"What About that Thing I Saw on TV That Helps You Hear Better? It's *only* $14.99!"

Personal Sound Amplification Products versus Hearing Aids

By Mark Ross

You see the ads everywhere, on TV, in magazines, for personal sound amplifiers that promise the wearer to hear better. What are they and how do they differ from a hearing aid?

While browsing through the aisles of my local pharmacy, I came across some device that looked like a Bluetooth receiver. Naturally, this piqued my curiosity. It turned out that it wasn't a Bluetooth receiver at all but, rather, a "personal sound amplifier" Reading the printed blurb on it I could see why it would be a tempting purchase for someone with a hearing loss. The blurb promised to turn "ordinary hearing into extraordinary hearing," that one need not ever miss a word at any lecture, show, or at church and that with it one could hear a pin drop across the room.

And all this for *only* $14.99.

The Clever Marketing of Amplifiers

I've been aware of this and other products like it for some time. Indeed, one can hardly watch TV without seeing a commercial extolling the virtues of one these products. Various scenarios are displayed that show someone using such a device hearing conversation across a noisy room, in a restaurant, watching TV with a sleeping spouse, attending to a sermon in church, and so on.

"Best of all," one catalog blurb for a $19.95 device says, "no one will know that you are wearing a sound amplifier" since it looks like a cell phone accessory. All of these devices, however, contain a microphone, an amplifier, a receiver (mini-loudspeaker), and some sort of insert to deliver amplified sounds into the ear. Of course, these are exactly the major components of every hearing aid on the market. So what makes them conceptually different from hearing aids?

In a word, nothing, except that they're explicitly not labeled "hearing aids," or at least they're not supposed to be so labeled. What they're called, instead, is "personal sound amplifier,"

"sound amplifier," "personal listening device," or other such terms.

The FDA Defines PSAPs

In February 2009, the Food and Drug Administration issued a guidance that attempted to clarify the distinctions between hearing aids and these devices, which it termed Personal Sound Amplification Products or PSAPs.

The FDA defines a hearing aid as a wearable sound-amplifying device intended to compensate for impaired hearing. As such, hearing aids are subject to different types of pre-market review requirements. Potential users of a hearing aid (over the age of 18) must be advised that it is in their best interest to see a physician prior to purchasing a hearing aid, or they must sign a waiver to indicate that they are explicitly declining this suggestion.

A PSAP, on the other hand, is defined by the FDA guidelines as a "wearable electronic product not intended to compensate for impaired hearing." It is, according to the FDA, designed to be used by consumers without hearing loss to amplify sounds related to various recreational activities (hunting, overhearing gossip, etc.).

As I look at the Internet material (by googling "Personal Sound Amplification Products"), published catalogs (such as "Dr. Leonard's") and observe TV commercials, it is quite apparent that in the marketing of these devices, the vendors have deliberately obfuscated the "intended" use of a PSAP.

The examples and wording most often used clearly suggest that the device is designed for people with hearing loss. This, in spite of the fact that sometimes the small print at the conclusion of a description explicitly states that the device is not a hearing aid—no matter that its appearance may be indistinguishable from a behind-the-ear or ear-level hearing aid.

Manufacturers and vendors of these devices are under no legal obligation to clarify for prospective purchasers the distinction between hearing aids and personal sound amplification products. The fact that there are so many of them available through so many varied sources, at costs from about $10 and upward, suggests a large and profitable market. It is not difficult to understand their appeal, given the average cost of hearing aids purchased through the traditional channels.

It turns out that someone whose hearing loss was much greater in the low frequencies, with practically normal hearing in the highs, would benefit from these devices. As it happens, this is a very rare type of audiogram in adults with acquired hearing losses, one which almost never occurs.

Do They Really Work?

The important question to ask is whether PSAPs can actually improve the hearing performance of people with hearing loss (ignoring the marketing deception that they are designed for normal hearing people).

The answer is, to a certain extent, probably yes. And to be fair, many of the consumer comments posted on some PSAP Internet sites are basically positive. But then, compared to no hearing device at all, it doesn't take much sound amplification for someone to hear a bit better. A cupped hand behind the ear will do it for someone with a mild hearing loss. So, for that matter, will a 19th century ear horn.

