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Designing of a Digital Behind-the-Ear Hearing Aid to Meet the World Health Organization Requirements

Ricardo Ferreira Bento[1] and Silvio Pires Penteado[1]

Abstract

Hearing loss is a common health issue that affects nearly 10% of the world population as indicated by many international studies. The hearing impaired typically experience more frustration, anxiety, irritability, depression, and disorientation than those with normal hearing levels. The standard rehabilitation tool for hearing impairment is an electronic hearing aid whose main components are transducers (microphone and receiver) and a digital signal processor. These electronic components are manufactured by supply chain rather than by hearing aid manufacturers. Manufacturers can use custom-designed components or generic off-the-shelf components. These electronic components are available as application-specific or off-the-shelf products, with the former designed for a specific manufacturer and the latter for a generic approach. The choice of custom or generic components will affect the product specifications, pricing, manufacturing, life cycle, and marketing strategies of the product. The World Health Organization is interested in making available to developing countries hearing aids that are inexpensive to purchase and maintain. The hearing aid presented in this article was developed with these specifications in mind together with additional contemporary features such as four channels with wide dynamic range compression, an adjustable compression rate for each channel, four comfort programs, an adaptive feedback manager, and full volume control. This digital hearing aid is fitted using a personal computer with minimal hardware requirements in intuitive three-step fitting software. A trimmer-adjusted version can be developed where human and material resources are scarce.

Keywords

digital hearing aids, hearing impaired, digital signal processing, World Health Organization

Introduction

Hearing loss is a common issue that affects the quality of life of patients and their family members and caretakers (Cook & Hawkins, 2006; Gratton & Vázquez, 2003). School-age children with hearing loss have been shown to suffer academically (Bess, Klee, & Culbertson, 1986; Lieu 2004; Matkin & Wilcox, 1999), and adults with hearing loss face consequences beyond the immediate loss of hearing that change their ability to function. Carmen (2001) stated that people with hearing loss experience increased anger, frustration, paranoia, insecurity, tension, anxiety, irritability, depression, fearful, disorientation, a sense of inferiority, social phobias, and other unhealthily emotional states. An extended life expectancy leads to an increase in the incidence of presbyacusis (Davanipour, Lu, Lichtenstein, & Markides, 2000; Stephens & Bellman, 1983), which impairs social interactions with a cost to society (Murphy, Daneman, & Schneider, 2006). Among the factors that maintain or increase the high rate of hearing loss are hereditary diseases, metabolic diseases, ototoxic drugs, acoustic traumas, noise-induced damage, neoplasia, vascular infections, and physical damage (Bento, Miniti, & Marone, 1998).

The hearing-impaired population in developed countries is estimated to be 10%, which is considered optimistic for developing countries (Smith, 2001). There are limited resources in developing countries to screen for, prevent, diagnose, and intervene in hearing loss (Jauhiainen, 2001). Little et al. (1993) studied a sample of 15,845 individuals in Nepal and concluded that 17% of the people had hearing loss more than 30 dBNA hearing level. Many cases of sensorineural hearing loss (SNHL) caused by infection, trauma, noise-induced damage, cretinism, and abnormalities at birth can be prevented. In Nigeria, Olusanya and Okolo (2006) found permanent hearing loss in children because of asphyxia and other perinatal issues as a result of consanguineous marriage and a familial history of hearing loss. In Saudi Arabia, researchers found causes of SNHL that include hereditary conditions, measles, rubella, and nonhereditary

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syndromes (El-Sayed & Zakzouk, 1996). Chakraborty, Khan, Samad, and Amin (2005) measured noise levels in the Dhaka metropolitan area, and the noise levels registered were as high as 104 dB in a bus station, 90 dB in a commercial area, and 72 dB in a residential area. Nearly 64% of the people interviewed were not aware of their hearing-impaired state.

