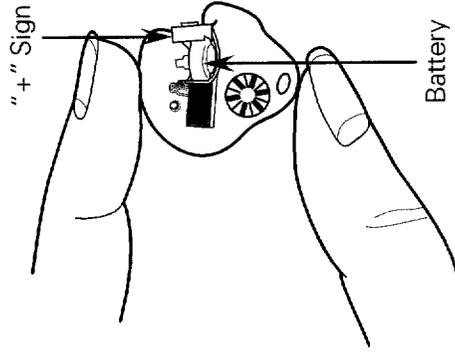
Before using your instrument, place the battery into the battery compartment. To insert the battery, hold the instrument as shown.

Using the fingernail of either your thumb or forefinger, pull the tab on the battery compartment outward until the compartment swings open all the way.



Example Shown: Right Ear Instrument

Place the proper size of battery (see "Battery" section or consult your Hearing Health Care Professional) into the battery compartment, observing the correct polarity. The "+" sign on the battery must match the "+" sign stamped on the top of the battery compartment door.



Example Shown: Right Ear Instrument

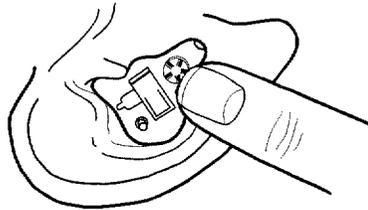
Gently close the battery compartment door. Avoid forcing the battery door shut. If it does not close easily, check to see if the battery was inserted properly. Once the battery is in its proper position, your instrument is ready to operate.

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To Insert and Remove the Instrument

Hold the instrument between your thumb and forefinger. With the face of the instrument towards the outside, place the canal portion into your ear. Gently work the instrument into its proper position by slightly twisting until it is firmly seated. Lightly press inward for a secure and comfortable fit.

When removing the instrument, push lightly on the back of the ear to help loosen it. Then, using your forefinger, gently pull the instrument from your ear.



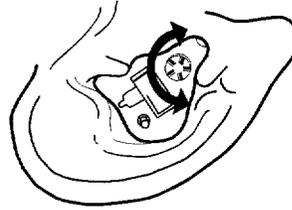
CAUTION! Never pull on the volume wheel or battery door to remove the instrument, as this could cause damage.

On-Off Switch/Volume Control

Since your model has a manual volume control, the on-off switch is built into the volume control. The wheel-shaped control is rotated to select the most desired listening position (louder or softer). Before placing the hearing instrument in your ear be sure that the hearing instrument is "off."

To turn the instrument "on" and increase the volume, place your forefinger gently against the wheel and rotate it towards your face, after it is placed in your ear. Full volume has been reached when the wheel stops. Do not force the volume control past the stops in either direction.

To reduce the volume, rotate the wheel in the opposite direction. When you reach the stop, the instrument is "off."



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Using the Memory Button (where provided)

This instrument may have a memory button to change the characteristics of the sound coming through the instrument for specific listening environments.

This button controls two "memories" (technically called programs), which are arranged in a cycle. Whenever you turn the instrument off and then on, or the battery is removed, then replaced, it will return to memory 1. You reach memory 2 by pushing the memory button once.

If you push the memory button still once more, you are back to memory 1. Each time you press the button you move to the next memory. The sequence is 1, 2, 1, 2,...

Memory Number	Listening Environment
1	_____
2	_____

Health Considerations

If soreness or skin irritation develops in the ear, discontinue wearing your instrument, and bring it to your Hearing Health Care Professional. Minor fit adjustments and polishing can often correct this condition. If soreness persists, discontinue wearing the instrument and see your physician.

If excessive ear wax accumulates when wearing your instrument, consult your Hearing Health Care Professional.

Battery

The chart below provides the battery size generally used in your instrument. However, since your instrument is a custom product, it's strongly recommended that you check with your Hearing Health Care Professional regarding the correct battery for your model.

