

CHAPTER EIGHT

An Amplification Protocol for Infants

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Introduction

Not long ago, identifying a one-year old child with significant hearing loss might have been considered to be an early identification. Now, it is somewhat of a surprise when the identification occurs that late. Unfortunately, there are still some children who elude identification or follow up until they are much older. However, for the most part, the growth of newborn hearing screening programs has resulted in earlier identification of hearing loss (Dalzell et al. 2000). This earlier identification has presented audiologists with the task of fitting amplification on younger infants.

Following an introduction of the factors that must be in place immediately prior to fitting amplification, a six-step fitting protocol will be delineated. It is critical to keep in mind that methods for the testing of infants and the technologies that are used to remediate hearing loss continue to change and improve. Still, it may be difficult to implement new procedures into clinical practice because of clinician uncertainty. It is incumbent on practitioners to continue to upgrade their skills and to expand their knowledge. The information provided here is intended to serve as a stepping-stone to audiologists whose task is to diagnose hearing loss in infants and initiate amplification. Each step in the protocol is only a summary of the factors that need to be considered. It will be necessary for the audiologist to seek additional information and specific training in this area.

Excluded from this discussion is fitting amplification for those with unilateral hearing loss, profound hearing loss, auditory neuropathy and atretic ears.

Overview of the Amplification Protocol

Prior to initiating this protocol, it is assumed that permanent hearing loss has been confirmed, and the degree and configuration of the hearing loss has been specified. In infants whose developmental age is 0–6 months, it is understood that testing is done with auditory brainstem response (ABR) procedures. It is also presumed that acute middle ear dysfunction has been ruled out as a major factor in the hearing loss. And last, but not least, the parents/caregivers must be ready to move forward.

A set of basic referrals must be made immediately following the confirmation of the hearing loss. These include referrals for early intervention services, otolaryngology, ophthalmology, and medical-genetics evaluations. Depending on the country or state/province of residence, referral for financial assistance for hearing instrument purchase may also be appropriate.

Even in hospitals where all newborns receive hearing screening, barriers to timely intervention and amplification exist (Dalzell et al. 2000). In some instances, parents might not return for follow-up until the child is older, or they might deny the presence of significant hearing loss and/or the need for amplification. In other cases, parents might seek a second opinion which, although necessary for parental confidence, might create a lag in intervention. Babies in the neonatal intensive care unit or those who have significant medical needs may receive amplification later than healthy babies. Other previously identified reasons for delays in amplification include the need for additional audiological tests and delays in third party payments (Harrison and Roush

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1996; Sjöblad, Harrison, Roush and McWilliams 2001).

The amplification protocol steps that will be addressed in this chapter are:

1. Taking ear impressions and obtaining earmolds;
2. Measuring the real-ear-to-coupler difference (RECD);
3. Using a prescriptive approach to determine target hearing instrument gain and output;
4. Choosing hearing instruments;
5. Verifying the chosen devices; and
6. Fitting the devices and providing a follow-up schedule.

Step 1: Ear Impressions and Obtaining Earmolds

Ear impressions can be taken as soon as the conditions outlined above have been met. The ear canals must be free of debris or cerumen, and the ear must be large enough to support earmold tubing and an earmold. There is not a specific age where this occurs, but a full-term, normal weight infant at one month is typically a candidate.

Prior to taking ear impressions, it is important to fully inform the parents of the entire amplification process. Ideally, examples of baby's earmolds and behind-the-ear hearing instruments are available for parents to view and examine. Many parents are familiar with adults who have hearing instruments, but they may never have seen an infant or young child wearing hearing instruments.

After inspecting the ear canals to ensure a clear path, the length of the ear canal must be estimated. Visualization of the ear canals in combination with data about infant ear canal lengths will assist in placement of the otoblock. Keefe, Bulen, Campbell and Burns (1994) provided data on ear canal length as a function of age. The values from that study are shown in table 1.

