

JUN - 1 2001

K011366

510(K) Summary for the Siemens Custom TCI-Combi

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-Combi
(Tinnitus Control
Instrument Combination)

4. **Device Common Name / Classification Name:** **Hearing Aid, Air Conduction and Tinnitus Masker**

Product Code: **ESD and 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:** K 97229
Siemens Hearing Instruments
Prisma Hearing Instrument
& K974751
General Hearing Instruments
Tranquil Tri-OE

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

10. **Indications for Use:**

The Custom TCI-Combi is an in-the-ear style electronic, air conduction broad-band noise generator and hearing aid 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-Combi is intended to be used by those individuals who experience tinnitus and 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 need amplification. This product may also be used with children 5 years of age or older.

11. **Description of Device:**

Custom TCI-Combi 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 shell, half shell, or in-the-canal shell style. It is programmable, with selectable noise and output levels. The output noise can be custom-tailored to the user's individual requirements. The Custom TCI-Combi is also a digital programmable hearing aid which provides sound amplification. This hearing aid is a four-channel instrument with wide dynamic range compression. The product has two programs that can be programmed independently to noise masker only, amplification only or both noise masker and sound amplification.

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

Custom TCI-Combi is the combination of a tinnitus masker and a conventional hearing instrument. Thus, two devices are specified here as predicate devices. The tinnitus masker portion of the Custom TCI-Combi is predicated by General Hearing Instruments Tranquil Tri-OE. The hearing instrument portion of the Custom TCI-Combi is predicated by Siemens Hearing Instruments Prisma hearing aid.

The Custom TCI-Combi 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 primary difference between the Siemens Custom TCI-Combi and the Tranquil is that the Custom TCI-Combi is digital with programmable noise characteristics which increases the flexibility of the device.

The Custom TCI-Combi is equivalent to the Siemens Hearing Instruments Prisma hearing instrument. The programmable hearing instrument parameters of the Custom TCI-Combi are the same as the programmable parameters of the Prisma.

The following table compares the Siemens Hearing Instruments Custom TCI-Combi device to the predicate devices – General Hearing Instruments Tranquil Tri-OE and Siemens Hearing Instruments Prisma.

	Siemens Hearing Instrument Custom TCI-Combi Device	Predicate Device: General Hearing Instruments Tranquil Tri-OE (GHI) and Siemens Hearing Instruments (SHI) Prisma
Intended Use	Mask tinnitus as part of tinnitus management program Provide amplification for compensation of hearing loss	Mask tinnitus as part of tinnitus management program (GHI) Provide amplification for compensation of hearing loss (SHI)
Target Population	Adults and children (≥ 5 years) with tinnitus and hearing loss that are participating in a tinnitus management program	GHI Adults with tinnitus and hearing loss that are participating in a tinnitus management program SHI Adults and children with hearing loss

<p>Operation</p> <p>Circuit type</p> <p>Programmable</p> <p>Available noises</p> <p>Volume control</p> <p>Number of channels</p> <p>Variable compression kneepoint</p> <p>Variable compression ratio</p> <p>Multiple programs/memories</p>	<p>Digital</p> <p>Yes</p> <p>One</p> <p>Yes</p> <p>Four</p> <p>Yes</p> <p>Yes</p> <p>Yes</p>	<p>GHI</p> <p>Analog</p> <p>No</p> <p>One</p> <p>Yes</p>	<p>SHI</p> <p>Digital</p> <p>Yes</p> <p>Yes</p> <p>Four</p> <p>Yes</p> <p>Yes</p> <p>Yes</p>
<p>Physical Description</p>	<p>Custom product, available as in-the-ear, half shell, and in-the-canal shell styles</p>	<p>Custom product, available as in-the-ear and mini-canal shell styles (GHI)</p> <p>Custom product, available as in-the-ear, half shell, in-the-canal, mini-canal, and completely-in-the-canal shell styles (SHI)</p>	
<p>Output Characteristics</p> <p>Noiser</p> <p>Hearing aid amplifier</p>	<p><u>In-the-ear:</u> 89 dB Broadband noise</p> <p><u>In-the-canal and half shell:</u> 84 dB Broadband noise</p> <p><u>In-the-ear:</u> 105 dB HF-Average OSPL 90 (ANSI S3.22-1996) (110/40/03 matrix)</p> <p><u>In-the-canal and half shell:</u> 107 dB HF-Average OSPL 90 (ANSI S3.22-1996) (110/35/03 matrix)</p>	<p>75 dB SPL High-tone noise (GHI)</p> <p><u>In-the-ear, half shell, in-the-canal:</u> 107 dB HF-Average OSPL 90 (ANSI-S3.22-1996) (113/40/03 matrix)</p>	
<p>Volume control range</p>	<p>Programmable: OFF, 8 dB, 16 dB, 32 dB</p>	<p>40 dB</p>	

Custom TCI-Combi Comparison with Predicate Devices

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

Risks

In-the-ear : The maximum output for the in-the-ear model of the noise masker is 88 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.

Half shell and In-the-canal: There are no risks associated with this device because the output of the noiser does not exceed OSHA exposure limits (OSHA Regulations, Standard – 29 CFR 1910.95 Occupational Noise Exposure).

Hearing Healthcare Professional Diagnosis:

The sale and fitting of the Siemens Custom TCI-Combi 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. Sound amplification may be of benefit to the individual with hearing loss when programmed for the user’s hearing loss.

Warnings for Safe Use

In-the-ear: 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. General use precautions are in the User’s Manual.

Half shell and In-the-canal: As this device cannot deliver damaging sound intensity, no warning is required about sound output level. General use precautions are in the User’s Manual.



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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: K011366
Trade Name: Custom TCI-Combi
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 (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.

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): **K011366**

DEVICE NAME: **CUSTOM TCI – COMBI**

INDICATIONS FOR USE:

The Custom TCI-Combi is an in-the-ear style electronic, air conduction broad-band noise generator and hearing aid 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-Combi is intended to be used by those individuals who experience tinnitus and 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 need amplification. This product may also be used with children 5 years of age or older.

(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) *JB*

OR

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

Karen Baker

(Division Sign-Off)

Division of Ophthalmic Devices

510(k) Number K011366



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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

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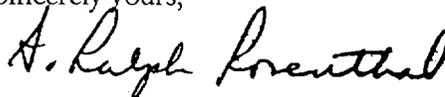
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Sincerely yours,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
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Center for Devices and
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
 (Per 21 CFR 801.109) *JB*

OR

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

Karen Baker

(Division Sign-Off)
 Division of Ophthalmic Devices

510(k) Number K011366

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

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

Subject: 510(k) Number K011366

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.)

- 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 NA

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 77 KLV

Review: Kovita
(Branch Chief)

EAIB
(Branch Code)

5/31/01
(Date)

Final Review: David M. Whyle for DEED 5/31/01
(Division Director)

Handwritten mark

Document # K011366

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 - Combi

CLASSIFICATION NAME: Tinnitus Masker and Hearing Aid, Air Conduction

COMMON NAME: Tinnitus Masker and Air Conduction Hearing Aid

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

K974751 - General Hearing Instruments Tranquil Tri-OE
Siemens Hearing Instruments Prisma Hearing Instrument

INTENDED USE STATEMENT: The Custom TCI-Combi is an in-the-ear style electronic, air conduction broadband noise generator and hearing aid 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-Combi is intended to be used by those individuals who experience tinnitus and 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.

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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, low level of concern)	yes
Sterility: (sterilized by user)	no
Single Use: multiple use by single user	yes
Home or prescription use:	yes
Drug or Biologic product:	no
Device a kit:	no

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	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?		- IF YES GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	x	- IF NO GO TO 10 - IF YES STOP
8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?		- 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?		

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 Custom TCI-Combi is also a digital programmable hearing aid which provides sound amplification. This hearing aid is a four-channel instrument with wide dynamic range compression. The product has two programs that can be programmed independently to noise masker only, amplification only or both noise masker and sound amplification.

The In-the ear model maximum output of the noise at 2700 Hz is 78 dB SPL, and the overall RMS output of the noiser function is 83 dB. The High Frequency Average OSPL 90 (ANSI S3.22-1996) for the In-the-ear model is 105 dB. The High Frequency Full On Gain is 32 dB.

The Half shell and In-the-ear maximum output of the noise at 2700 Hz is 72 dB SPL, and the overall RMS output of the noiser function is 83 dB. The High Frequency Average OSPL 90 (ANSI S3.22-1996) for these models is 107 dB. The High Frequency Full On Gain is 28 dB.

The programming of the noise level and the hearing aid is accomplished using Siemens CONNEXX software. The hearing professional adjusts the noise spectrum and output 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

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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 hearing aid portion is exempt from 510(k) review and is therefore not discussed here. The CONNEXX software has previously been reviewed and cleared for marketing, as well.

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 for safe use statement that informs the user and the hearing professional that the noise level of the in-the ear model does fall into the range which can cause hearing loss (OSHA Regulations (Standard – 29 CFR 1910.95 Occupational Noise Exposure)).

H. 510(k) Summary or Statement

A 510(k) Summary is provided.

SUMMARY: The Siemens Custom TCI-Combi is a programmable digital tinnitus masker and hearing aid allowing the programming of the noise masker and sound amplification through use of software installed on a personal computer. 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. The electroacoustic characteristics of the hearing aid as measured using the ANSI S3.22-1996 specifications. The noise spectrum can be adjusted to fit the individuals tinnitus requirements.

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The hearing aid portion of the device is exempt from premarket notification and therefor is not reviewed,

This reviewer asked Teri Cygnarowicz to comment on the output characteristics and the warning as provided in the labeling. Ms. Cygnarowicz stated that the output characteristics and the labeling are consistent with similar tinnitus masker/hearing aid devices currently marketed. Ms. Cygnarowicz consulted with James Kane, Ph.D., DOED audiologist who concurred. Ms. Cygnarowicz had no questions and stated that the device is substantially equivalent to other devices currently marketed.

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

RECOMMENDATION:

The Siemens Custom TC10-Combi is substantially equivalent to the cited predicate tinnitus masker and hearing aid devices.

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: <u>Custom TCI - Combai</u>						K011366						
Submitter (Company): <u>Siemens Hearing Instruments</u>												
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:						GO TO # 2,3		GO TO # 2,4,5		GO TO # 2,5		
a) "Special 510(k): Device Modification"												
b) "Abbreviated 510(k)"												
c) <u>Traditional 510(k)</u>												
2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS								✓ IF ITEM IS NEEDED AND IS MISSING				
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		
						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)										N/A		
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)										N/A		
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										N/A		
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												

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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:							N/A
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:							N/A
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: Kevin Baker
 Concurrence by Review Branch: [Signature]

510(K) NUMBER (IF KNOWN): **K011366**

DEVICE NAME: **CUSTOM TCI – COMBI**

INDICATIONS FOR USE:

The Custom TCI-Combi is an in-the-ear style electronic, air conduction broad-band noise generator and hearing aid 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-Combi is intended to be used by those individuals who experience tinnitus and 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 need amplification. This product may also be used with children 5 years of age or older.

(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)

SK11

14

K 011366 / H1

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

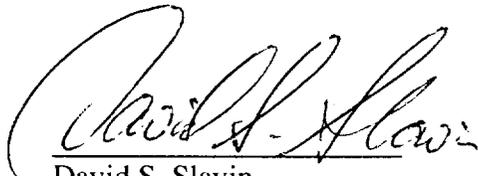
May 14, 2001

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.



David S. Slavin
Director of Quality Assurance and Regulatory Affairs

5/14/01

Date

SK 11 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: K011366
10 CONSTITUTION AVE. Received: 04-MAY-2001
P.O. BOX 1397 Product: CUSTOM TCI-COMBI
PISCATAWAY, NJ 08855 (TINNITUS CONTROL
ATTN: DAVE SLAVIN INSTRUMENT
COMBINATION)

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

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

SIEMENS

1011366

(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

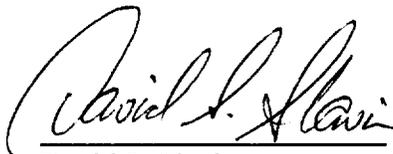
Attn: Document Mail Clerk

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

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

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Custom TCI-Combi

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 Devices
12	Bibliography

510(K) Summary for the Siemens Custom TCI-Combi

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-Combi
(Tinnitus Control
Instrument Combination)

4. **Device Common Name / Classification Name:** **Hearing Aid, Air Conduction and Tinnitus Masker**

Product Code: **ESD and 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:** K 97229
Siemens Hearing Instruments
Prisma Hearing Instrument
& K974751
General Hearing Instruments
Tranquil Tri-OE

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

10. **Indications for Use:**

The Custom TCI-Combi is an in-the-ear style electronic, air conduction broad-band noise generator and hearing aid 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-Combi is intended to be used by those individuals who experience tinnitus and 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 need amplification. This product may also be used with children 5 years of age or older.