The listening comparison that the new user of a PSAP makes is between nothing at all and the sound produced by one of these devices. Since the devices do amplify sound, some degree of hearing help may be superficially apparent, at least in some optimal acoustical situations. But the important question to ask is how well do these devices amplify sound? Is their quality comparable to conventional hearing aids? For this information we can turn to two recent articles in the professional journals.

In the first one, the authors evaluated the electroacoustic performance of 11 over-the-counter (OTC) hearing aids. An OTC aid is considered to be one that is relatively inexpensive and can be directly purchased by consumers via the Internet or some retail store. The 11 hearing aids were separated into two price groups: a low-range group of eight analog aids (ranging from $10 to $73), and three mid-range digital aids costing between $395 and $495.

At the time this study was published, the devices were considered to meet the FDA criteria for a hearing aid; the guidelines distinguishing hearing aids from PSAPs were not released until after this article was submitted for publication. The fact that these devices continue to evolve can be seen in the fact that none of the 11 so-called hearing aids investigated in this study looks like a Bluetooth cell phone, while those that do look like a Bluetooth accessory are low-priced units that have just recent-ly been introduced.

Each hearing aid underwent an extensive battery of tests to determine its electroacoustic performance. It turns out that the low-range group could not be analyzed using the criteria established by the American National Standards Institute, since their performance did not meet the minimum standards necessary for analysis.

Instead, if a device had measurable electroacoustic characteristics—that is, if it simply amplified sound—it was included in the study by using a special-purpose average to describe its performance. Indeed, just judging from the way they worked, it is a reach to describe these devices as hearing aids at all. The three mid-range products, on the other hand, could all be tested using accepted national standards for hearing aids.

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Results of the Low-Range Group

The results indicate some systematic problems with the low-range group: all of them tended to provide too much amplification (gain) in the lower frequencies and too little gain above about 1,000-2,000 Hz (the more important frequencies for understanding speech). Listening to such a system could give users an illusion of hearing better, while in actual fact their comprehension of speech would still be rather limited (though perhaps superior to nothing at all).

In addition, several low-range devices also demonstrated isolated peaks of amplification at some high frequencies; these would tend to produce acoustic feedback as soon as a user turned the volume control up a bit. Except for one device, all of them had internal noise levels that exceeded accepted standards (less than 28 dB). These ranged from 30 to 48 dB. The internal noise levels of the three mid-range devices all met the required national standards.

Low-Range and Mid-Range Group Differences

From an audiological perspective, there were major differences between the low-range and mid-range groups. Overall, the mid-range group proved to be far superior in all respects and reached "prescription" targets at most (not all) frequency points in the three types of audiogram examples given. The authors state that, from a technical standpoint, these devices are good quality hearing aids that could potentially benefit users with mild and moderate flat and sloping hearing losses.

Considering the large differences in cost between them and the cost of traditionally purchased hearing aids, a potential hearing aid user could easily be tempted to purchase one of them rather than go through the traditional channels. But a note of caution should be sounded at this point.

None of these three mid-range hearing aids contained any special hearing aid features, such as noise and feedback management, directional microphones, etc., some of which could be very helpful (and would add to the cost of a hearing aid); not to mention the necessity of a comprehensive audiological evaluation, individualized hearing aid fitting, and scheduled follow ups that are included (or should be) in the traditional selection process. It is these factors that are primarily responsible for the high price of individually selected hearing aids, not the cost of the basic electronic package of a hearing aid itself.

The second recent article on a low-range device describes the evaluation results found by two audiologists when one of their clients dropped two of them off at their office, telling the audiologists that "You can have these…they don't help at all." These cost the client $49.95 each and came with a product manual that stated the devices could provide a "better and happier lifestyle" and that it was a "high-tech device."

