Rationale for Inclusion of Auditory Training Units Under Standards and Rules Applicable to Hearing Aids*

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INTRODUCTION

I have been invited to make this presentation largely as a result of correspondence with Mr. Gluck of the Food and Drug Administration and Mr. Lybarger of the ANSI writing group redrafting the standards for hearing aids. This correspondence took place while I was serving as President of the Academy of Rehabilitative Audiology and carrying out the mandate of the membership with respect to our concerns about standards for hearing aids and auditory training units. The Academy of Rehabilitative Audiology "is an organization of professionals dedicated to foster and stimulate professional education, research, and interest in habilitative and rehabilitative programs for hearing impaired persons." This organization consists of approximately 175 individuals who hold a graduate degree in audiology, language pathology, education of the hearing impaired, or allied fields, and have demonstrated interest and experience in the rehabilitation of those with hearing impairment. The organization was formed and incorporated in 1966 because it was the feeling that insufficient attention was being directed to the research and service aspects of the rehabilitative process. The Academy has become a strong and aggressive advocate for those who deliver rehabilitative services and for the hearing impaired individuals they serve. In 1972 the Academy identified topics of critical concern and task force committees were named and charged with the responsibility of producing conclusions and recommendations that could be implemented in some fashion. The task force on development of standards for hearing aids and auditory training units produced a list of recommendations which was approved by the Academy in November, 1974, and forwarded immediately to the

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ANSI writing group and to the Food and Drug Administration. This document was not as all-encompassing as it might have been because of time limitations, but did represent some aspects of the collective concern of professionals daily involved in the rehabilitative process and an expression of their concern for the deficiencies in present standards for amplification systems. Improvements in design and operation related to user comfort and convenience and improvements in quality and durability were felt to be sufficiently important that a permanent committee on amplification was named. In November, 1975, this committee recommended that the ARA take a position that auditory training units be included in any standards written for hearing aids, and that the Food and Drug Administration be notified that we strongly endorse a cautionary statement on all amplification systems having an MPO of 132 dB or more. The Membership unanimously approved these resolutions and I, as President, forwarded them to Mr. Lybarger and to Mr. Gluck. Apparently the question of whether auditory training units are or should be covered by the proposed ANSI standard (S3.22, 1976) or should be regulated in some other way has come before this committee and it is my understanding that this is the background precipitating the invitation for this presentation.

HISTORICAL ASPECTS RELATED TO AUDITORY TRAINING UNITS

Before I address myself to the need for ANSI and the FDA to give attention to auditory training units, it will be worthwhile to historically review the distinctions between hearing aids and auditory training units, the development of standards, and the development of licensure laws.

There are several types of auditory training unit systems being used in educational facilities around the country. I will briefly mention the various types in chronological order. The oldest group units are hard-wired systems where the children wore audiometer-type earphones and the primary input microphone was in the hands of the teacher, which provided for a reasonable signal-to-noise ratio. Individual self-contained units were also available if better acoustical properties than provided by hearing aids were required. The primary difficulty with these systems was lack of flexibility in that the mobility of the children was limited to the length of the earphone cord. Some of these units are still in existence, for example, one of the finest aural programs for hearing-impaired children in the metropolitan Detroit area uses such equipment as the basic amplification system throughout the elementary years. The induction loop then appeared as a means of modifying a hard-wire system to increase individual mobility and classroom flexibility. The children either wore their own hearing aid, providing it contained an induction coil, or specially purchased receivers. Because these first induction loop systems posed spillover problems into other classrooms, the next development was energizing the loop with an RF signal, which required the use of an RF receiver rather than the child's own hearing aid. The most recent development has been the use of the FM wireless microphone transmitter-receiver combination and elimination of the loop. One will find all of these systems in operation in educational facilities; however, most programs utilize ILA systems or wireless FM systems. It should be kept in mind that the receiver the child wears for use in the loop system or in an FM system can be defined as a hearing aid since it performs all functions of a typical hearing aid with the added capability of receiving FM signals.

