

K003559

APR 26 2001

510(K) Summary for the Siemens TCI

REVISED 4/16/01

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:** TCI (Tinnitus Control Instrument)

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

Product Code: **KLW**

5. **Establishment Registration Number:** 2217809

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

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

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

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

10. **Indications for Use:**

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

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

11. **Description of Device:**

TCI is a fully digital, low-level noise generator that was developed to be used along with appropriate counseling and/or tinnitus therapy. This product is programmable, with four selectable noises and variable output level. The output noise can be custom-tailored to the user's individual requirements. The unit is housed in a conventional behind-the-ear case.

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

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

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

	Siemens Hearing Instrument TCI Device	General Hearing Instruments Tranquil Tri OE
Intended Use	Mask tinnitus as part of tinnitus management program	Mask tinnitus as part of tinnitus management program
Target Population	Adults and children (≥ 5 years) with tinnitus that are participating in a tinnitus management program	Adults with tinnitus that are participating in a tinnitus management program
Operation Circuit type Programmable Available noises Volume control	Digital Yes Four Yes	Analog No One Yes
Physical Description	Standard behind-the-ear instrument housing	Custom in-the-ear product
RSM Output Characteristics White noise Pink noise Speech noise High-tone noise	71 dB SPL 69 dB SPL 69 dB SPL 76 dB SPL	75 dB SPL
Volume control range	Programmable: OFF, 8 dB, 16 dB, 32 dB	40 dB

TCI Comparison with Predicate Device

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

Risks:

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 TCI will only be conducted through a Hearing Healthcare Professional, such as an audiologist or otolaryngologist.

Benefits:

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

Warnings for Safe Use:

As this device cannot deliver damaging sound intensity, no warning is required about sound output level. General use precautions are given in the User's Manual.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 26 2001

Mr. Dave Slavin, Director
Quality Assurance and Regulatory Affairs
Siemens Hearing Instruments
10 Constitution Avenue
P.O. Box 1397
Piscataway, NJ 08855

Re: K003559
Trade Name: TCI (Tinnitus Control Instrument)
Regulatory Class: II
Product Code: KLW
Regulation: 21 CFR 874.3400
Dated: February 20, 2001
Received: February 22, 2001

Dear Mr. Slavin:

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

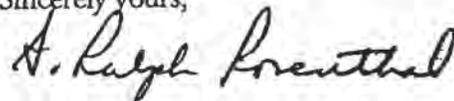
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Mr. Dave Slavin, Director

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,

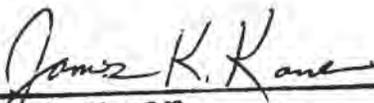


A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

10. Indications for Use:

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



(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003559





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 26 2001

Mr. Dave Slavin, Director
Quality Assurance and Regulatory Affairs
Siemens Hearing Instruments
10 Constitution Avenue
P.O. Box 1397
Piscataway, NJ 08855

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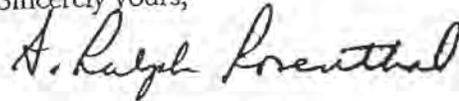
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Sincerely yours,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
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Center for Devices and
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10. **Indications for Use:**

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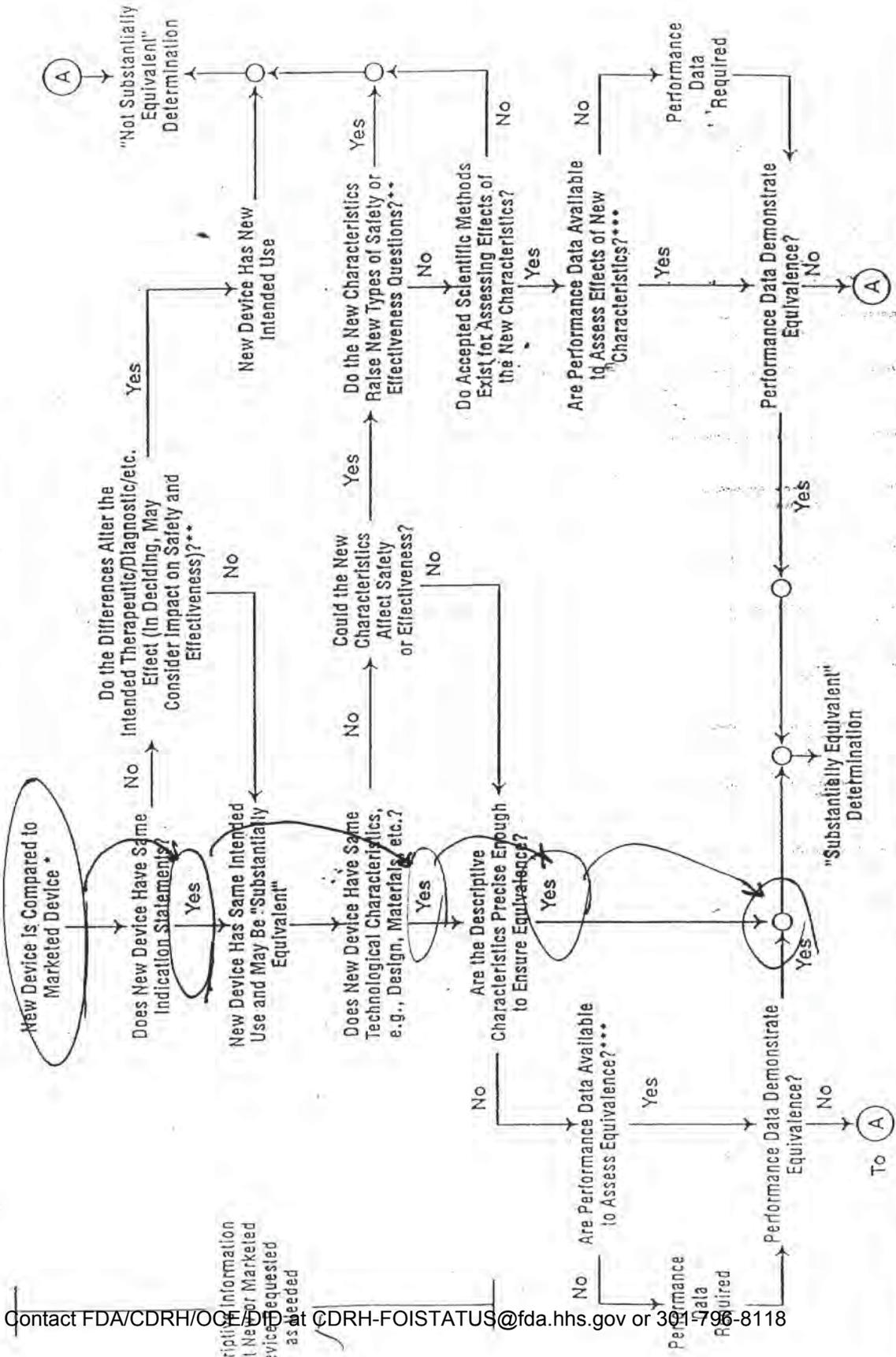
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(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003559



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



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

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

Center for Devices and Radiological Health

(ODE/DOED/ENTB)

Memo

To: The Record
CC:
From: James K. Kane, Ph.D.
Date: 4/11/01
Re: K003559/S1 (TCI)

I phoned Dave Slaven, Regulatory Affairs, Siemens Hearing Instruments, Inc. this date and left a message stating that the current 510(k) Summary references "Sections" that are not a part of the Summary, that this was not acceptable format, and that the Summary, therefore, needs to be modified by either eliminating the references or by including the referenced information within the Summary. Secondly, the last sentence in the 2nd paragraph, Section 2, Page 1, states that, "...the clinical efficacy of this device with children has not been proven." This sentence needs to be rewritten to indicate that current efficacy data is based on subjective reports, not objective data. If he has any questions, he is to contact me for clarification.

The issue of a disconnect between the sponsor stating that no efficacy data exist for tinnitus masking in children but my recommending approval of the sponsor's 510(k) was raised by and discussed with Dave Whipple on 4/9/01. The issue, however, is not that there are no efficacy data, but, rather, that all tinnitus masking efficacy data (for both children and adults) is based on subjective reports of benefit, not objective data. The perception of tinnitus, a phantom sound in the head, is purely subjective and, to date, no objective methodology is available to prove or disprove its existence. Therefore, tinnitus treatment effects, regardless of methodology (e.g., medication, counseling, masking,) necessarily are based on subjective reports of benefit as well.


James K. Kane, Ph.D.
Scientific Reviewer/Audiology

4/11/01
Date

Center for Devices and Radiological Health

(ODE/DOED/ENTB)

To: The Record
From: James K. Kane, Ph.D.
Date: March 19, 2001
Through: James F. Saviola, O.D.
Branch Chief, VEDB
Acting Chief, ENTB
Re: K003559 /S1 Review Summary
Product Code: 77 KLW (Tinnitus Masker)

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

Document #: K003559
Company Name: Siemens Hearing Instruments
Contact Person: Dave Slavin
Device Name: TCI (Tinnitus Control Instrument)

CLASSIFICATION NAME: Tinnitus Masker

COMMON NAME: Tinnitus Masker

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

K974751 Tranquil Tri-OE General Hearing Instruments

INTENDED USE STATEMENT: The TCI is a behind-the-ear style electronic, air-conduction broadband-noise generator intended to generate noise of sufficient intensity and bandwidth to be used for tinnitus habituation therapy and is also suitable for tinnitus masking therapy. TCI is intended to be used by those individuals who experience tinnitus, and do not need or desire amplification. The intended use of this device includes it's fitting by a qualified audiologist or other hearing healthcare professional familiar with the diagnosis of tinnitus and subsequent rehabilitation therapies.

The target population is primarily the adult population over 18 years of age. This product may also be used with children five (5) years of age or older.

	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 - SE
8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?		- IF YES, STOP - NE
9. ACCEPTED SCIENTIFIC METHODS EXIST?		- IF NO, STOP -NE
10. PERFORMANCE DATA AVAILABLE?		-IF NO, REQUEST DATA
11. DATA DEMONSTRATE EQUIVALENCE?		FINAL DECISION

SUBMISSION PROVIDES:

Comparative Specifications:	YES
Comparative Lab Data:	N/A
Summary of Animal Testing:	N/A
Summary of Clinical Testing:	N/A
510(K) Summary:	YES

GENERAL INFORMATION SUMMARY:

Life-Supporting or Life-Sustaining:	N/A
Is it an Implant? (Long Term or Short Term)	NO
Software Driven:	YES
Level of Concern	
Certification	LOW

Sterility:	N/A
Single Use:	YES
Home or prescription use:	YES
Drug or Biologic product:	NO
Device a kit:	NO

Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Provide a summary about the device design, materials, physical properties and toxicology profile if important.

Device Description:

The TCI is a fully digital, low-level noise generator that was developed to be used along with appropriate counseling and / or tinnitus therapy. TCI is meant to be used by those individuals with symptoms of tinnitus, but with hearing sensitivity within-normal-limits. This product is programmable, with an 8-channel equalizer, and allows the signal to be custom-tailored to the user's individual requirements. A choice of four, noise-types (hightone, white, pink, speech) are available for selection, but a maximum of two types can be programmed into device memories. Within-channel gain is limited to 81 dB for any of the noises.

The technical specification sheets state that the device is digitally programmable via the sponsor's proprietary software fitting system (CONNEXX). This software is used for programming all of the sponsor's hearing instruments and has been in commercial use for several years.

The particular masker noise stored in memory may be selected via a "program switch" by the user.

B. Device Materials and Toxicity

No new materials are being proposed. All components are commonly used by the hearing aid industry.

The sponsor states that there are no risks associated with this device because the output noise intensity does not exceed OSHA exposure limits (OSHA Regulation 1910.95: Occupational Noise Exposure). Therefore, the device poses no risk to induce hearing loss.

C. Comparative Specifications

The sponsor stated that the TCI is substantially equivalent to the General Hearing Instruments Tranquil Tri-OE, a tinnitus masking device. The sponsor noted that the Siemens device was a programmable digital product, which provided greater flexibility than the Tranquil. Detailed comparative data are provided in Table 2 (Section 7).

D. Physical Properties and Performance Testing

The sponsor did not cite any specific performance standards in this submission because none exist for tinnitus maskers.

E. Clinical Testing

N/A

F. Sterilization

N/A

G. Device Labeling

The labeling supplied by the sponsor included draft "Preliminary Technical Information for Tinnitus Control Behind-the-Ear Instruments" and a "User's Manual for SERENTI Tinnitus Control Instrument (TCI). The manual described tinnitus, discussed appropriate use of the device, and noted that the output noise levels were not sufficient to induce hearing loss in normally-hearing individuals. They also noted (Section 2, Page 1; User's Manual, Page 1) that while some hearing health professionals (e.g., audiologists, otolaryngologists) recommend use of this type of device with children age five years or older, the clinical efficacy of tinnitus maskers with children has not been proven.

H. 510 (k) Summary

A 510(k) Summary included necessary information to demonstrate that the device is similar in its intended use to the predicate device. The primary differences between the two devices lie in the physical descriptions and differences between analog and digital technology. The TCI digital device permits greater flexibility noise-types and adjustment of relevant parameters.

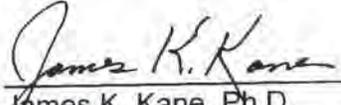
RECOMMENDATION:

The device, TCI (Tinnitus Control Instrument), is substantially equivalent to the predicate device cited above. No additional questions / concerns regarding safety and / or effectiveness of this device were noted during review of this applicant's (Siemens Hearing Instruments) Premarket Notification (510(k)

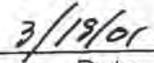
CFR# 874.3400

Product Code 77-KLW

CLASS II



James K. Kane, Ph.D.
Scientific Reviewer/Audiology



Date

SIEMENS

Siemens Hearing Instruments
10 Constitution Avenue
Piscataway, NJ 08855

732/562-6600
732/562-6696 (fax)

Fax

To: James Kane, Ph.D., FDA
Center for Devices & Radiological Health
Office of Device Evaluation

From: Therese M. Velde

Fax: 301-480-4201 **Pages:** 55

Phone: **Date:** 03/15/01

Re: 510(k) submissions K003558 & K003559 **CC:**

Urgent **For Review** **Please Comment** **Please Reply** **Please Recycle**

• **Comments:**

Attached are the revised Sections 1, 2, 4, 7, 8 and 9 for the 510(k) submission K003558 – Siemens TCI Combi and the 510(k) submission K03559 – Siemens TCI

We believe that we have addressed each of the questions and issues discussed in the telephone conversation with you on March 7, 2001.

If you need any additional information, please do not hesitate to contact Dave Slavin at 723-562-6658.

Thank you and best regards,



Therese M. Velde, Ph.D.

Research Audiologist

*Hand copy files reviewed
1/16/01 faxed into reviewed*

JRK

Center for Devices and Radiological Health

(ODE/DOED/ENTB)

Memo

To: The Record
CC:
From: James K. Kane, Ph.D.
Date: 03/07/01
Re: K003559/S1 (TCI)

I phoned Dave Slavin, Regulatory Affairs, Siemens Hearing Instruments, Inc, and discussed the following issues with him regarding this device. He advised that he would make the appropriate modifications to the submission, fax them to me, and also send hard-copy follow-up to the Document Mail Center.

K003559/S1 Tinnitus Control Instrument

1. The indications for use statement (Section 1 Page 2) provided in the 510(k) Summary for the tinnitus control instrument (TCI) references additional information in Section 2. The target population described in Section 2 should be added to the indications for use statement in the 510(k) summary.
2. You have expanded the target population to include children. You need to specify the age range of the population appropriate for this device. None of the studies described in the referenced article (Baguley, D.M. and McFerran, D.J., (1999). "Tinnitus in childhood" International J. of Pediatric Otorhinolaryngology, p99-105) discussed tinnitus in children less than five years of age. Further, the reference in the statement needs to be correctly cited. As now written, only one author is named.
3. The "Comparison Information to Predicate Device" section of the 510(k) summary references additional information in Section 7. Table 2 and the last two paragraphs of the discussion should be included as part of the comparison information in the 510(k) summary. However, the target

population listed in Table 2 reports that the predicate device, General Hearing Instrument's Tranquil Tri OE, has the same target population that you describe for the TCI. I was unable to find a reference to children and tinnitus masking / management program in the indications for use statement for the Tranquil 510(k) application (K974751).

4. The Baguley and McFerran article stated that, "there have been no controlled trials determining the efficacy of tinnitus management strategies in childhood..." (5. Reports of tinnitus management in children). Therefore, this efficacy issue should be addressed in your labeling, e.g., disclaimer statement, or consider eliminating children (<age 18) from the target population.
5. You should reference 29 CFR 1910.95 (OSHA Regulation 1910.95 – Occupational Noise Exposure) in your 510(k) summary, because it is referenced within the body of your submission ensuring safety from toxic noise exposure from using the device (TCI).


James K. Kane, Ph.D.
Scientific Reviewer/Audiology

3/7/01
Date

journals

International Journal of Pediatric Otorhinolaryngology

Volume 49, Issue 2
5 August 1999
Pages 99-105

SummaryPlus
▶ **Article**
[Journal Format-PDF \(71 K\)](#)

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Review

Tinnitus in childhood

D. M. Baguley  and **D. J. McFerran**

Tinnitus Clinic, Department of Otorhinolaryngology, Addenbrooke's Hospital, Hills Road, Cambridge CB2 2QQ, UK

Received 4 December 1998; revised 23 March 1999; accepted 28 March 1999. Available online 16 August 1999.

Abstract

Tinnitus is a common symptom in adults and there is a wealth of published information on the pathogenesis and management of the condition. Tinnitus in childhood is likewise quite common when children are directly asked about the symptom. However, children rarely spontaneously complain of tinnitus. Little is known about effective management strategies for paediatric tinnitus. We review the literature regarding the prevalence and nature of paediatric tinnitus and suggest a logical and practical approach to managing this symptom.

Author Keywords: Childhood; Tinnitus; Tinnitus retraining therapy

Article Outline

1. Introduction
2. Tinnitus in normally hearing children

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

14

3. Tinnitus in children with otological disorders
 - 3.1. Conductive hearing loss
 - 3.2. Sensorineural hearing loss
 4. Specific causes of childhood tinnitus
 - 4.1. Tinnitus in childhood due to ototoxicity
 5. Reports of tinnitus management in children
 6. Tinnitus management in adults
 7. A tinnitus management strategy for children
 8. Conclusion
- References

1. Introduction

Tinnitus is well recognised as a significant health care problem in the adult population with Davis reporting a 33% prevalence of spontaneous tinnitus and 2-4% of adults attending specialist clinics because of tinnitus [1]. Similarly, tinnitus has been well documented in children [2, 3, 4, 5, 6, 7 and 8], although producing prevalence statistics is more problematic than with adults. Some researchers suggest that prevalence figures in children are underestimates owing to communication difficulties [4], but on the other hand it can be argued that children over-report tinnitus when questioned in an effort to please the questioner [8]. Tinnitus is rarely reported spontaneously by children. Work by Mills et al. [4] recorded unprompted complaints of tinnitus in only 13 out of 403 (3%) children attending an ear, nose and throat (ENT) clinic. All those that did complain had aural pathology. Other work has confirmed that when children specifically complain of tinnitus there is likely to be significant pathology in contrast to adults with the symptom [2 and 9].

The management of tinnitus in adults is a rapidly advancing field with a sophisticated neurophysiological model [10] and treatment strategies such as tinnitus retraining therapy [11 and 12]. There is evidence from observational studies that this approach is effective in treating adults with tinnitus, although independent randomised controlled trials have yet to be published [13], and criticism of the 'retraining' concept has been voiced [14]. It is unclear how far observations made on the management of adult patients can be extrapolated to a paediatric population. The aim of this study is to review the literature concerning tinnitus in childhood, and to draw from that review some indications of the various therapeutic approaches that may be taken.