Designing a low-cost hearing aid (HA) for developing countries is justified as a systematic rehabilitation tool. The amplification system presented here is being developed and improved to minimize the side effects of up to a severe degree of hearing loss. A HA is a portable amplification system based on three electronic components—the microphone and receiver (the transducers) and a digital signal processor (DSP; Schaub, 2008). These components are not necessarily manufactured by the HA manufactures but rather by their supply chain (Lybarger, 1988), as is the case in the auto industry and in consumer electronics. Some DSPs are tailored to a specific customer for a specific project—called application-specific integrated circuits (Blamey, 2005)—others are off-the-shelf components. In general, the transducers are off-the-shelf components. The remaining parts, such as the switch, button, programming socket, volume control, plastic items, and consumables, are not value-added items and can be sourced to a greater number of suppliers. A frequent complaint about HAs is their high cost to patients despite the relative simplicity of the devices (Chao & Chen, 2008; Franks & Beckmann, 1985; Joore, Van Der Stel, Peters, Boas, & Anteunis, 2003; McPherson & Brouillette, 2004; Newman, Hug, Wharton, & Jacobson, 1993). Bilateral fittings are more expensive than unilateral fittings but result in better performance (Boymans, Goverts, Kramer, Festen, & Dreschler, 2008; Erdman & Sedge, 1981).

HA manufacturers push for product innovation while guaranteeing profitability because of the purchasing power of their home countries, which have much higher per capita incomes than developing countries. These pushes for innovation have led to technological products with more features than customers need or are willing to pay for even in developed countries (Christensen, 2001).

In 1988, the World Health Organization (WHO) and Christoffel-Blindenmission (WHO, 1988) released the first specifications for HAs in developing countries. The WHO began talks in 1991 with a group working on the Prevention of Deafness and Hearing Impairment (PDH) to develop a PDH program with nongovernmental organizations. The cornerstone document (WHO, 1991) stated that “the technology should take into consideration the existing resources constraints, poor infrastructure and the dearth of suitably trained human resources.” Some of the recommendations are about the “development of appropriate technology, with particular reference to audiometer, otoscope and hearing aids,” which “need to be simple to operate and to maintain, available at an affordable cost.” The primary concern of this document was prevention, followed by hearing loss detection and medical intervention, as rehabilitation tools were not available at that time.

Table 1. World Health Organization Minimal Performance Requirements

Parameter	Requirement
Maximum OSPL$_{90}$	118 dB ($^{+}$/– 4 dB)
OSPL$_{90}$ at 1 kHz	114 dB ($^{+}$/– 4 dB)
Maximum full-on acoustic gain	45-55 dB ($^{+\ 5}$/$_{–\ 0}$ dB)
Full-on acoustic gain at 1 kHz	42 dB ($^{+\ 5}$/$_{–\ 0}$ dB)
Basic frequency response	200-4,500 Hz (200-2,000 Hz ($^{+}$/– 4 dB) (2,000-4,000 Hz ($^{+}$/– 6 dB) on nominal frequency response curve
Total harmonic distortion at 70 dB SPL input	500 Hz < 5% 800 Hz < 5% 1,600 Hz < 2%
Equivalent input noise	<25 dB SPL
Battery current	≤1 mA

In 2004, the WHO released the “Guidelines for Hearing Aids and Service for Developing Countries” (WHO, 2004) with some important highlights: total world production of HAs is less than 10% of the global need, HAs and their services are generally expensive and often inappropriate for developing countries, and HAs can be produced at low cost in bulk with the current technology. The WHO suggested that HAs be produced to meet the minimal requirements, which are “necessary because of scarcity in resources of skills, training, services, and financing in developing countries.”

The optimal operating temperature for HAs is between 5°C and 45°C (32°F to 113°F), and the optimal humidity range is 0% to 80%. The HA must allow one to reduce the gain at frequencies below 750 Hz by means of a preset or other control. The volume control must have at least a 30 dB range with a scale printed on the wheel. A telecoil (induction coil to assist phone conversations) and a means to reduce the output, preferably AGC control, are optional but preferred. The external parts should be designed so that they do not have any sharp edges and must be constructed from durable and hypoallergenic materials. The on/off switch must be omitted to minimize the number of moving parts, which is a strategy to minimize repairs. The battery compartment should only allow the battery to be inserted with the correct polarity. HA manufacturers should use ISO 9001 for quality management. The WHO minimal performance requirements are shown in Table 1.