11. **Description of Device:**

Custom TCI-Combi 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 shell, half shell, or in-the-canal shell style. It is programmable, with selectable noise and output levels. The output noise can be custom-tailored to the user's individual requirements. The Custom TCI-Combi is also a digital programmable hearing aid which provides sound amplification. This hearing aid is a four-channel instrument with wide dynamic range compression. The product has two programs that can be programmed independently to noise masker only, amplification only or both noise masker and sound amplification.

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

Custom TCI-Combi is the combination of a tinnitus masker and a conventional hearing instrument. Thus, two devices are specified here as predicate devices. The tinnitus masker portion of the Custom TCI-Combi is predicated by General Hearing Instruments Tranquil Tri-OE. The hearing instrument portion of the Custom TCI-Combi is predicated by Siemens Hearing Instruments Prisma hearing aid.

The Custom TCI-Combi 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 primary difference between the Siemens Custom TCI-Combi and the Tranquil is that the Custom TCI-Combi is digital with programmable noise characteristics which increases the flexibility of the device.

The Custom TCI-Combi is equivalent to the Siemens Hearing Instruments Prisma hearing instrument. The programmable hearing instrument parameters of the Custom TCI-Combi are the same as the programmable parameters of the Prisma.

The following table compares the Siemens Hearing Instruments Custom TCI-Combi device to the predicate devices – General Hearing Instruments Tranquil Tri-OE and Siemens Hearing Instruments Prisma.

	Siemens Hearing Instrument Custom TCI-Combi Device	Predicate Device: General Hearing Instruments Tranquil Tri-OE (GHI) and Siemens Hearing Instruments (SHI) Prisma
Intended Use	Mask tinnitus as part of tinnitus management program Provide amplification for compensation of hearing loss	Mask tinnitus as part of tinnitus management program (GHI) Provide amplification for compensation of hearing loss (SHI)
Target Population	Adults and children (≥ 5 years) with tinnitus and hearing loss that are participating in a tinnitus management program	GHI Adults with tinnitus and hearing loss that are participating in a tinnitus management program SHI Adults and children with hearing loss

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<p>Operation</p> <p>Circuit type</p> <p>Programmable</p> <p>Available noises</p> <p>Volume control</p> <p>Number of channels</p> <p>Variable compression kneepoint</p> <p>Variable compression ratio</p> <p>Multiple programs/memories</p>	<p>Digital</p> <p>Yes</p> <p>One</p> <p>Yes</p> <p>Four</p> <p>Yes</p> <p>Yes</p> <p>Yes</p>	<p>GHI</p> <p>Analog</p> <p>No</p> <p>One</p> <p>Yes</p>	<p>SHI</p> <p>Digital</p> <p>Yes</p> <p>Yes</p> <p>Four</p> <p>Yes</p> <p>Yes</p> <p>Yes</p>
<p>Physical Description</p>	<p>Custom product, available as in-the-ear, half shell, and in-the-canal shell styles</p>	<p>Custom product, available as in-the-ear and mini-canal shell styles (GHI)</p> <p>Custom product, available as in-the-ear, half shell, in-the-canal, mini-canal, and completely-in-the-canal shell styles (SHI)</p>	
<p>Output Characteristics</p> <p>Noiser</p> <p>Hearing aid amplifier</p>	<p><u>In-the-ear</u>: 89 dB Broadband noise</p> <p><u>In-the-canal and half shell</u>: 84 dB Broadband noise</p> <p><u>In-the-ear</u>: 105 dB HF-Average OSPL 90 (ANSI S3.22-1996) (110/40/03 matrix)</p> <p><u>In-the-canal and half shell</u>: 107 dB HF-Average OSPL 90 (ANSI S3.22-1996) (110/35/03 matrix)</p>	<p>75 dB SPL High-tone noise (GHI)</p> <p><u>In-the-ear, half shell, in-the-canal</u>: 107 dB HF-Average OSPL 90 (ANSI-S3.22-1996) (113/40/03 matrix)</p>	
<p>Volume control range</p>	<p>Programmable: OFF, 8 dB, 16 dB, 32 dB</p>	<p>40 dB</p>	

Custom TCI-Combi Comparison with Predicate Devices

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

Risks

In-the-ear : The maximum output for the in-the-ear model of the noise masker is 88 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.

Half shell and In-the-canal: There are no risks associated with this device because the output of the noiser does not exceed OSHA exposure limits (OSHA Regulations, Standard – 29 CFR 1910.95 Occupational Noise Exposure).

Hearing Healthcare Professional Diagnosis:

The sale and fitting of the Siemens Custom TCI-Combi 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. Sound amplification may be of benefit to the individual with hearing loss when programmed for the user’s hearing loss.

Warnings for Safe Use

In-the-ear: 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. General use precautions are in the User’s Manual.

Half shell and In-the-canal: As this device cannot deliver damaging sound intensity, no warning is required about sound output level. General use precautions are in the User’s Manual.

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 with hearing loss and 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 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

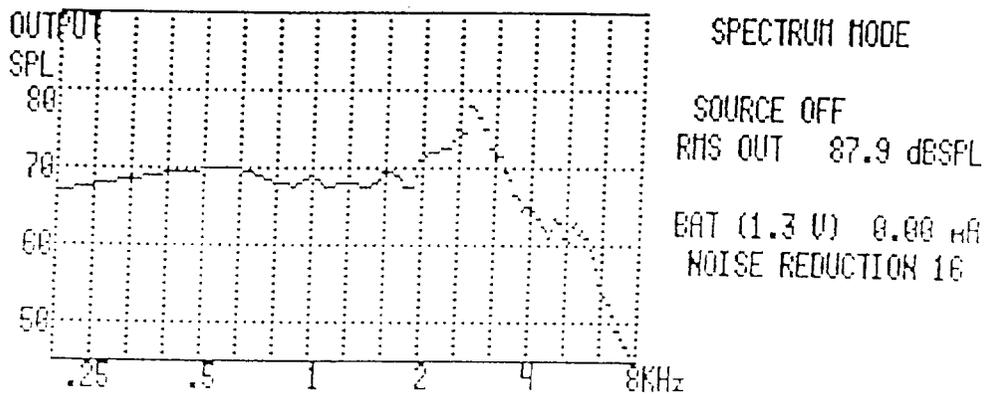
The device is a programmable digital tinnitus masker and hearing aid, allowing the programming of the noise masker and sound amplification through the use of software installed on a personal computer. Figure 1, panels A and B, displays the maximum output level of the noise. Panels C and D in Figure 1 show the electroacoustic characteristics of the hearing aid as measured using the ANSI S3.22-1996 specifications. This noise spectrum 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.

The hearing aid portion of the device has four channels for selective sound amplification. Up to 32 digitally adjustable parameters are available in each of up to

two listening programs (memories) to shape and modify the instrument's overall frequency response. These control features include: channel gain, channel delineation, compression kneepoint, and compression threshold. The hearing health professional programs the instrument using Siemens CONNEX software with HiPro™ hardware (K942749).

Figure 1 – Maximum output of the Custom TCI-Combi

A. Maximum output of the in-the-ear noise masker



B. Maximum output of the half shell and in-the-canal noise masker

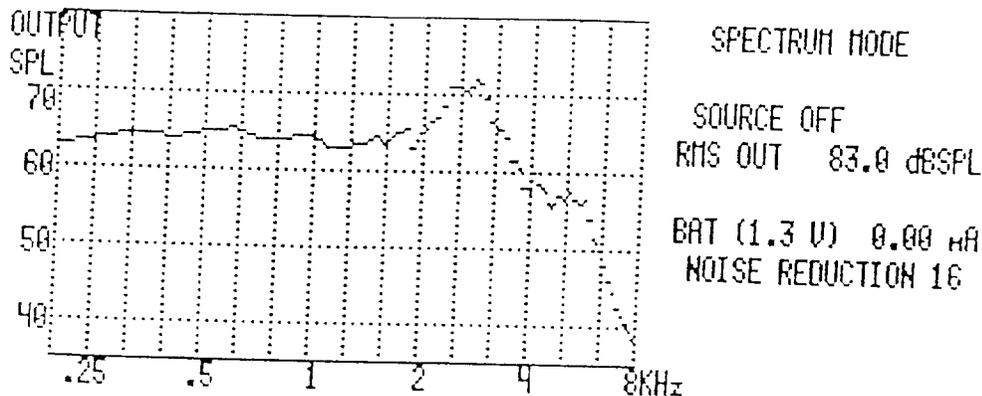
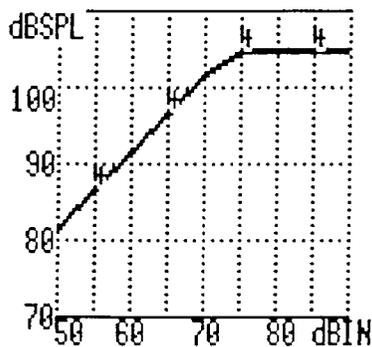
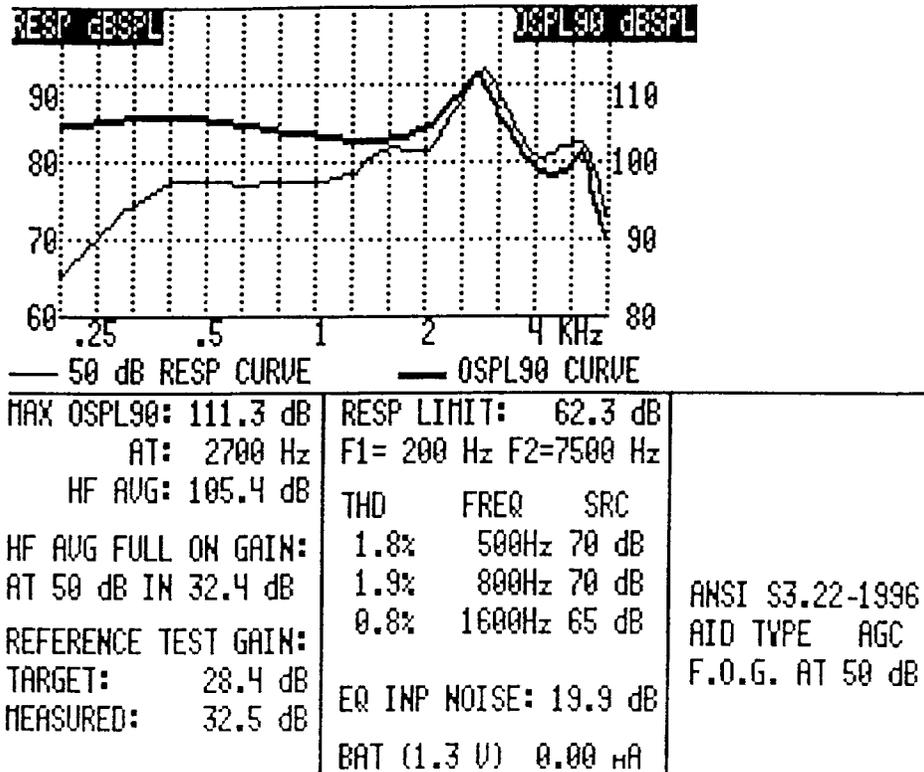


Figure 1

C. Maximum output of the in-the-ear hearing aid



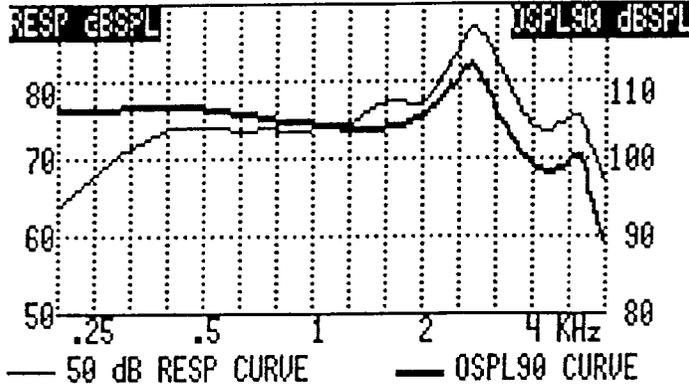
I/O CURVES	
250Hz	-1-
500Hz	-2-
1000Hz	-3-
2000Hz	-4-
4000Hz	-5-

FREQ (Hz)	ATTACK (msec)	RELEASE (msec)
250		
500		
1000		
2000	3	97
4000		
MAX:	2000	2000