Using these ear canal lengths as a guide and otoscope examination, the otoblock is inserted to the desired depth. It is important to note that the smallest cotton otoblock takes up approximately 3 mm in the ear canal. If the desired termination of canal portion of the ear impression is within approximately 5 mm of the tympanic membrane, the otoblock will be placed 3 mm deeper than this ($5 + 3 = 7$ mm). Thus, for an ear impression on a 3-month old infant with an

Table 1. Data from Keefe et al. (1994) showing ear canal length as a function of age.

Age (months)	Length (mm)
1 month	14.0
3 months	16.5
6 months	17.5
12 months	20.0
24 months	21.0

ear canal length of approximately 16.5 mm, the otoblock should be placed approximately 8.5 mm beyond the ear canal opening. In this case, $16.5 - (5 + 3) = 8.5$. Marking the otoprobe at 8.5 mm would ensure that the insertion depth is adequate. Caution must be used when working with a premature infant, an infant who is small for his/her age, or who has an ear anomaly. In these cases, average ear canal lengths based on age will be incorrect.

For some very small ear canals, the diameter of the earmold sound bore may be narrower than the standard #13 tubing, essentially making it a stepped-down bore. This will cause the high frequencies in the hearing instrument's response to roll-off. This effect will have to be accounted for in the fitting process. When the earmolds arrive from the manufacturer, it is critical to ensure that the earmolds' sound bores are patent.

It is important to use an earmold material that is soft, but not too soft. The material should be firm enough so that the sound bore of the earmold remains patent when inserted in the ear canal. Also, the earmold material should be relatively soft for comfort. To satisfy these conditions, a vinyl earmold material is appropriate. Another benefit of vinyl (over silicone) is that the tubing can be glued in place.

Because of the small size of the infant's ear and its changing dimensions during infancy and early childhood, acoustic feedback is a common problem. Changes in growth will require frequent earmold remakes. To temporarily reduce or minimize feedback, water-based lotions (e.g., Otoferm™) can be used on the earmold. Care must be taken not to get the lotion too near the sound bore because there is a risk of clogging the sound bore. Another temporary solution is to use a Comply wrap™ which was designed for use with in-the-ear, in-the-canal or completely in-the-canal devices. As shown in Figure 1, the adhesive wrap can be placed directly on #13 tubing, beginning with the medial end and terminating laterally. More or less of the wrap can be used depending

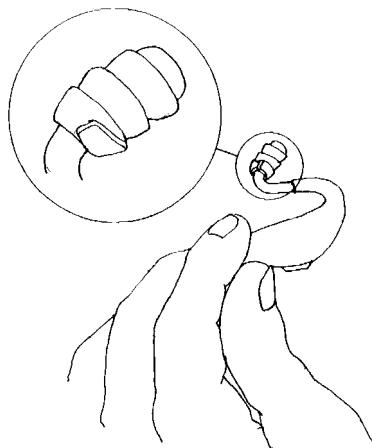


Figure 1. A Comply wrap used with #13 tubing as a temporary earmold for a small ear canal. More or less of the wrap can be used depending on the diameter of the ear canal. Illustration used with permission of manufacturer.

on the diameter of the ear canal. Caution must be exercised to apply the wrap so that it covers the cut edge of the tube, protecting the ear canal from the edge with soft wrap while at the same time not occluding the tube opening (Oliveira 2001). The tubing is attached to a behind-the-ear hearing aid in the usual way. This earmold has offered relief from feedback for some babies in the clinic. This solution also can be employed when there is a need for a temporary earmold. The wrap needs to be replaced when it becomes soiled or when it no longer adheres to the tube.

Step #2: Measuring the Real-Ear-to-Coupler Difference (RECD)

The infant ear does not approximate the adult ear in length, diameter, volume or impedance. One effect of this is that a greater sound pressure level (SPL) is developed in the infant ear as compared to the adult ear for the same input (Feigin, Kopun, Stelmachowicz and Gorga 1989; Westwood and Bamford 1995). This effect needs to be accounted for on an individual basis. Further, traditional probe microphone measures are difficult to obtain in infants and young children because of their movement, vocalizations, and lack of head control during testing. This combination of factors requires use of a method to more precisely specify thresholds and to assess hearing instruments on infants and young children. The measurement of the real-ear-to-coupler difference (RECD) (Moodie,

Seewald and Sinclair 1994) allows for specification of thresholds and predictions of real-ear amplified gain (REAG) and real-ear saturation response (RESR) (Seewald, Moodie, Sinclair and Scollie 1999). The RECD should be applied to estimates of threshold and to hearing instrument measures.