Sound Design Technologies Ltd. (SDT; Burlington, Ontario, Canada) designs and manufactures ultra-low-power semiconductor solutions for hearing instruments and has a broad portfolio of DSPs for analog and digital applications. SDT supplies the world market with application-specific integrated circuits (ASICs) and off-the-shelf DSPs. SDT supplies the Application Resource Kit™ (ARK; SDT, 2008a) as a set of software building blocks that works behind the scenes to make

Table 2. A Work Breakdown Structure to the DSP

Description	Features
1.1 General	• Off-the-shelf • High-quality CODEC • Programmable • Allow 2-comfort memories • 1- or 2-channel WDRC compression strategy • Allow 3- or 5-pin analog volume control • Trimpot applications ready • AGC (AGCi or AGCo) • Low dimensions (ideal for CIC applications)
1.2 External programming	• Allow universal hearing aids programmer (i.e., HI-PRO)
1.3 Firmware programming	• Easy, quick, without any additional hardware or investment
1.4 Amplifier	• Class AB or Class D
1.5 Development resources/tools	• Available at low cost
1.6 Phase-out	• No phase-out within 5 years
1.7 Numerical specifications (Standard IEC 60.118-7)	• 8 kHz bandwidth • Total harmonic distortion below 4% at 1,600 Hz • Battery drain less than 1 mA • Stable gain of 80 dB • Sampling rate of 8 kHz
1.8 Environment	• Working temperature: 32°F to 113°F (0°C to 45°C) • Relative humidity: 10% to 90%
1.9 Pluses	• CE mark • One hearing aid with the related DSP with FDA approved

Note: DSP = digital signal processor.

it easier to develop HAs using off-the-shelf components (SDT, 2007a). To help engineers with the development of HAs, an introductory document and datasheet were released (SDT, 2007b).

Material and Methods

The HA described in this work was not designed to be fitted on subjects for testing in a laboratory environment only. The entire development process was conducted at the Otorhinolaryngology Department of the Medical School University of Sao Paulo. A third party laboratory was hired to assemble the HA.

Material

The general and the electro-acoustic specifications are those listed by the WHO. The authors have previous experience designing low-cost HAs tailored to open tenders in Brazil (named Manaus). The Manaus platform was used to develop the new HA—named Manaus-W. During the development of the Manaus, DSPs from three manufacturers were tested: Texas Instruments Inc. (Houston, TX), Etymotic Research Inc. (Elk Grove Village, IL), and SDT. ON Semiconductor Corp. (Phoenix, AZ) and IntriCon Corp. (Arden Hills, MN) refused any level of participation in the study. Texas Instruments and SDT generously sent free samples, whereas samples from Etymotic were acquired indirectly. The transducers were also kindly sent free of charge by Knowles Electronics LLC (Itasca, IL) and Sonion A/S (Roskilde, Denmark). From its Deltek division (a now closed unit), Knowles sent volume controls, push buttons, telecoils, and programming sockets, all free of charge. In'Tech Industries Inc. (Ramsey, MN) sent behind-the-ear (BTE) cases, also free of charge.

The WHO requirements were used as our specifications, and we implement the final product based on off-the-shelf components. The digital BTE HA design includes the following components: DSP, transducers, volume control, push button, telecoil, programming socket, case, presentation case (acquired locally), fitting software, and consumable materials including silicone tubes, wires, serial number labels, solder, and adhesives. The work breakdown structure (WBS) was implemented to identify the components required to build the BTE, excluding the consumables. Table 2 shows the WBS for the DSP. The WBS was helpful in identifying the DSP supplier.

Method

The electronic architecture is defined as the DSP plus the transducers. The GA3226 DSP (by SDT) was chosen because it satisfied most of the DSP WBS requirements. ARK Online®, a set of development tools available on the SDT server, can be used for easy, low-cost development without any complementary hardware or additional disbursement to use its server capabilities.