26

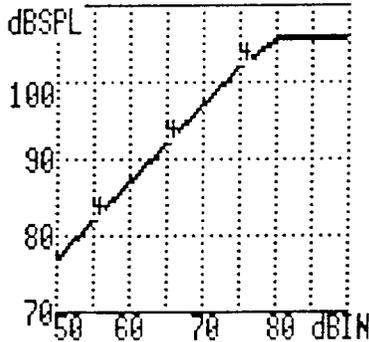
Figure 1

D. Maximum output of the half shell and in-the-canal hearing aid



MAX OSPL90: 112.3 dB	RESP LIMIT: 58.4 dB
AT: 2700 Hz	F1= 200 Hz F2=7100 Hz
HF AVG: 106.5 dB	THD FREQ SRC
HF AVG FULL ON GAIN:	1.3% 500Hz 70 dB
AT 50 dB IN 28.4 dB	1.6% 800Hz 70 dB
REFERENCE TEST GAIN:	0.4% 1600Hz 65 dB
TARGET: 29.5 dB	EQ INF NOISE: 21.2 dB
MEASURED: 28.4 dB	BAT (1.3 V) 0.00 mA

ANSI S3.22-1996
AID TYPE AGC
F.O.G. AT 50 dB



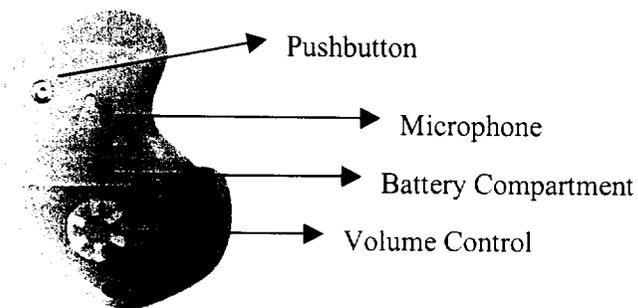
I/O CURVES	
250Hz	-1-
500Hz	-2-
1000Hz	-3-
2000Hz	-4-
4000Hz	-5-

FREQ (Hz)	ATTACK (msec)	RELEASE (msec)
250		
500		
1000		
2000	1	66
4000		
MAX:	2000	2000

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-Combi in-the-ear device. Half shell and in-the-canal TCI-Combi devices have the same features.

Figure 2 – Custom TCI-Combi In-the-Ear Device



Technical Specifications

Output Characteristics

Figure 1 in the previous section shows the maximum output for the noiser and hearing aid functions of a typical Custom TCI-Combi instrument, for the available models.

In-the-ear:

The maximum output of the noise at 2700 Hz is 78 dB SPL, and the overall RMS output of the noiser function is 88 dB. The High Frequency Average OSPL 90 (ANSI S3.22-1996) for the In-the-ear model is 105 dB. The High Frequency Full On Gain is 32 dB.

Half shell and In-the-ear:

The maximum output of the noise at 2700 Hz is 72 dB SPL, and the overall RMS output of the noiser function is 83 dB. The High Frequency Average OSPL 90 (ANSI S3.22-1996) for these models is 107 dB. The High Frequency Full On Gain is 28 dB.

Programming

The programming of the noise level and the hearing aid is accomplished using Siemens CONNEXX software. The hearing professional adjusts the noise spectrum and output 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 hearing health professional programs the hearing instrument according to the patient's hearing loss. Up to 32 digitally adjustable parameters are available in each of the two listening programs. The frequency response is shaped in the four channels and the gain is set to the individual hearing loss.

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. The volume control can be programmed to change the intensity of the masker noise or the amplified sound. 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 up to 4 dB (or 8 dB or 16 dB respectively).

Figure 3 shows the programming of a device for anticipated use. In this example, the masker noise is approximately 42 dB SPL overall output, and volume control range for the noise is 16 dB. The gain of the hearing aid is set to 24 dB.

Power Consumption

A standard 1.3 Volt battery is used with a current drain of 0.6 mA for the in-the-ear, half shell and in-the-canal models.

Risks

Output

In-the-ear:

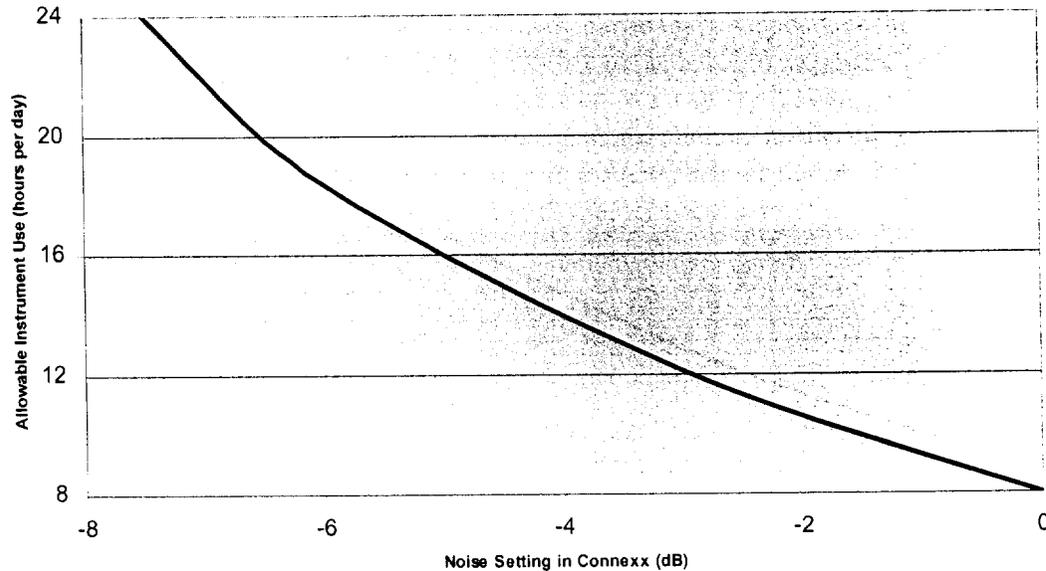
The High Frequency Average OSPL 90 (ANSI S3.22-1996) of the hearing aid of the custom TCI-Combi is 105 dB for the in-the-ear model, in linear mode. This value is taken from Figure 1C in Section 2. This level is below 132 dB, which is the level requiring additional labeling because it “may risk impairing the remaining hearing of the hearing aid user” (Medical Device Regulations (Standard - 21 CFR 801.420, Hearing aid devices; professional and patient labeling)).

The nominal maximum output of the noise masker is 89 dB for this model (88 dB in the sample device in Figure 1A). The maximum output of the masker noise measured with an A-weighted filter is 88 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 In-the-ear TCI-Combi 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 -7.5 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.

Maximum Allowable Instrument Use



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.

Half shell and In-the-canal

The High Frequency Average OSPL 90 (ANSI S3.22-1996) of the hearing aid of the custom TCI-Combi is 107 dB for the in-the-canal and half shell models, in linear mode. This value is taken from Figure 1D in Section 2. This level is below 132 dB, which is the level requiring additional labeling because it "may risk impairing the remaining hearing of the hearing aid user" (Medical Device Regulations (Standard – 21 CFR 801.420, Hearing aid devices; professional and patient labeling)).

The nominal maximum output of the noise masker is 84 dB for this model (83 dB in the sample device in Figure 1B). The maximum output of the masker noise measured with an A-weighted filter is 83 dBA. The result of the noise measured in the two methods being similar reflects the high-frequency emphasis of the noise. The half shell and in-the-canal TCI-Combi models do not present a risk of inducing or increasing hearing loss for custom TCI-Combi users because the sound output has a sound pressure level insufficient to cause hearing damage. As described in the Output Characteristics of the Technical Specifications in Section 3 Page 1, the RMS

output is a maximum of 83 dB SPL. This level poses no significant risk as it is below the compliance levels currently in place on OSHA Regulations (Standard – 29 CFR 1910.95 Occupational Noise Exposure). In Appendix A, Noise Exposure Computation, of Standards – 29 CFR 1910.05, Table G-16A specifies that for a 16-hour exposure period, the maximum permissible noise level of exposure is 85 dBA. A participant in a tinnitus retraining program may wear the half shell or in-the-canal TCI-Combi for all their waking hours. Thus, if a half shell or in-the-canal TCI-Combi user wore the device at maximum output for a 16-hour period, he would not meet the maximum allowable exposure under OSHA regulations.

Labeling

Technical Information

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

User's Manual

User's manual for the Custom TCI-Combi instrument and "General Information for Hearing Aid Users" are located in Section 9, Appendix B.

Software Validation

(b)(4)

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Comparison of Siemens Hearing Instruments Custom TCI-Combi Device and Predicate Devices

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

	Siemens Hearing Instrument Custom TCI-Combi Device	Predicate Device: General Hearing Instruments Tranquil Tri-OE (GHI) and Siemens Hearing Instruments (SHI) Prisma
Intended Use	Mask tinnitus as part of tinnitus management program Provide amplification for compensation of hearing loss	Mask tinnitus as part of tinnitus management program (GHI) Provide amplification for compensation of hearing loss (SHI)
Target Population	Adults and children (≥ 5 years) with tinnitus and hearing loss that are participating in a tinnitus management program	GHI Adults with tinnitus and hearing loss that are participating in a tinnitus management program SHI Adults and children with hearing loss
Operation		GHI Analog SHI Digital
Circuit type	Digital	No
Programmable	Yes	Yes
Available noises	One	One
Volume control	Yes	Yes
Number of channels	Four	Four
Variable compression		

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kneepoint	Yes	Yes
Variable compression ratio	Yes	Yes
Multiple programs/memories	Yes	Yes
Physical Description	Custom product, available as in-the-ear, half shell, and in-the-canal	Custom product, available as in-the-ear and mini-canal (GHI) Custom product, available as in-the-ear, half shell, in-the-canal, mini-canal, and completely-in-the-canal (SHI)
Output Characteristics Noiser	<u>In-the-ear:</u> 89 dB Broadband noise <u>In-the-canal and half shell:</u> 84 dB Broadband noise	75 dB SPL High-tone noise (GHI)
Hearing aid amplifier	<u>In-the-ear:</u> 105 dB HF-Average OSPL 90 (ANSI S3.22-1996) (110/40/03 matrix) <u>In-the-canal and half shell:</u> 107 dB HF-Average OSPL 90 (ANSI S3.22-1996) (110/35/03 matrix)	107 dB HF-Average OSPL 90 (ANSI-S3.22-1996) (113/40/03 matrix)
Volume control range	Programmable: OFF, 8 dB, 16 dB, 32 dB	40 dB

Table 2 – Custom TCI-Combi Comparison with Predicate Devices

Discussion

The physical description of the Custom TCI-Combi and the predicate devices are comparable, since all are standard custom models. The intended use of the TCI-Combi

and the predicate devices are the same as both are to be used as part of a tinnitus management program.

The target population of the Custom TCI-Combi is adults and children 5 years of age and older. The target population of the GHI predicate device is adults.

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

The TCI-Combi digital circuitry allows greater flexibility in defining the noise output than the General Hearing Instruments Tranquil Tri-OE. 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.

The hearing aid portion of the Custom TCI-Combi was patterned after the Siemens Hearing Instruments Prisma. Thus, all programmable parameters in the Prisma are also in the TCI-Combi.