2. Tinnitus in normally hearing children

Many normally hearing adults report tinnitus experiences and similarly there is an incidence of generally non-distressing tinnitus experience among normal children. Nodar [2] in a survey of 2000 normally hearing children aged 11-18 years found a tinnitus prevalence of 15% though no study was made of severity. Mills et al. [4] questioned 93 normally hearing children (aged 5-16 years, mean age 5.7 years) about tinnitus. Of these 27 children (29%) reported tinnitus, and nine children (10%) stated that they were 'bothered' by their tinnitus. The authors felt that this prevalence of tinnitus might have been an underestimate due to difficulties communicating with the children. A study by Stouffer et al. [8] attempted to circumvent the problems of communicating with children by use of a carefully

crafted questionnaire that incorporated questions that could not be answered 'yes/no' and repeated some questions using different wording. According to how rigorously the examiners applied their own criteria, 6% or 13% of normally hearing children had experienced episodes of tinnitus lasting for 5 min or longer.

3. Tinnitus in children with otological disorders

3.1. Conductive hearing loss

Mills and Cherry [15] reported a series of 66 children (ages 5-15 years) presenting to an ENT outpatient facility with secretory otitis media. In this series 29 children (43.9%) reported tinnitus compared to a control group of 44 children with sensorineural hearing loss (SNHL) in whom 13 (29.5%) reported tinnitus. There was no use of a normal hearing control group. Mills et al. [4] considered a group of 403 children (ages 5-18 years) seen by two otologists. Of these 267 (66%) children were said to have evidence of ear disease whilst the remainder did not; this ear disease included both SNHL and conductive hearing loss. There was said to be a statistically significant difference between the prevalence of tinnitus in the ear disease group but figures are not clearly given and no distinction was made between the sensorineural and conductive losses. Thus it is difficult to make inference about the role of secretory otitis media in tinnitus experience in children.

3.2. Sensorineural hearing loss

Several studies have investigated the prevalence of tinnitus in children with SNHL. The results are summarised in Table 1. There are flaws in the methodology of all of these studies but some general conclusions can be drawn. Firstly, the prevalence of tinnitus in children with sensorineural hearing loss appears greater than that in normally hearing children. Secondly, the prevalence of tinnitus in children with profound SNHL appears lower than in those children with moderate or severe SNHL. Lastly, it is rare for a child with SNHL to volunteer a complaint of tinnitus. One problem in the study of paediatric tinnitus is highlighted by Table 1: many studies used different age ranges and there ~~is~~ seems little agreement on what constitutes a 'child'. It is possible that some of the differences that have been described could be explained by the fact that there has been no standardisation of the test populations.

Table 1. The prevalence of tinnitus in paediatric populations with normal hearing or a variety of hearing losses



(13K)

4. Specific causes of childhood tinnitus

Although it is rare for a child to spontaneously complain of tinnitus it is useful to examine this subgroup in more detail. Martin and Snashall [16] considered children who had originally presented with a complaint of tinnitus in five centres in the UK. Sixty-seven questionnaires were distributed of which 42 were completed and returned. Among these 42 patients, 35 still had bothersome tinnitus (83%). In the total series of 67 a diagnosis of migraine was made in 13 cases (19%) and features

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suggestive of juvenile Menière's disease were present in five cases (7%). Other diagnoses included hydrops (three cases), chronic suppurative otitis media (three cases), noise induced hearing loss (three cases) and a brainstem tumour (one case). Thus the possibility of treatable and potentially serious pathology in childhood tinnitus should be borne in mind, though this is a very selective series.

Other studies have also described serious otological pathology in childhood that had tinnitus as a symptom. Other cases of juvenile Menière's disease have been reported by Hausler et al. and Telischi et al. [17 and 18]. Similarly perilymph fistula has been described in childhood by Telischi et al. and Parnes and McCabe [18 and 19]. Vestibular schwannomas have been reported in children; in such cases the differential diagnosis of sporadic unilateral vestibular schwannoma and neurofibromatosis II should be undertaken (D.A. Moffat and D.M. Baguley, unpublished).

4.1. Tinnitus in childhood due to ototoxicity

There are three categories of situation in which a young person may develop tinnitus due to ototoxicity. The first is following the use of recreational drugs: there is anecdotal evidence that the use of alcohol, cannabis and ecstasy may be implicated in tinnitus emergence. Such cases should be dealt with sensitively and with care to maintain the strictest confidentiality. A small number of young people may develop tinnitus after a failed attempt to take their lives through overdose of medication (such as aspirin); in such cases managing the tinnitus can only be accomplished with the support of psychiatric colleagues. A third category are the tinnitus cases where onset is associated with doses of prescribed medication such as gentamicin and cisplatin; these drugs are given for life threatening conditions and so the context for tinnitus management is unpromising.

5. Reports of tinnitus management in children

Although there have been no controlled trials determining the efficacy of tinnitus management strategies in childhood, some generalisations can be made from the studies cited above. Firstly, much childhood tinnitus is associated with specific aural pathology. Secondly, many children do not find the experience of tinnitus distressing, and in some of those who do there is evidence that this resolves with time. Most adult tinnitus sufferers state that their symptom started in adulthood and reports of childhood tinnitus continuing into adulthood are rare, supporting the theory that much of childhood tinnitus is self-limiting. As with adults, a reassuring explanation of the nature of tinnitus is often beneficial: Viani [7] reported that many of the group of 24 children that she studied were surprised and relieved to discover that there were other paediatric tinnitus sufferers and that they were not alone. There is suggestion in the literature that the use of white noise generators is justified [9] where there is evidence of significant distress, although care should be taken to make this cosmetically acceptable. The role of hearing aids remains contentious. Viani [7] reported that hearing aids failed to provide tinnitus suppression in all her sample group. Gabriels [9] suggested that in certain cases wearing a hearing aid could be counterproductive as the mould occludes the ear canal.

An alternative approach to the management of tinnitus in children was considered by Rosanowski et al. [20]. A group of 31 children (aged 6–17 years) experiencing chronic troublesome tinnitus but with normal hearing on audiometry were reported. Tinnitus counselling was performed in 24 cases in whom no "significant psychological components"¹ were identified in the case history: the remaining seven cases in whom a depressive episode was identified were admitted to hospital and underwent intravenous lignocaine infusion in order to treat the "somatic component of the disorder". After follow-up of 12–44 months, remission of the tinnitus was reported as complete in the counselling

group and in four of the seven cases treated with lignocaine infusion. In the remaining three of seven cases in the lignocaine group the tinnitus was still apparently present but no longer annoying. The design of this study is such that it is not possible to determine the effect of the therapy against controls or placebo.

6. Tinnitus management in adults

The management of distressing tinnitus in adults has been greatly facilitated by the development of a neurophysiological model of tinnitus [10 and 11], which is congruent with modern psychological theory [21]. In the model (often entitled the Jastreboff model after the instigator) tinnitus may originate from a pathological lesion in the auditory pathway, or may arise by abnormal perception of normal background activity in the auditory system. Normally, neural filtering networks in the brainstem suppress such signals. In tinnitus sufferers this filtering fails allowing the tinnitus signal to be perceived at a cortical level. Thalamic and cortical connections to the limbic system, and in particular the amygdala, facilitate the tinnitus signal in evoking an emotional and sympathetic autonomic response to the tinnitus, which thereby increases the sensitivity of the auditory system to that tinnitus signal, producing a positive feedback loop. This limbic system response results in non-auditory systems contributing to the distress experienced by tinnitus patients and this aspect demands management as much as does the tinnitus signal itself.

A management strategy that derives from the Jastreboff model of tinnitus has become known as tinnitus retraining therapy (TRT) [11 and 12] which has the objectives of habituation of the distress evoked and of the perception of the tinnitus itself. This therapeutic technique uses a multifaceted approach. The constituents of this therapy are:

1. Directive counselling as to the nature of the tinnitus signal and the distress experienced by the patient.
2. The use of white noise to reduce the starkness of the tinnitus signal and hence facilitate habituation.
3. The use of relaxation techniques to reduce autonomic arousal.
4. Environmental sound enrichment to reduce cortical perception of the tinnitus signal.

Initial reports of the success of this therapeutic strategy have been encouraging [22 and 23], but a rigorous randomised, controlled and blinded trial has yet to be undertaken, causing an independent review in the UK to strongly urge caution [13]. Additional criticism has come from the psychological community [14 and 21], who have cogently and robustly argued that the directive counselling element of TRT is inadequately defined and may in fact represent a form of cognitive therapy. As such they argue for a role for the psychologist in the treatment of tinnitus in adults.

Despite these significant published concerns TRT appears to be the tinnitus management strategy of choice in 148 of 230 audiology departments dealing with adult tinnitus patients in the UK [24].

The question then becomes one of the applicability of the neurophysiological model of tinnitus to tinnitus in childhood. Indications from the existing literature are that children, in the main, do not experience distress as a consequence of the perception of tinnitus. In those who do, the opportunities for changing negative beliefs about tinnitus should be at least as great if not greater in children than adults if explanation and discussion is undertaken in age appropriate language. The opportunities for 'retraining' auditory filtering mechanisms should also be greater in children than adults due to the greater neural plasticity in the child. From first principles, the neurophysiological model appears to be

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as applicable in childhood as it is in adulthood.

One should be aware that a distressed child will often have distressed parents, and so childhood tinnitus may become problematic for the whole family. In such situations careful explanation and development of understanding of the origin of the tinnitus and of the distress will be appropriate for these troubled and anxious parents, and an appropriate form of the neurophysiological model may well prove helpful in this regard.

7. A tinnitus management strategy for children

In view of the above the authors suggest the following management strategy for a child with a complaint of tinnitus.

The initial appointment should be with a paediatric otologist. The objectives of this session will be twofold: firstly to exclude significant potentially treatable pathology, and secondly to introduce the concept that tinnitus (and the associated distress) is a treatable condition. Any investigations undertaken to meet the first of these objectives should be undertaken sensitively and with care not to further alarm the patient or parents. In particular it should be noted that children with tinnitus have difficulty in performing audiometry, and that the intense noise of a magnetic resonance scanner may temporally exacerbate tinnitus perception.

Once otological pathology has been excluded or treated the therapy should focus upon the objective of the reduction of tinnitus associated distress and of reduction of tinnitus awareness. The neurophysiological model provides the most robust framework for such an undertaking. Therapy should be facilitated by a professional who is skilled in interacting with children in age appropriate language and who is familiar with tinnitus management in adults. Initial discussion should focus upon the child's beliefs about the tinnitus, involving the origin and cause of the perception and the child's concerns about their future experience with this symptom. These beliefs should be placed in the context of a model of tinnitus that is helpful for the child: a dialogue with the child should then ensue. Once this has reached a natural conclusion the concerns and needs of the parents should be addressed: the tinnitus therapist should carefully consider in each individual case whether the child should or should not be present, or indeed whether the parents should be present when one is counselling the child. The preference of the authors is that parents and child should be present at all times. Care should be taken to avoid blame over the onset of the tinnitus when this is associated with loud music or perhaps recreational drugs, as negative association with the tinnitus will hamper progress in habituation.

The use of white noise generators or hearing aids should then be considered. The presence of even a mild unilateral hearing loss has been demonstrated to place a child at an educational disadvantage [25 and 26], and so quite apart from tinnitus management there are strong indications that attempts should be made to correct such losses with amplification. If a hearing aid is to be fitted care should be taken to ensure that the mould does not occlude the ear, thus exacerbating the tinnitus perception, and that comfortable loudness levels are not exceeded. Use of ear level white noise generators should be considered. If utilised these should be worn at a level such that the white noise and the tinnitus mix, rather than the tinnitus being masked entirely. Children who find the tinnitus is only bothersome when they are in quiet or silent surroundings may prefer to use environmental sound, such as a fan or quiet music, to lessen their awareness of the tinnitus. Children are generally delighted when told they may have a radio on when doing their homework! Where a child is acutely aware of the tinnitus when trying to fall asleep the use of a white noise generator that fits within a pillow and switches off

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automatically after an hour is indicated, such devices being readily commercially available.

Depending upon the age of the child such a strategy can be put in place on three or four visits to the clinic. Follow up should balance the line between the need for follow up data and provision of an opportunity to modify therapy as appropriate, and the need to reduce awareness and negative beliefs about tinnitus. Cases should be followed up on an individual basis.

8. Conclusion

Whilst the literature indicates that the number of children experiencing distressing tinnitus is small, there is an association with pathology that necessitates the opinion of an experienced paediatric otologist. When distressing tinnitus is present whilst such pathology is being treated, or in the absence of such pathology, the treatment strategy indicated is a modified age appropriate version of that utilised in adult patients. Care should be taken to address the concerns and anxieties of the parents.

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✉ Corresponding author; email: dmb29@cam.ac.uk

¹ Quotes taken from Medline abstract translation.

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Table 1. The prevalence of tinnitus in paediatric populations with normal hearing or a variety of hearing losses

Authors	n	Age range (years)	Prevalence of tinnitus (%)		
			Normal hearing	Moderate/severe hearing loss	Profound hear
Nodar (1972) [2]	2000	11-18	15		
Nodar and Lezak (1984) [3]	55	11-18		100	35
Mills and Cherry (1984) [15]	110	5-15		29, 5	
Mills et al. (1986) [4]	202	5-16	29		
Graham (1987) [5]	158	12-18		66	29
Viani (1989) [7]	102	6-17			23
Druckier (1989) [6]	331	6-18			33 ^c
Stouffer et al. (1992) [8]	161	7-10	6-13 ^b		

^aOME, otitis media with effusion.

^bThe authors of this paper gave different figures depending on how rigorously they interpreted their data.

^cPrevalence when hearing aids not worn.

^a OME, otitis media with effusion.

^b The authors of this paper gave different figures depending on how rigorously they interpreted their data.

^c Prevalence when hearing aids not worn.

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ons with normal hearing or a variety of

(s) Prevalence of tinnitus (%)

	Normal hearing	Moderate/severe hearing loss	Profound hearing loss	Mixed/unstated hearing loss
	15	100	35	43.9 (OME) ^a
		29.5		38.5
	29	66	29	
			23	
			33 ^c	
	6-13 ^b			24-29 ^b

on how rigorously they interpreted their data.

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From: Dave Slavin

Pages: 17
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Remarks: RE: Siemens TCI and TCI combi 510K

Hi Jim,
Here are the revised summaries and
wording regarding target population.

We have also submitted full copies of the
document to the Document mail clerk.

Regards,
Dave Slavin

Siemens Hearing Instruments, Inc.

10 Constitutional Questions? Contact FOIA/CDRH/OC/DO at CDRH-FOI@FDA.HHS.gov or 301-796-8118 <http://www.siemens-hearing.com>

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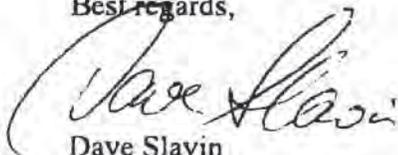
Re: Additional Information Request for 510(k) Submission K003559 – Seimens TCI

Dear Dr. Kane:

Enclosed please find the slight changes to our submission as per your request. We have revised the summary section so that it is stand-alone, and makes no references to any other part of the submission. As per our discussion, we have also made a slight wording change under Section 2, Target Population.

I believe that these changes should resolve the final questions regarding our submission. Should any further questions arise during your review, please feel free to contact me directly at the phone number indicated on the summary page.

Best regards,



Dave Slavin
Director of Quality Assurance and Regulatory Affairs

Siemens Hearing Instruments, Inc.

10 Constitution Avenue P.O. Box 1397 Piscataway, New Jersey 08855-1397 (732) 562-6600 <http://www.siemens-hearing.com>

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510(K) Summary for the Siemens TCI

REVISED 4/16/01

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:** TCI (Tinnitus Control Instrument)

4. **Device Common Name / Classification Name:** **Tinnitus Masker**
Product Code: **KLW**

5. **Establishment Registration Number:** 2217809

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

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

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

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

10. **Indications for Use:**

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

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

11. **Description of Device:**

TCI is a fully digital, low-level noise generator that was developed to be used along with appropriate counseling and/or tinnitus therapy. This product is programmable, with four selectable noises and variable output level. The output noise can be custom-tailored to the user's individual requirements. The unit is housed in a conventional behind-the-ear case.

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

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

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

	Siemens Hearing Instrument TCI Device	General Hearing Instruments Tranquil Tri OE
Intended Use	Mask tinnitus as part of tinnitus management program	Mask tinnitus as part of tinnitus management program
Target Population	Adults and children (≥ 5 years) with tinnitus that are participating in a tinnitus management program	Adults with tinnitus that are participating in a tinnitus management program
Operation Circuit type Programmable Available noises Volume control	Digital Yes Four Yes	Analog No One Yes
Physical Description	Standard behind-the-ear instrument housing	Custom in-the-ear product
RSM Output Characteristics White noise Pink noise Speech noise High-tone noise	71 dB SPL 69 dB SPL 69 dB SPL 76 dB SPL	75 dB SPL
Volume control range	Programmable: OFF, 8 dB, 16 dB, 32 dB	40 dB

TCI Comparison with Predicate Device

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

Risks:

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 TCI will only be conducted through a Hearing Healthcare Professional, such as an audiologist or otolaryngologist.

Benefits:

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

Warnings for Safe Use:

As this device cannot deliver damaging sound intensity, no warning is required about sound output level. General use precautions are given 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 who experience tinnitus as a part of a tinnitus management program. Patients should receive medical evaluations to rule out medically or surgically treatable diseases for which tinnitus is a symptom before proceeding with non-medical tinnitus management. Tinnitus management programs include a complete audiologic assessment, tinnitus evaluation, directive counseling, and extended use of a low-level noise generator to facilitate habituation of the tinnitus. While not specifically endorsed by Siemens Hearing Instruments, the TRT (Tinnitus Retraining Therapy) method is one example of a tinnitus management program (Jasterboff, 1993).

