



ETYMOTIC RESEARCH, INC.

513(f) Reclassification Petition – TV-TIP Sound Amplifier

SECTION G - SUPPORTING DATA PER SEC. 860.7 REQUIREMENTS

1. Description of Device

The TV-TIP Sound Amplifier is a high-fidelity in-the-ear amplification device designed to amplify sound for that part of the general population considered to have normal to marginal hearing loss who desire an additional boost in sound for occasional use in various listening environments. This device is intended to be a “starter” type device that will serve those who feel they have an occasional need for a small amount of amplification. The device would be available to the general public over-the-counter (OTC) at retail outlets. Thus, individuals may purchase the device without professional assistance as an entry point into the hearing care system, much like reading glasses. The device is manufactured and delivered completely assembled to the retailer using materials and techniques widely used by manufacturers of hearing devices.

2. Safety and Effectiveness Supporting Data

The following is a device description and summary of safety and effectiveness based on the literature regarding amplification. The research cited refers to hearing aids. Although hearing aids are currently restricted Class I exempt devices that require a medical evaluation or a signed waiver for the medical exam by the hearing impaired patient and fitting of the device by a professional hearing aid dispenser, this classification is the closest comparative device to the device in question regarding documented safety of this type of device. Based on the following information, we do not believe that the TV-TIP Sound Amplifier device warrants a medical evaluation or a signed waiver for the medical exam by the general public and fitting of the device by a professional hearing aid dispenser and that it should be made available as an over-the-counter device, much like reading glasses as stated above.

The design follows traditional principles of operation, i.e., a standard hearing aid microphone transduces the air-borne sound into an electronic signal. The signal is processed by an integrated circuit and is converted back to air-borne sound by a standard hearing aid receiver similar to the one used in the Etymotic ER-6 High-Fidelity earphones. See number 4 in this section for performance specifications. A standard hearing aid battery powers the device.

The integrated circuit is the K-AMP amplifier. This circuit is well known and widely used in currently marketed hearing devices. The K-AMP technology, developed by Mead Killion¹, is designed as a “four-stage compression amplifier, with the greatest amount of gain for low-level inputs, less gain for the moderate-level inputs, and no gain for high-level inputs. The K-AMP amplifier also includes frequency-dependent compression, so that for low-level inputs, high frequency sounds are amplified more than



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low-frequency sounds. Distortion for high level input signals is reduced through the inclusion of a Class B amplifier in the custom integrated circuit.

In order to ensure safe operation for the user, the level-dependent gain and level-dependent frequency response described above are set so that loud sounds are not amplified. A two-position volume control allows introduction of an additional 8 dB overall gain.

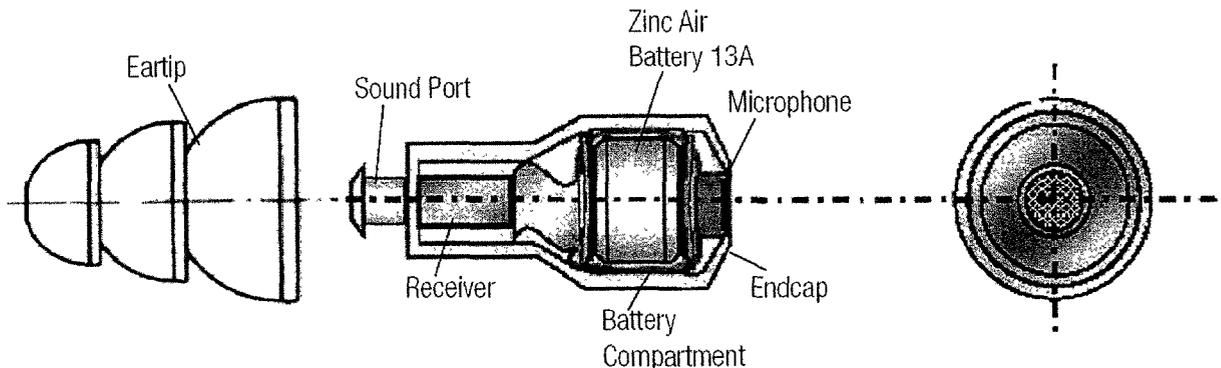
Although it is documented that there is risk of overamplification by hearing aids,^{2,3,4} research has indicated through various mathematical models that output levels from a hearing aid appropriate for a mild to moderate sensorineural hearing loss would not cause any damage to a person with normal hearing.^{5,6} The maximum sound level output of the TV-TIP Sound Amplifier remains below 108 dB SPL throughout the frequency range of 200 to 8000 Hz as measured by standard testing equipment used in the hearing aid industry. Extensive research has indicated that output levels of this magnitude are safe for the intended population for this device.^{7,8,9,10,11}