Appendix A

Technical Specifications

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SIEMENS

SERENITI™ TCI C

Preliminary Technical Information for Custom Tinnitus Control Combination Instruments

Digital Hearing Instruments

SERENITI™ TCI C

	Matrix	Operating Current	Therapy Noise Level
	Peak Output / Peak Gain / Slope		Broadband Noise (2cc Coupler)
	110/40/03	0.6 mA	89 dB
	110/35/03	0.6 mA	84 dB

Features

- Programmable, fully digital four channel hearing aid with an integrated tinnitus therapy function, also applicable for patients with hyperacusis
- Excellent speech intelligibility in difficult listening environments due to adaptive noise suppression
- Exceptional signal fidelity due to high-resolution loudness equalization and extended signal dynamics
- Precise therapy noise signal adjustment
- Volume control with programmable range
- Professional fitting system with easy-to-use CONNEXX™ software

Options

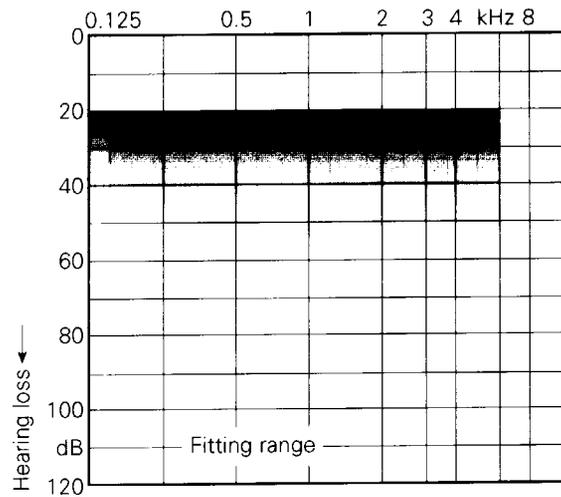
- Additional listening program (Includes program button)
- Program selection available with different combinations, including:
 1. Hearing Instrument plus Therapy Noise
 2. Therapy Noise only
 3. Hearing Instrument only

ef

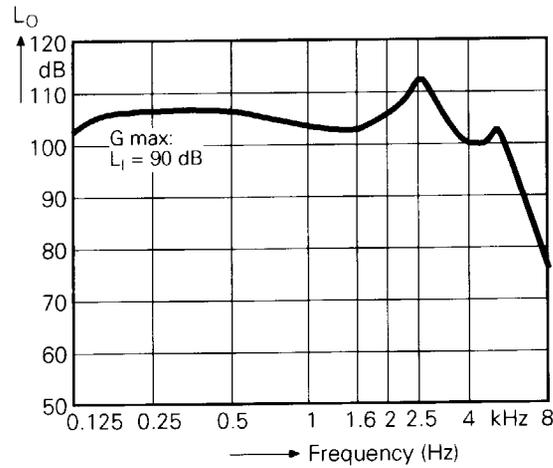
ITE Technical Data

Hearing Instrument Characteristics

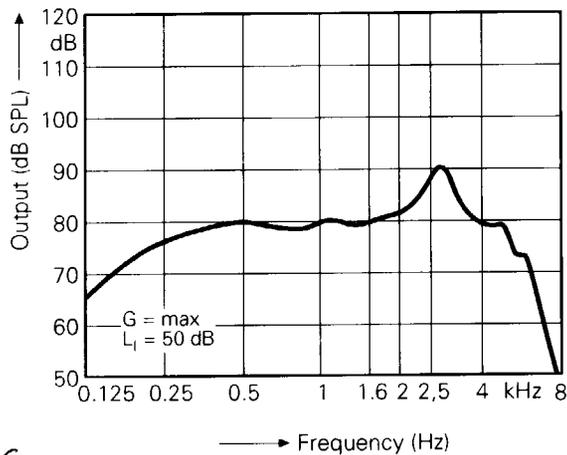
110/40/03



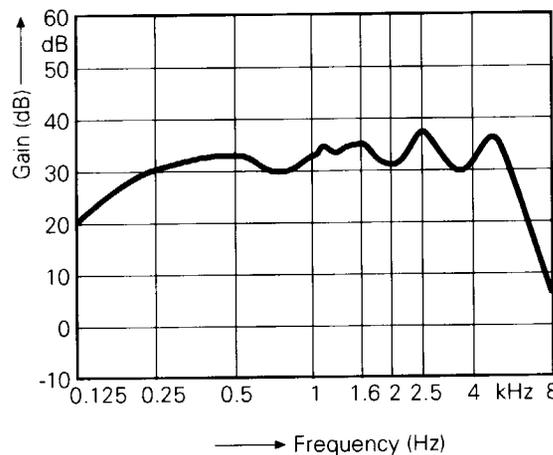
**Output Sound Pressure Level
2 cc Coupler ANSI S3.22 - 1996**



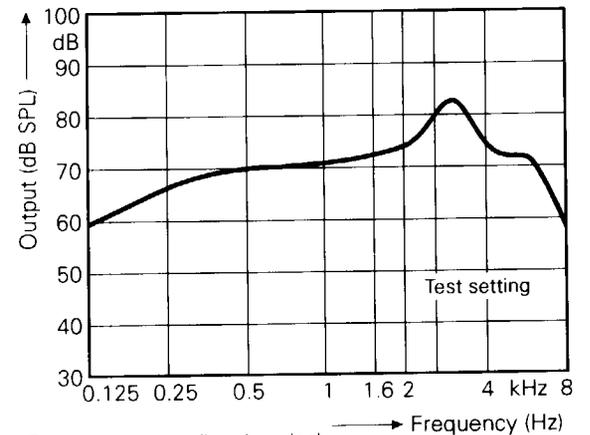
**Gain
2 cc Coupler ANSI S3.22 - 1996**



**KEMAR
Maximum insertion gain**



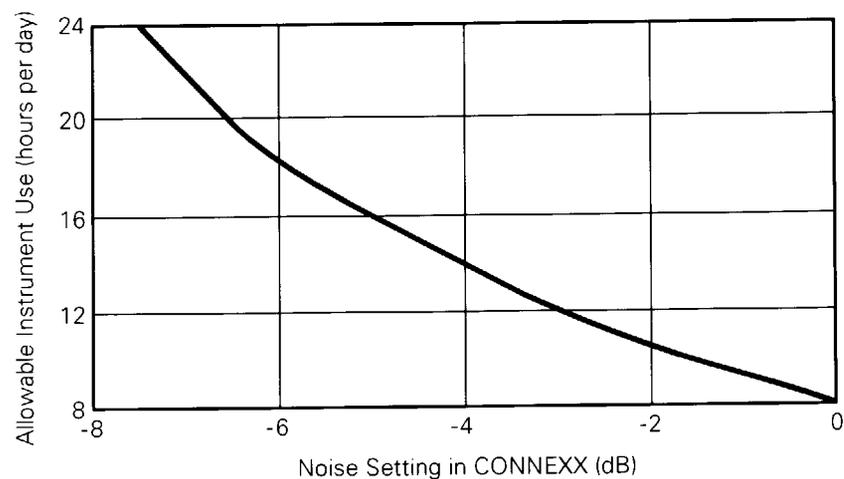
**Therapy Noise Characteristic
Noise in 1/3 Octave Bands - 2 cc Coupler**



Test setting: (broadband setting)
Microphone off, VC setting range off

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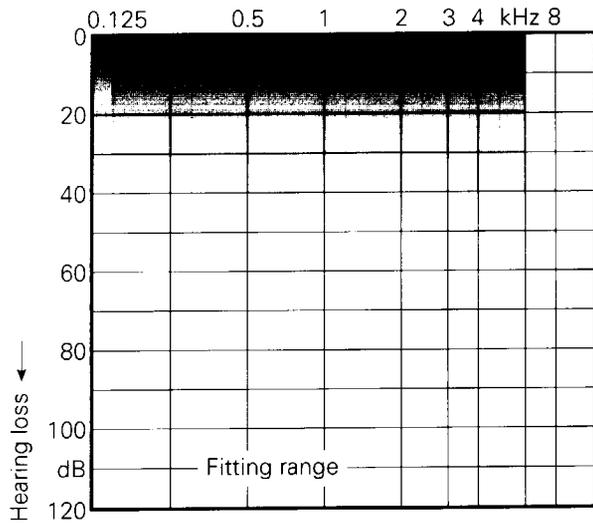
Maximum Allowable Instrument Use



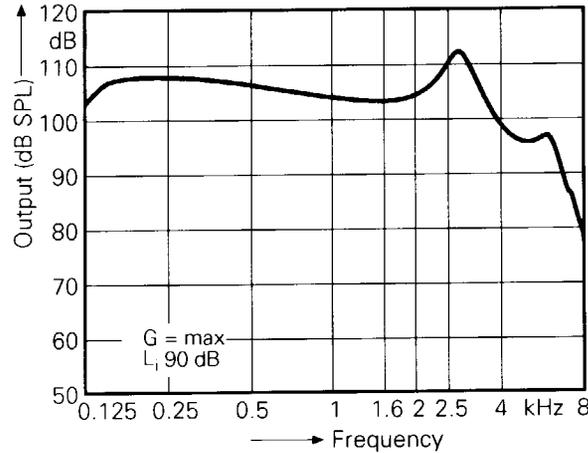
Note: Anticipated use of the In-the-Ear TCI-Combi should not reach damaging output levels. However, the output of the noise may be of sufficient intensity level to cause hearing loss if exposure is excessive. If the noise level exceeds 82 dB, which corresponds to a Noise Level of -7.5 dB in CONNEXX, 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 aid setting are shown in the above graph.

JP

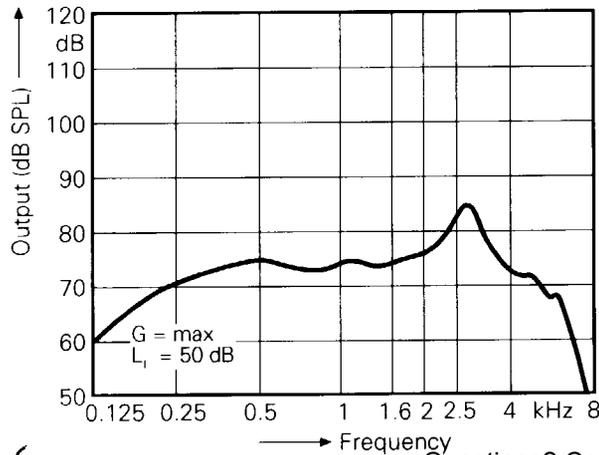
110/35/03



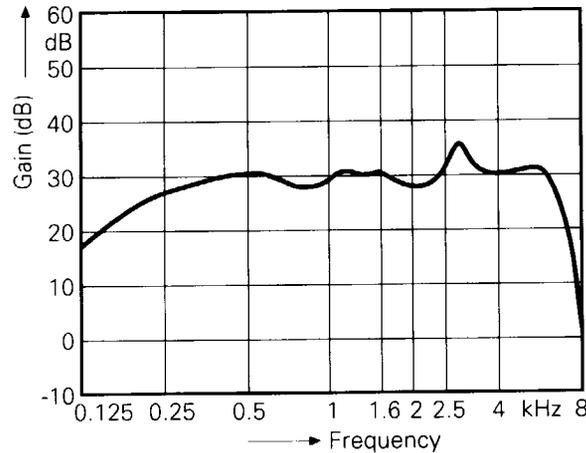
**Output Sound Pressure Level
2 cc Coupler ANSI S3.22 - 1996**



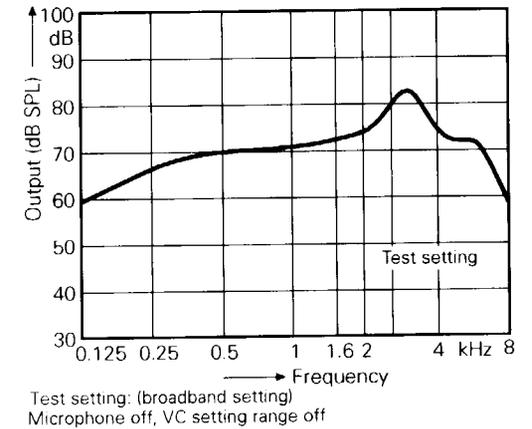
**Gain
2 cc Coupler ANSI S3.22 - 1996**



**KEMAR
Maximum insertion gain**



**Therapy Noise Characteristics
Noise in 1/3 Octave Bands - 2 cc Coupler**



SD

Hearing Instrument Technical Data

SERENITI™ TCI C

Hearing Instrument Compression Characteristics

	Type	Attack time	Release time	
Output Limiter	AGC-O	2 ms	80 ms	
Channel-AGC	Syllabic compression	5 ms	80 ms	
	Dual Compression	fast detector	2 ms	35 ms
		slow detector	135 ms	5 s

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Fitting Parameters

SERENITI™ TCI C

		Hearing Instrument				Tinnitus Therapy Noise Path				
Output limiter	Type	PC – AGC-O								
	Threshold	0 – 3 – 6 – 9 – 12 – 15 – 18 – 21								
Volume control	VC assignment	Acoustic ←				or	→ Therapy Noise			
	VC-range setting	32, 16, 8, off								
Gain	Master gain	Max: gain Reduction in 3 dB steps				Therapy Noise Level Reduction in 1.5 dB steps				
	Channel gain	1 max. gain Reduction in 3 dB steps min. gain	2 max. gain Reduction in 3 dB steps min. gain	3 max. gain Reduction in 3 dB steps min. gain	4 max. gain Reduction in 3 dB steps min. gain					
Channel-AGC	Channel Delineator					2000, 2140, 2280, 2430, 2600, 2770, 2960, 3160, 3380, 3600, 3850, 4110, 4390, 4680, 5000, off /Hz				
	Compression threshold	36, 42, 48, 54, 60, 66, 72, off	400 565 Hz	36, 42, 48, 54, 60, 66, 72, off	800 1130 1600 Hz	36, 42, 48, 54, 60, 66, 72, off	2000 2520 3200 Hz	36, 42, 48, 54, 60, 66, 72, off	off, 800, 900, 1010, 1130, 1270, 1420, 1600, 1790, 2010, 2250, 2530, 2840, 3180, 3570, 4000 Hz	High frequency shaping Corner frequency Slope Low frequency shaping
	Compression ratio	1.0, 1.3, 1.5, 1.7, 2.0, 2.4, 2.8, 3.0		1.0, 1.3, 1.5, 1.7, 2.0, 2.4, 2.8, 3.0		1.0, 1.3, 1.5, 1.7, 2.0, 2.4, 2.8, 3.0		1.0, 1.3, 1.5, 1.7, 2.0, 2.4, 2.8, 3.0		Corner frequency
	Dynamic characteristic	Dual Syllabic Compression	max. med. min. off	Dual Syllabic Compression	max. med. min. off	Dual Syllabic Compression	max. med. min. off	Dual Syllabic Compression	6, 12 dB/oct.	Slope
	Channel Coupling					6, 12, 18, off				Stopband attenuation
Adaptive Features	Voice activity detection SSP	max. med. off		max. med. off		max. med. off		max. med. off		
	Microphone noise reduction	on – off				on – off				
	Microphone	on – off				on – off				Therapy Noise Source

Test settings in bold

Subject to change without prior notice

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

Lab

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

Appendix B

User's Manual and General Information for Hearing Aid Users

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SIEMENS

Your Hearing Health Care Professional:

User's Manual for SERENITI™ Tinnitus Control
Combi Instrument with Hearing Amplification
In-the-Ear, In-the-Canal,
and Half-Shell Models



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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SHI04454-1

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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-Combi is a hearing aid with a therapy noise option. On its own, it 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.