Target Population

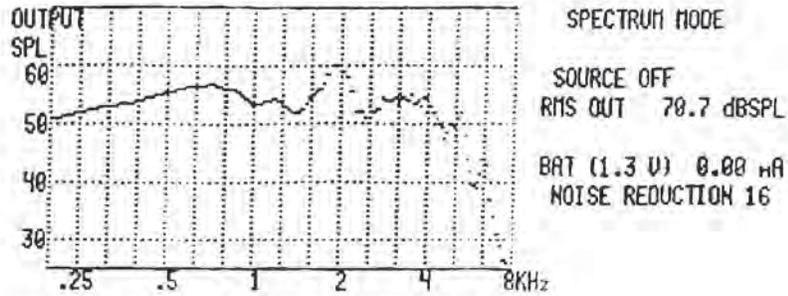
The target population is primarily the adult population over 18 years of age. It has been estimated 17 percent of the adult population reports tinnitus, including 33 percent of the population over 60 reporting some degree of tinnitus (Bauman, 1998). The target group for this product includes individuals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

Principles of Operation

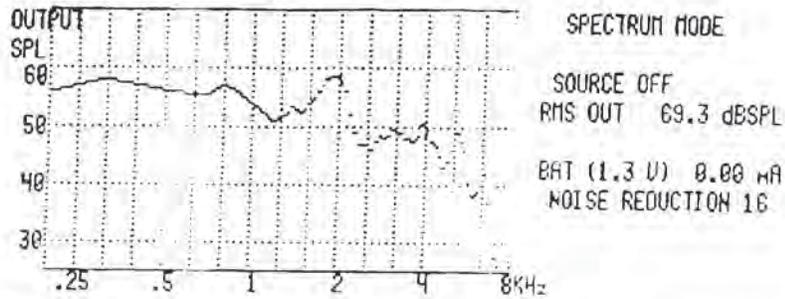
The device is a programmable digital tinnitus masker, allowing the programming of the noise characteristics through the use of software installed on a personal computer. Four types of noise spectra are pre-programmed as noisers – white noise, pink noise, speech noise, and high-tone noise. Figure 1 displays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

Figure 1 – Noise Types

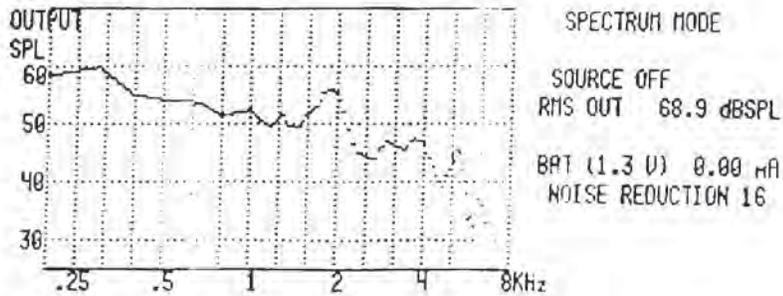
A. White Noise



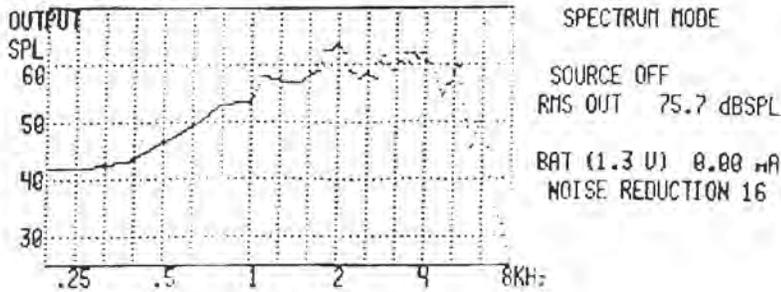
B. Pink Noise



C. Speech Noise



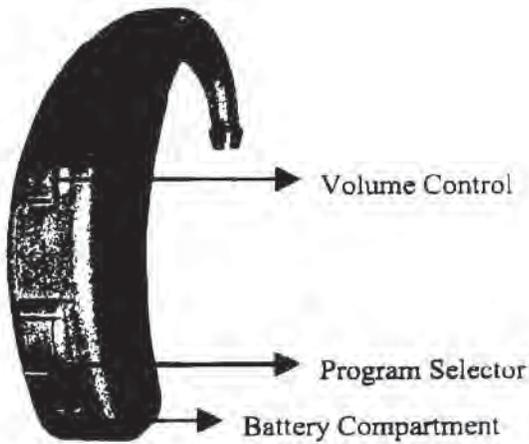
D. High-tone Noise



Physical Description

The product is housed in a standard behind-the-ear casing. The material and composition of this case is identical to behind-the-ear hearing aids in use by Siemens. This housing type is similar to that of the Siemens Hearing Instruments Piano Series behind-the-ear devices (K942857). Figure 2 displays the TCI behind-the-ear device.

Figure 2 – TCI Behind-the-Ear Device



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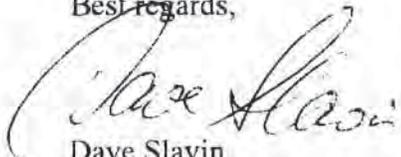
Re: Additional Information Request for 510(k) Submission K003559 – Seimens TCI

Dear Dr. Kane:

Enclosed please find the slight changes to our submission as per your request. We have revised the summary section so that it is stand-alone, and makes no references to any other part of the submission. As per our discussion, we have also made a slight wording change under Section 2, Target Population.

I believe that these changes should resolve the final questions regarding our submission. Should any further questions arise during your review, please feel free to contact me directly at the phone number indicated on the summary page.

Best regards,



Dave Slavin
Director of Quality Assurance and Regulatory Affairs

APR 17 0 59 AM '01

Siemens Hearing Instruments, Inc.

10 Constitution Avenue, P.O. Box 139, Roseland, New Jersey 07068
Questions? Contact FDA/CDRH/OCE/DID at CDRH.FOISTATUS@fda.hhs.gov or 301.796.8118
www.siemens-hearing.com

SK1

K003559
TCI
Siemens Hearing Instruments, Inc.

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

510(K) Summary for the Siemens TCI

REVISED 4/16/01

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** TCI (Tinnitus Control Instrument)

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

Product Code: **KLW**

5. **Establishment Registration Number:** 2217809

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

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

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

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

10. **Indications for Use:**

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

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

11. **Description of Device:**

TCI is a fully digital, low-level noise generator that was developed to be used along with appropriate counseling and/or tinnitus therapy. This product is programmable, with four selectable noises and variable output level. The output noise can be custom-tailored to the user's individual requirements. The unit is housed in a conventional behind-the-ear case.

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

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

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

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	Siemens Hearing Instrument TCI Device	General Hearing Instruments Tranquil Tri OE
Intended Use	Mask tinnitus as part of tinnitus management program	Mask tinnitus as part of tinnitus management program
Target Population	Adults and children (≥ 5 years) with tinnitus that are participating in a tinnitus management program	Adults with tinnitus that are participating in a tinnitus management program
Operation Circuit type Programmable Available noises Volume control	Digital Yes Four Yes	Analog No One Yes
Physical Description	Standard behind-the-ear instrument housing	Custom in-the-ear product
RSM Output Characteristics White noise Pink noise Speech noise High-tone noise	71 dB SPL 69 dB SPL 69 dB SPL 76 dB SPL	75 dB SPL
Volume control range	Programmable: OFF, 8 dB, 16 dB, 32 dB	40 dB

TCI Comparison with Predicate Device

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

Risks:

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 TCI will only be conducted through a Hearing Healthcare Professional, such as an audiologist or otolaryngologist.

Benefits:

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

Warnings for Safe Use:

As this device cannot deliver damaging sound intensity, no warning is required about sound output level. General use precautions are given 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 who experience tinnitus as a part of a tinnitus management program. Patients should receive medical evaluations to rule out medically or surgically treatable diseases for which tinnitus is a symptom before proceeding with non-medical tinnitus management. Tinnitus management programs include a complete audiologic assessment, tinnitus evaluation, directive counseling, and extended use of a low-level noise generator to facilitate habituation of the tinnitus. While not specifically endorsed by Siemens Hearing Instruments, the TRT (Tinnitus Retraining Therapy) method is one example of a tinnitus management program (Jasterboff, 1993).

Target Population

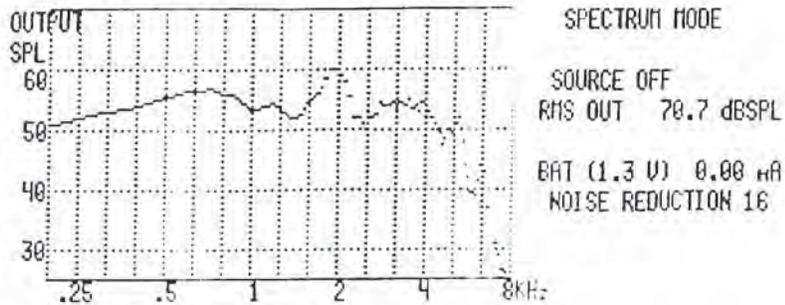
The target population is primarily the adult population over 18 years of age. It has been estimated 17 percent of the adult population reports tinnitus, including 33 percent of the population over 60 reporting some degree of tinnitus (Bauman, 1998). The target group for this product includes individuals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

Principles of Operation

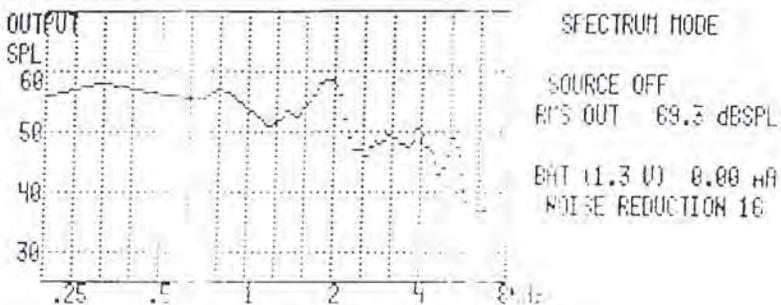
The device is a programmable digital tinnitus masker, allowing the programming of the noise characteristics through the use of software installed on a personal computer. Four types of noise spectra are pre-programmed as noisers – white noise, pink noise, speech noise, and high-tone noise. Figure 1 displays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

Figure 1 – Noise Types

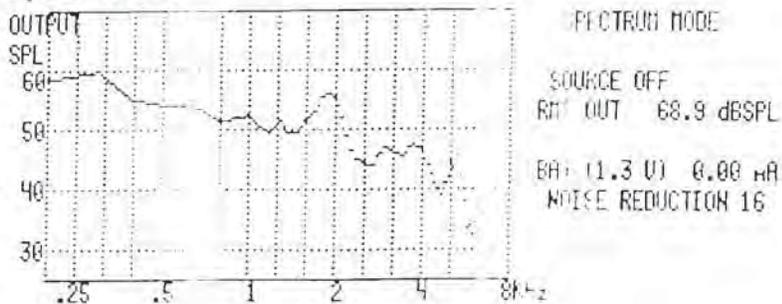
A. White Noise



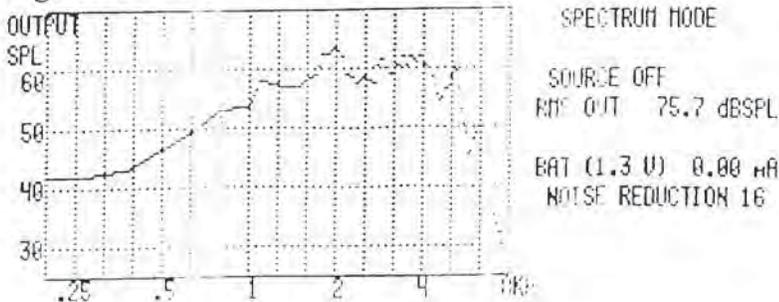
B. Pink Noise



C. Speech Noise



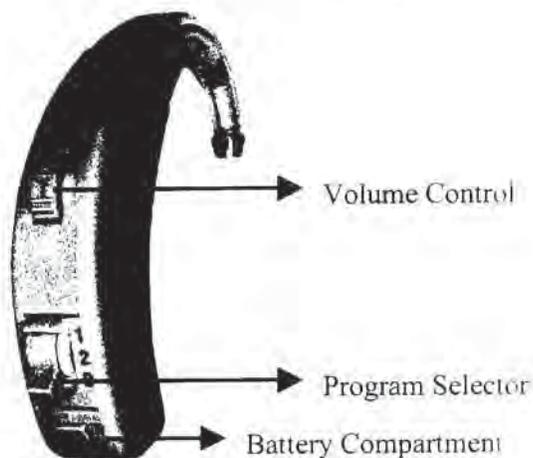
D. High-tone Noise



Physical Description

The product is housed in a standard behind-the-ear casing. The material and composition of this case is identical to behind-the-ear hearing aids in use by Siemens. This housing type is similar to that of the Siemens Hearing Instruments Piano Series behind-the-ear devices (K942857). Figure 2 displays the TCI behind-the-ear device.

Figure 2 – TCI Behind-the-Ear Device



Technical Specifications

Output Characteristics

Figure 1 in the previous section shows the maximum output for the four noise types. As shown in the figure, the output at any one frequency of the white noise, pink noise, and speech noise does not exceed 60 dB SPL. The maximum output at 2000 Hz of the high-tone noise is 63 dB SPL. Table 1 displays the overall RMS output of the four noises.

Noise Type	RMS Output
White Noise	70.7 dB SPL
Pink Noise	69.3 dB SPL
Speech Noise	68.9 dB SPL
High-tone Noise	75.7 dB SPL

Table 1- RMS Output of TCI Noises

Programming

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

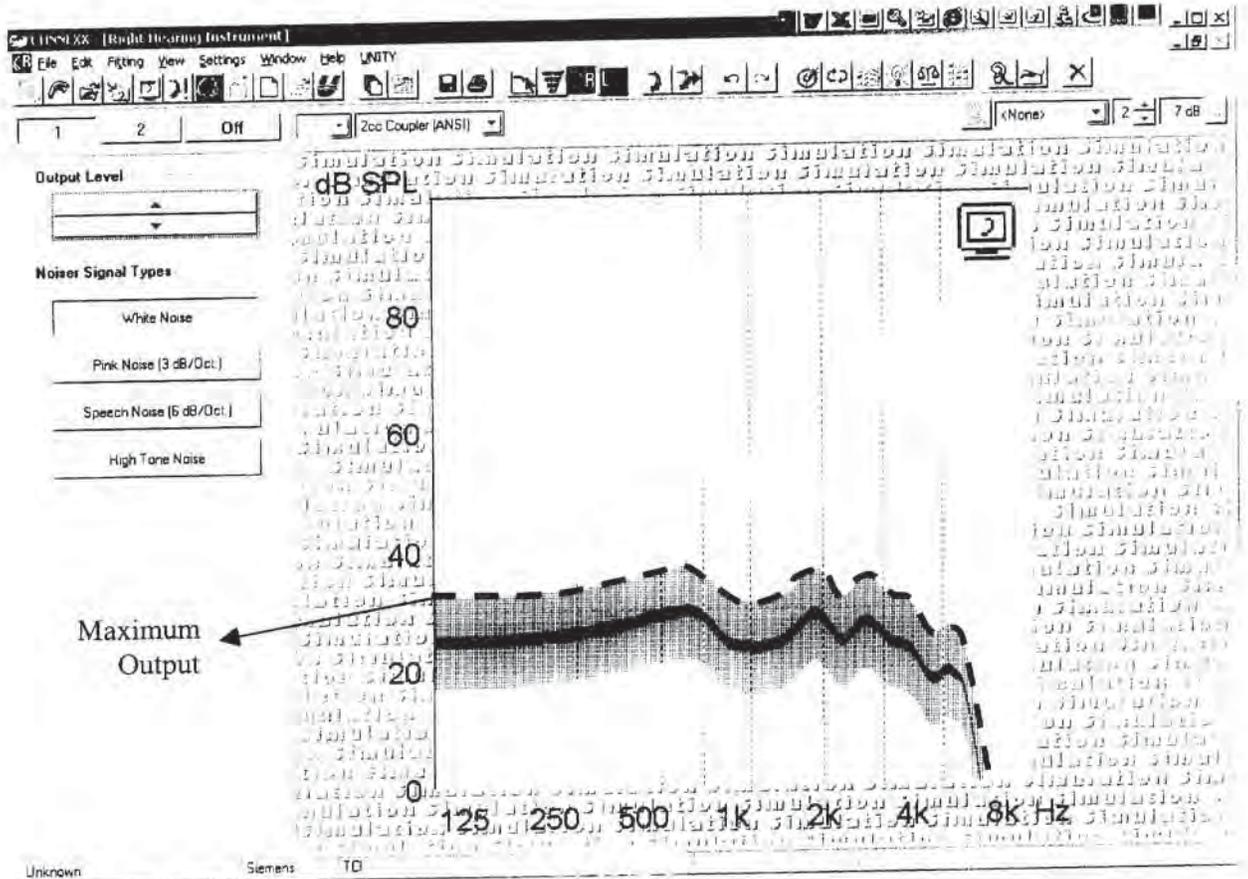


Figure 3 – Sample of white noise, overall output of 30 dB SPL and volume control range of 16 dB.

Power Consumption

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

Standards

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

Risks

Output

The TCI does not present a risk of inducing or increasing hearing loss in TCI 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 76 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 TCI for all their waking hours. Thus, if a TCI user wore the device at maximum output for a 16-hour period, he would not meet the maximum allowable exposure under OSHA regulations.

Battery door

The battery door on the device includes a lock to prevent access to the battery by children.

Note:

The initial submission for the TCI made reference to the TCI not posing a risk since the output was below 132 dB. This reference was to labeling requirements for hearing aid (CFR 801.420), “special care when selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user”. This reference is no longer valid since the TCI is a tinnitus masker, not a hearing aid.

Labeling

Technical Information

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

User's Manual

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

Software Validation

(b) (4)

Comparison of Siemens Hearing Instruments TCI Device and the Predicate Device

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

	Siemens Hearing Instrument TCI Device	General Hearing Instruments Tranquil Tri OE
Intended Use	Mask tinnitus as part of tinnitus management program	Mask tinnitus as part of tinnitus management program
Target Population	Adults and children (≥ 5 years) with tinnitus that are participating in a tinnitus management program	Adults with tinnitus that are participating in a tinnitus management program
Operation Circuit type Programmable Available noises Volume control	Digital Yes Four Yes	Analog No One Yes
Physical Description	Standard behind-the-ear instrument housing	Custom in-the-ear product
RMS Output Characteristics White noise Pink noise Speech noise High-tone noise	71 dB SPL 69 dB SPL 69 dB SPL 76 dB SPL	75 dB SPL
Volume control range	Programmable: OFF, 8 dB, 16 dB, 32 dB	40 dB

Table 2 - TCI Comparison with Predicate Device

Discussion

The intended use of the TCI and predicate device are the same. The RMS output levels between the two devices are comparable. The target population of the TCI is adults and children 5 years of age and older. The target population of the predicate device is adults.

The primary differences between the two devices lie in the physical descriptions and differences between analog and digital technology. While the TCI is a behind-the-ear instrument and the predicate device is an in-the-ear instrument, both devices deliver sound energy to the external ear canal. The location of the noise-producing transducer is unimportant; the noise itself is the important functional consideration.

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

Appendix A

Technical Specifications

SIEMENS

SERENITI™ TCI

Preliminary Technical Information for Behind-The-Ear Tinnitus Control Instruments

04224•SERENITI TCI BTE.qxd 4/16/01 11:08 AM Page 2

FILE NAME 04224•SERENITI TCI BTE
SUBMITTIVE #

Timnus Control Instruments

SERENITI™ TCI

Premium Features

- Programmable, fully digital BTE-instrument for Tinnitus therapy
- 2 individual therapy programs available with manual selection
- 4 pre-programmed noise types, with fine-tuning possible in 8 channels
- Wide range of output levels
- Volume control with programmable range
- Professional fitting with powerful, easy-to-use CONNEXX™ software fitting system

Fitting Parameters

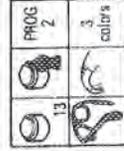
- Programmable:
 - 8-channel filterbank
 - Volume control range
 - Output level

Options

- Standard colors: Beige, Grey, Tobacco

Accessories

- Eyeglass adapter
- Small ear hook

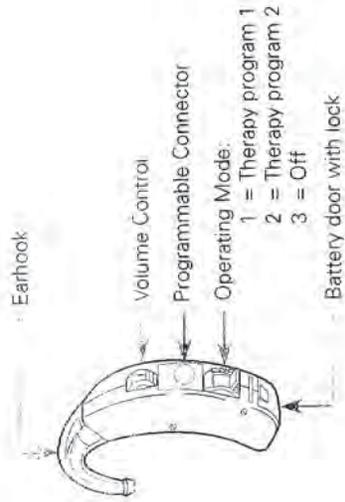


Technical Data

SERENITI™ TCI

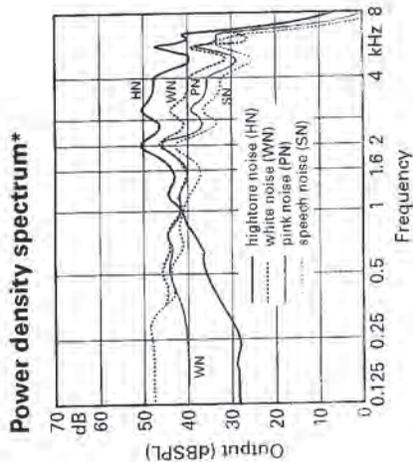
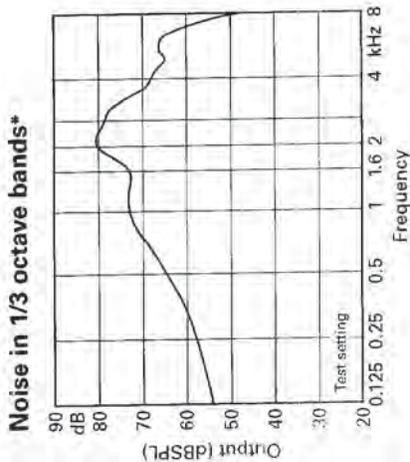
Output Sound Pressure Level	
Broadband	85 dB
Master Output Level (L) Range	81 dB
VC range (programmable)	32 - 16 - 8 - off (dB)

Battery	
Voltage	1.3 V
Current Drain	0.6 mA
Battery Life (typical) Type 13 Zinc Air	approx. 400 h



Therapy Noise Characteristics

SERENITI TCI



* Measurement conditions: 2 cc coupler



Fitting Parameters

Volume Control Range

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

Master Level Control

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

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

Output Level

MAX

Δ Test setting

Technical Description

SERENITI™ TCI

Standard features

Lock for battery door

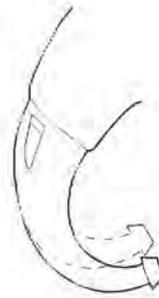
Unintentional access to the battery compartment is minimized with a lock located on the inner side of the instrument. The feature is helpful with small children and the mentally challenged.