After obtaining a user login and password from SDT, our first step is to define a map, which means defining the resources and features of the HA based on the selected DSP (SDT, 2007a). This procedure includes features such as the number of equalizer steps, the crossover limits, the compression ratio limits, squelch values, attack and release times, and volume control range.

The second step is to define the library, which means adding the transducers to the map. Once the DSP behavior is defined and the transducers are added to the library (from a predefined transducer list), ARK Online generates output and gain curves. If necessary, it is possible to add other transducers to the library in addition to the ones in the predefined list.

Once the map and the library are defined, the third step is to download the library files. Two files must be downloaded: one dynamic-link library (extension .dll) and one resource file (extension .src). These files come in a compressed format and must be decompressed before they are installed on the patch: C:\\Windows\ARK.

The fourth step involves installing the respective libraries using ARK Component Manager, an application that can also be used to uninstall undesired libraries. These libraries must be installed at: C:\\Windows\ARK. The fifth step is to solder the electrical components to the electronic architecture (Knowles Electronics, 2006; SDT, 2007b, 2007c).

After soldering the components, it is possible to test the connectivity between the DSP programmer and the electro-electronic architecture using an application called Controller Toolbox. In this work, the HI-PRO by GN ReSound (Taastrup, Denmark) is used, which is a long-time industry standard DSP programmer.

The seventh step is to customize some of the HA functions, including the determination of the behavior of the comfort program push-button (temporary or continuous), whether or not the beep indicator will operate, and the initial compression rates of the HA. The Interactive Data Sheet application is used for this step. Next, the firmware settings are burned into the GA3226.

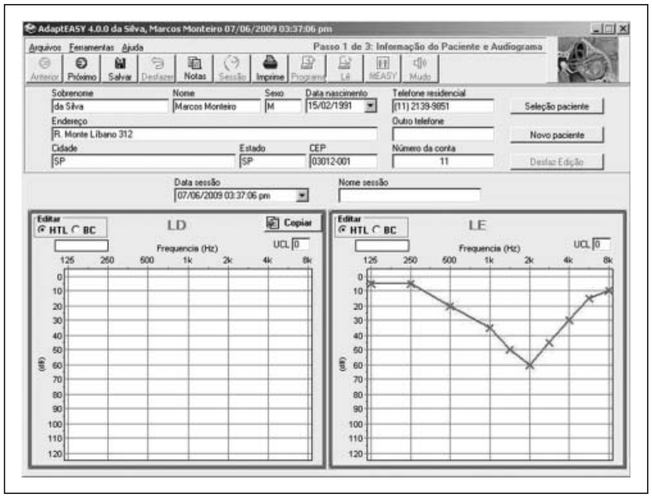
The eighth step is to download the standard fitting software SOUNDFIT® from the SDT server. SOUNDFIT must be installed at path C:\\Soundfit.

Next, the SOUNDFIT interface can be partially customized to one's needs by adding figures and changing its visual appearance using the SOUNDFIT Customization Tool®, which is quite simple and also allows almost the entire fitting to be translated to another language. In our case, the interface was translated to Portuguese and was named AdaptEASY.

To summarize the previous steps, the electro-electronic architecture was defined, the GA3226 firmware was defined, and the fitting interface was customized. The application packages used in this development are listed in Table 3.

Table 3. The Application Packages Used in the Development of Manaus-W

Description	Version
ARK Online®	4.8.3
ARK Component Manager	Not informed
Controller Toolbox	1.0.6
Interactive Data Sheet	4.2.0
SOUNDFIT®	4.0.0.14


AdaptEASY 4.0.0 da Silva, Marcos Monteiro 07/06/2009 03:37:06 pm

Passo 1 de 3: Informação do Paciente e Audiograma

Sobrenome: da Silva
Nome: Marcos Monteiro
Sexo: M
Data nascimento: 15/02/1991
Telefone residencial: (11) 2139-9851
Endereço: R. Monte Líbano 312
Outro telefone:
Cidade: SP
Estado: SP
CEP: 03012-001
Número da conta: 11
Data sessão: 07/06/2009 03:37:06 pm
Nome sessão:

Figure 1. The first screen of the AdaptEASY fitting software

The 10th step is to place the electro-electronic architecture inside the case carefully to avoid bending the wirings or causing acoustic feedback. Silicone tubing and other generic consumables were used to assemble the electronics inside the case because custom parts such as microphone and receiver suspensions were not available.