This device has a volume control that can either be used to adjust the loudness of the hearing aid signal or the therapy noise. Your Hearing Health care Professional will set the volume control function to your preference.

In-The-Ear TCI Combi: 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.

1

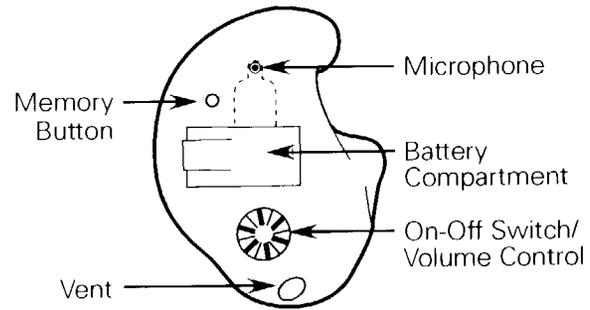
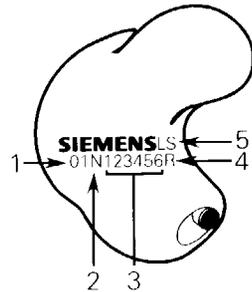
Half-Shell and In-the-Canal TCI-Combi: the output of the noiser on the custom TCI-Combi is within safe limits for noise exposure set by OSHA and poses no risk to induce or increase hearing loss in normal hearing individuals {Federal Register 448 (46) 9737-9785, March 8, 1983}.

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.

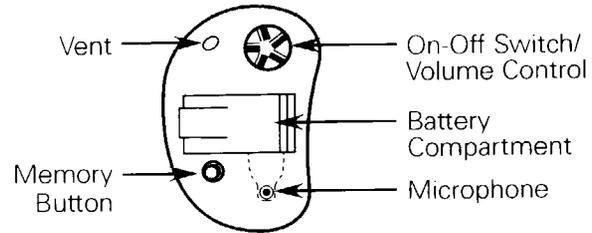
Getting Familiar with Your Instrument

The 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 In-the-Ear Instrument



Example Shown: Right Ear In-the-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.

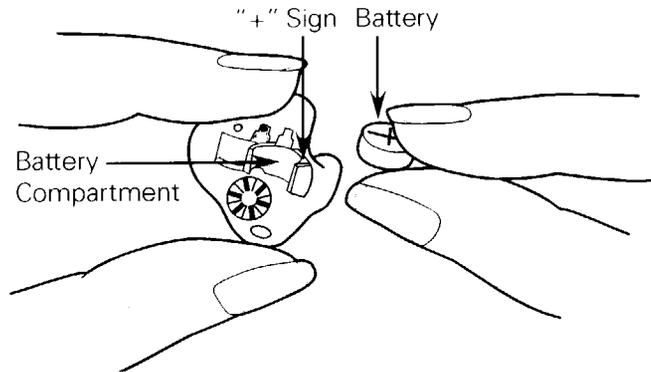
The microphone picks up sound waves and converts them to electrical signals.

CS

Using Your Instrument

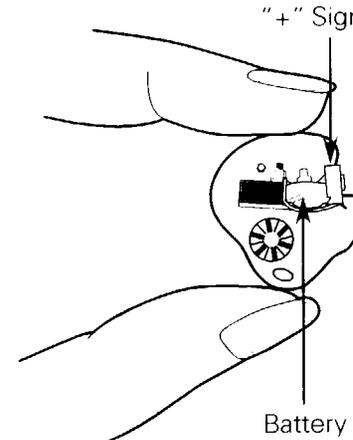
Before using your instrument, place the battery into the battery compartment. To insert the battery, hold the instrument as shown.

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 instrument in your ear be sure that it 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."



SP

Using the Memory Button

This instrument has 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.

<u>Models</u>	<u>Battery Size</u>
SERENITI™ <i>Tinnitus Control Instrument with Hearing Amplification</i>	
In-the-Ear	13
In-the-Canal	312
Half Shell	312

SIEMENS

**General
Information for
Hearing Aid Users**



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Owner Information

Hearing Aid Serial Number(s)

Left: _____ Right: _____

Hearing Aid Model(s)

Left: _____ Right: _____

Battery Size(s)

Left: _____ Right: _____

Follow Up Visits

It is very important to see your Hearing Health Care Professional for follow up care. Frequent checkups and cleaning are essential to maintain the quality performance expected of your hearing aid. Use the form below to record your visits to the Hearing Health Care Professional and any follow up care suggested.

Date of Visit: _____

Reason for Visit: _____

Comments: _____

Date of Visit: _____

Reason for Visit: _____

Comments: _____

Introduction

This brochure contains information common to all Siemens hearing aids. You have also received a user's manual which contains the instructions you need to get the best performance from the specific model hearing aid you have purchased. By following the instructions in these two brochures, you should be able to wear and care for your hearing aid satisfactorily. Make certain to read both brochures thoroughly.

Use these brochures to supplement the guidance you receive from the Hearing Health Care Professional from whom you purchased your aid. This professional can assist you with advice that addresses your individual hearing aid experience.

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1

Congratulations!



As the owner of a Siemens hearing aid, you may once again enjoy the sounds of your environment and conversation with your family and your friends.

Your decision to purchase a Siemens hearing aid reflects the importance you place on quality and reliability. With over 85 years of manufacturing experience, we have the most expertise in the world.

Siemens hearing aids have gained international recognition for their superior performance and durability.

Acclaimed by Hearing Health Care Professionals for their excellent electroacoustic characteristics, each instrument must meet strict quality assurance requirements before it leaves our premises.

Your hearing improvement with any hearing aid depends on the fit of the hearing aid, the type and degree of hearing loss, and proper diagnostic testing. Of course, no hearing aid can restore normal hearing, and not everyone can benefit equally.

Remember, each instrument is a fine-tuned device that has been specially designed and expertly adjusted for your individual needs. Please handle it with proper care.

Also, please keep in mind that learning to use your hearing aid requires a period of adjustment and patience. Just as hearing is generally not lost overnight, it may take time to get accustomed to sounds you haven't heard for a while. This period varies for each person depending on the extent of the hearing loss and individual circumstances.

Take the time to familiarize your family with your new aid and ask them to work with you and to be patient as you reenter the world of hearing.



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Meet Siemens

World leader in technology

Siemens Hearing Instruments, Inc. is a member of the Siemens worldwide group of companies specializing in electronics and electromedical products. An acknowledged leader in many fields, Siemens is the 2nd largest electronics company in the world and ranks within the top 25 of Fortune's listing of international companies.

Founded in 1847, Siemens now employs nearly 416,000 people in 190 countries. Siemens' long tradition of research continues to this day with over 46,700 employees and \$5.1 billion assigned annually to Research and Development. Presently, Siemens holds 41,000 patents, 6,300 of which are recorded in the U.S.

In fact, our contributions to the advancement of health care range from an early prototype of the in-the-ear hearing aid and the first implantable cardiac pacemaker, to pioneering innovations in diagnostic imaging and radiation therapy systems.

Your Siemens hearing aid is the result of generations of technological experience and leadership. Siemens is not only the world's largest manufacturer of hearing aids, but is also a world leader in advanced electronic health care systems that support and enhance life.

Getting the Most Satisfaction from Your Hearing Aid

- Remember, there may be sounds, both desirable and undesirable, you may not have heard for a long time. Practice ignoring sounds which, at first, may be disturbing to you.
- Practice using the aid's volume control, if present, to find a comfortable listening level.
- If, at first, you feel nervous or tired, turn your hearing aid off and rest awhile. Don't use it too long at first – proceed in easy steps, increasing its use a little each day.
- Experiment with finding a good place to sit in church, the theater, etc., where you can hear best. Don't be discouraged. It may simply be a matter of finding the proper spot in order to hear more clearly in the sounds surrounding you.
- Learn to concentrate more fully on the conversations of persons around you.
- Do listen to radio or television right away since these are electronic instead of natural sounds. Continuous use of your hearing aid should improve your listening ability.
- Don't be frustrated by words that are not clear to you. Increased hearing aid use should improve your ability to hear and understand.

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- Focus on reading lips. This can be very helpful during early stages of hearing aid adjustment.
- Ask persons with whom you are conversing to attract your attention before speaking to you.
- To improve clarity and enunciation, ask people to speak slowly.
- Converse with only one person at a time initially, until you feel comfortable using your hearing aid in group conversation.
- Encourage one person to speak at a time when engaging in group conversations.

Battery Tips

- **CAUTION!** Batteries can be harmful if swallowed. Be sure to keep batteries out of the reach of small children or persons of diminished mental capacity. Batteries can often be mistaken for medication due to their small size.
- If a battery is accidentally swallowed, seek medical attention immediately, or call The National Button Battery Hotline collect at **202-625-3333**.
- Always use the battery size recommended on your warranty card or in the specific manual for your model for best performance.
- Remove the battery from your aid when not in use. This prevents possible damage from expansion or leakage of the battery, if the aid is not fully turned off.
- Always carry spare batteries in the event that your current battery goes dead. Place each spare battery in an individual, non-metallic container to prevent contact with other batteries or metal objects, such as keys or coins.
- Follow your local recycling rules for battery disposal.

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Maintenance and Care

The hearing aids need to be cleaned daily. You can wipe them with a tissue or a soft cloth.

Always store your hearing aid (and earmold if it's a BTE model) inside its case. A soft carrying pouch is also included for your convenience when traveling.

When storing the hearing aid for an extended period of time, always remove the battery to prevent damage from corrosion.

Store the aid in a dry area, preferably at room temperature. If you perspire heavily or live in an area of high humidity, you may find it beneficial to use a dry-aid kit when the aid is not in use. This product can be purchased from your Hearing Health Care Professional.



Do not let your hearing aid get wet.



Do not expose your hearing aid to excessive moisture or heat.



Be careful to avoid physical shock, such as dropping the aid on the floor.

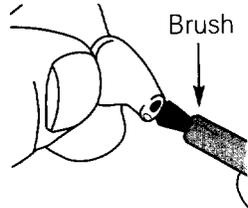


Do not use hair spray while wearing your hearing aid.

Wax Cleaning Brush

A wax cleaning brush may be packaged with your hearing aid.

To use this tool, hold the hearing aid so that the canal portion (the open end which is inserted into the ear) faces downward, and any wax particles fall away from the opening. Gently sweep the brush across the canal opening where most of the wax collects. Be careful not to push any wax further into the tubing at the end of the hearing aid. Wash the brush and dry it thoroughly before each use.



Do not insert either end of the tool into the opening or into your ear canal.

Wax Guards

Some hearing aids feature external or internal wax guards which help protect the aid from damage due to ear wax. Ask your Hearing Health Care Professional if your aid is equipped with a wax guard. They will also instruct you on the proper cleaning procedure.

Warranty and Service

Your hearing aid, with the exception of the battery (and earmold if it's a BTE model), is covered by a one year warranty against loss or defects in material and workmanship from original date of purchase. All covered aid parts received for

warranty service at the Service Center will be repaired or replaced with new or reconditioned components, without charge, to meet the performance specifications for that model.

This warranty only applies to original factory manufactured aids and does not cover used or rebuilt units.

Warranty service must only be performed by an authorized Siemens Service Center. Improper service performed by unauthorized service depots voids this warranty and repairs so necessitated will be done on a parts and labor cost basis.