Use a tool suited to the purpose to open or close the safety device. Pushing the slide upwards unlocks the battery compartment, pushing the slide downward locks the battery compartment.



Heat-shaped earhook

Can be heat-shaped for a precise fit

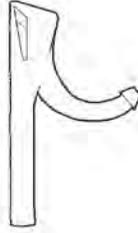


Accessories

Eyeglass adapter

To fit the instrument onto eyeglasses
Transparent

Order No. 29 22 289



Small earhook

For children, as well as adults with small ears

Order No. 25 23 322



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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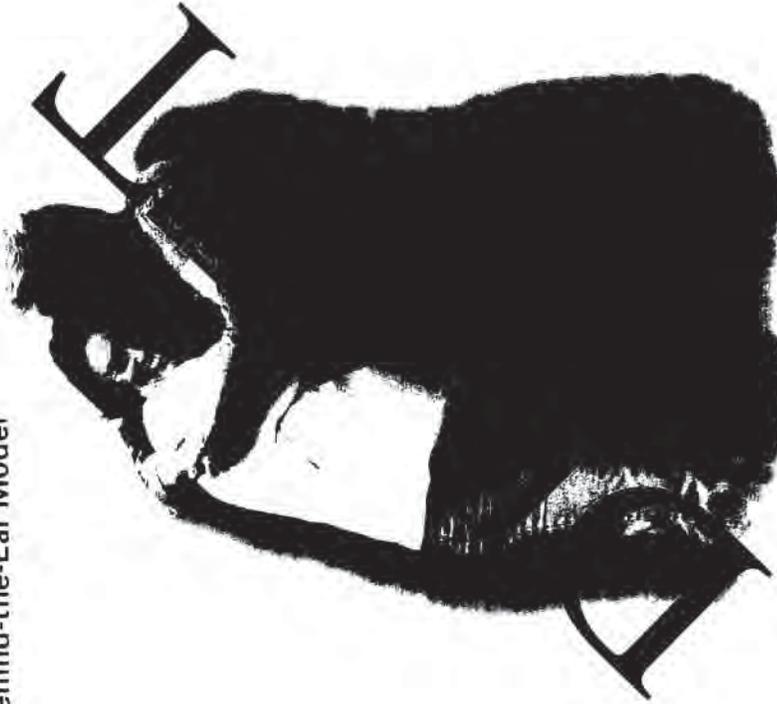
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Appendix B

User's Manual

SIEMENS

User's Manual for SERENITI™
Tinnitus Control Instrument (TCI)
Behind-the-Ear Model



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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SHI/04229-1

TCI
Administrative

Introduction

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

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

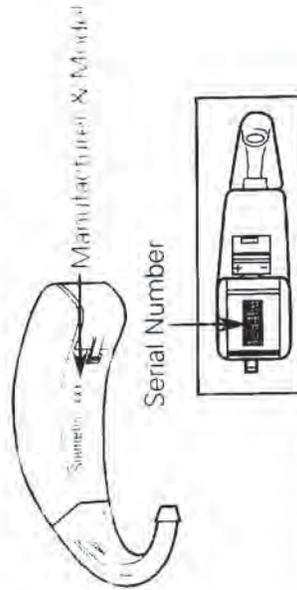
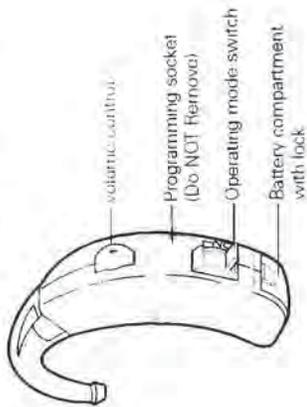
Most tinnitus therapy programs recommend the volume of noise be set equal to or slightly lower than the perceived level of the tinnitus (5-10 dB Sensation Level (SL)). This noise level should not interfere with speech understanding. Your Hearing Health Care Professional can instruct you on specific volume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

The output of the TCI noiser (masker) 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).

Note: While some Hearing Health Care Professionals recommend use of this type of device with children 5 years of age or older, the clinical efficacy of this device with children has not been proven.

Getting Familiar with Your Instrument

The Siemens behind-the-ear (BTE) instrument is designed for comfort, performance and durability. It fits comfortably behind your ear and is attached to a custom-made earmold.



Each instrument has its model and manufacturer on the case. The serial number can be found where illustrated.

The battery compartment holds the battery that powers the instrument.

The volume control allows you to adjust the level of the therapy sound for your comfort.

The "1-2-0" switch indicates the instrument's operational mode or turns the instrument off.

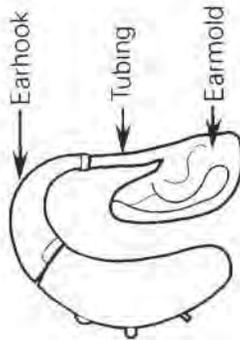
When the instrument is in the "0" position, the instrument is Off.

Your Hearing Health Care Professional can advise you on the proper use of all function settings.

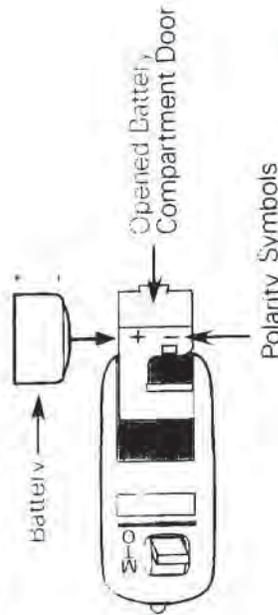
Using Your Instrument

Attaching the Earmold

Gently insert the earhook of the instrument into the tubing and earmold supplied by your Hearing Health Care Professional.



Inserting the Battery



To place the battery into the instrument, swivel open the door of the battery compartment. Place the proper size battery (see "Battery" section or consult your Hearing Health Care Professional) so that the "+" symbol on the battery coincides with the "+" mark on the battery compartment.

Gently close the battery compartment. Do not force the battery door shut. If the door does not close easily, check to see if the battery is inserted upside down. When the battery door is completely closed, your instrument is ready for operation.

Inserting the Instrument

Take the earmold between your thumb and index finger. Gently work the earmold into its proper position by slightly adjusting it until it is firmly seated in your ear. Then lift the instrument over the top of your ear and adjust it to fit behind your ear. Press it in gently for a secure and comfortable fit (as illustrated).



Removing the Instrument

When removing the instrument from your ear, gently push on the back of the ear to help release the earmold and gently pull it out (as illustrated).



Health Considerations

If soreness or skin irritation develops, 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.

Using the Operating Mode Switch

This instrument has an operating mode switch which you use to change the characteristics of sound coming through the instrument.

To change the response of the instrument, simply change the position of the operating mode switch and the sound will change.

These modes are arranged in a line. You reach therapy program #1 or #2 by moving the switch to those positions. When the switch is in the "O" position, the instrument is off.

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Administrative

Behind-the-Ear Earmold Maintenance and Care

The earmolds should be cleaned daily by wiping them with a tissue or a soft cloth. When necessary, remove the earmold from the instrument and soak it in a mild soap solution and wipe it dry.

Never immerse your instrument!

Allow the earmold to completely dry overnight before reconnecting it to the instrument.

If the earmold is not dry, do not attach it to the instrument as this can cause damage. Do not use a hair dryer, oven or microwave oven to dry the earmold.

Battery

The chart below provides the battery size used in your instrument. It's recommended that you also check with your Hearing Health Care Professional regarding the correct battery.

<u>Model</u>	<u>Battery Size</u>
SERENITI™ Behind-the-Ear	13

ble

CDRH
Administration

Appendix C

Documentation of Product Software Review

61

SIEMENS

R & D / AES

Jörg Bindner

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

Phone No.: +49 / 9131 / 308 – 323

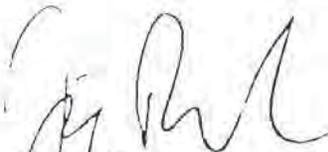
Fax No.: +49 / 9131 / 308 – 406

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

Date: February 16, 2001

OFFICIAL STATEMENT

I confirm, that TCI BTE and TCI Combi BTE was included for the release for SIFIT 3.3



(Jörg Bindner)
Head of software development

lk

(b)

(4)

Appendix D

Technical Specifications of Predicate Device

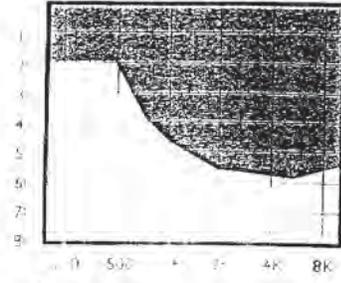
TRANQUIL™

Introducing the Tranquil - Offered Exclusively by General Hearing Instruments!

The Tranquil is a Class B low level noise generator that was developed specifically to be used with a program that addresses the psychological and neurobiological 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.

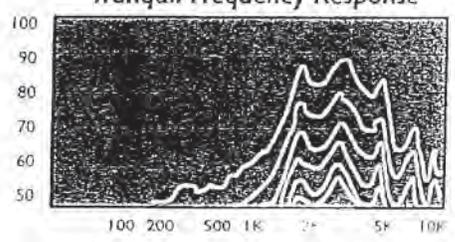
Suggested Fitting Range



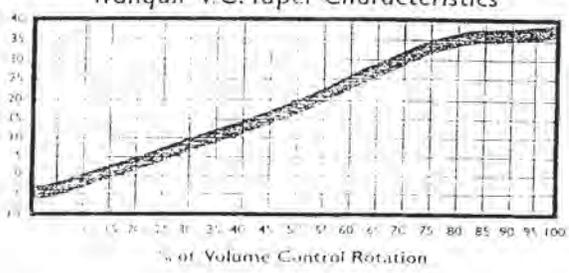
Typical Output: 75 dB SPL

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 miniature canal 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 more based open ear design which houses the circuitry in the helix portion of the ear shell. It incorporates a 312 battery and a cavity retention arm to properly direct the receiver and maintain the open inferior canal.

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



Bibliography

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SIEMENS

March 11, 2001

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

Attn: Document Mail Clerk

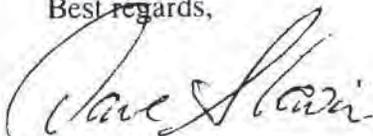
Re: Additional Information Request for 510(k) Submission K003559 – Siemens TCI

Dear Dr. Kane:

Enclosed please find the additional information that you requested concerning the above referenced 510(k) submission. We feel that we have addressed the issues that we discussed in our phone conversation on March 7, 2001.

Should any further questions arise during your review, please feel free to contact me directly at the phone number indicated on the summary page.

Best regards,



Dave Slavin
Director of Quality Assurance and Regulatory Affairs

MAR 16 3 57 AM '01

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K003559

TCI

Siemens Hearing Instruments, Inc.

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

Mar 15 8 57 AM '01

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TV

510(K) Summary for the Siemens TCI

REVISED 2/15/01

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:** TCI (Tinnitus Control Instrument)
4. **Device Common Name / Classification Name:** **Tinnitus Masker**
Product Code: **KLW**
5. **Establishment Registration Number** 2217809
6. **Address of Manufacturing Site:** Siemens Hearing Instruments
10 Constitution Ave.
PO Box 1397
Piscataway, NJ 08855
7. **Classification of Device:** Class II
8. **Marketed Devices to which the claim of substantial equivalence is made:** K974751
General Hearing Instruments
Tranquil Tri-OE

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

10. **Indications for Use:**

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

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

11. **Description of Device:**

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

See additional information in Sections 2 and 3.

12. **Proposed Labeling:**

Technical Specifications are in Section 8, Appendix A, and revised User's Manual is in Section 9, Appendix B

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

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

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

	Siemens Hearing Instrument TCI-Comb Device	General Hearing Instruments Tranquil Tri OE
Intended Use	Mask tinnitus as part of tinnitus management program	Mask tinnitus as part of tinnitus management program
Target Population	Adults and children (≥ 5 years) with tinnitus that are participating in a tinnitus management program	Adults with tinnitus that are participating in a tinnitus management program
Operation Circuit type Programmable Available noises Volume control	Digital Yes Four Yes	Analog No One Yes
Physical Description	Standard behind-the-ear instrument housing	Custom in-the-ear product
RMS Output Characteristics White noise Pink noise Speech noise High-tone noise	71 dB SPL 69 dB SPL 69 dB SPL 76 dB SPL	75 dB SPL
Volume control range	Programmable: OFF, 8 dB, 16 dB, 32 dB	40 dB

TCI Comparison with Predicate Device

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

Risks:

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). See additional information in Section 4.

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Hearing Healthcare Professional Diagnosis:

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

Benefits:

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

Warnings for Safe Use:

As this device cannot deliver damaging sound intensity, no warning is required about sound output level. General use precautions are on pages 6 and 8 of the User's Manual, Section 9, Appendix B.

Specifications:

See details in Sections 2 and 3 and Technical Specifications for the Hearing Health Care Professional in Section 8. Appendix A.

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Product Description

Indications for Use

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

Target Population

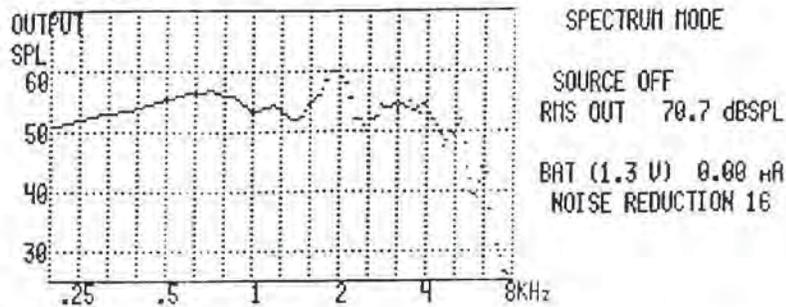
The target population is primarily the adult population over 18 years of age. It has been estimated 17 percent of the adult population reports tinnitus, including 33 percent of the population over 60 reporting some degree of tinnitus (Bauman, 1998). The target group for this product includes individuals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

Principles of Operation

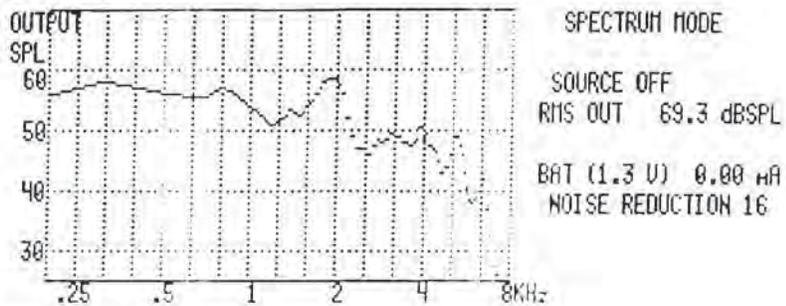
The device is a programmable digital tinnitus masker, allowing the programming of the noise characteristics through the use of software installed on a personal computer. Four types of noise spectra are pre-programmed as noisers – white noise, pink noise, speech noise, and high-tone noise. Figure 1 displays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

Figure 1 – Noise Types

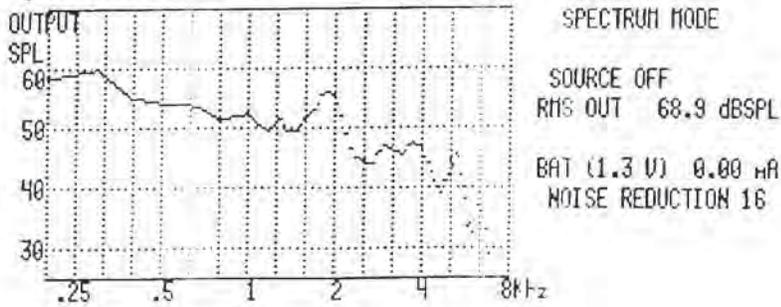
A. White Noise



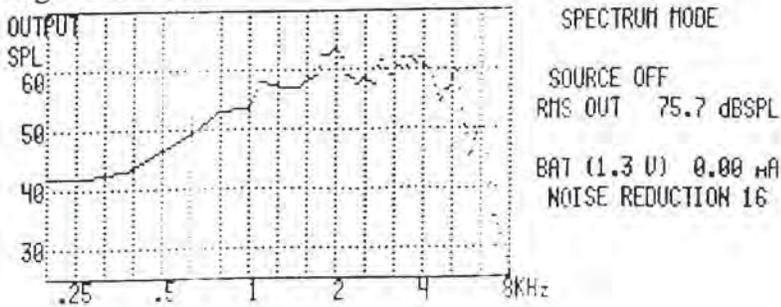
B. Pink Noise



C. Speech Noise



D. High-tone Noise

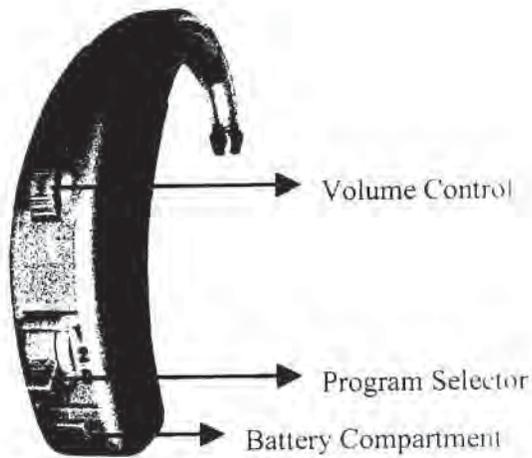


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Physical Description

The product is housed in a standard behind-the-ear casing. The material and composition of this case is identical to behind-the-ear hearing aids in use by Siemens. This housing type is similar to that of the Siemens Hearing Instruments Piano Series behind-the-ear devices (K942857) Figure 2 displays the TCI behind-the-ear device.

Figure 2 – TCI Behind-the-Ear Device



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Technical Specifications

Output Characteristics

Figure 1 in the previous section shows the maximum output for the four noise types. As shown in the figure, the output at any one frequency of the white noise, pink noise, and speech noise does not exceed 60 dB SPL. The maximum output at 2000 Hz of the high-tone noise is 63 dB SPL. Table 1 displays the overall RMS output of the four noises.