Models	Battery Size
SERENITIT™ <i>Tinnitus Control Instruments</i>	
Helix	10
Concha	13
Canal/Half Shell	312

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Appendix C

Documentation of Product Software Review

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Records Processed under FOIA Request 2015-6437; Released by CDRH on 10/07/2015

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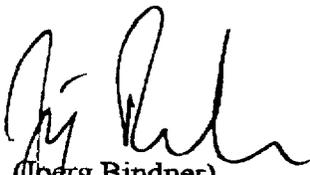
Date: March 27, 2001

OFFICIAL STATEMENT

I confirm, that TCI LS-I VC was included for the release of SIFIT 3.3

I confirm, that the following devices were included for the release of SIFIT 3.4

- TCI-Combi LS-C VC 110/35/03
- TCI-Combi LS-C VC + 110/35/03
- TCI-Combi LS-I VC 110/40/03
- TCI-Combi LS-I VC + 110/40/03



(Jörg Bindner)
Head of software development

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(b) (4)

Appendix D

Technical Specifications of Predicate Device

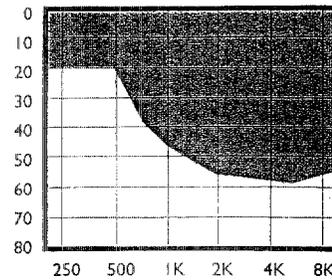
TRANQUIL™

Introducing the Tranquil - Offered Exclusively by General Hearing Instruments!

The Tranquil is a Class D, low-level noise generator that was developed specifically to be used with a program that addresses the psychological and neurological aspects of tinnitus with a comprehensive individualized treatment approach. The Tranquil may be used for tinnitus habituation as well as hyperacusis treatment.

Due to the non-occluding, open ear design, the Tranquil is very comfortable to wear and has cosmetic appeal. The sound pressure level of the broad band noise remains constant, even with head movement, and can be worn while sleeping.

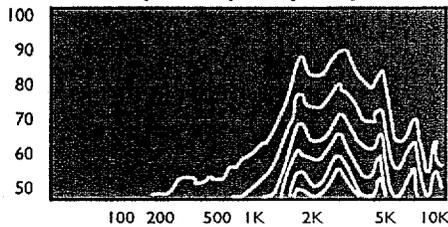
Suggested Fitting Range



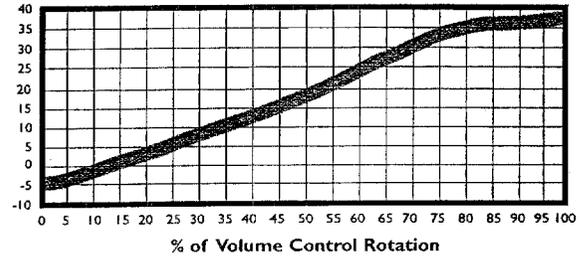
All thresholds need not fall within the shaded area.

Typical Output . . . RMS 75 dB SPL
Battery Drain0.4 - 0.45 mA

Tranquil Frequency Response



Tranquil V.C. Taper Characteristics



10A Battery	
Battery Life Chart	
24	5.8
23	6.1
22	6.4
21	6.7
20	7.0
19	7.4
18	7.8
17	8.2
16	8.8
15	9.4
14	10.0
13	10.8
12	11.7
11	12.8
10	14.1
9	15.6
8	17.6
7	20.1
6	23.5
5	28.2
4	35.2
3	47.0
2	70.5
1	141

Hours of use per day (left side)
Life of battery in days (right side)



CANAL OPEN EAR

The Canal Open Ear or COE is a micro-mini canal shell design incorporating a 10A battery and small retention arms to properly direct the receiver and keep the interior external ear canal open.



OPEN EAR

The Open Ear or OE is a helix based open ear IHD design which houses the circ. circuitry in the helix portion of the ear shell. It incorporates a 312 battery and a cavity retention arm to properly direct the receiver and maintain the open inferior canal.

The Tranquil is Recommended For Tinnitus and/or Hyperacusis Patients.

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