Historically, hearing aids and auditory training units have always had one thing in common; i.e., they provided amplification for the hearing impaired. As such, both could be defined as hearing aids. However, because of certain dissimilarities, some have historically been referred to as hearing aids while others have been called auditory training units. Hearing aids have always been wearable while auditory training units traditionally have not, (although this is rapidly changing). Auditory training units tended to have wider frequency response characteristics and higher fidelity largely because they used better quality transducers. Even today, while many auditory training units use hearing aid-type receivers, the option to use earphones is available. Auditory training units were also distinguished because they were capable of employing external inputs that permitted group work and provided some control over the signal-to-noise ratio at input. Classically, then, auditory training units and hearing aids were identified on the basis of one or more of these characteristics. Individual portable auditory training units resembled hearing aids in that the microphone, amplifier, and receiver were self-contained, but were typically not referred to as hearing aids because they were not wearable and because they used audiometer-type earphones; and, group units were not called hearing aids because they were hard-wire, non-portable, non-wearable units with several input sources possible including an external microphone under control of the teacher or therapist. In those days, anyone could distinguish between an auditory training unit and a hearing aid even though all systems existed for the same fundamental purpose, that is, to provide amplification for the hearing impaired.

Auditory training units are primarily used with children in the educational process or with severely impaired adults attending rehabilitation programs in community centers, hospitals, or universities. Some companies manufacture auditory training units as well as hearing aids; some companies manufacture only hearing aids; and some companies manufacture only auditory training units. All hearing aid dealers sell hearing aids, but only a few sell auditory training units, while most auditory training units are sold by sales organizations outside of the hearing aid distribution system. The point of these comments is that from the very beginning, hearing aids and auditory training units were conceived of as separate and independent entities by manufacturers, sales organizations, professionals, and potential users. This differentiation is still implied today even though there have been such significant changes in auditory training units that the classical distinctions have been blurred or obliterated. For example, most modern auditory training units are wearable; many hearing aids have as good frequency response characteristics as auditory training units, partly because of the increased use of hearing aid receivers with auditory training units and partly because of improved microphone and receiver technology being applied to hearing aids; and most modern auditory training units, in addition to being wearable, incorporate all the features of a hearing aid that permit freedom of movement and flexibility of use. Modern loop or FM auditory training unit receivers bear much more similarity to hearing aids than ever before. In fact they can be worn as hearing aids. They do tend to be physically larger, capable of accepting earphone receivers, and receiving input from external sources. On the other hand, many hearing aids today can be conceived of as auditory training units since they contain an induction coil so that they can function as a receiver in a loop system. Even though it is getting increasingly difficult to distinguish hearing aids from the newer type auditory training units, many people still think of auditory training units and hearing aids as distinctly different probably because of distribution differences rather than differences in purpose or function. The Academy of Rehabilitative Audiology, along with many other people who are knowledgeable about the state of the art and the uses to which these systems are directed, have come to the conclusion that the day has long since arrived when hearing aids and auditory training units should be subjected to the same basic kind of standards.

In 1960 the American Standards Association developed a standard for measurement of electro-acoustical characteristics of hearing aids (S3.3,-1960). The purpose of that standard was to "describe practicable and reproduceable methods of determining certain physical performance characteristcs of air conduction hearing aids"; however, hearing aids were not otherwise defined so as to infer that the standard also applied to devices labeled as auditory training units. If the intent of the writing group was to include auditory training units as hearing aids, then we should question the value of consensus standards because no apparent effort has been made by manufacturers to utilize the incorporated procedures.

IEC publication 118 also addresses itself to electro-acoustic characteristics of hearing aids. The fact that this organization is drafting a supplement to this publication entitled "Recommended Methods for Measurement of the Electroacoustical Characteristics of Hearing Aid Equipment Not Worn on the Person" would seem to imply that there is some need for such a standard and further that such components should be defined as hearing aid equipment.