Noise Type	RMS Output
White Noise	70.7 dB SPL
Pink Noise	69.3 dB SPL
Speech Noise	68.9 dB SPL
High-tone Noise	75.7 dB SPL

Table 1- RMS Output of TCI Noises

Programming

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

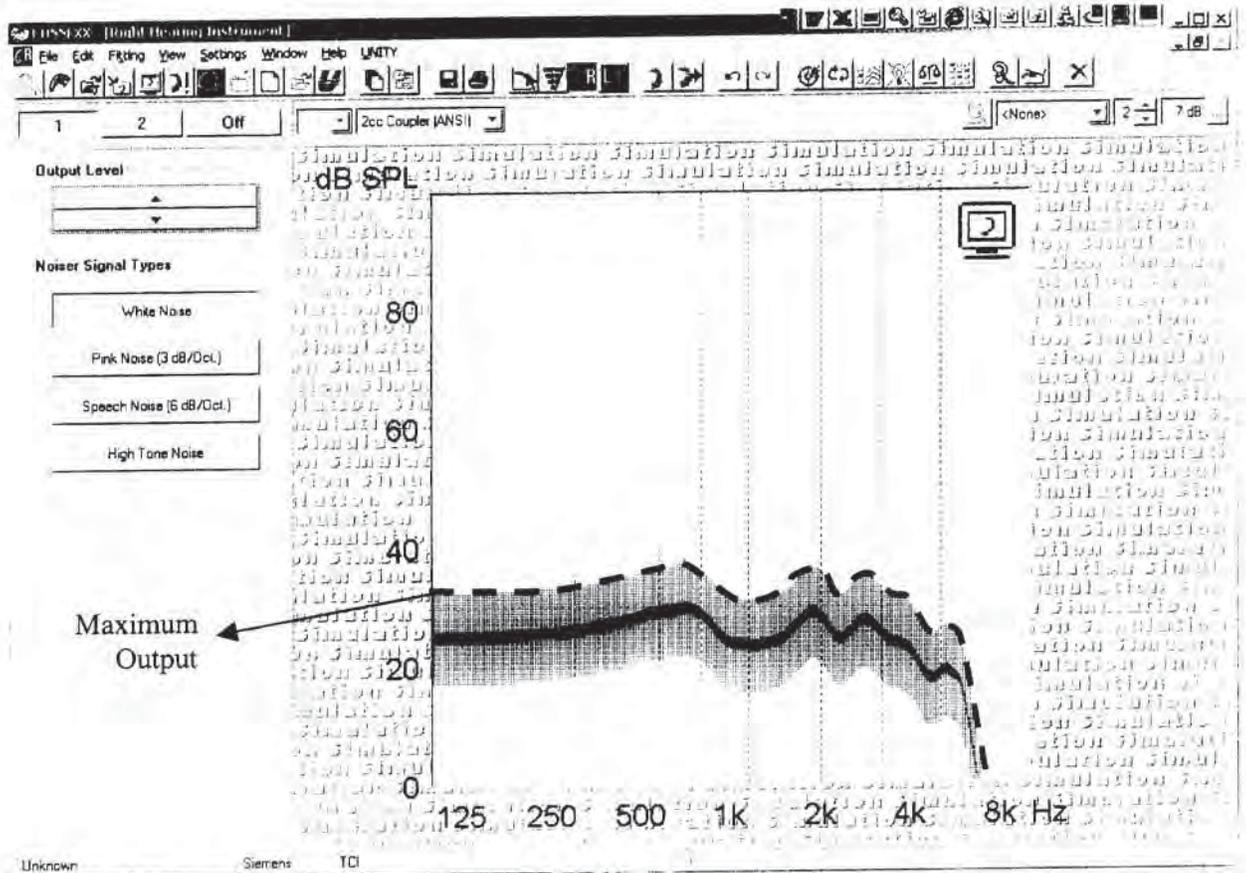


Figure 3 – Sample of white noise, overall output of 30 dB SPL and volume control range of 16 dB.

Power Consumption

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

Standards

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

Risks

Output

The TCI does not present a risk of inducing or increasing hearing loss in TCI 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 76 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 TCI for all their waking hours. Thus, if a TCI user wore the device at maximum output for a 16-hour period, he would not meet the maximum allowable exposure under OSHA regulations.

Battery door

The battery door on the device includes a lock to prevent access to the battery by children.

Note:

The initial submission for the TCI made reference to the TCI not posing a risk since the output was below 132 dB. This reference was to labeling requirements for hearing aid (CFR 801.420), “special care when selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user”. This reference is no longer valid since the TCI is a tinnitus masker, not a hearing aid.

Labeling

Technical Information

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

User's Manual

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

Software Validation

(b) (4)

Comparison of Siemens Hearing Instruments TCI Device and the Predicate Device

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

	Siemens Hearing Instrument TCI-Combi Device	General Hearing Instruments Tranquil Tri OE
Intended Use	Mask tinnitus as part of tinnitus management program	Mask tinnitus as part of tinnitus management program
Target Population	Adults and children (≥ 5 years) with tinnitus that are participating in a tinnitus management program	Adults with tinnitus that are participating in a tinnitus management program
Operation Circuit type Programmable Available noises Volume control	Digital Yes Four Yes	Analog No One Yes
Physical Description	Standard behind-the-ear instrument housing	Custom in-the-ear product
RMS Output Characteristics White noise Pink noise Speech noise High-tone noise	71 dB SPL 69 dB SPL 69 dB SPL 76 dB SPL	75 dB SPL
Volume control range	Programmable: OFF, 8 dB, 16 dB, 32 dB	40 dB

Table 2 - TCI Comparison with Predicate Device

Discussion

The intended use of the TCI and predicate device are the same. The RMS output levels between the two devices are comparable. The target population of the TCI is adults and children 5 years of age and older. The target population of the predicate device is adults.

The primary differences between the two devices lie in the physical descriptions and differences between analog and digital technology. While the TCI is a behind-the-ear instrument and the predicate device is an in-the-ear instrument, both devices deliver sound energy to the external ear canal. The location of the noise-producing transducer is unimportant; the noise itself is the important functional consideration.

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

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Appendix A

Technical Specifications

04224•SERENITI TCI PTF qxd 3/14/01 5:27 PM Page 1

SIEMENS

Preliminary Technical Inform

FILE NAME: SERENITI TCI PTF qxd
LOC: Administrative

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JCBF/SHI4200-4299/4224 2/27/01

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SERENITI™ TCI

tion for Tinnitus Control Behind-the-Ear Instruments

Tinnitus Control Instruments

Premium Features

- Programmable, fully digital BTE-instrument for Tinnitus therapy
- 2 individual therapy programs available with manual selection
- 4 pre-programmed noise types, with fine-tuning possible in 8 channels
- Wide range of output levels
- Volume control with programmable range
- Professional fitting with powerful, easy-to-use CONNEXX™ software fitting system

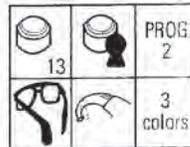


SERENITY™ TGI

Fitting Parameters

Programmable:

- 8-channel filterbank
- Volume control range
- Output level



Options

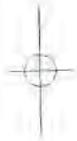
- Standard colors: Beige, Grey, Tobacco

Accessories

- Eyeglass adapter
- Small ear hook

Technical Data

Output Sound Pressure Level	
Broadband	
Master Output Level (L) Range	
VC range (programmable)	



Battery	
Voltage	1.3 V
Current Drain	0.6 mA
Battery Life (typical) Type 13 Zinc Air	approx. 400 h

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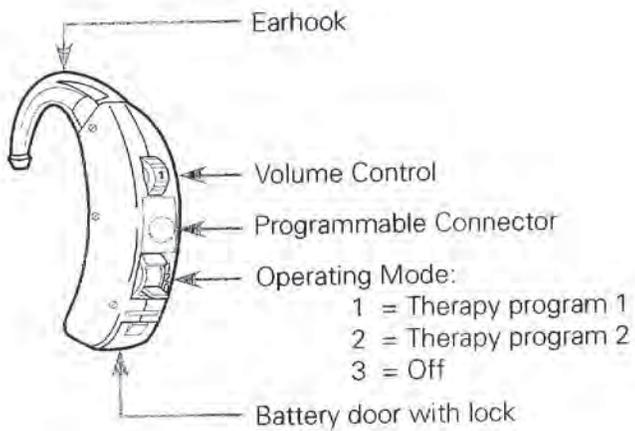
SERENITI™ TCI

2 cc Coupler

85 dB

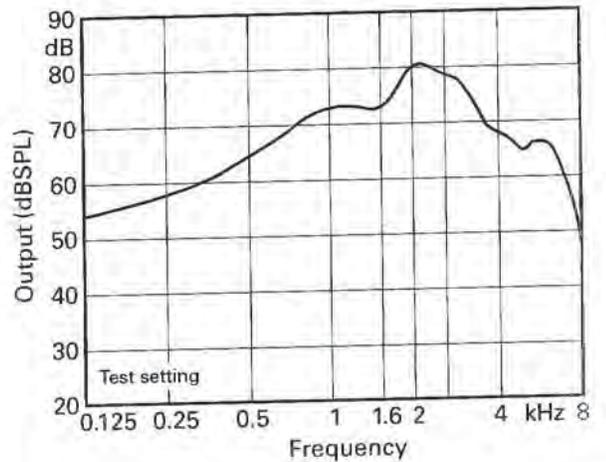
81 dB

32 - 16 - 8 - off (dB)



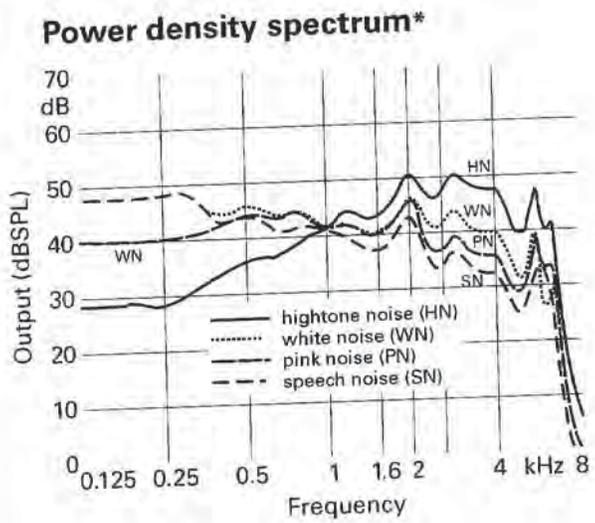
Therapy Noise Characteristics

Noise in 1/3 octave bands*



*Measureme

SERENITI™ TC1



nt conditions; 2 cc coupler

Fitting Parameters

Volume Control-Range

Master Level Control

81 dB combined adjustment



1

2

3

MAX

MAX

MAX

Channel Level Control

Reduction
in 1.5 dB
steps

Reduction
in 1.5 dB
steps

Reduction
in 1.5 dB
steps

 Test setting

SERENITI™ TCI

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

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

4

MAX

5

MAX

6

MAX

7

MAX

8

MAX

Reduction
in 1.5 dB
steps

Output Level

MAX

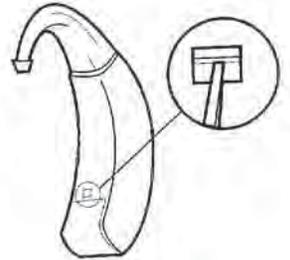
Technical Description

Standard features

Lock for battery door

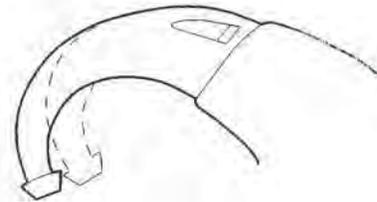
Unintentional access to the battery compartment is minimized with a lock located on the inner side of the instrument. The feature is helpful with small children and the mentally challenged.

Use a tool suited to the purpose to open or close the safety device. Pushing the slide upwards unlocks the battery compartment, pushing the slide downward locks the battery compartment.



Heat-shaped earhook

Can be heat-shaped for a precise fit.



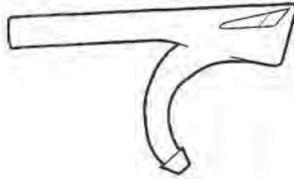
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SERENITY™ TCI

Accessories

Eyeglass adapter

To fit the instrument onto eyeglasses.
Transparent.



Order No. 29 22 289

Small earhook

For children, as well as adults with small ears.



Order No. 29 23 923

04224•SERENITI TCI BTE.qxd 3/14/01 5:27 PM Page 6



Siemens Hearing Instruments, Inc.

Northeast/US HQ: P.O. Box 1397, Piscataway, NJ 08855-1397 • (732) 562-6600 or (800) 422-4540

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) 422-4540

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LOC: Administrative/SHI Jobs/SHI4200-4299/4224 2/27/01

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SHI/04224-1

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Appendix B

User's Manual

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SIEMENS

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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**User's Manual for SERENITI™
Tinnitus Control Instrument (TCI)
Behind-the-Ear Model**



03727109.3001.1.0.22P753.15K
SHI04229-1

FILE NAME: 04229-1*TCI BTE User Manual
LOC: Administrative/SHI Jobs/SPT04200-04299/04229 3/15/01

FILE NAME: 04229-1*TCI BTE User Manual
LOC: Administrative/SHI Jobs/SPT04200-04299/04229 3/15/01

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

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

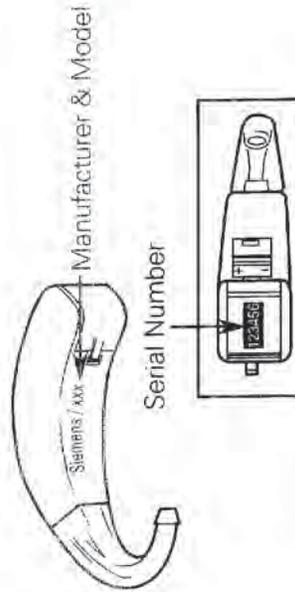
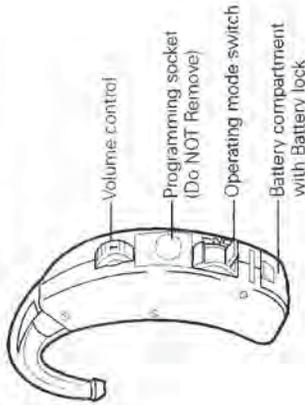
The output of the TCI noiser (masker) is within safe limits for noise exposure set by OSHA and poses no risk to induce or increase hearing loss in normal hearing individuals (Federal Register 448 (46) 9737-9785, March 8, 1983).

Note: While some Hearing Health Care Professionals recommend use of this type of device with children 5 years of age or older, the clinical efficacy of this device with children has not been proven.

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Getting Familiar with Your Instrument

The Siemens behind-the-ear (BTE) instrument is designed for comfort, performance and durability. It fits comfortably behind your ear and is attached to a custom-made earmold.



Each instrument has its model and manufacturer on the case. The serial number can be found where illustrated.

The battery compartment holds the battery that powers the instrument.

The volume control allows you to adjust the level of the therapy sound for your comfort.

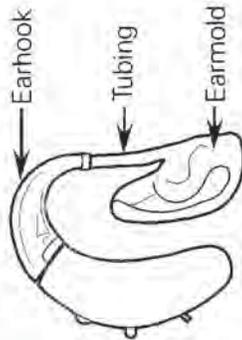
The "1-2-0" switch indicates the instrument's operational mode or turns the instrument off.

When the instrument is in the "0" position, the instrument is Off.

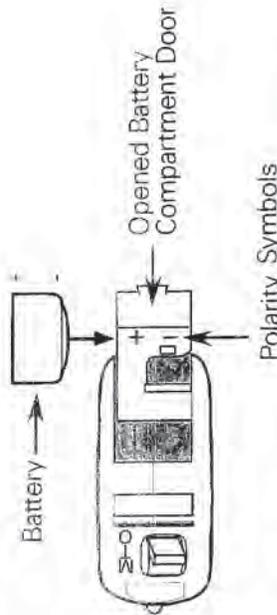
Your Hearing Health Care Professional can advise you on the proper use of all function settings.

Using Your Instrument Attaching the Earmold

Gently insert the earhook of the instrument into the tubing and earmold supplied by your Hearing Health Care Professional.



Inserting the Battery



To place the battery into the instrument, swivel open the door of the battery compartment. Place the proper size battery (see "Battery" section or consult your Hearing Health Care Professional) so that the "+" symbol on the battery coincides with the "+" mark on the battery compartment.

Gently close the battery compartment. Do not force the battery door shut. If the door does not close easily, check to see if the battery is inserted upside down. When the battery door is completely closed, your instrument is ready for operation.

Inserting the Instrument

Take the earmold between your thumb and index finger. Gently work the earmold into its proper position by slightly adjusting it until it is firmly seated in your ear. Then lift the instrument over the top of your ear and adjust it to fit behind your ear. Press it in gently for a secure and comfortable fit (as illustrated).



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Removing the Instrument

When removing the instrument from your ear, gently push on the back of the ear to help release the earmold and gently pull it out (as illustrated).



Health Considerations

If soreness or skin irritation develops, 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.

Using the Operating Mode Switch

This instrument has an operating mode switch which you use to change the characteristics of sound coming through the instrument.

To change the response of the instrument, simply change the position of the operating mode switch and the sound will change.

These modes are arranged in a line. You reach therapy program #1 or #2 by moving the switch to those positions. When the switch is in the "O" position, the instrument is off.

Behind-the-Ear Earmold Maintenance and Care

The earmolds should be cleaned daily by wiping them with a tissue or a soft cloth. When necessary, remove the earmold from the instrument and soak it in a mild soap solution and wipe it dry.

Never immerse your instrument!

Allow the earmold to completely dry overnight before reconnecting it to the instrument.

If the earmold is not dry, do not attach it to the instrument as this can cause damage. Do not use a hair dryer, oven or microwave oven to dry the earmold.

Battery

The chart below provides the battery size used in your instrument. It's recommended that you also check with your Hearing Health Care Professional regarding the correct battery.

<u>Model</u>	<u>Battery Size</u>
SERENITI™ Behind-the-Ear	13

TOP

Appendix C

Documentation of Product Software Review

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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: February 16, 2001

OFFICIAL STATEMENT

I confirm, that TCI BTE and TCI Combi BTE was included for the release for SIFIT 3.3



(Jörg Bindner)
Head of software development

100

(b)

(4)

Appendix D

Technical Specifications of Predicate Device

1/2

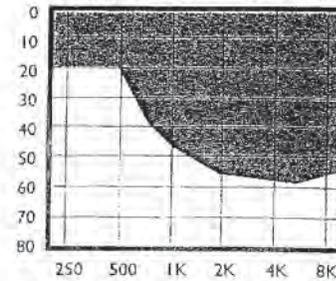
TRANQUIL™

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.

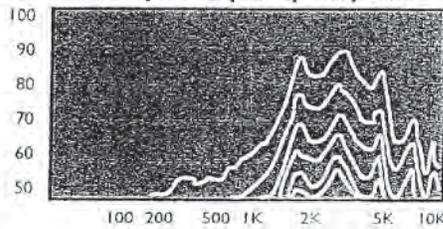
Suggested Fitting Range



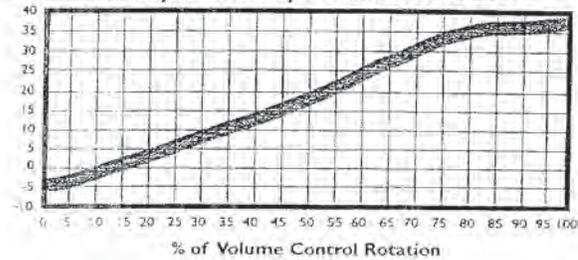
All thresholds need not fall within the shaded area.