The 11th step is to test the HA. With the HA prototype assembled, some subjective tests were performed: the entire course of the volume control wheel can be scrolled to identify potential bugs such as artifacts, feedback, or other issues that could damage the functionality of the HA. For this procedure, it is important to use a fresh battery, because an old battery can cause the HA to behave incorrectly.

The 12th step is to connect the HA to the fitting software so that it is able to simulate what audiologists experience with patients at the clinic. It is good practice to connect/disconnect the HA and AdaptEASY many times to verify the functionality of the entire system, including the HA, programming cables, HA programmer, and the fitting software. SDT strongly recommends that the HA should never be disconnected during the programming process: it must be done after closing the fitting software. The whole fitting process is performed in three steps: inserting patient data, selecting the HA, and performing the adjustments. Figure 1 shows a screenshot of the first screen of AdaptEASY.

The final step is to submit the HA to quality control (QC) assurance. Although different standards could be used, the most requested standard in Brazil is IEC 60.118-7.

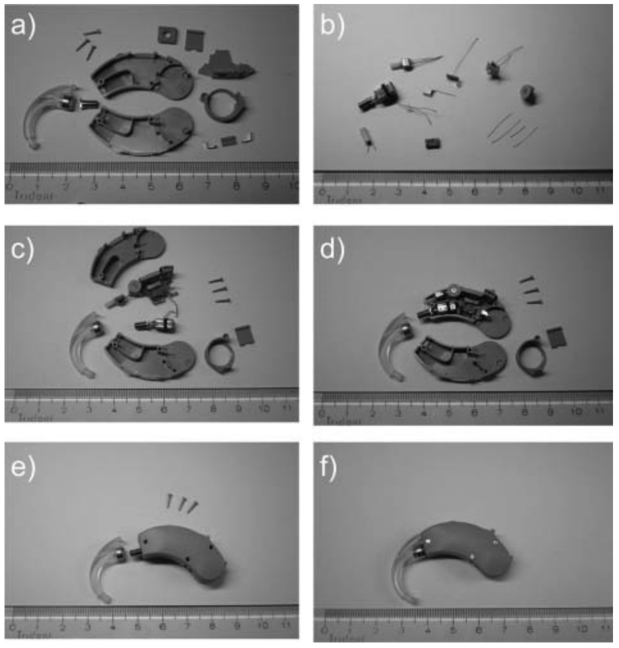
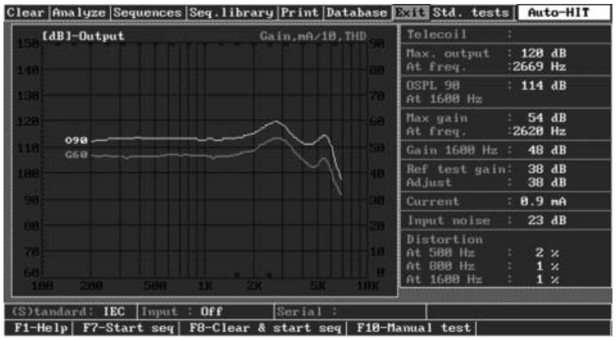


Figure 2. Simplified photo sequence of the Manaus-W assembly



```
Telecoil          :
Max. output       : 120 dB
At freq.          :2669 Hz
OSPL 90           : 114 dB
At 1600 Hz
Max gain          :  54 dB
At freq.          :2620 Hz
Gain 1600 Hz      :  48 dB
Ref test gain     :  38 dB
Adjust            :  38 dB
Current           : 0.9 mA
Input noise       :  23 dB
Distortion
At 500 Hz         :   2 %
At 800 Hz         :   1 %
At 1600 Hz        :   1 %
(S)tandard: IEC   Input : Off   Serial :
```

Figure 3. Manaus-W dynamic curves, Standard IEC 60.118-7

The resulting digital BTE HA was named Manaus-W. Figure 2 displays a simplified photo sequence of the Manaus-W assembly. Figure 3 shows the Manaus-W electro-acoustic curves. The Manaus-W electronic architecture consists of the components listed in Table 4.