A further development that documents the historical differentiation of hearing aids from auditory training units is the advent of state licensure of hearing aid dealers. I have not had the time to peruse all of these licensure laws, but I did have access to three that I think are probably representative. In New York and Ohio the hearing aid dealer licensing law defines a hearing aid as "any wearable instrument or device designed or offered for the purpose of aiding or compensating for impaired human hearing" while in the state of Michigan, a hearing aid is defined as "any instrument or device designed for regular and constant use in or proximate to the human ear and represented as aiding or improving defective human hearing." It is interesting to note that the New York and Ohio definitions would seem to include auditory training units if they are wearable, but would exclude portable devices or the older hard-wire auditory training systems. I wonder, however, whether in New York and Ohio if it is necessary for representatives of companies that produce RF auditory training units to be licensed? In the state of Michigan I can speak with more certainty. Even though the definition of hearing aid would seem to encompass auditory training units, I can assure you that such is not the case. The only individuals required to be licensed are those who sell instruments that fit the traditionally accepted definition of a hearing aid.

Certainly we can conclude that the present situation is most confusing. We have had consensus standards for reporting electro-acoustic characteristics of hearing aids for some years with considerable evidence that manufacturers of auditory training units do not define their products as hearing aids and thus feel no obligation to comply with those standards. It can be noted of the exhibits presented in Appendix A that only two of the companies advertising auditory training units (Zenith & Telex) present data that is consistent with the existing hearing aid standard. These two companies are also manufacturers of hearing aids. One company that manufacturers hearing aids does not indicate how the obtained data was derived (Maico). The other manufacturers confine their production to auditory training equipment and apparently make no attempt to comply with the standard, or at least it can not be readily ascertained by reviewing the data they present. We presently have an ANSI writing group in the final stages of drafting a new proposal for measuring the electro-acoustic characteristics of hearing aids with considerable historical evidence that these new standards will not apply, nor were intended to apply, to devices described as auditory training units. Certainly, the draft proposal does not say that it pertains to any devices other than those commonly understood to be covered by the old standard. Mr. Gluck of the Food and Drug Administration reported to me in a letter (dated 1-28-76) that a rule has been prepared for professional and patient labelling of hearing aid devices, and that a hearing aid is defined as: "Any wearable instrument or device designated for, offered for the purpose of, or represented as aiding persons with or compensating for impaired hearing." He then reports that "some auditory trainers, or portions thereof, may be covered by this definition; undoubtedly, some would not. At present hearing aids are on our highest priority list, while auditory trainers are not." If the FDA is granted authority to make such rules and providing the rule as stated is promulgated perhaps a large part of the problem will disappear in that all manufacturers of wearable devices whether labelled as hearing aids or auditory training units will have to comply with the new ANSI standard. However, *will* the Phonic Ear HC-421 Binaural Auditory Trainer/FM Receiver or the Bioacoustics Model 70 Receiver or the EFI Model 140-FM Travel Ear II Receiver be defined as wearable instruments or as a component of a larger non-wearable system? I think this point needs to be clarified because it obviously has impact not only in terms of required conformance to ANSI standards, but impact with respect to licensure of sales personnel in the various states. My opinion (supported by the Executive Committee of the Academy of Rehabilitative Audiology and the Audiology Committee of the Michigan Speech and Hearing Association) is that the definition as proposed by the Food and Drug Administration should be modified by striking out the word "wearable." This would have the immediate effect of requiring all manufacturers of both hearing aids and auditory training units to subject their instruments to the same performance tests and would provide the basis for realistic comparisons by people entering the marketplace for "auditory training units."