This warranty does not cover malfunctions due to unusual wear and tear or mistreatment of the aid such as physical shock, excessive wax build-up, or tampering with the aid, any of which voids all warranties. Loss coverage is one time only, regardless of length of warranty coverage. (Please note that your Hearing Health Care Professional may charge a service fee for processing warranty coverage.)

Procedure

In case of malfunction or loss, take your Siemens hearing aid and proof of purchase to the Hearing Health Care Professional from whom the unit was purchased. If factory service or replacement is needed, your Hearing Health Care Professional will forward the unit to an authorized Siemens Service Center.

Extended Warranty Programs

Siemens offers extended warranty and service programs for your hearing aids. Please consult with your Hearing Health Care Professional for more details on these programs.

IMPORTANT

This warranty gives you specific legal rights and you may have other rights which may vary from location to location. For more information contact your local or state Department of Consumer Affairs.

Using the Telephone

You may use the telephone in a natural manner. If you get a whistling sound (feedback), tilt the phone receiver away from your ear and/or reduce the volume until the whistling stops. By trying various positions of the telephone receiver, you will discover what works best for you.

T-Coil

Your hearing aid may be equipped with a T-Coil (tele-coil) switch, a special circuit designed to improve your hearing when using the telephone. Ask your Hearing Health Care Professional how to adjust it during phone use.

Please note that it requires your phone be hearing-aid compatible. Check with your phone's manufacturer for more information.

Important Notices

Binaural Amplification

Nature gave us two ears for a reason. Binaural amplification (the wearing of two hearing aids) is recommended to provide the full benefits of amplification.

With two aids, sound signals are received by both ears for improved clarity, a sense of direction and more balanced sound. You will be more relaxed because there is less strain on one ear to hear all sounds.

Unfortunately, when volume is turned up on a single aid to improve hearing, the sound is not only louder but can become more distorted. Binaural amplification usually overcomes this problem, providing greater understanding, as well as hearing. If you wish to try two hearing aids, ask your Hearing Health Care Professional about the possibility at your next checkup.

Children with Hearing Loss

In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist, since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

Important Notice for Prospective Hearing Aid Users

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists.

The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid.

The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation.

The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid to your individual needs. If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program.

Many hearing aid dispensers now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee, after which you may decide if you want to purchase the hearing aid.

Only those fully informed adults who have either obtained medical evaluation from a licensed physician or signed a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician, may purchase a hearing aid. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

Warning to Hearing Aid Dispensers

A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid dispenser determines through inquiry, actual observation or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

- Visible congenital or traumatic deformity of the ear.
- Acute or chronic dizziness.
- History of active drainage from the ear within the previous 90 days.
- History of sudden or rapidly progressive hearing loss within the previous 90 days.

- Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- Audiometric air-bone gap equal to or greater than 15 decibels (dB) at 500 Hertz (Hz), 1000 Hz, and 2000 Hz.
- Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- Pain or discomfort in the ear.

Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels (dB), because there may be risk of impairing the remaining hearing of the hearing aid user.

A hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions.

The use of a hearing aid is only part of hearing rehabilitation and may need to be supplemented by auditory training and instructions in lip reading. Consistent use of the aid is recommended. In most cases, infrequent use does not permit the wearer to attain full benefit from it.

Troubleshooting Guide for Hearing Aids

PROBLEM	CAUSE	POSSIBLE SOLUTION
Aid has no sound or sound is weak	Battery polarity reversed	Make sure battery is inserted correctly
	Weak or dead battery	Replace with fresh battery
	Aid not turned on	Rotate volume control to "on," put switch to "M" position, or close battery door completely ■
	Aid clogged with wax	Clean aid ●
	Volume too low	Turn up volume control ●
Aid whistles	Improper seating in ear	Try reinserting the aid until it fits securely
	Volume control too high	Lower volume control ●
	Clogged with wax or excessive wax in your ears	Clean aid or consult your Hearing Health Care Professional
Sound is distorted or intermittent	Volume control too high	Lower volume ●
	Weak battery	Replace battery
"Buzzing" or "Motorboating" sound	Battery compartment is not completely closed	Gently close the battery compartment
	Weak battery	Replace battery

- These solutions depend on the model.
- May also need to consult your Hearing Health Care Professional.

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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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Protected by one or more of the following patents and other U.S. and Foreign patents pending 5,915,031; 4,953,215; 4,689,818; 5,710,820; 5,606,621; 5,448,644; 4,987,597; 5,835,606; 4,947,433; 5,799,095; 4,750,207; 5,404,408; 5,835,611; 5,912,977; 4,845,757; 5,796,848; 5,724,431; 5,654,530; 5,613,008; 5,524,150; 5,378,933; 4,852,175; 4,815,140; 5,708,720; 5,341,433; 5,265,168; 5,768,397; 4,763,752; 5,875,254; 5,889,874

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SHI/04207-1

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Appendix C

Documentation of Product Software Review

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

SIEMENS

**Audiologische Technik GmbH
Gebbertstr. 125
D-91058 Erlangen**

R & D / AES

Phone No.: +49 / 9131 / 308 – 323

Fax No.: +49 / 9131 / 308 – 406

e-mail joerg.bindner@med.siemens.de

Jörg Bindner

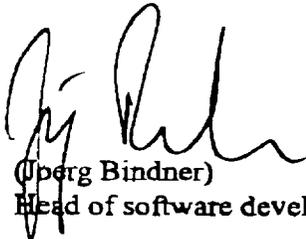
Date: March 27, 2001

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

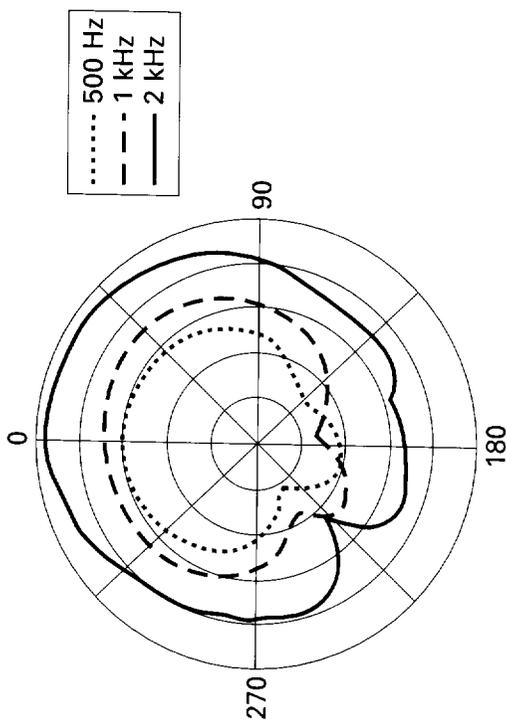


Appendix D

Technical Specifications of Predicate Devices

KEMAR

TwinMic™ System



Directional characteristic

Directional microphone switchable by pushbutton.
Program 1 : omnidirectional mode
Program 2: directional mode (default setting)

Siemens Hearing Instruments, Inc.

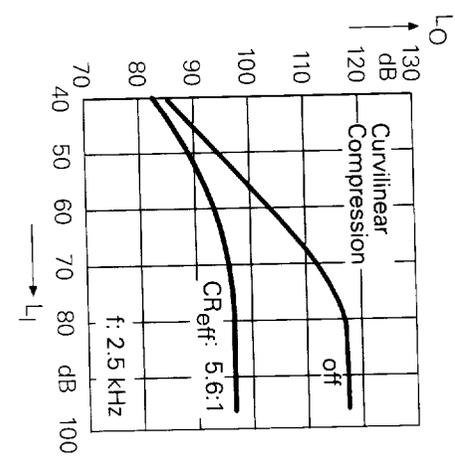
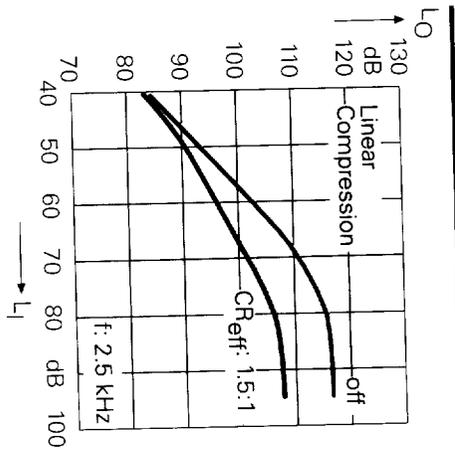
Northeast/US HQ: P.O. Box 1397, Piscataway, NJ 08855-1397
847-562-6600 or 800-766-4500 <http://www.siemens-hearing.com>
South: 770-422-4540 or 800-922-9998 West: 562-404-4531 or 800-998-9787
Midwest/Professional Products: 847-808-1200 or 800-333-9083
Southwest/All-Make Repair: 281-875-8060 or 800-255-6253

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320 Pinebush Road, Cambridge, Ontario, Canada N3C 2V3 • 519-622-5200 or 800-663-0620

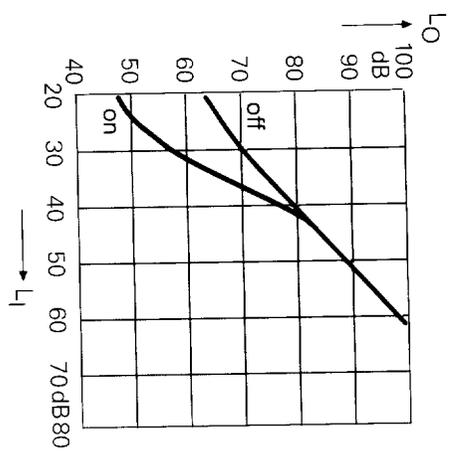
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Linear and curvilinear compression characteristics (examples)

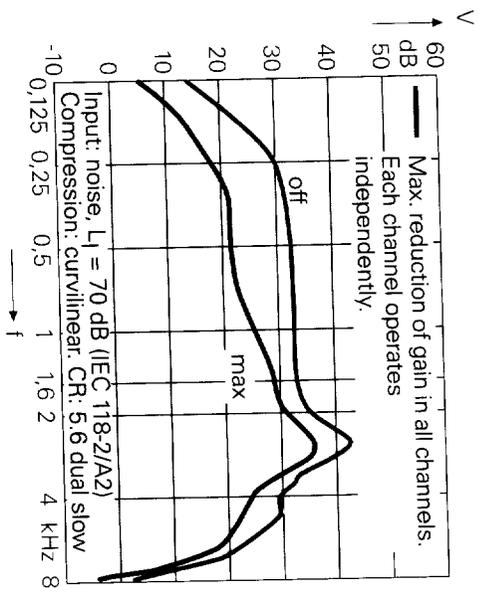


The ratio of the input level difference between 40 and 90 dB to the respective output level difference is called: Effective compression ratio CR_{eff}.