Typical Output . . . RMS 75 dB SPL
 Battery Drain . . . 0.4 - 0.45 mA

Tranquil Frequency Response



Tranquil V.C. Taper Characteristics



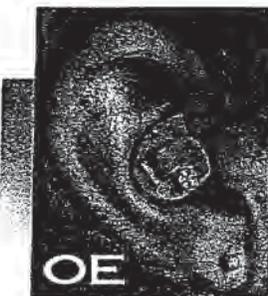
10A Battery	
Battery Life Chart	
24	5.8
23	6.1
22	6.4
21	6.7
20	7.0
19	7.4
18	7.8
17	8.2
16	8.8
15	9.4
14	10.0
13	10.8
12	11.7
11	12.8
10	14.1
9	15.6
8	17.6
7	20.1
6	23.5
5	28.2
4	35.2
3	47.0
2	70.5
1	141

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 canal 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 design which houses the circuitry in the helix portion of the ear shell. It incorporates a 312 battery and a cavity retention arm to properly direct the receiver and maintain the open inferior canal.

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

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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.

SIEMENS

K003559/s1

February 20, 2001

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

Attn: Document Mail Clerk

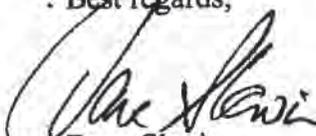
Re: Additional Information Request for 510(k) Submission K003559

Dear Dr. Kane:

Enclosed please find the additional information that you requested concerning the above referenced 510(k) submissions. We have included the 510(k) summary, following the required format. We believe that we have addressed each of the questions put forth in your letter dated, January 24, 2001. We have also included a table of contents for each submission and have provided a duplicate copy for each submission.

Should any further questions arise during your review, please feel free to contact me directly at the phone number indicated on the summary page.

Best regards,



Dave Slavin
Director of Quality Assurance and Regulatory Affairs

FDA/CDRH/OCE/DAC
FEB 22 9 11 AM '01

SK4 142

Siemens Hearing Instruments, Inc.

10 Constitution Avenue P.O. Box 1397 Piscataway, New Jersey 08855-1397 (732) 562-8000 <http://www.siemens-hearing.com>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA.HHS.GOV or 301-796-8118

K003559

TCI

Siemens Hearing Instruments, Inc.

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

510(K) Summary for the Siemens TCI

REVISED 2/15/01

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:** TCI (Tinnitus Control Instrument)

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

Product Code: **KLW**

5. **Establishment Registration Number:** 2217809

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

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

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

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

10. **Indications for Use:**

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

See additional information in Section 2.

11. **Description of Device:**

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

See additional information in Sections 2 and 3.

12. **Proposed Labeling:**

Technical Specifications are in Section 8, Appendix A, and revised User's Manual is in Section 9, Appendix B.

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

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

See additional information in Section 7.

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

Risks:

There are no risks associated with this device because the output of the noiser does not exceed OSHA exposure limits. See additional information in Section 4.

Hearing Healthcare Professional Diagnosis:

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

Benefits:

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

Warnings for Safe Use:

As this device cannot deliver damaging sound intensity, no warning is required about sound output level. General use precautions are on pages 6 and 8 of the User's Manual, Section 9, Appendix B.

Specifications:

See details in Sections 2 and 3 and Technical Specifications for the Hearing Health Care Professional in Section 8, Appendix A.

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Product Description

Indications for Use

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

Target Population

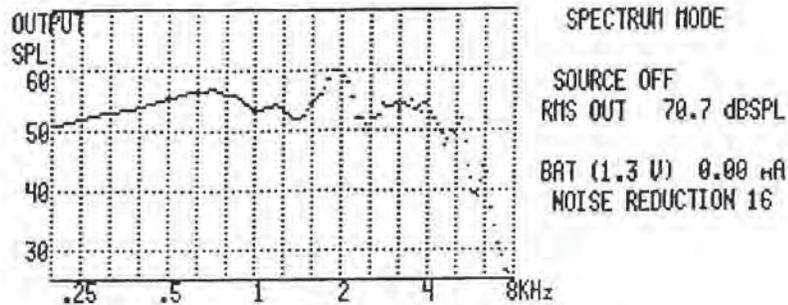
The target population is primarily the adult population over 18 years of age. It has been estimated 17 percent of the adult population reports tinnitus, including 33 percent of the population over 60 reporting some degree of tinnitus (Bauman, 1998). The target group for this product includes individuals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

Principles of Operation

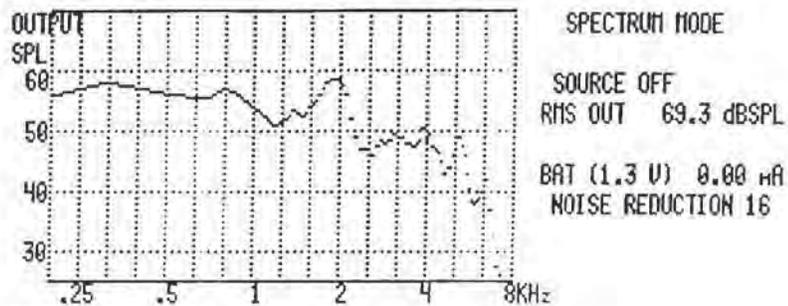
The device is a programmable digital tinnitus masker, allowing the programming of the noise characteristics through the use of software installed on a personal computer. Four types of noise spectra are pre-programmed as noisers – white noise, pink noise, speech noise, and high-tone noise. Figure 1 displays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

Figure 1 – Noise Types

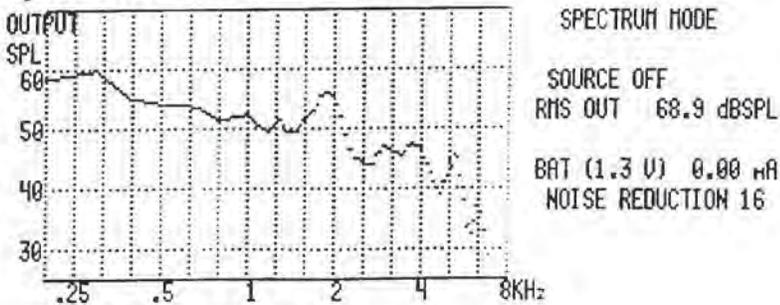
A. White Noise



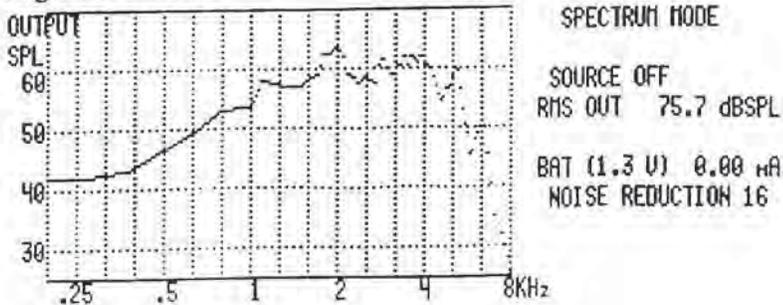
B. Pink Noise



C. Speech Noise



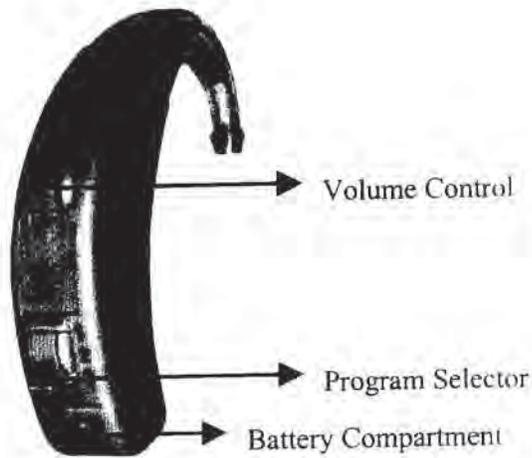
D. High-tone Noise



Physical Description

The product is housed in a standard behind-the-ear casing. The material and composition of this case is identical to behind-the-ear hearing aids in use by Siemens. This housing type is similar to that of the Siemens Hearing Instruments Piano Series behind-the-ear devices (K942857). Figure 2 displays the TCI behind-the-ear device.

Figure 2 – TCI Behind-the-Ear Device



Technical Specifications

Output Characteristics

Figure 1 in the previous section shows the maximum output for the four noise types. As shown in the figure, the output at any one frequency of the white noise, pink noise, and speech noise does not exceed 60 dB SPL. The maximum output at 2000 Hz of the high-tone noise is 63 dB SPL. Table 1 displays the overall RMS output of the four noises.

Noise Type	RMS Output
White Noise	70.7 dB SPL
Pink Noise	69.3 dB SPL
Speech Noise	68.9 dB SPL
High-tone Noise	75.7 dB SPL

Table 1- RMS Output of TCI Noises

Programming

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

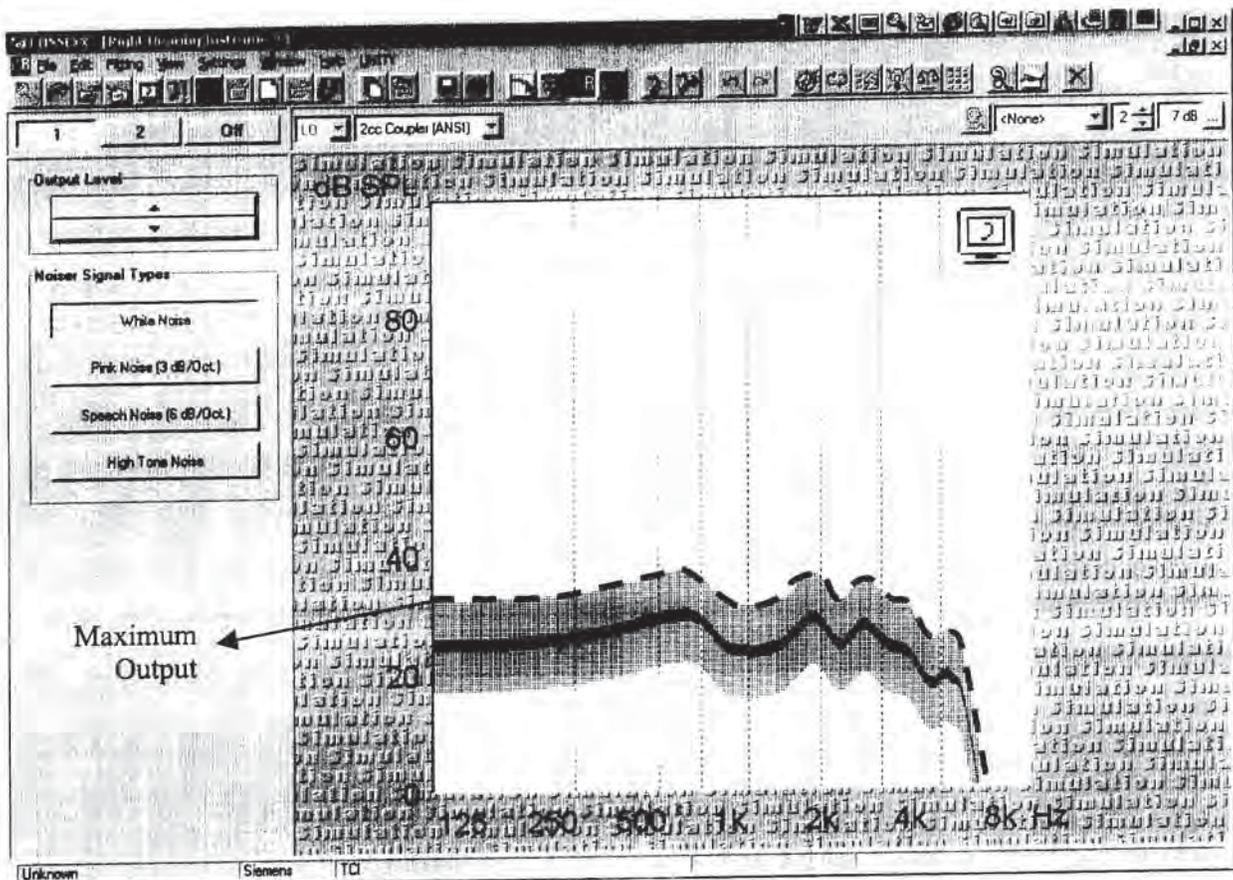


Figure 3 – Sample of white noise, overall output of 30 dB SPL and volume control range of 16 dB.

Power Consumption

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

Standards

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

Risks

Output

The TCI does not present a risk of inducing or increasing hearing loss in TCI 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 76 dB SPL. This level poses no significant risk as it is below the compliance levels currently in use by OSHA (Federal Register 448 (46) 9737-9785, March 8, 1983). These regulations specify 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 TCI for all their waking hours. Thus, if a TCI user wore the device at maximum output for a 16-hour period, he would not meet the maximum allowable exposure under OSHA regulations.

Battery door

The battery door on the device includes a lock to prevent access to the battery by children.

Note:

The initial submission for the TCI made reference to the TCI not posing a risk since the output was below 132 dB. This reference was to labeling requirements for hearing aid (CFR 801.420), "special care when selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user". This reference is no longer valid since the TCI is a tinnitus masker, not a hearing aid.

Labeling

Technical Information

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

User's Manual

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

Software Validation

(b) (4)

Comparison of Siemens Hearing Instruments TCI Device and the Predicate Device

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

	Siemens Hearing Instrument TCI-Combi Device	General Hearing Instruments Tranquil Tri OE
Intended Use	Mask tinnitus as part of tinnitus management program	Mask tinnitus as part of tinnitus management program
Target Population	Adults and children with tinnitus that are participating in a tinnitus management program	Adults and children with tinnitus that are participating in a tinnitus management program
Operation Circuit type Programmable Available noises Volume control	Digital Yes Four Yes	Analog No One Yes
Physical Description	Standard behind-the-ear instrument housing	Custom in-the-ear product
RSM Output Characteristics White noise Pink noise Speech noise High-tone noise	71 dB SPL 69 dB SPL 69 dB SPL 76 dB SPL	75 dB SPL
Volume control range	Programmable: OFF, 8 dB, 16 dB, 32 dB	40 dB

Table 2 - TCI Comparison with Predicate Device

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Discussion

The intended use and target population of the TCI and predicate device are the same. The RMS output levels between the two devices are comparable.

The differences between the two devices lie in the physical descriptions and differences between analog and digital technology. While the TCI is a behind-the-ear instrument and the predicate device is an in-the-ear instrument, both devices deliver sound energy to the external ear canal. The location of the noise-producing transducer is unimportant; the noise itself is the important functional consideration.

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

Appendix A

Technical Specifications

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SIEMENS

Preliminary Technical Informa

FILE NAME: 04224 1•SERENITI TCI.jxd
LOC: Administrative S1 rev/SHT4200-4299/4224 2/16/01

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SERENITI™ TCI

on for Tinnitus Control Behind-the-Ear Instruments

04224•SERENITI TCI BIE qxd 2/16/01 12:15 PM Page 2

FILE NAME: 04224•SERENITI TCI BIE qxd
LOC: Administrative B SH14200-4299/4224 2/16/01

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Tinnitus Control Instruments

Premium Features

- Programmable, fully digital BTE-instrument for tinnitus therapy
- 2 individual therapy programs available with manual selection
- 4 pre-programmed noise types, with fine-tuning possible in 8 channels
- Wide range of output levels
- Volume control with programmable range
- Professional fitting with powerful, easy-to-use CONNEXX™ software fitting system



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SERENITI™ TCI

Fitting Parameters

Programmable:

- 8-channel filterbank
- Volume control range
- Output level

 13	 2	PROG 2
		3 colors

Options

- Standard colors: Beige, Grey, Tobacco

Accessories

- Eyeglass adapter
- Small ear hook

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Technical Data

Output Sound Pressure Level

Broadband

Master Output Level (L) Range

VC range (programmable)



Battery

Voltage	1.3 V
Current Drain	0.6 mA
Battery Life (typical) Type 13 Zinc Air	approx. 400 h

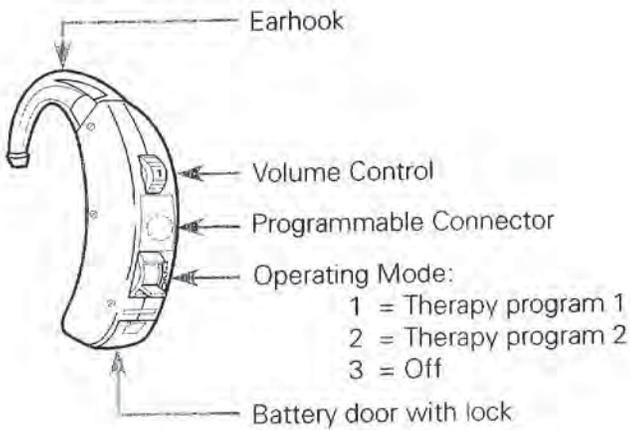
SERENITI™ TCI

2 cc Coupler

85 dB

81 dB

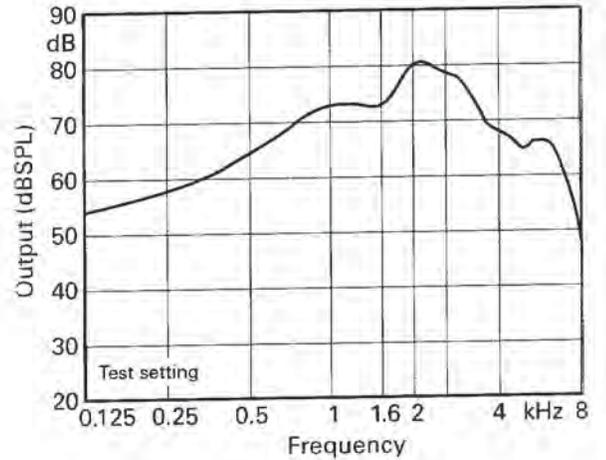
32 - 16 - 8 - off (dB)



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Therapy Noise Characteristics

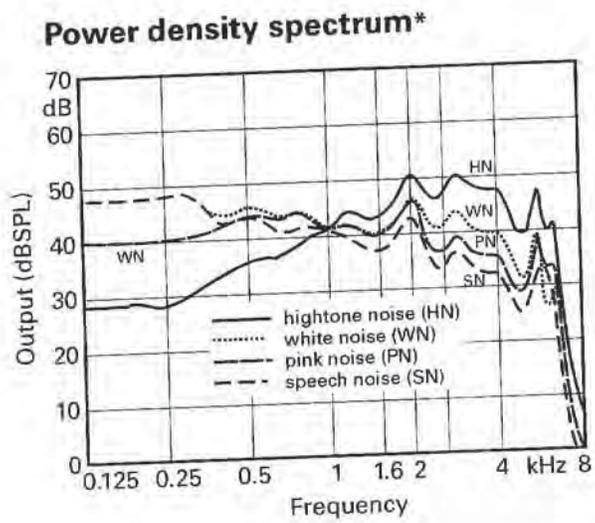
Noise in 1/3 octave bands*



*Measurement

140

SERENITI™ TCI



Conditions: 2 cc coupler

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Fitting Parameters

Volume Control-Range

Master Level Control

81 dB combined adjustment



1

2

3

MAX

MAX

MAX

Channel Level Control

Reduction
in 1.5 dB
steps

Reduction
in 1.5 dB
steps

Reduction
in 1.5 dB
steps

Δ Test setting

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SERENITI™ TCI

f - 8 dB - 16 dB - 32 dB

range (54 x 1.5 dB) from to minimum level - off

4	5	6	7	8	
<input type="text" value="MAX"/>					
Reduction in 1.5 dB steps					

Output Level

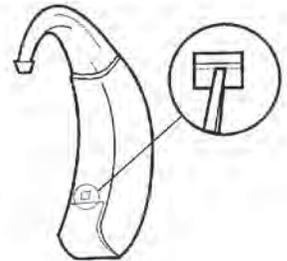
Technical Description

Standard features

Lock for battery door

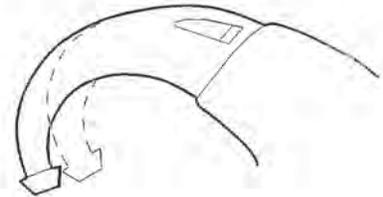
Unintentional access to the battery compartment is minimized with a lock located on the inner side of the instrument. The feature is helpful with small children and the mentally challenged.