All developments were carried out using the Windows XP® operating system; the Windows Vista® system has also been reported to be compatible with SDT applications (SDT, 2008b).

Results and Discussion

The initial proof-of-principle electronic architectures were lacking in many aspects, although they provided many insights for later design improvements. A series of experiments in a laboratory environment were conducted to determine the best hardware configuration with the same DSP, map, and library developed on Chapter 2.2 Method. With same microphone (EM 23046-000), several receivers were tested. A Knowles receiver (FC-21671-000) was tested with input noise higher than what was given in the specifications and demonstrated a relatively flat response for gain and output. Another Knowles receiver was tested (PHF 23854-000) with excellent gain and output, but the flat response was lost and the current drain exceeded the specifications. Knowles ED-27305-000, which was tested to show a flat curve with a few small peaks, low input noise, low battery drain to attain a maximum output of 129 dB, shows that it is possible to increase output and gain for a more powerful HA based on same architecture. The configuration using the GA3226 DSP with Knowles transducers delivered good results (Table 4) and exceeded WHO specifications. We did not investigate the coupling matching between the DSP and the receiver because we believe that it is a determining factor of why one receiver was a better match than the others. The datasheets show receiver FC-216171-000 having an impedance of 225 Ω, PHF 23854-000 of 155 Ω, and ED-27305-000 of 100 Ω (impedances measured at 1 kHz), and the Zout of the DSP as 15 Ω. When looking at the PHF-23854-000 datasheet, we observed five peaks on its response curves with FC-26271-000, and ED-27307-000 had two peaks. None of the transducers and DSP showed flat responses (Watkinson, 2001). Therefore, the SDT DSP with Knowles transducers was used to turn our proof-of-principle into a prototype. The case was provided by In'Tech Industries. As mentioned earlier, the electrical parts (volume control, push button, telecoil, and programming socket) were supplied by Deltek.

Table 4. Manaus-W Electronic Architecture Configuration

Component	Manufacturer	Reference
DSP	Sound Design Technologies Ltd.	GA3226
Microphone	Knowles Electronics LLC	EM-23046-000
Receiver	Knowles Electronics LLC	ED-27305-000

Note: DSP = digital signal processor.

IEC 60.118-7 was used to certify the performance of the Manaus-W, and some of its features are presented in Table 5. The dynamic curves obtained for a specific HA analyzer (model CAS, by defunct Danavox) are presented in Figure 3.

Although Manaus-W was entirely designed with off-the-shelf components, it delivers a complete package of benefits, including up to 4-channel WDRC, adaptive feedback management, 12-band equalizer, and an almost unlimited client databank. There is a commitment to minimizing costs, as it uses a universal HA programmer, universal standard cables, and low investment in hardware. AdaptEasy runs on a PC with Windows XP and a 4 GB hard drive and 1 GB RAM.