The equation to move from thresholds in dB HL to real-ear threshold in dB SPL follows:

$$\text{Real-ear threshold (dB SPL)} = \text{Threshold (dB HL)} + \text{RECD} + \text{RETSPL}$$

where, RETSPL is the reference equivalent threshold for SPL. It is apparent that the larger the RECD, the greater the real-ear SPL threshold for the same dB HL threshold.

The equations for target or predicted REAG and RESR follow:

$$\text{REAG} = \text{RECD} + \text{coupler gain} + \text{head diffraction and microphone location effects}$$

$$\text{RESR} = \text{RECD} + \text{coupler output for a 90 or 100 dB SPL input}$$

Age-based transforms do exist for RECDs (Sinclair et al. 1996), however, it is more precise to measure the RECD for each patient. As with any average data, variability exists. Further, normative values will not predict real-ear SPLs for very small birth weight babies or premature infants. It is also known that ears with anomalies are not well characterized by average values (Tharpe, Sladen, Huta and Rothpletz 2001). Otitis media with effusion and tympanostomy tubes also influence the RECD. In general, the presence of otitis media with effusion results in a larger than average RECD in the 200–3000 Hz region (Martin, Westwood and Bamford 1996). In contrast, the presence of a tympanostomy tube yields an RECD that is smaller than average in the low-frequencies (Martin, Munro and Langer 1997).

The RECD measurement is repeatable (Tharpe et al. 2001; Sinclair et al. 1996). It has recently been demonstrated that the RECD for one ear is a good predictor of the other ear in the absence of middle ear dysfunction or ear anomalies (Tharpe et al. 2001). Thus, if a child is highly uncooperative or has cerumen in one ear, the clinician has the option of testing just one ear. Using one ear's RECD to predict the other ear's RECD is preferable over using age-normed data.

The RECD procedure is quick to obtain and it is a straightforward measurement (Moodie et al. 1994; Bagatto 2001). The first step is to obtain the coupler response. A broadband signal is presented to a 2 cm³ coupler via an insert earphone. The probe microphone

is inserted into the base of the coupler, and the output is measured. In some hearing instrument analysis equipment, this coupler response is stored for retrieval; but in other systems, it must be measured each time. The second step is to obtain the real-ear response. For this second step, the same broadband signal is presented to the child's ear canal via the same insert earphone, which is now attached to the child's earmold. The probe microphone is placed in the ear canal a specified distance beyond the intra-tragal notch, and at least 4–5 mm beyond the medial end of the earmold. This real-ear response is measured. The coupler response is subtracted from the real-ear response. The result is the RECD.

The insertion depth of the probe microphone into the infant ear canal is typically 10 mm past the ear canal entrance or 15 mm from the intra-tragal notch. It is important to keep in mind that the length of the ear canal changes rapidly with age. Insertion depth should be adjusted accordingly.

It is necessary to obtain updated RECD measurements whenever new earmolds are obtained. Earmold changes and ear canal growth will both change the RECD measurements.

Step #3: A Prescriptive Approach to Determine Target Gain and Output

When working with infants and young children, a prescriptive method that uses threshold data to set targets for gain, output and compression ratio should be used. It is further useful for the method to use RECD values and/or have age-related transforms to convert dB HL thresholds to real ear SPL thresholds. If thresholds have been measured in the sound field, it is necessary to have age-related defaults for the real-ear unaided response (REUR) as well. The Desired Sensation Level (DSL) [i/o] Method is a prescriptive approach that meets these criteria (Seewald et al. 1997). Further, the intention of the DSL targets is to ensure the audibility of amplified speech. The verification portion of the DSL yields estimates of the audibility of the amplified long-term average speech spectrum (LTASS), and the audiologist can observe whether the RESR is below the predicted upper limit of discomfort.