RATIONALE FOR STANDARDS OR MANDATORY RULES FOR AUDITORY TRAINING UNITS

When invited to address you this morning I was charged with the responsibility for developing a rationale for the need to provide the same degree of regulation of auditory training units as that being contemplated for hearing aids. My first reaction was to reply that I should be invited to listen to a rationale of why auditory training units should *not* be subject to the same regulations. If it was deemed important 20 years ago to specify the characteristics of hearing aids in some standardized fashion, then it was obviously equally important that the same need existed for this other category of amplification for the hearing impaired. Why it did not happen is a mystery to me. The FDA in its proposed rules (Federal Register, April 21, 1976, p. 16760) requires "that manufacturers use the American National Standard for specification of hearing aid characteristics in determining the technical data for the hearing aid labeling which will assure that there is uniformity and comparability in testing and measuring the electro-acoustical properties of hearing aids. Hearing health professionals who select and fit hearing aids consider it essential to the selection of the appropriate hearing aid that there be uniformity and comparability in testing and measuring hearing aid performance parameters". Those of us who are familiar with auditory training units and their utilization in the classroom wish you to know that the same statement is as applicable to auditory training units as it is to individual hearing aids. These units are used in the very same ears in which we fit hearing aids with great care and concern about the electro-acoustic properties delivered and their relevance to the individual hearing loss. Not including auditory training units in these requirements makes a mockery of our attempts to provide quality amplification for hearing impaired children. This equipment has been provided by the school system for several reasons but probably the major one is that it provides for more positive control of the signal/noise ratio through the primary microphone which is usually located near the teachers mouth. As indicated in other places in this paper, most auditory training units are purchased by parental surrogates who know little more about amplification systems than parents do; their use in the classroom is monitored by teachers who cannot be regarded as experts with respect to the technical aspects of amplification or residual hearing. Since it is imperative that maximum use be made of residual hearing for purposes of insuring optimal development of educational potential while at the same time guarding the precious residual hearing, there is really no excuse for our not requiring these units to meet the same standards as devices sold to the general public under the label of hearing aids even if there was no evidence of need.

It might be asked how many special education programs we are talking about and also how many hearing impaired children there are in special class placements. Checking the annual census published in the *American Annals of the Deaf* (April 1974), allows us to make some reasonable estimates. The October 1973 census indicates that there are over 1200 special class programs for hearing impaired children in the United States serving some 52,000 children. We should keep in mind that this census is a conservative estimate since the return rate of questionnaires was less than 100%. There are obviously several thousand other hearing impaired children, not at the present time in special class programs, who may be using FM systems. If we can assume that most if not all of these special class programs have auditory training equipment then we know that we are talking about a considerable amount of time and money that has been spent over the years in obtaining adequate auditory training units; but more important, we know we have the responsibility for the residual hearing and educational achievement of a sizable group of handicapped children. We can not ignore them nor presume that because the children don't complain they are receiving optimal amplification or because administrators don't complain that no problems exist for those who try to select good equipment for them.

We will begin by taking a look at the study conducted by the California State Department of Education in conjunction with the San Diego Speech and Hearing Center, entitled *Educational Amplification Response Study* (EARS) which was published in 1968. Part of this study consisted of electroacoustic analysis of 27 different models of auditory training units provided by nine different manufacturers. Workmanship and durability were also evaluated by a highly competent person from General Dynamics Corporation. Several parameters of auditory training unit performance were evaluated including acoustic gain, acoustic output, frequency response curve, frequency response uniformity, harmonic distortion, tone control variability, uniformity between channels, control calibration—gain—power output—tone, and compression attack and recovery time. Gain, output, and frequency response were obtained utilizing standardized HAIC test procedures. They established a method of rating frequency response uniformity, harmonic distortion, tone control variability, uniformity between channels, control calibration, and compression attack and recovery time that made it possible for them to qualify performance as excellent, good, fair, or poor. Since it was not known from specification sheets whether manufacturers evaluated their systems in conformity with HAIC procedures, they had no immediate way of knowing whether the gain, output, and frequency response curves should agree with manufacturers' statements. For whatever reason, no comparisons were made between the obtained results and the manufacturers' specifications.

In the introduction to the study, they posed the following quoted or paraphrased questions to the manufacturer: How were design criteria established?; "Was this done after much research into the needs of the hearing handicapped?"; "Why isn't your system as flexible as some hearing aids?"; "Why has not the industry set standards in, for instance, the marking of controls?"; "Do you use the same systems of reporting such as is used by the hearing aid industry conference?; If not, why not?" (p. viii)

Of those parameters that were subjected to rating scales, the following breakdown of ratings occurred:

1. *Frequency response uniformity.* One unit received an excellent rating, seven good, eight fair, ten poor. To earn an excellent rating, the unit had to produce a frequency response curve within ±3 dB through the frequency range of 100 to 5000 Hz if earphones were used, and a frequency range of 200 to 4000 Hz for insert-type receivers. The results are certainly an indictment of the industry, especially since most manufacturers of auditory training units report frequency response curves of ±3 dB across a frequency range as wide or wider than this (see pp. 67, 68, 73, appendix C, and E.)
2. *Uniformity between channels.* Five units were rated excellent, five good and eight fair. While no units received a poor rating, it should be pointed out that "fair" meant there could be as much as 8dB difference delivered to the two earphones or inserts.
3. *Harmonic distortion.* Thirteen units rated excellent, five good, two fair, and two poor.
4. *Tone control variability.* Three units rated excellent, four good, and four fair.
5. *Control calibration*—gain, power output, and tone. Four units rated excellent, one good, two fair, and two poor.
6. *Compression attack and recovery time.* One unit rated excellent and three units rated poor (attack time in excess of 100 ms and recovery time exceeding 500 ms).

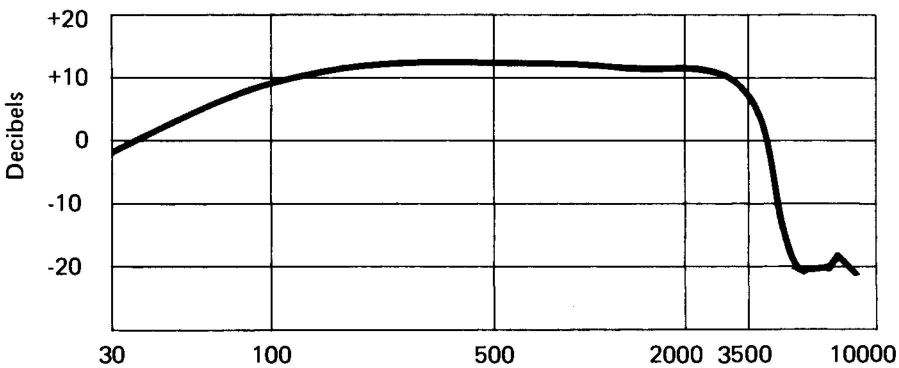
Thus we can see that very few of the units evaluated measured up to the reasonable criteria imposed by those doing the study. At this point let us take a look at comparisons between obtained results and manufacturers' claims as reported on their specifications sheets.

Example I. Enclosed are excerpts from the specification sheet for the Acousta model WT 10 broadcasting unit and the WR 10 receiver along with data sheets from the EARS study. Inspection of this information makes it obvious that the manufacturer did not obtain the reported frequency response characteristics by HAIC procedures. He does not report how he obtained the data so reproducibility is complicated. His specification sheet clearly gives the impression that this is a wide band hi-fidelity system when using either the earphone or the hearing aid receiver, while the EARS data provides us with quite a different picture.

Example II. Enclosed are excerpts from the specification sheet for the Eckstein Brothers, Model 20 monaural amplifier with binaural earphones and data sheets from the EARS study. It can be seen that there is some discrepancy between HAIC gain and that reported by the manufacturer. How the manufacturer determined acoustical gain is unreported. There is also

Example I

Response characteristics of ACOUSTA RF WIRELESS AUDITORY TRAINING SYSTEM, MODEL WT-10 and WR-10 as reported on Manufacturers Specification Sheet.



Frequency in CPS

FREQUENCY RESPONSE

OPTIONAL ACCESSORIES FOR THE ACOUSTA WR-10 STUDENT RECEIVER

The NEW Acousta AYC-S Binaural Cord has much improved frequency response over standard previous ear buttons or driver units. (See Graph)

It is ideal for playground/outdoor use and older students as well, or as a variation from regularly supplied headsets. The Binaural Cord will accommodate student's earmolds.

SPECIFICATIONS

Overall System:

Frequency response: ±3 db 70 to 10,000 cycles.

Distortion: Less than 2%

*Output: 125 db reference .0002 dynes per centimeter squared.

*Measured over voice frequencies with B&K SPL meter weighted with network curve "C".

WT-10:

Frequency response: 60 to 10,000 cps. ±3 db.

Weight: 8 oz.

WR-10

Student Microphone frequency response: 70 to 10,000 cps.

Sensitivity: -58 db.