Three units of Manaus-W were intensively tested in the laboratory, including operation in an environment with high temperatures (up to 45°C, 113°F). To further stress the Manaus-W

Table 5. Manaus-W Performance and Some Features

Parameter	Outcome
Maximum OSPL_{90}	120 dB
OSPL_{90} at 1 kHz	114 dB
Maximum full-on acoustic gain	54 dB
Full-on acoustic gain at 1 kHz	47 dB
Basic frequency response	200-4,500 Hz (200-2,000 Hz = 4 dB maximum) (2,000-4,000 Hz = 6 dB maximum)
Total harmonic distortion	500 Hz = 2% 800 Hz = 2% 1,600 Hz = 1%
Equivalent input noise	23 dB SPL
Battery size	675
Drain current	0.9 mA
Battery life	440 hours
Number of comfort programs	4
Sound processing strategy	WDRC (1, 2, or 4 channels)
Feedback manager	Adaptive
Sound equalizer	12 bands

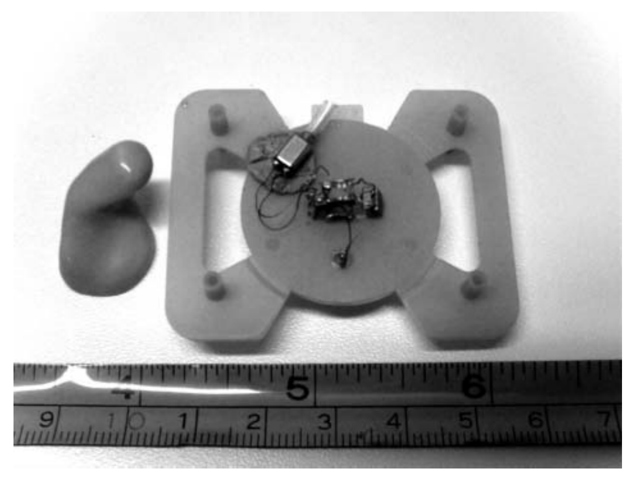


Figure 4. Manaus-W generic electro-electronic configuration on a faceplate

units, they were operated continuously for 2 months, only replacing the battery when indicated by the HA. Immediately following these procedures, QC tests were performed and the results before and after the endurance test were compared. The three units behaved the same both before and after testing.

Manaus-W was designed using the concept of generic electro-electronic configuration, which means its electro-electronic architecture can be used on custom designs such as CIC (completely-in-the-canal), ITC (in-the-canal), and ITE (in-the-ear). A wider product portfolio can be obtained using generic electro-electronic configuration to design BTE, CIC, ITC, and ITE with different criteria, that is, curbing gain, modifying the number of comfort programs, and removing the volume control (in CIC designs it is not possible to include volume control because of space restrictions). Figure 4 shows the Manaus-W generic electro-electronic configuration on a faceplate next to an ear shell. This is the design for CIC, ITC, and ITE.

These design changes can be easily implemented by modifying the maps and libraries, by updating the fitting software, and by adding faceplates in the case of custom HAs. The broader the use of standard components to make HAs, the greater the benefits for economy of scale (decreased per-unit cost because of greater production), economy of scope (fewer components used), and better service control (shorter response time and more reliable service). Our generic electro-electronic configuration shares many of the same economic benefits as generics drugs on the market.

The standardization of programming cables benefited the audiologist and facilitated the fitting process by lowering hardware requirements and simplifying updates. Training can be done remotely through printout educational documents, CD-ROM, or the Internet (Sooful, Van Dijk, & Avenant, 2009). Telemedicine is becoming popular, and it promises to provide health care services across geographic, social, and cultural barriers. Tele-audiology demonstrates significant potential in areas such as education and training of hearing health care professionals, parents, and adults with hearing disorders; screening for auditory disorders; diagnoses of hearing loss; and intervention services (Swanepoel et al., 2010). Digital HAs can be fitted through tele-audiology as described by Wesendahl (2003). The use of off-the-shelf components translates to a lower cost to maintain the HA and results in more affordable repair costs to the patient after the warranty expires (Penteado, 2009). Killion (1979) highlighted not only the purchase price but the operating costs (battery issue) and maintenance costs (repairs) as important factors in the total cost of an HA as a rehabilitation tool. The pricing of an HA and its services is critical to the success of an HA dispenser clinic and can significantly affect the bottom line of a practice. Furthermore, most of clinics have difficulties in applying the correct pricing to their products and services (Nagle & Holden, 1995). Prahalad (2005) cited a cost structure of 52% as operating costs of an international organization compared with 4% of a nongovernmental organization in the business of artificial limbs and calipers. Marketing, promoting, and advertising products and services worldwide to create a long-lasting business is a costly and risky operation that demands core competencies aimed at achieving favorable margins (Kotler, 1967).