The DSL software system is accessed at the beginning of the fitting process to establish targets for the hearing instruments. It is also accessed later during the verification portion of the fitting process. Over

time, the program is accessed again when new information becomes available (e.g., new or more specific threshold information or when there are new RECDs because of new earmolds). Changes in the device's electroacoustic characteristics should also be imported into the program to ensure that the targets are achieved as closely as possible.

The DSL software provides three different speech spectra from which to choose: Cox and Moore, International and UWO-child. The choice of spectra will change the targets and predicted audibility of both amplified and unamplified speech information. Because the UWO-child spectrum attempts to account for a child's monitoring of his/her own speech (Cornelisse, Gagné and Seewald 1991), it is the most appropriate choice when fitting infants and children.

While the DSL program does allow viewing of the amplified and unamplified LTASS, it must be remembered that this is an average. This average may not be an accurate predictor of any of the baby's conversational partners. Specific conversational partners may be louder or softer than the LTASS at any given frequency. With this limitation in mind, the LTASS has value in providing an estimation of the audibility of speech. It also is a valuable counseling tool for parents because it graphically displays the audibility of speech in the amplified and unamplified conditions.

The goal of the DSL Method is to "... amplify an average conversational speech input to the listener's estimated most comfortable level across frequencies." (Seewald et al. 1996) Real-ear saturation response targets are set one standard deviation below the mean from data provided by Pascoe (1988). The DSL Method also provides targets for compression ratios (CR) as a function of frequency. It does not specify compression threshold; the audiologist will set this parameter based on the degree and configuration of hearing loss and other factors. In general, the lowest tolerated compression threshold affords the best audibility of soft sounds. One possible disadvantage of a low compression threshold is that feedback is more likely to occur.

Step #4: Choosing Hearing Instruments

Targets for gain and output are not the only factors to consider in the pediatric fitting process. There are some hearing instrument options that are con-

sidered standard when working with infants and young children, including style and safety precautions. Although size is a consideration in fitting small ears, it is not appropriate to sacrifice power for size. With few exceptions, hearing instruments will be binaural and behind-the-ear.

Tamper-resistant battery compartments and controls are basic in pediatric fittings, especially as the infant begins to explore his/her environment. It is likely that the hearing instruments will find their way into the child's mouth, especially when the babies begin teething. Parents should be cautioned about accidental battery ingestion and potential hearing instrument damage from moisture.

Pediatric-size tone hooks can significantly improve retention of the instruments. Tone hooks can also be used to shape the frequency response of the instruments and help reach target values.

Compatibility with an FM (frequency modulated) system is also considered basic in the pediatric fitting process (The Pediatric Working Group 1996). Children are often in noisy listening backgrounds and at a distance from their parents, necessitating the use of a remote microphone to improve the signal to noise ratio. Some young children spend a significant amount of time in the back seat of vehicles as they commute with their parents. This can be an important communication and language learning time as songs are sung and the passing landscape is discussed!

Directional microphones have been shown to be advantageous in many listening environments, even for younger children (Gravel, Fausel, Liskow and Chobot 1999). Their application with infants and toddlers, however, remains questionable because these young listeners are often not face-to-face with their parents or caregiver. Instead, when they begin to crawl and walk, they often are faced away from those in pursuit of them. Directional microphones may impede incidental learning from overhearing messages that are not directly intended for them. Also, the directional microphone may reduce the child's ability to detect a warning signal that originates from the back. With those warnings in mind, we also have to consider that there may be situations where directional microphones can be helpful (e.g., the baby is seated in a baby seat at a restaurant). Some hearing instruments have the capacity to have the directional microphone as a switchable feature.

On a practical level, parents must be informed of the loss and damage warranties for the instruments,

and given options for extended warranties or for obtaining separate insurance.

Hearing instrument circuitry choices have become increasingly extensive and expensive. As more digital and programmable instruments become available, the audiologist must attempt to balance cost and proven effectiveness. Not all families or government agencies can afford digital devices. Added to the cost of the hearing instruments are the costs of the FM system. While there is no equation to indicate when a digital device will be best for a given patient, it is clear that the digital trend will continue and that all hearing aids will have digital circuitry in the not-so-distant future. At this time, there are no data to demonstrate that one manufacturer's proprietary processing scheme has an advantage over another, even for adults with hearing loss. Selection should be based on a combination of factors, including cost, practical considerations, individual factors, and family considerations.