Weight, less headset: 12 oz.
AH-1S Headset:

Frequency response: 16 to 15,000 cps.
Distortion: Less than 2%.

From *Educational Amplification Response Study* (EARS), pp. 33, 34, 35.

ACOUSTICAL SUMMARY

ACOUSTA

Mode	HAIC Gain—dB	HAIC Range—Hz	HAIC MPO—dB
trainer control and receiver	40	175—3300	121
receiver only	37	250—3400	124

ACOUSTA

Note: Teacher unit WT-10 broadcasting to student unit WR-10. Muff type earphones (AH-1) used except where noted.

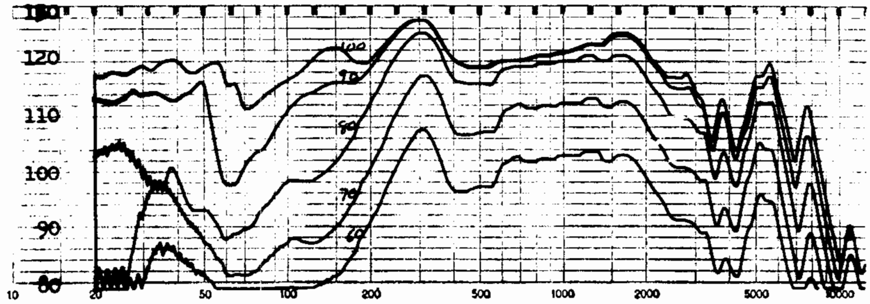


Figure 1—Series of curves with inputs of 60, 70, 80, 90, & 100 dB. Earphone balance control set at maximum. Receiver control set at maximum.

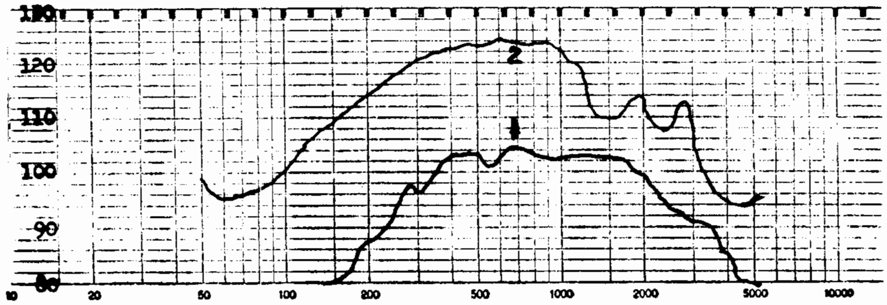


Figure 5—Difference in response between muff type earphone (1) and insert type (2) earphone. Input of 60 dB. Earphone balance control set at 10 dB down from maximum. Receiver gain set at maximum.

Example II

Response Characteristics of ECKSTEIN BROS. AUDITORY TRAINER, MODEL 20 as Reported on Manufacturers Specification Sheet.

This desk type hearing amplifier incorporates advanced features never before found in a low priced unit . . . Built in high fidelity microphone, wide range low distortion amplifier and high quality dual dynamic headphones for excellent reproduction.

Excellent for auditory training in the school or home. Controls easy to operate. Simply turn volume control on, adjust balance control for proper loudness balance between earphones. After the balance control and the tone switch are adjusted, they are left as is. Thereafter only the volume control need be adjusted for comfortable listening in both ears.

The two position tone switch allows either a flat frequency response or a high frequency boost.

SPECIFICATIONS

Acoustical gain: 80 dB
Max power output: 135 dB re 0 dB SPL
Frequency response (tone switch in flat position) ± 3 dB
with Model S or SI earphones 100-5500 CPS
with Model HF earphones 80-8000 CPS.
EB-20 *S*: (with lightweight under-the-chin headset)
EB-20 SI: (with individual receivers for use with earmolds)
EB-20 HF: (with high fidelity dynamic headset)

From *Educational Amplification Response Study* (EARS), pp. 76, 77, 78.