The audiologists proceeded to subject the devices to an electroacoustic analysis and then also calculated the type of hearing loss for which the devices would be suitable. Basically the results duplicated the results found earlier: the low frequencies were unduly emphasized, with little or no amplification in high frequencies. Using an HA programmer, the authors then generated the kind of audiogram that the devices would be best suited for (ignoring other acoustical factors, such as harmonic distortion and the internal noise levels).

It turns out that someone whose hearing loss was much greater in the low frequencies, with practically normal hearing in the highs, would benefit from these devices. As it happens, this is a very rare type of audiogram in adults with acquired hearing losses, one which almost never occurs.

Other Devices

There is another device which seems to fall between the PSAPs and hearing aids; i.e., devices such as the Pocketalker. The FDA Guidelines do not seem to apply to this kind of gadget, as it does not neatly fall into any one of the categories defined by the FDA.

With no apologies, I have often recommended [PocketTalkers] for use in nursing homes, various kinds of social service agencies, and for sedentary adults who primarily communicate to one person at a time. While they do not have the advantages of personal hearing aids (special features, individual programming, etc.), they can provide an excellent signal-to-noise ratio when the unit is located close to the lips of the person talking.

This device (and others like it) are used and recommended for people with hearing loss, but no medical evaluation or waiver is usually asked for or given. It looks like a body-worn hearing aid and, in many respects, functions as one. However, the sound is delivered to the individual through earphones (preferably bilateral) of some sort rather than personal earmolds. A neckloop can also be used with it.

While their cost (about $150) is considerably more than the usual PSAPs, they are much less expensive than hearing aids. Often they contain an externally plugged in microphone, a volume control, and possibly a tone control as well. All they do is amplify sound but, unlike the low-range PSAPs the sound quality they provide can be excellent.

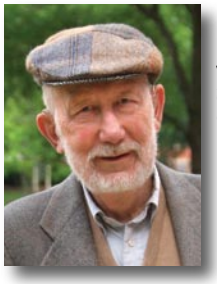
They can, and often do, serve as an introduction to amplified sound for many people or as a temporary substitute when one's personal hearing aids are not available. With no apologies, I have often recommended one of these devices for use in nursing

homes, various kinds of social service agencies, and for sedentary adults who primarily communicate to one person at a time. While they do not have the advantages of personal hearing aids (special features, individual programming, etc.), they can provide an excellent signal-to-noise ratio when the unit is located close to the lips of the person talking.

The Human Touch

It is no wonder that consumers trying to work their way through this morass of possibilities are often confused. Most of them are, understandably, looking for the best possible help for their hearing loss, at the lowest possible cost. We should keep in mind, however, that often more is involved in reducing the effects of a hearing loss than hearing aids themselves (i.e., help with other devices, information about the best communication strategies, etc.).

The route I usually suggest is via a trusted professional source, and I still think this is the best way to go for most potential hearing aid users. There is merit, I believe, in face-to-face encounters with a human being, particularly since some recommended procedures (such as real-ear measures) cannot be accomplished via remote location (such as through the Internet). But events and possibilities are moving rather rapidly these days and what the future holds in this regard is anybody's guess. HLM



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Here Comes the Bride… Wearing White, a Hearing Aid, and a CI

HLAA Member Sara Laufer Marries John Batinovich

Last year at this time, September 21, 2008, to be exact, Sara and John tied the matrimonial knot. In Sara's words, "In a lovely, family affair in my aunt and uncle's backyard in Los Angeles. We are settling into life up in Washington state."

Sara is known to *Hearing Loss Magazine* readers from her articles about her and her hearing dog Bogie. In fact, since Sara's father passed away several years ago, Bogie did double duty at the wedding as hearing dog and "Father of the Bride."

Sara wears both a cochlear implant and a hearing aid, which are shown on the lovely bride enjoying the party with her handsome groom. She is a demographer and has an upcoming book, published by Gallaudet University Press, targeted toward the working-age population segment, which will include her research on the politics, demography, and epidemiology of hearing loss in this age group. For more information, go to **www.saralaufer.com**. HLM

The newlyweds burned up the dance floor.

Bogie, hearing dog and "Father of the Bride," and Sara get ready to walk down the aisle.

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