Step #5: Verification of Hearing Instruments Performance

There are objective and subjective methods to verify that the hearing instruments are providing what the audiologist intended. Two objective verification methods will be highlighted: the DSL and the Situational Hearing Aid Response Profile (SHARP). Verification through parent report or others subjective outcome measures is not pursued in this chapter; however, the reader is referred to Stelmachowicz (1999) for details.

It is important to use verification methods to determine that target REAG and RESR have been achieved. It is critical to verify the fitting electro-acoustically. Programming the hearing aid or adjusting the potentiometers is insufficient.

In the DSL program, verification can be completed for soft, average and loud input levels and for high input levels (90 or 100 dB SPL). The input stimuli can be constant-level or speech-weighted. The goal of verification is to ensure that the prescribed targets for gain, output, compression ratio, and the compression threshold have been met. Subjective comments from an older child or an adult could lead you to alter some of the parameters; however, for the infant patient, real-ear electroacoustic measures will be the primary method of verification.

Verification of the real-ear saturation response/maximum output should be done using an appropri-

ate stimulus level. Linear peak clipping and compression limiting hearing instruments tend to be in saturation for a 90 dB SPL swept pure-tone input. In contrast, nonlinear devices often are not in saturation for a 90 dB SPL input. Thus, a 100 dB SPL swept pure-tone input should be used for nonlinear devices. Further, if there is a volume control on the device, it must be set to its maximum position to run the saturation response. The goal is to reduce the likelihood of inadvertent overamplification. Figure 2 demonstrates how linear and nonlinear hearing instrument differ in their responses to high-level inputs.

Another method that can be used to verify performance is called the Situational Hearing Aid Response Profile (SHARP) (Stelmachowicz, Kalberer and Lewis 1996). The program does not provide recommendations for gain or output. Rather, it demonstrates the audibility of amplified and unamplified speech (long-term average) for a variety of speech spectra. SHARP includes a variety of speech spectra, including two that are specific to infants: average conversation at 1 meter, raised voice at 1 meter, average conversation at 4 meters, own voice, shout, head shadow at 1 meter, classroom teacher at 1, 3, 4, and 7 meters, and the hip and cradle positions.

The user enters audiometric thresholds, RECDs, and hearing instrument information (e.g., gain, output, CR and compression threshold). The program calculates unamplified audibility, the aided RESR, and an aided audibility index (AAI) for the chosen spectra. Like the DSL, comparisons can be made between unamplified and amplified conditions. The SHARP can be an excellent counseling tool. Limitations of the SHARP are that it is time intensive, as all values must be entered manually. Like other programs that estimate audibility of speech, it assumes a quiet listening environment.

Functional gain is another verification measure. Functional gain is the difference between unamplified and amplified sound field thresholds. Obviously, infants and young children who cannot reliably perform visual reinforcement audiometry (VRA) are not candidates for functional gain. A comparison of coupler measures with RECD or probe microphone measure versus functional gain should demonstrate why functional gain has limited value. These comparisons are shown in table 2.

Aided sound field thresholds, however, are appropriate for some types of devices (e.g., bone conduction hearing instruments, frequency transposition