Use a tool suited to the purpose to open or close the safety device. Pushing the slide upwards unlocks the battery compartment, pushing the slide downward locks the battery compartment.



Heat-shaped earhook

Can be heat-shaped for a precise fit.



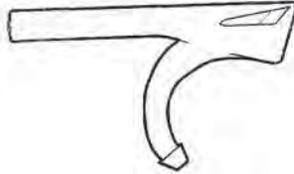
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SERENITI™ TCI

Accessories

Eyeglass adapter

To fit the instrument onto eyeglasses.
Transparent.



Order No. 29 22 289

Small earhook

For children, as well as adults with small ears.



Order No. 29 23 923



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Siemens Hearing Instruments, Inc.

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South: (770) 422-4540 or (800) 922-9998

West: (562) 404-4531 or (800) 998-9787

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

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Appendix B

User's Manual

SIEMENS

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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*User's Manual for SERENITI™
Tinnitus Control Instrument (TCI)
Behind-the-Ear Model*



03727109 2/01 1.0 22P753 15K
SHI/04229-1

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

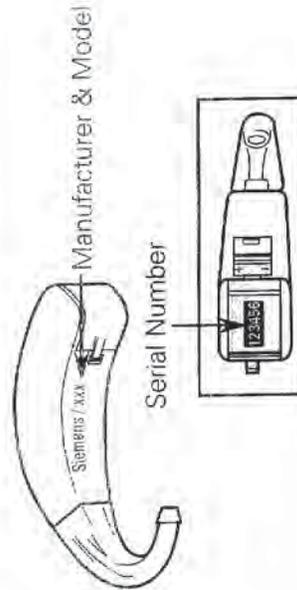
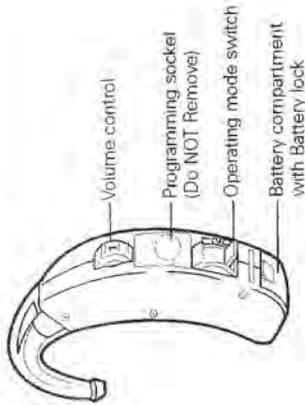
Most tinnitus therapy programs recommend the volume of noise be set equal to or slightly lower than the perceived level of the tinnitus (5-10 dB Sensation Level (SL)). This noise level should not interfere with speech understanding. Your Hearing Health Care Professional can instruct you on specific volume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

The output of the TCI noiser (masker) 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).

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Getting Familiar with Your Instrument

The Siemens behind-the-ear (BTE) instrument is designed for comfort, performance and durability. It fits comfortably behind your ear and is attached to a custom-made earmold.



Each instrument has its model and manufacturer on the case. The serial number can be found where illustrated.

The battery compartment holds the battery that powers the instrument.

The volume control allows you to adjust the level of the therapy sound for your comfort.

The "1-2-O" switch indicates the instrument's operational mode or turns the instrument off.

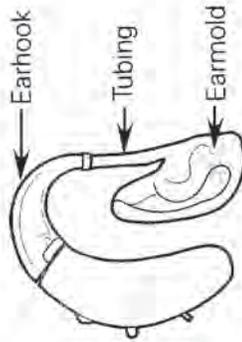
When the instrument is in the "O" position, the instrument is Off.

Your Hearing Health Care Professional can advise you on the proper use of all function settings.

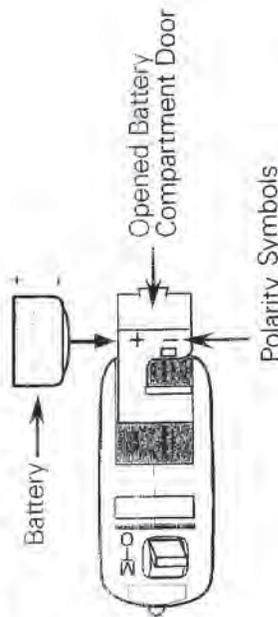
Using Your Instrument

Attaching the Earmold

Gently insert the earhook of the instrument into the tubing and earmold supplied by your Hearing Health Care Professional.



Inserting the Battery

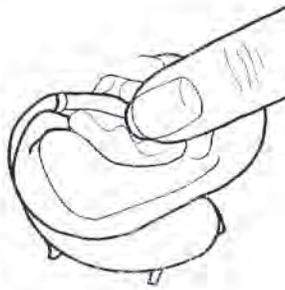


To place the battery into the instrument, swivel open the door of the battery compartment. Place the proper size battery (see "Battery" section or consult your Hearing Health Care Professional) so that the "+" symbol on the battery coincides with the "+" mark on the battery compartment.

Gently close the battery compartment. Do not force the battery door shut. If the door does not close easily, check to see if the battery is inserted upside down. When the battery door is completely closed, your instrument is ready for operation.

Inserting the Instrument

Take the earmold between your thumb and index finger. Gently work the earmold into its proper position by slightly adjusting it until it is firmly seated in your ear. Then lift the instrument over the top of your ear and adjust it to fit behind your ear. Press it in gently for a secure and comfortable fit (as illustrated).



Removing the Instrument

When removing the instrument from your ear, gently push on the back of the ear to help release the earmold and gently pull it out (as illustrated).



Health Considerations

If soreness or skin irritation develops, 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.

Using the Operating Mode Switch

This instrument has an operating mode switch which you use to change the characteristics of sound coming through the instrument.

To change the response of the instrument, simply change the position of the operating mode switch and the sound will change.

These modes are arranged in a line. You reach therapy program #1 or #2 by moving the switch to those positions. When the switch is in the "O" position, the instrument is off.

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Behind-the-Ear Earmold Maintenance and Care

The earmolds should be cleaned daily by wiping them with a tissue or a soft cloth. When necessary, remove the earmold from the instrument and soak it in a mild soap solution and wipe it dry.

Never immerse your instrument!

Allow the earmold to completely dry overnight before reconnecting it to the instrument.

If the earmold is not dry, do not attach it to the instrument as this can cause damage. Do not use a hair dryer, oven or microwave oven to dry the earmold.

Battery

The chart below provides the battery size used in your instrument. It's recommended that you also check with your Hearing Health Care Professional regarding the correct battery.

<u>Model</u>	<u>Battery Size</u>
SERENITI™ Behind-the-Ear	13

Appendix C

Documentation of Product Software Review

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: February 16, 2001

OFFICIAL STATEMENT

I confirm, that TCI BTE and TCI Combi BTE was included for the release for SIFIT 3.3



(Jörg Bindner)
Head of software development

(b)

(4)

Appendix D

Technical Specifications of Predicate Device

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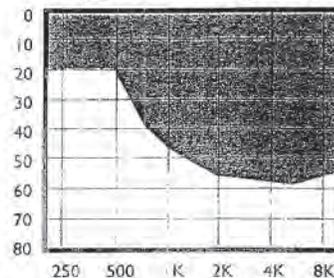
TRANQUIL™

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.

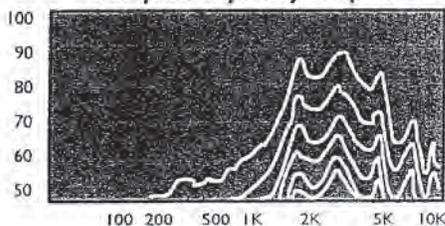
Suggested Fitting Range



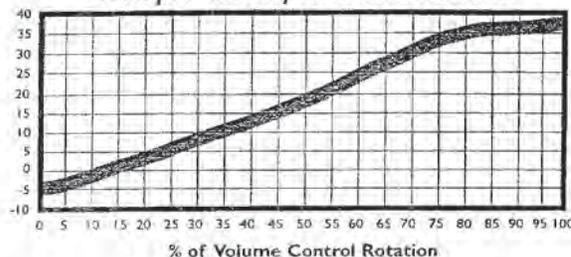
All thresholds need not fall within the shaded area.

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-mesh canal 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 fit 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.

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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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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 24 2001

Siemens Hearing Instruments
c/o David Slavin
10 Constitution Avenue
PO Box 1397
Piscataway, NJ 08855

Re: K003558 and K003559
Trade Name: TCI Combi (Tinnitus Control Instrument Combination)
and TCI (Tinnitus Control Instrument)
Dated: November 14, 2000
Received: November 28, 2000

Dear Mr. Slavin:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above. We cannot determine if the devices are substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following additional information:

(b) (4)

(b)

(4)

Page 3 – Mr. David Slavin

(b) (4)

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>.

You may not market these devices until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the devices without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute these devices for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of these devices must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

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Page 4 – Mr. David Slavin

The requested information, or a request for an extension of time, should reference your above 510(k) numbers and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact James K. Kane, Ph.D. at (301)594-2080. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,


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

Memorandum

From: Reviewer(s) - Name(s) JAMES K. KANE, Ph.D.

Subject: 510(k) Number K 003559

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

- Refused to accept.
- Requires additional information (other than refuse to accept). *AI Letter sent for 3558 + 3057*
- 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? | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Is this device subject to the Tracking Regulation? | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Was clinical data necessary to support the review of this 510(k)? | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Is this a prescription device? | <input checked="" type="checkbox"/> YES | <input type="checkbox"/> NO |
| Was this 510(k) reviewed by a Third Party? | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Special 510(k)? | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> 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
- 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): _____

77KLE, CLASS II, 874,3400

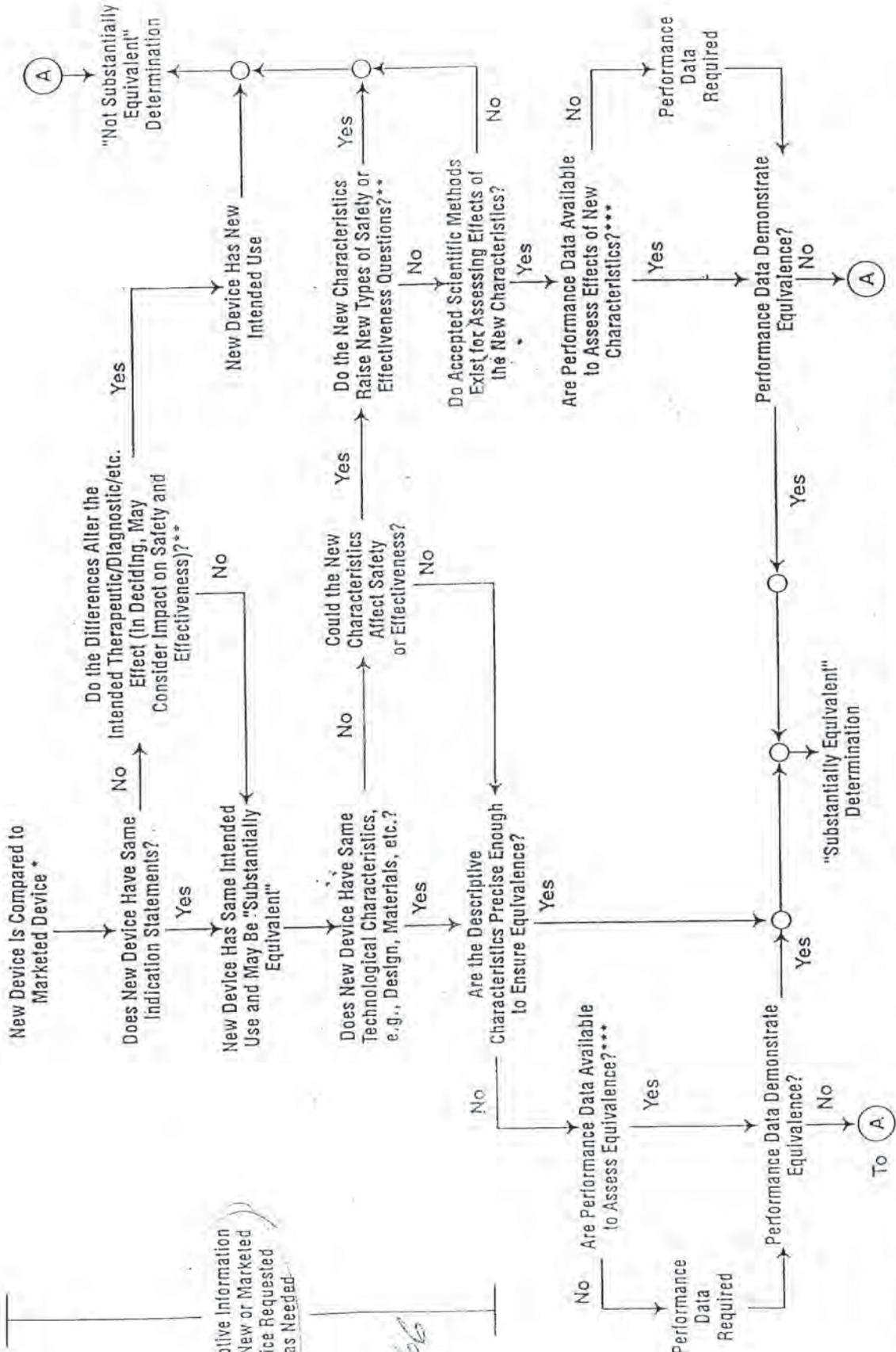
Review: [Signature] (Branch/Chief) [Signature] (Branch Code) _____ (Date)

Final Review: [Signature] (Division Director) 1/23/01 (Date)

Revised: 8/17/99

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



Descriptive Information about New or Marketed Device Requested as Needed

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

Center for Devices and Radiological Health

(ODE/DOED/ENTB)

To: The Record
From: James K. Kane, Ph.D.
Date: January 23, 2001
Through: James F. Saviola, O.D.
Branch Chief, VEDB
Acting Chief, ENTB
Re: K003559 Review Summary
Product Code: 77 KLW (Tinnitus Masker)

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

Document #: K003559
Company Name: Siemens Hearing Instruments
Contact Person: Dave Slavin
Device Name: TCI (Tinnitus Control Instrument)

CLASSIFICATION NAME: Tinnitus Masker

COMMON NAME: Tinnitus Masker

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

K974751 Tranquil Tri-OE General Hearing Instruments

INTENDED USE STATEMENT: The TCI is a behind-the-ear style electronic, air-conduction broadband-noise generator intended to generate noise of sufficient intensity and bandwidth to be used for tinnitus habituation therapy and is also suitable for tinnitus masking therapy. The intended use of this device includes it's fitting by a qualified audiologist or other hearing healthcare professional familiar with the diagnosis of hearing impairment and tinnitus and subsequent rehabilitation therapies for both. This device is seen as substantially equivalent to other hearing aid and tinnitus masker devices existing in the marketplace today (i.e., General Hearing Instruments Tranquil Tri-OE).

	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 - SE
8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?		- IF YES, STOP - NE
9. ACCEPTED SCIENTIFIC METHODS EXIST?		- IF NO, STOP -NE
10. PERFORMANCE DATA AVAILABLE?		X
		-IF NO, REQUEST DATA
11. DATA DEMONSTRATE EQUIVALENCE?		FINAL DECISION

SUBMISSION PROVIDES:

Comparative Specifications:	NO
Comparative Lab Data:	N/A
Summary of Animal Testing:	N/A
Summary of Clinical Testing:	N/A
510(K) Summary:	YES

GENERAL INFORMATION SUMMARY:

Life-Supporting or Life-Sustaining:	N/A
Is it an Implant? (Long Term or Short Term)	NO
Software Driven:	YES
Level of Concern	
Certification	LOW
Sterility:	N/A

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Single Use:	YES
Home or prescription use:	YES
Drug or Biologic product:	NO
Device a kit:	NO

Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Provide a summary about the device design, materials, physical properties and toxicology profile if important.

Device Description:

The TCI is a fully digital, low-level noise generator that was developed to be used along with appropriate counseling and / or tinnitus therapy. TCI is meant to be used by those individuals with symptoms of tinnitus, but with hearing within-normal-limits. This product is programmable, with an 8-channel equalizer, and allows the signal to be custom-tailored to the user's individual requirements. A choice of four, noise-types (hightone, white, pink, speech) are available for selection, but a maximum of two types can be programmed into device memories. Within-channel gain is limited to 81 dB for any of the noises.

Though the application lacks descriptive detail, the technical specification sheets state that the device is digitally programmable via the sponsor's proprietary software fitting system (CONNEXX). This software is used for programming all of the sponsor's hearing instruments and has been in commercial use for several years.

The particular masker noise stored in memory may be selected via a "program switch" by the user.

B. Device Materials and Toxicity

No new materials are being proposed. All components are commonly used by the hearing aid industry.

The sponsor, in reporting potential "risks", makes the statement that there are no risks associated with this device because the output noise intensity does not exceed 132 dB SPL. However, this statement was not supported by data or literature, and the draft technical information did not list this value anywhere. This level of noise exposure is toxic and known to cause hearing loss. In contrast, the technical specification sheet reported that the overall broadband noise level was 85 dB, a nontoxic intensity level. Therefore, the sponsor needs to clarify this issue ensuring that the device does not have the potential to cause hearing loss.

C. Comparative Specifications

The sponsor stated that the TCI is substantially equivalent to the General Hearing Instruments Tranquil Tri-OE, a tinnitus masking device. The sponsor noted that the Siemens device was a programmable digital product, which provided greater flexibility than the Tranquil. No other comparative data were provided.

D. Physical Properties and Performance Testing

The sponsor did not cite any specific performance standards in their submissions. However, the technical data sheets reference ANSI S3.22-1996, "Specifications of Hearing Aid Characteristics, and IEC-118-7 (title unknown). The use of a hearing-aid standard for parameter specification is inappropriate. This device does not have a

microphone to pick-up external sounds to amplify for hearing-impaired individuals. Rather, it functions solely as a noise generator.

E. Clinical Testing

N/A

F. Sterilization

N/A

G. Device Labeling

The "Proposed Labeling" supplied by the sponsor included a booklet entitled "*General Information for Hearing Aid Users*" and draft paperwork entitled, "*User's Manual for TCI BTE Hearing Aids*." The former booklet was not device specific and did not address the operational characteristics of the device. The draft technical sheets discussed general operational principles of a hearing-aid having multiple memories, along with its care and use. However, a definition of tinnitus and an operational description of the masker function of the device was absent from the draft material. All references to hearing-aid usage and function need to be eliminated.

H. 510 (k) Summary

A 510(k) Summary or Statement (per 21 CFR 807.87(h) clearly identified as such, having the necessary content and format as required by 21 CFR 807.92c was not a part of the submission. Rather, two pages of information entitled, "*510(k) Submission for the Siemens TCI*" was included and obviously was meant to meet the 510(k) Summary requirement.

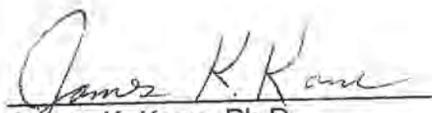
RECOMMENDATION:

Based on the material provided, I cannot determine if the device is substantially equivalent to the predicate device cited by the sponsor. A request for additional information about the device is necessary before a final decision can be made.