Additional safety concerns may be complications arising if a person presents conditions such as a congenital deformity of the ear, history of active drainage, history of sudden hearing loss, significant cerumen accumulation, a foreign body in ear canal, vertigo, or ear pain or discomfort. These conditions are listed in the precautions section of the User Manual.

3. Physical Configuration

Figure 1 identifies the parts of the TV-TIP Sound Amplifier. The device is composed of an eartip, sound port, receiver, microphone, battery compartment, and endcap. The device requires a 13A zinc-air battery to function.

Figure 1: TV-TIP Sound Amplifier





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4. Performance and Technical Characteristics

Performance curves and electrical and acoustical data per American National Standards Institute, Specification of Hearing Aid Characteristics, (ANSI S3.22-1996), American National Standards Institute, New York, 1996 are provided in this section.

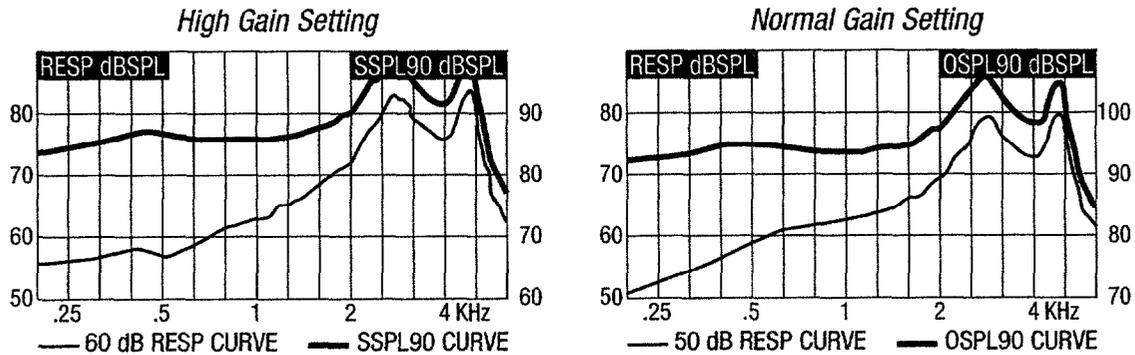


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SPECIFICATIONS

Frequency Response



Electrical & Acoustical Data

<i>data per ANSI S 3.22 1996</i>		<i>High Gain Setting</i>	<i>Normal Gain Setting</i>
SSPL 90 (OSPL-90)	<i>max</i>	110 dB	102 dB
	<i>HFA</i>	98 dB	90 dB
FULL ON GAIN	<i>peak</i>	30 dB	22 dB
	<i>HFA</i>	18 dB	10 dB
TOTAL HARMONIC DISTORTION	500 Hz	<3%	<2%
	800 Hz	<3%	<2%
	1600 Hz	<2%	<2%
REFERENCE TEST GAIN		18 dB	
EQUIVALENT INPUT NOISE	<i>max</i>	38 dB	35 dB
BATTERY CURRENT		.3 mA	
FREQUENCY RANGE		200-8000 Hz	
ATTACK/RELEASE TIME	<i>attack time</i>	30 msec	
	<i>release time</i>	400 msec	
COMPRESSION RATIO		2:1	
POWER SOURCE		1.3 V type 13ZA	