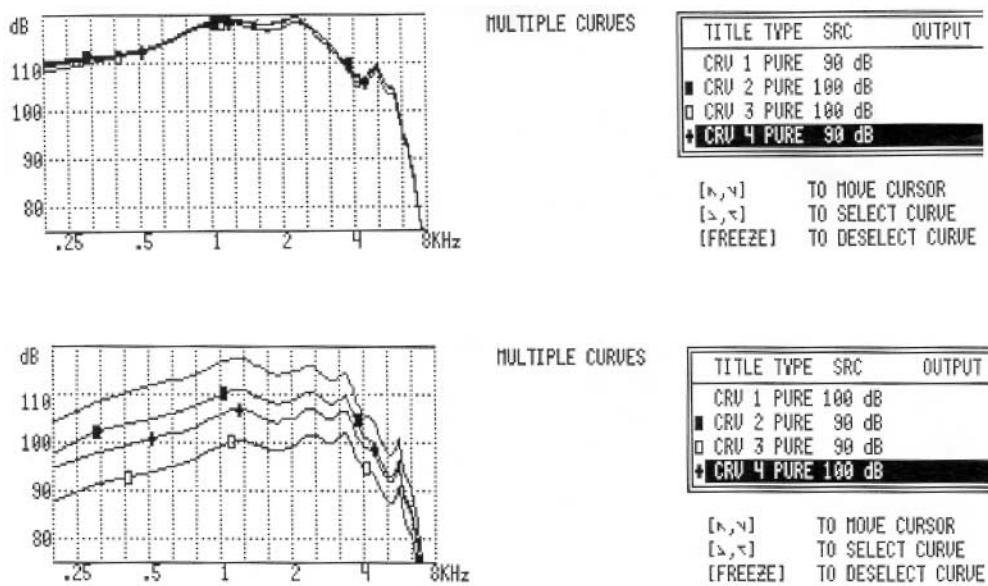


Figure 2. The top half of the figure shows output curves for a linear device that is set at use and at full-on volume control settings for 90 dB SPL and 100 dB SPL swept pure-tone inputs. All four of these curves overlap. The bottom half of the figure shows that same response curves for a nonlinear device, however, for this device each input and each volume control setting yield different outputs. The bottom pair curves are the outputs for 90 and 100 dB SPL inputs at the use volume control setting. The higher pair curves are the outputs for 90 and 100 dB SPL inputs at a full-on volume control setting. For each pair the 100 dB SPL input results in greater output.

Table 2. Comparisons between probe microphone/coupler measures with RECD and functional gain.

Probe Microphone or coupler with RECD	Functional Gain
No age constraints	Age and developmental constraints
Low variability within session	High variability within session
High frequency and intensity resolution	Low resolution for frequency and intensity
Fast	Time consuming
Evaluates at speech-level inputs	No assessment of speech-level inputs
Provides RESR	No assessment of RESR
Accurate in regions of normal hearing	Inaccurate in regions of normal hearing

devices and cochlear implants). Also, for patients whose unaided responses are in the severe-profound hearing loss range, assessing sound field amplified thresholds will assist in determining if the unamplified thresholds are vibrotactile responses. Finally, a quick demonstration of aided responses to speech can be useful in demonstrating aided benefit and can be reassuring for parents. Lack of aided responses in some children may signal other problems.

Step #6: Fitting and Follow-Up Planning

The final step in the process is to ensure that the hearing instruments can be worn without feedback, that they will stay in place behind the ears, and that the parents are familiar with use and care of the devices. Options to keep the devices in place behind the ears include: toupee tape, medical adhesives (e.g., ItStays!™ Adhesive), and Huggies™. To ensure that the devices will not be lost if taken out by the infant, a retention cord should be affixed between the hearing instrument and the child. There are a few products available that for this purpose such as the Phonak Kids Clip, Westone's Critter Clips™ and similar devices that are available through some of the hearing instrument manufacturers. Parents also can fashion their own clips using dental floss (tied around the tone hook) or eyeglass cords and diaper pins, pinned to the back of the infants shirt.

Parents and caregivers need training to ensure that they are adept at inserting, removing and operating the devices. Risks of accidental battery ingestion should be emphasized. Methods and tools to care for the devices must also be provided. Because the first fitting session can be emotional for the parents, a review of the details of this fitting session must be reviewed at later appointments.

Typical audiological follow-up schedules for young children are every 3 months to age 3 years, every 6 months until six years of age, and annually after 6 years. This schedule made sense when the average age of identification was 18–24 months. However, when fitting amplification on infants less than 6 months of age, more frequent visits may be required because more frequent earmold remakes may be needed. Also, more frequent follow up is required when there are risk factors for progressive hearing loss and when there is otitis media with effusion.

Summary

The steps in fitting amplification on infants are similar to the approach used with toddlers and young children. Essentially every step has differences when compared to adult fitting protocols. As outlined above, many special considerations must be taken into account when working with this vulnerable population. Further, the audiologist must remain cognizant of the fact that hearing instruments are just one component of the rehabilitative process.

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