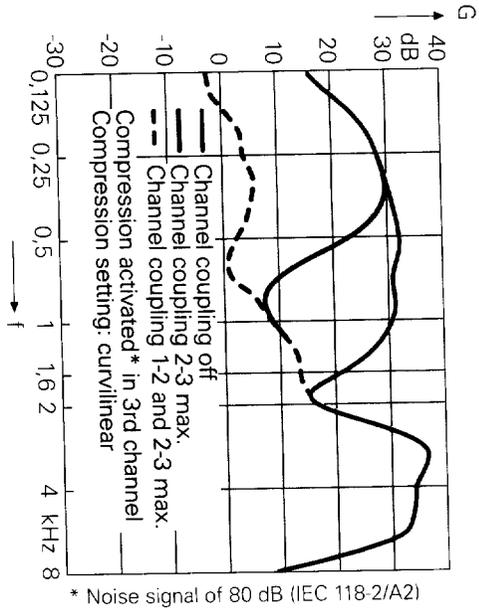
Microphone noise reduction



Voice Activity Detection



G Cross channel coupling

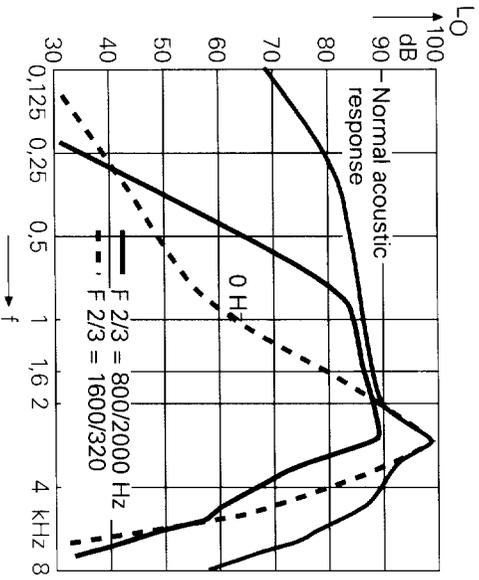


72

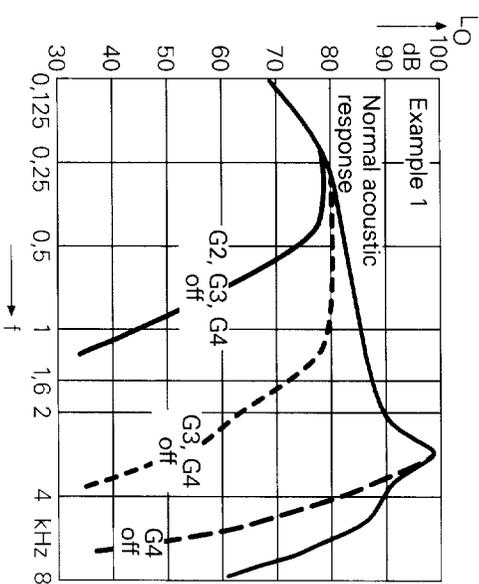
23

High-resolution frequency response shaping

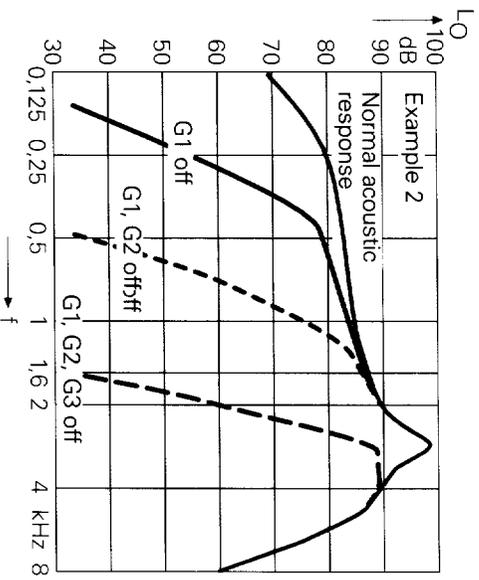
Effect of channel delineator



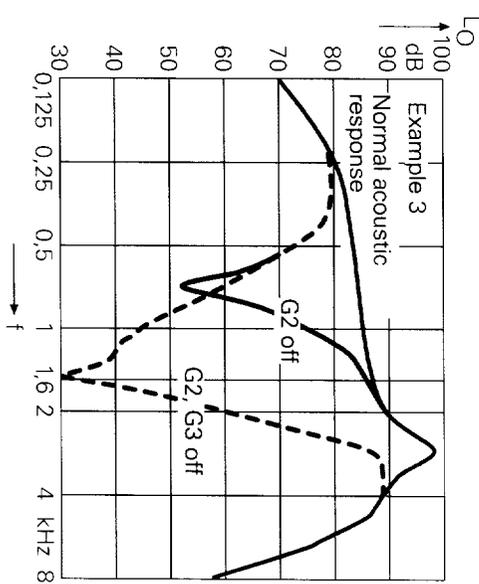
Gain control for separate channels



Gain control for 4 separate channels



Gain control for 4 separate channels



Sample Data Set

PRISMA

74

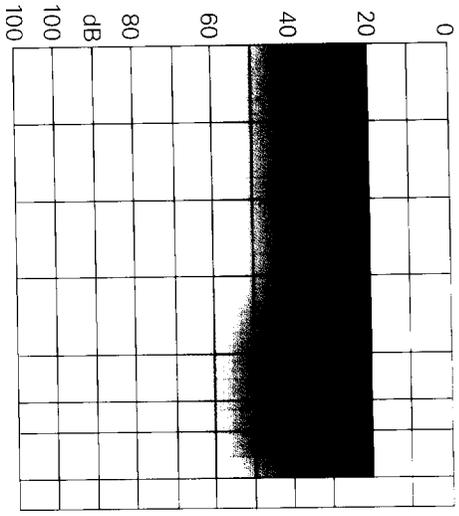
**These measurements were produced with:
PRISMA ITE 118/50/03**

PRISMA

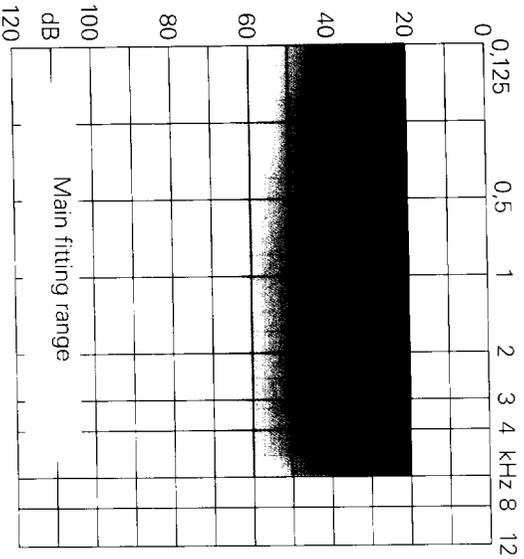
MC/CIC

PRISMA

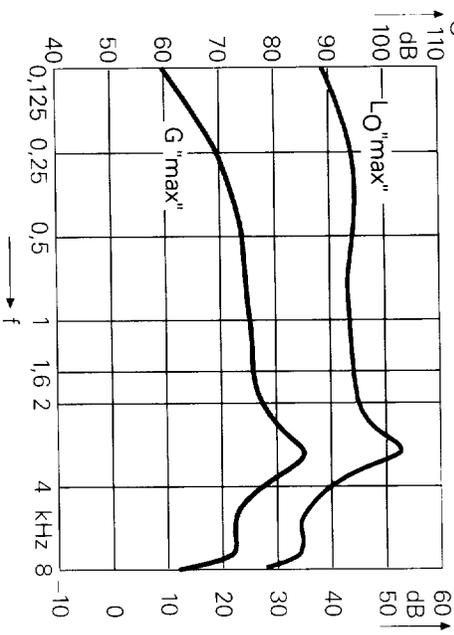
103/35/00



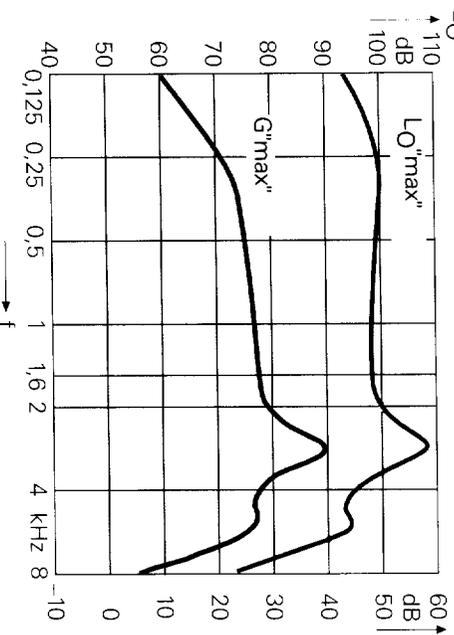
108/40/00



2 cc coupler ANSI S3.22 - 1987



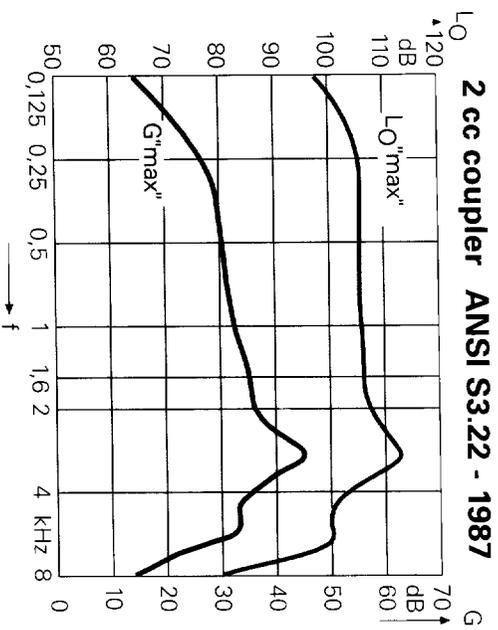
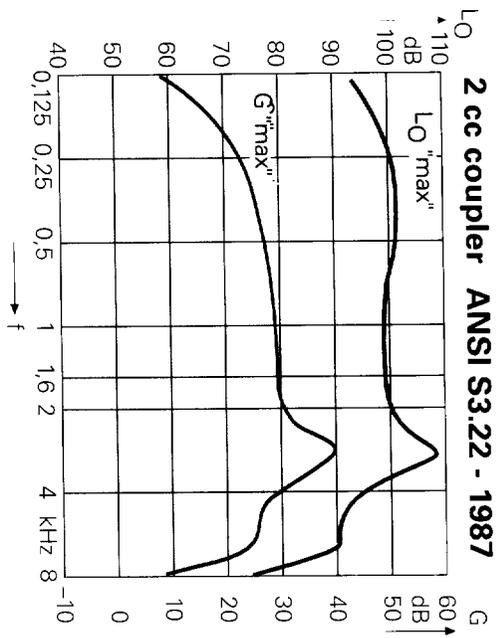
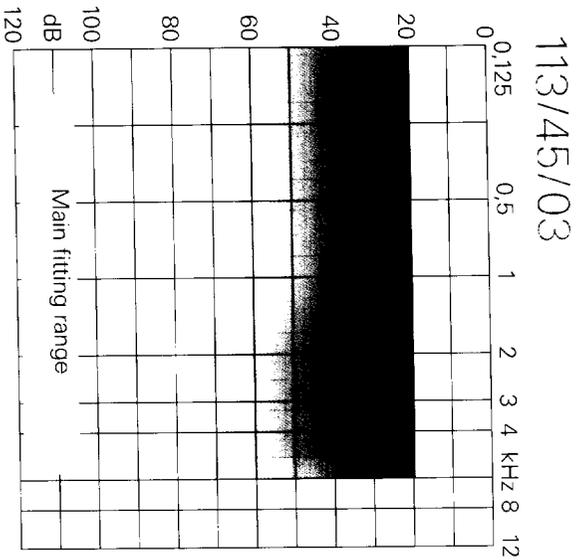
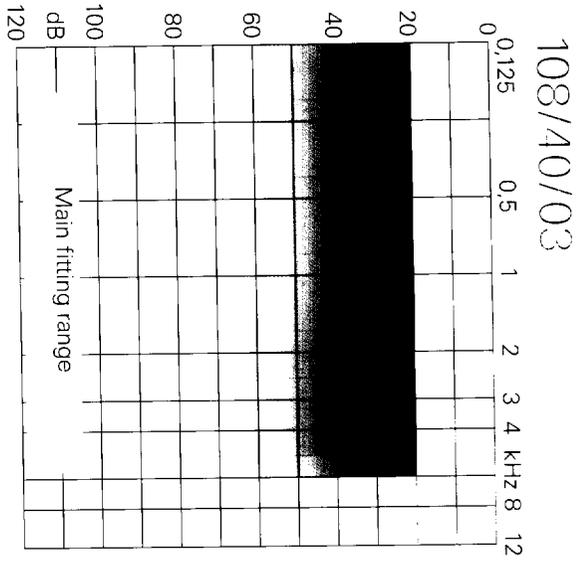
2 cc coupler ANSI S3.22 - 1987