ACOUSTICAL SUMMARY

Mode	HAIC Gain–dB	HAIC Range–Hz	HAIC MPO–dB
TDH 39 C earphone	59	100–6000	126
Insert earphone	67	80–4700	––

ECKSTEIN BROTHERS AUDITORY TRAINER MODEL 20

Note: Except where noted, the following curves were run using the TDH-39 earphones with the MX41AR cushion.

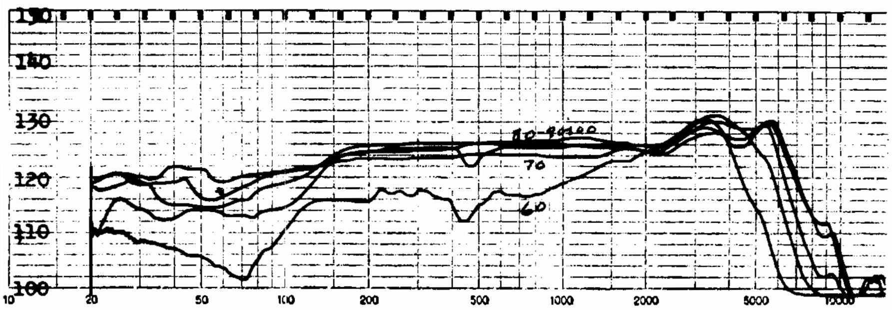


Figure 1–Series of curves with inputs of 60, 70, 80, 90, & 100 dB. Volume control set at maximum. Balance control set at zero. Tone switch set at normal.

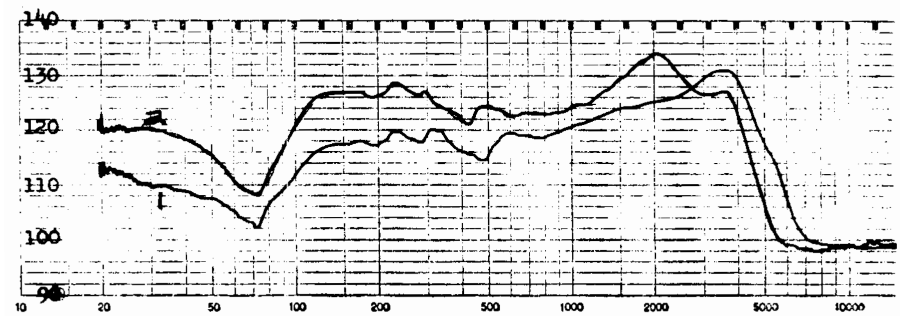


Figure 5–Comparison of TDH-39 earphone (curve 1) with insert earphone (curve 2). Input of 60 dB. Volume control set at maximum. Balance control set at zero. Tone switch set at normal.

Example III

Response Characteristics of ECKSTEIN BROS. AUDITORY TRAINER, MODEL 31 (two channel) as Reported on Manufacturers Specification Sheet.

Maximum output power delivered with extremely low distortion.

Model 31-S or 31-SI:
frequency response 100-6500 cps
maximum output 135 dB re 0 dB SPL
Model 31-HF:
frequency response 80-8500 cps
maximum output 130 dB re 0 dB SPL

FEATURES

Completely transistorized—rugged—stable
Battery operated: uses popular leakproof mercury batteries with approximately one year reliable operation
Tone control: (two position)
normal: for flat frequency response
high: for accentuation of frequencies above 1000 cps
Permits individual compensation of each ear
Very stable, high gain, low noise amplifiers
Noiseless volume control
Fully guaranteed for one year

EB31-S complete with model S under-the-chin lightweight headset and batteries
EB-31SI complete with individual earphones (for use with earmolds) and batteries
EB31-HF complete with audiometer type dynamic headset and batteries

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Reproduced from *Educational Amplification Response Study* (EARS), p.p. 83, 84, 85.