A cochlear implant (CI) system is recommended for persons with greater hearing losses that ordinary HAs cannot attend to. The cost of a CI system ranges from $50,000 to $100,000 in the United States, or £40,0000 per device in the United Kingdom. Zeng (2007) stated that CI manufacturers could make use of the same DSP rather than ASIC, which would lower DSP costs from $1,000 to $10. The CI market is an oligopoly, with only three companies dominating the world market (Zeng, 2004). With governmental support, CI research and development in China dates back to 1979, and different approaches have been used to challenge this oligarchy, at least in China (Zeng, 1995). Competition is the best method to lower the price of CIs.

In the HA industry, the WHO (2004) alerted that the production of HAs is only one tenth of the global need, and only one quarter of these are distributed to developing countries. In both industries, there are economic issues to be addressed. The WHO electro-acoustic requirements differ from those of other HAs on the market because the WHO demands flatter response curves than those of commercial HAs. It is difficult to fit patients' audiogram curves to the nonflat curves of an HA, a task that demands more experienced audiologists and results in a more time-consuming process, both of which are barriers to good HA fitting (Hecox & Punch 1988). The Manaus-W is a digital HA that is fitted using fitting software, but a digital trimmer-adjusted version can be obtained by adding trimmers to the electro-electronic.

Sandlin (1994) stated that no development has been more significant than the debut of digitally controlled HAs. Unfortunately, this push for innovation increased the cost of the product to the audiologist (e.g., by the introduction of expensive programmers, constant hardware updates, constant training, and a wide range of cables) and to the patient (new HA models are typically more expensive than previous models). Shih (2006) described a technology-push when industries offer products to customers based on industry requirements and a demand-pull when customers define a set of products to be supplied. Manaus-W can be categorized as a demand-pull.

There is a time lag between when the WHO posted its requirements and the launch of the GA3226. This DSP offers additional resources such as implementing adaptive directionality (a useful feature that allows for an increase of the intelligibility of the noise and assists in identifying sound sources) by adding another microphone or using a microphone with two ports; the Manaus-W case is able to accept both. It will also be necessary to update the map, the library, and the fitting by altering the application tools resulting in a new HA item to be added to AdaptEASY.

Parving and Christensen (2004) detailed their experience with an HA designed to meet the WHO requirements produced in Botswana and concluded that they offer a substantial benefit to the hearing impaired, although 8% of these HAs were defective on receipt, 11% were defective on fitting, and 12% were defective during the first year. Although clinical trials should be performed with solar-powered batteries, these authors did not clarify why they used zinc-air batteries instead. Rechargeable solar-powered batteries are a promising technology, even though the WHO (2004) classifies zinc-air batteries as a primary resource and rechargeable batteries as a secondary resource.

Different strategies can be implemented to avoid products obsolescence, such as being aware of the products that international companies are supplying to the market, being informed about changes to the WHO specifications or policies, and having more sophisticated products ready for launch. Because the hearing industry supply chain is limited to a few suppliers, it is important to have products designed by different suppliers in the case of mergers and acquisitions.

The Manaus-W end cost ($140.13)—which includes third party labor—could drop dramatically with mass production; therefore, it could be a viable low-cost HA for open tenders. The Manaus-W and a new breed of HA can be traded on the retail market. Brazilian regulatory laws impose the heaviest importation tariffs and taxes for HAs and their parts; thus, local production could not only lower costs and provide job opportunities but also could be used to develop other products, such as assistive listening devices or audiological equipment.

Conclusions

Designing an HA based on off-the-shelf components is a task that can be done with a low level of investment. An HA with an SDT DSP and Knowles transducers exceeds the WHO requirements for a BTE HA for use in developing countries. Other HA designs can be developed to offer audiologists and the hearing impaired more options for hearing rehabilitation when low cost is a key concern.

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