MS

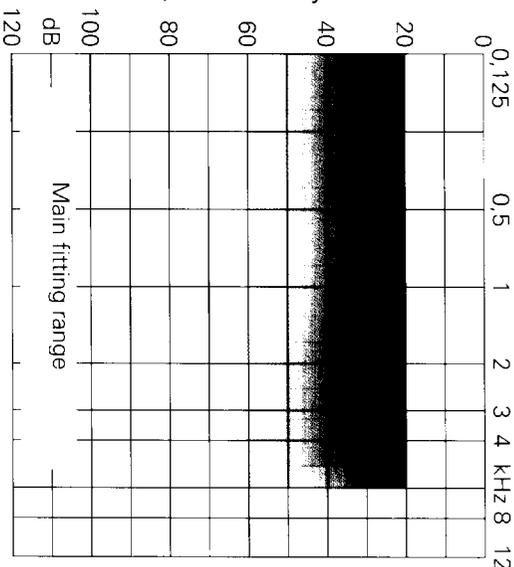
HS/ITC

PRISMA

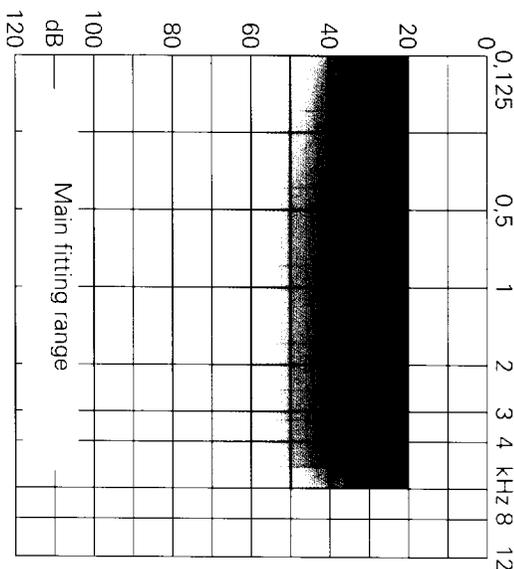


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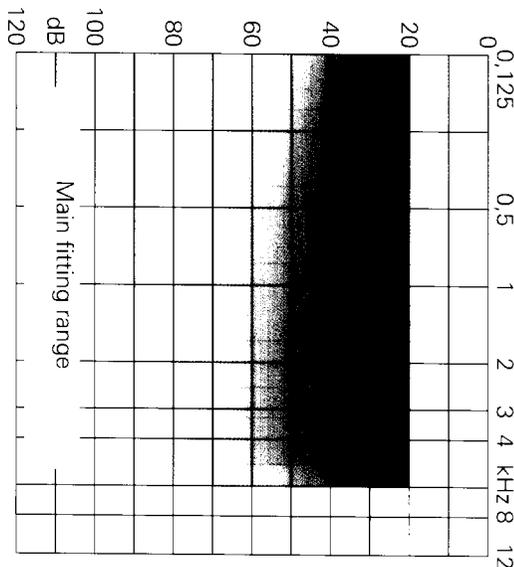
108/40/03



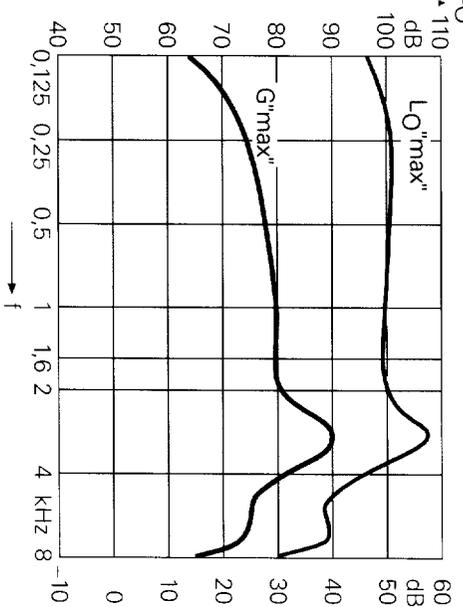
113/45/03



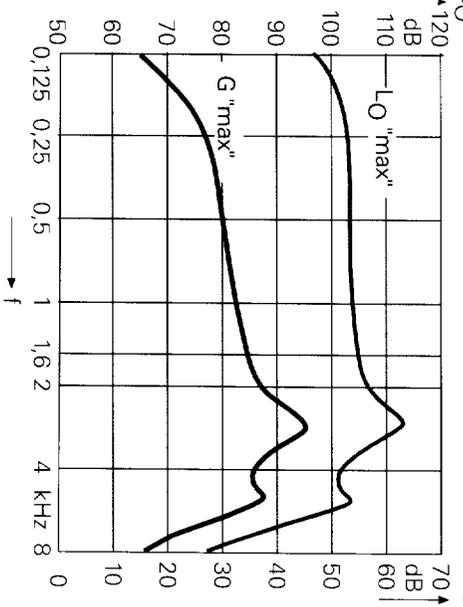
118/50/03



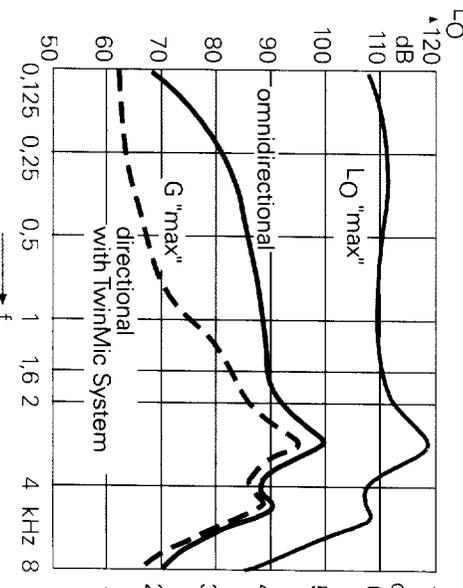
Zcc coupler ANSI S3.22 - 1987



Zcc coupler ANSI S3.22 1987



Zcc coupler ANSI S3.22 1987



Matrix and Fitting Range

PRISMA

**Unless otherwise stated:
Measurements were performed
using the test mode settings**

Summary of Signal Processing Features

PRISMA

Cross Channel Shaping: reduction at low frequencies: off - 1600 - 2000 - 2800 - 4000 Hz
 reduction above 3000 Hz: off - on

Master gain : max reduction in 3 dB steps

Channel 1

Gain: max reduction in 3 dB steps

Compression: off
 (Crossover frequency, F)

1	2	3
<input type="checkbox"/> off	curvi-linear	linear
	5.6	3.1
	3.8	2.5
	2.8	2.0
	2.2	1.7
	1.7	1.5
	1.5	1.3
	1.3	1.2
	1.1	1.1
	1.0	1.0

Compression method:

syllabic compression
 dual compression slow
 dual compression fast

Voice activity detection: off
 min
 med
 high
 max

Channel 2

Gain: max reduction in 3 dB steps

Compression: off
 (Crossover frequency, F)

1	2	3
<input type="checkbox"/> off	curvi-linear	linear
	5.6	3.1
	3.8	2.5
	2.8	2.0
	2.2	1.7
	1.7	1.5
	1.5	1.3
	1.3	1.2
	1.1	1.1
	1.0	1.0

Compression method:

syllabic compression
 dual compression slow
 dual compression fast

Voice activity detection: off
 min
 med
 high
 max

Channel 3

Gain: max reduction in 3 dB steps

Compression: off
 (Crossover frequency, F)

1	2	3
<input type="checkbox"/> off	curvi-linear	linear
	5.6	3.1
	3.8	2.5
	2.8	2.0
	2.2	1.7
	1.7	1.5
	1.5	1.3
	1.3	1.2
	1.1	1.1
	1.0	1.0

Compression method:

syllabic compression
 dual compression slow
 dual compression fast

Voice activity detection: off
 min
 med
 high
 max

Channel 4

Gain: max reduction in 3 dB steps

Compression: off
 (Crossover frequency, F)

1	2	3
<input type="checkbox"/> off	curvi-linear	linear
	5.6	3.1
	3.8	2.5
	2.8	2.0
	2.2	1.7
	1.7	1.5
	1.5	1.3
	1.3	1.2
	1.1	1.1
	1.0	1.0

Compression method:

syllabic compression
 dual compression slow
 dual compression fast

Voice activity detection: off
 min
 med
 high
 max

Mic noise reduction channel 1 and 2: off - on

Mic noise reduction channel 3 and 4: off - on

Twin Mic System: omnidirectional directional

Matrix Operating Current Options

Peak / Peak /
Output / Gain / Slope



ITE

118/50/03	1.00mA	TwinMic™ system with
113/45/03	0.95mA	2nd memory (includes program button)
108/40/03	0.80mA	2nd memory only (includes program button)



ITC/HIS

113/45/03	0.95mA	2nd memory (includes program button)
108/40/03	0.80mA	



MC/CIC

108/40/00	0.85mA	
103/35/00	0.80mA	

Dual and syllabic compression

Type	Attack time	Release time
Syllabic compression	5 ms	100 ms
Dual Compression (slow) ¹⁾		
fast level detection	5 ms	50 ms
slow level detection	500 ms	5000 ms
Dual Compression (fast) ²⁾		
fast level detection	1 ms	50 ms
slow level detection	500 ms	5000 ms

1) Used with voice activity detection
2) not possible with voice activity detection

Voice Activity Detector

Attack time	8 -12 s
Release time	500 ms

Microphone Noise Reduction System

Attack time	32 ms
Release time	7 ms

Prisma Technical Data Important information regarding the data contained in this guide:

PRISMA contains an assortment of adaptive signal processing features. These features will interact in a complex manner that depends upon the setting and test conditions.

Careful consideration should always be given to the set up of PRISMA signal processing and test conditions. This is especially important when interpreting the results measured on the typical equipment found in most dispensing practices.

The ability to verify functionality is important, however, for quality control practices. Siemens has added an important feature to PRISMA that permits the hearing health care professional to test the basic functionality of PRISMA using standardized test equipment against standardized test protocols.

The test mode, selectable from the CONNEX fitting menu, configures PRISMA for full on gain, no compression and all adaptive signal analysis and processing turned off.

While this mode will probably not be used by the hearing impaired consumer, it does provide a benchmark for assessing PRISMA, using existing test equipment and performance standards. It also permits the product to be explained using classic matrix definitions.

Unless stated otherwise, the data shown in this guide is the static response of PRISMA to sinusoidal swept tones. This data does not represent the complex adaptive signal types, or the additive effects of combinations of multiple signal processing algorithms.

PRISMA combines fully digital signal processing with multi-channel capability, multiple memories, and wearer controlled directional microphone technology.

PRISMA is the digital hearing aid with the most advanced microchip technology.

- **150,000 calculations per second** - the fastest digital signal processing in a hearing instrument
- **High Resolution A/D conversion** using 640,000 samples per second and 3rd order modulator for reduced quantization noise
- **32 bit digital processing** for improved dynamic range and minimizing noise
- **0.5 micron technology** for a small package
- **Low current consumption**, as low as 0.8mA.
- **Fully Digital Output stage** that eliminates the need for D/A converter for reduced battery consumption and reduced size.
- **Full range of design style** - ITE, HS, ITC, MC, CIC
- **18,000,000,000,000,000, possible settings** for flexibility in fitting a wide range of hearing loss
- **TwinMic switchable directional microphone system** on the ITE model for spatial noise reduction
- **Integrated multilevel fitting system using CONNEXX, and open access to all signal-processing features. The PRISMA product guide contains a detailed description of these performance enhancing features:**
 - 4 channels with three adjustable cross over frequencies
 - Master gain and independent gain control in each channel
 - Cross Channel frequency reponse shaping
 - Selectable compression algorithms that determine the frequency, amplitude and temporal characteristics for compression in each channel
 - Selectable Voice Activity Detection in each channel affords enhanced signal processing
 - Inter-band communication through Cross Channel Coupling
 - Microphone Noise Reduction System

SIEMENS

PRISMA™

Technical Information
Custom Hearing Instruments

01071000

01071000

PRISMA™

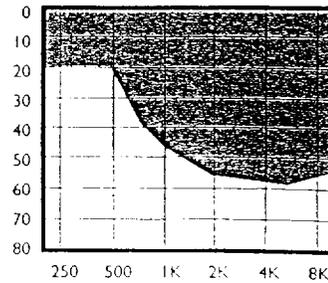
TRANQUIL™

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

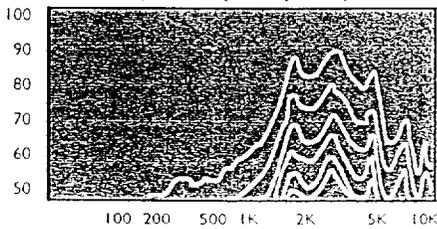


All thresholds need not fall within the shaded area.

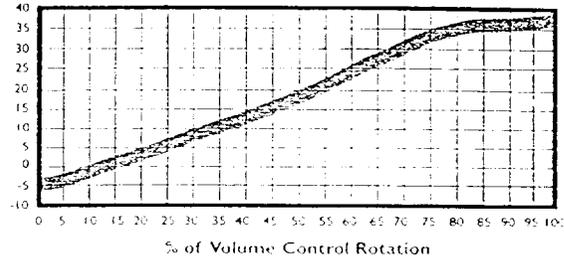
Typical Output ... RMS 75 dB SPL

Battery Drain ... 0.4 - 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 ear shell design incorporating a 10A battery and small retention arms to properly direct the receiver and keep the inferior external ear canal open.



OPEN EAR

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

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

Bibliography

Baguly, D. M., McFerran, D. J. (1999) Tinnitus in childhood. *International Journal of Pediatric Otorhinolaryngology* **49**: 99-105.

Bauman, N. (1998) Tinnitus...Old Problem, New Treatment. *Hearing Health* September-October.

Jasterboff, P. J., Hazell, J. W. P. (1993) A neurophysiological approach to tinnitus: clinical implications. *British Journal of Audiology* **27**: 7-17.

Mueller, H. Gustav, Hall, James W. (1998) *Audiologists' Desk Reference Volume II*. Singular Publishing Group Inc., San Diego.

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