CFR# 874.3400

Product Code 77-KLW

CLASS II


James K. Kane, Ph.D.
Scientific Reviewer/Audiology

1/23/01
Date

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Screening Checklist For all Premarket Notification 510(k) Submissions

Device Name: <i>TCI (Tinnitus Control Instrument)</i>						K008669						
Submitter (Company):												
Items which should be included (circle missing & needed information)						S P E C I A L	A B B R E V I A T E D	T R A D I T I O N A L	✓ 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) Traditional 510(k)												
2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS								✓ IF ITEM IS NEEDED				
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)						NA		YES		NO		AND IS MISSING
						SPECIALS		ABBREVIATED		TRADITIONAL		
						YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, device class										✓		
b) OR a statement that the device is not yet classified						FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device						NA				✓		
d) compliance with Section 514 - performance standards						NA						
e) address of manufacturer										✓		
f) Truthful and Accurate Statement										✓		
g) Indications for Use enclosure										✓		
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)												
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)												
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals										✓		
k) Proposed Labeling:										✓		
i) package labeling (user info)										✓		
ii) statement of intended use										✓		
iii) advertisements or promotional materials										✓		
i) MRI compatibility (if claimed)										✓		
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:												
i) Labeling												✓
ii) intended use												✓
iii) physical characteristics												✓
iv) anatomical sites of use												✓
v) performance (bench, animal, clinical) testing						NA						✓
vi) safety characteristics						NA						✓
m) If kit, kit certification												
3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE												
a) Name & 510(k) number of legally marketed (unmodified) predicate device												
b) STATEMENT - INTENDED USE AND INDICATIONS												* If no - STOP not a special

FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS 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:							
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:							
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:							
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

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

Passed Screening Yes No
 Date: 12/26/00

Reviewer: James R. Rom, Ph.D.
 Concurrence by Review Branch: [Signature]

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Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?		4/3
4. If, not, has POS been notified?	✓	✓
5. Is the product a device?		✓
6. Is the device exempt from 510(k) by regulation or policy?	✓	
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

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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

November 17, 2000

SIEMENS HEARING INSTRUMENTS, INC. 510(k) Number: K003559
10 CONSTITUTION AVE. Received: 17-NOV-2000
P.O. BOX 1397 Product: TCI (TINNITUS
PISCATAWAY, NJ 08855 CONTROL INSTRUMENT)
ATTN: DAVID S. SLAVIN

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

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

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

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

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation

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SIEMENS

K003559-A1

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

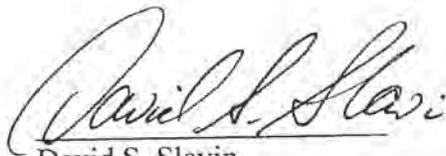
November 14, 2000

Attn: Document Mail Clerk

Re: 510(K) Submissions K003559 and K003558, Indications for Use Request

Enclosed please find the separate page "Indications for Use" as requested in your correspondence dated November 17, 2000 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

11/27/2000

Date

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FDA/CDRH/OCE/DHC

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SKJ

Siemens Hearing Instruments, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI STATUS@fda.hhs.gov or 301-796-8118
10 Constitution Avenue P.O. Box 1397 Piscataway, New Jersey 08855-1397 (NJ) Tel: 732-326-7000 Fax: 732-326-7001 www.siemens-hearing.com

510(K) NUMBER (IF KNOWN): **K003559**

DEVICE NAME: **TCI**

INDICATIONS FOR USE:

The TCI is a behind-the-ear style electronic, air conduction broad-band noise generator intended to generate noise of sufficient intensity and bandwidth to be used for tinnitus habituation therapy and is also suitable for tinnitus masking therapy. The intended use of this device includes it's fitting by a qualified audiologist or other hearing healthcare professional familiar with the diagnosis of tinnitus and subsequent rehabilitation therapy. This device is seen as substantially equivalent to other devices existing in the marketplace today (i.e. General Hearing Instruments Tranquil Tri-OE).

(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)

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K 0-3559



(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

November 14, 2000

Attn: Document Mail Clerk

Re: 510(K) Submission - Siemens Hearing Instruments TCI Device

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

Truthful and Accurate Statement:

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

David S. Slavin
Director of Quality Assurance and Regulatory Affairs

11/14/2000
Date

100, 11/14/2000

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Siemens Hearing Instruments, Inc.

10 Constitution Avenue, Rockville, MD 20850
Questions? Contact FDA/CDRH/OCE/DD at CDRH-FOI STATUS@fda.hhs.gov or 301-796-8118 <http://www.siemens-hearing.com>

SKL

510(K) Submission for the Siemens TCI

1. Applicant's Name & Address: Siemens Hearing Instruments
10 Constitution Ave.
PO Box 1397
Piscataway, NJ 08855
2. Contact Person, Telephone and e-mail Address: Dave Slavin
732-562-6658
dslavin@siemens-hearing.com
3. Device Trade or Proprietary Name: TCI (Tinnitus Control Instrument)
4. Device Common Name / Classification Name: Hearing-Aid, Air-Conduction
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 claimed: K974751
General Hearing Instruments
Tranquil Tri-OE
9. Compliance with Section 514, Performance Standards: Not Applicable
10. Indications for Use:

The TCI is a behind-the-ear style electronic, air conduction broad-band noise generator intended to generate noise of sufficient intensity and bandwidth to be used for tinnitus habituation therapy and is also suitable for tinnitus masking therapy. The intended use of this device includes it's fitting by a qualified audiologist or other hearing healthcare professional familiar with the diagnosis of tinnitus and subsequent rehabilitation therapy. This device is seen as substantially equivalent to other devices existing in the marketplace today (i.e. General Hearing Instruments Tranquil Tri-OE).
11. Description of Device:

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TCI is a fully digital, low-level noise generator that was developed to be used along with appropriate counseling and/or tinnitus therapy. TCI is meant to be used by those individuals with symptoms of tinnitus, but with hearing within normal limits. This product is programmable, with an 8 channel equalizer, and allows the signal to be custom-tailored to the user's individual requirements.

For physical appearance of the device, see Attachment I

12. Proposed Labeling: See Attachment II

13. Comparison information to predicate device:

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

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

Risks: There are no risks associated with this device since the output of the noiser does not exceed 132 dB SPL, as identified in the draft technical information page 2, included within Attachment II.

Hearing Healthcare Professional Diagnosis: The sale and fitting of the Siemens TCI will only be conducted through a Hearing Healthcare Professional.

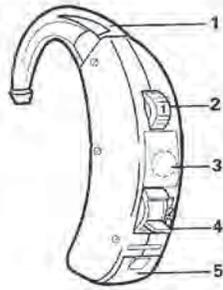
Benefits: Relief of symptoms of tinnitus, provided the device is utilized along with appropriate counseling and/or tinnitus therapy.

Warnings for Safe Use: These are included in the "General Information for Hearing Aid Users" booklet on pages 7, 13, and 14, which is included within Attachment II.

Specifications: These are addressed in the draft technical data sheets included within Attachment II.

TCI 510(K) ATTACHMENT I

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1. Microphone opening
2. Volume control
3. Programming socket
4. Selection of operating mode
1: Therapy program 1
2: Therapy program 2
0: Off
5. Battery compartment
with Battery lock

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TCI 510(K)
ATTACHMENT II

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SIEMENS

General
Information for
Hearing Aid Users



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: _____

Reason: _____

Comments: _____

Date of visit: _____

Reason for visit: _____

Comments on visit: _____

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.

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.

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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.



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.

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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.

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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.



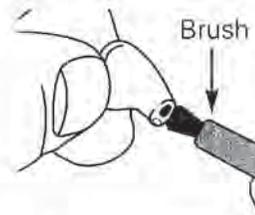
Be careful to avoid physical shock, such as dropping the aid on the floor.



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

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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.

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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.

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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.

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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.

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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.

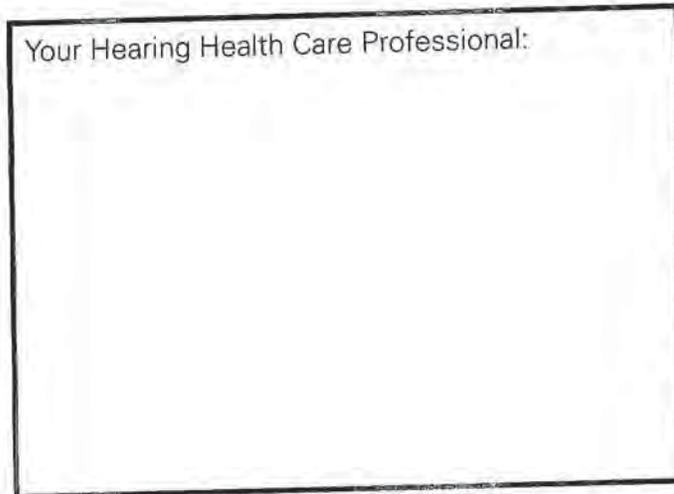
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Troubleshooting Guide for Hearing Aids

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.

001



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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SHI/03956-0

SIEMENS

LEVER

*User's Manual
for TCI BTE
Hearing Aids*

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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SH/04229-1

FILE NAME: 04229-1.TCI BTE User Manual

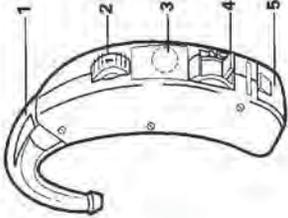
LOC: **Administrative**/SHI Jobs/SHI Jobs/SHI4200-4299/04229

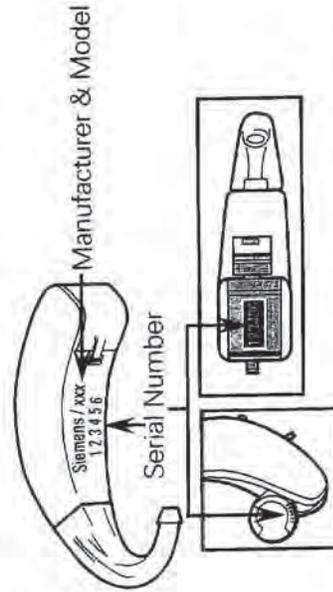
FILE NAME: 04229-1.TCI BTE User Manual

LOC: **Administrative**/SHI Jobs/SHI Jobs/SHI4200-4299/04229 11/14/00

Getting Familiar with Your Hearing Aid

The Siemens behind-the-ear (BTE) hearing aid is designed for comfort, performance and durability. The hearing aid fits comfortably behind your ear and is attached to a custom-made earmold.

- 
1. Microphone opening
 2. Volume control
 3. Programming socket
 4. Selection of operating mode
 - 1: Therapy program 1
 - 2: Therapy program 2
 - 0: Off
 5. Battery compartment with Battery lock

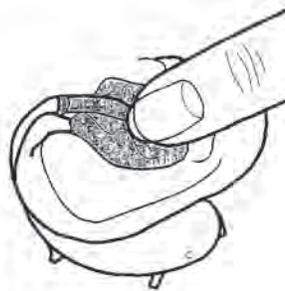


Each aid has its model and manufacturer on the case. The serial number can be found in one of the three locations illustrated. The battery compartment holds the battery that powers the aid.

Gently close the battery compartment. Do not force the battery door shut. If the door does not close easily, check to see if the battery is inserted upside down. When the battery door is completely closed, your hearing aid is ready for operation.

To Insert The Aid

Take the earmold between your thumb and index finger. Gently work the aid into its proper position by slightly adjusting it until the earmold is firmly seated in your ear. Then lift the hearing aid over the top of your ear and adjust it to fit behind your ear. Press it in gently for a secure and comfortable fit (as illustrated).



To Remove The Aid

When removing the aid from your ear, gently push on the back of the ear to help release the earmold and gently pull it out (as illustrated).



Health Considerations

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

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

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Using the Memory Switch (where provided)

This hearing aid has a memory switch which you use to change the characteristics of sound coming through the hearing aid.

To change the response of the hearing aid, simply change the position of the memory switch and the sound will change.

These memories are arranged in a line. You reach memory 2 by clicking the switch to the middle position.

Each memory is different. Your Hearing Health Care Professional will provide you with the number of memories most appropriate to meet your needs.

Behind-the-Ear Earmold Maintenance and Care

The earmolds should be cleaned daily by wiping them with a tissue or a soft cloth. When necessary, remove the earmold from the hearing aid and soak it in a mild soap solution and wipe it dry. **Never immerse the hearing aid!**

Allow the earmold to completely dry overnight before reconnecting it to the hearing aid.

If the earmold is not dry, do not attach it to the hearing aid as this can cause damage. Do not use a hair dryer, oven or microwave oven to dry the earmold.

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Battery

The chart below provides the battery size used in your hearing aid. It's recommended that you also check with your Hearing Health Care Professional regarding the correct battery.

<u>Model</u>	<u>Battery Size</u>
TCI Behind-the-Ear	13

TCI should not be considered a cure for tinnitus. The unit was designed for use in association with appropriate tinnitus therapy and/or counseling to address the psychological and neurological aspects of tinnitus in a completely individualized treatment approach.

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SIEMENS



DRAFT

Preliminary Tech

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TCI

ical Information for Tinnitus Control Instruments



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Digital Hearing Instruments

Premium Features

- Programmable, fully digital BTE-instrument for Tinnitus therapy
- 2 therapy programs manual selection
- Programmable noise spectrum with selection of 4 noise types, modify with filterbank
- Wide range output level
- Programmable range of volume control (off – 8 – 16 – 32 dB)
- Professional fitting system CONNEXX™

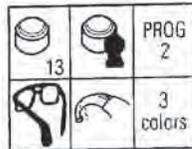


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TCI

Fitting Parameters

Programmable:
8-band filterbank
VC range
Output level



Options

Colors: beige, grey, tobacco

Accessories

Eyeglass adapter, transparent
small ear hook

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Technical Data

Saturation Sound Pressure Level

Broadband

Range of master level control L

VC-range (programmable)



Battery

Voltage	1.3V
Current Drain EIC	0.6 mA
Battery Life (typical) Type 13 Zinc Air	approx. 400 h

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TCI

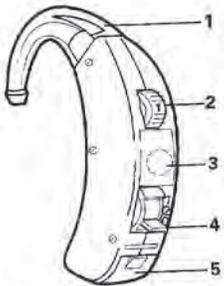
2 ccm³ coupler

Standard ANSI S3.22-1996

85 dB

81 dB

32 - 16 - 8 - off (dB)



- 1. Microphone opening
- 2. Volume control
- 3. Programming socket
- 4. Selection of operating mode
 - 1: Therapy program 1
 - 2: Therapy program 2
 - 0: Off
- 5. Battery compartment with Battery lock

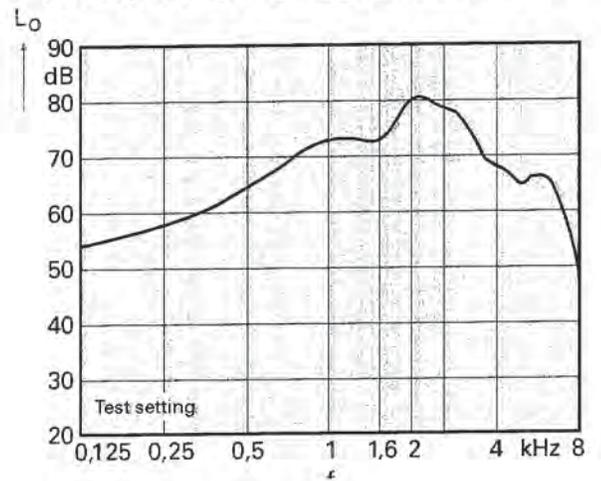


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Tinnitus-Noise Characteristics

2 ccm coupler ANSI S3.22-1996

Noise in 1/3 octave bands IEC 118-7

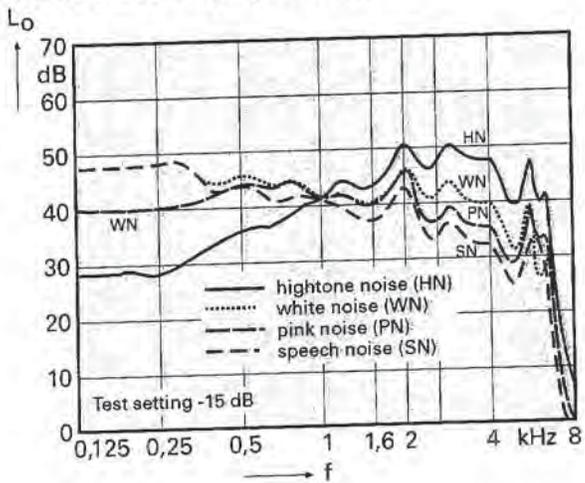


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TCI

2 ccm coupler ANSI S3.22-1996

Power density spectrum



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Fitting Parameters

Volume Control-Range

Master Level Control

81 dB combined adjust



1	2	3
reduc- tion	reduc- tion	reduc- tion

Band Level Control

in	in	in
1.5 dB steps	1.5 dB steps	1.5 dB steps

Δ Test setting

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TGI

f - 8 dB - 16 dB - 32 dB

ent range (54 x 1.5 dB) from maximum to minimum level - off

4	5	3	4	5
reduc- tion	reduc- tion	reduc- tion	reduc- tion	reduc- tion
in	in	in	in	in
1.5 dB steps				



Noise source

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Technical Description

Standard features

Volume control

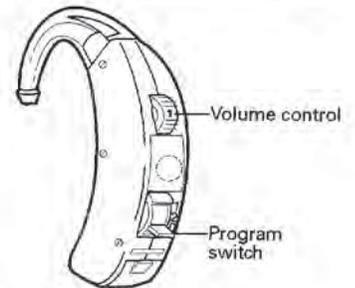
Individual definition of the volume control range simplifies the fast and optimum determination of the right volume setting.

The volume control range, with possible settings of 32 dB, 16 dB, 8 dB and 0 dB, is programmed during fitting of the TCI

Program selection switch

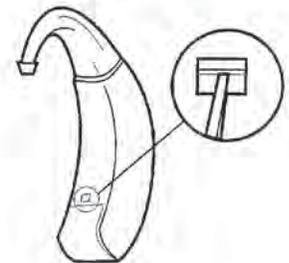
Program selection takes place with a three-step switch (1-2-0 positions), providing dependable operation. Different program combinations are possible, such as:

- switch position 1: therapy noise 1
- switch position 2: therapy noise 2
- switch position 0: off



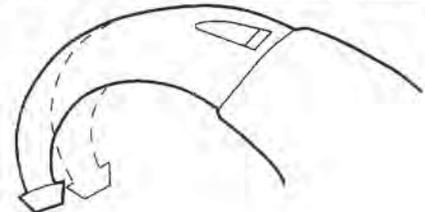
Lock for battery compartment

The instrument is equipped with a lock for the battery compartment. This is intended to prevent the unintentional removing of batteries, for instance by small children. This safety device is on the inner side of the hearing instrument. Use a tool suited to the purpose to open or close the safety device. Pushing the slide upwards unlocks the battery compartment, pushing the slide downward locks the battery compartment.



Heat-shaped earhook as standard

The earhook can be heat-shaped to fit individual preferences in regard to instrument position.

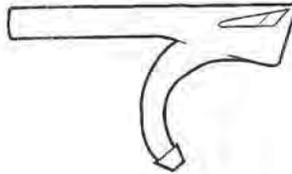


TCI

Accessories

Eyeglass adapter

To enable fit the instrument onto eyeglasses, transparent adapters are available.



Small earhook

For optimal fitting to the ear, not only for children, a small earhook is available.



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Siemens Hearing Instruments, Inc.

Northeast/US HQ: P.O. Box 1397, Piscataway, NJ 08855-1397 • (732) 562-6600 or (800) 422-4540

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) 661-2211

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