ACOUSTICAL SUMMARY

Mode	HAIC Gain–dB	HAIC Range–Hz	HAIC MPO–dB
insert earphone	66	100–3000	––
TDH 39 N earphone	56	100–6000	127

ECKSTEIN BROTHERS BINAURAL AUDITORY TRAINER MODEL 31

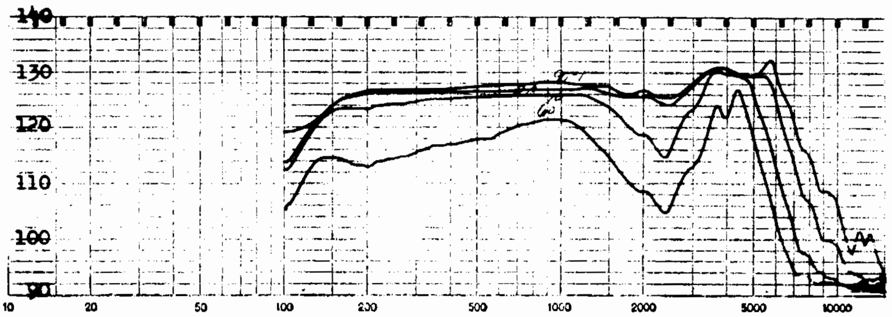

Figure 1—Series of curves with inputs of 60, 70, 80, & 90 dB. Gain control set at maximum and time control set at normal.

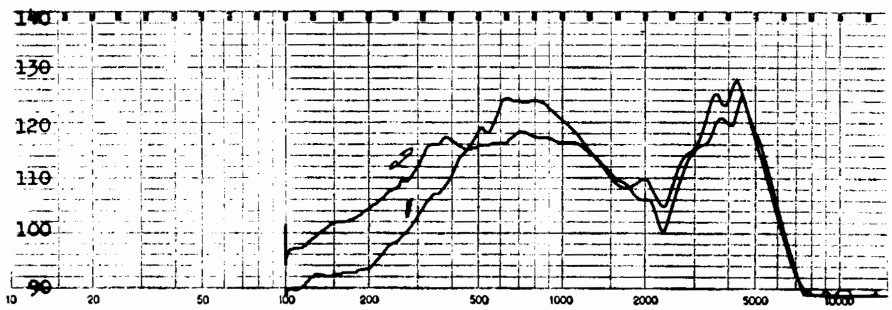

Figure 4—Uniformity between channels with an input of 60 dB. Volume control set at maximum. Tone control set at normal. Curve 1 is right phone; curve 2 is left phone.

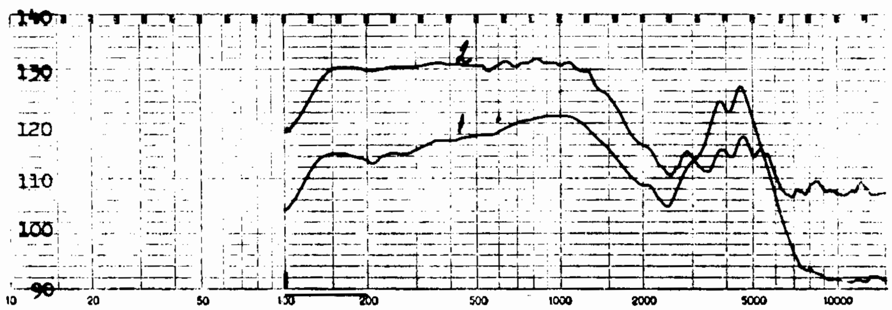

Figure 5—Comparison of TDH 39 earphones (curve 1) with insert type earphone (curve 2). Input of 60 dB. Volume control set at maximum with tone control set at normal.

Example IV

Response Characteristics of PHONIC EAR, MODEL HC 219 as Reported on Manufacturers Specification Sheet.

A BINAURAL AUDITORY TRAINER THE SIZE OF A HEARING AID . . . AT ONLY ONE-HALF THE PRICE.

BINAURAL AUDITORY TRAINER

Complete binaural separation (two separate microphones and amplifiers.)

Mikes attach to any garment. Instrument fits in a shirt pocket or harness (body belts).

Here is an instrument with superior frequency response (300-5300 Hz, flat ±2½ dB). A maximum SPL of 140 dB. No transformer. No low-end distortion.

All with unprecedented acoustic signal-to-noise ratio of 60 dB.

Yet it has all the cosmetic advantages of the conventional hearing aid. At only one-half the usual price!

SPECIFICATIONS

Frequency Response:
- 300-5300 Hz (flat within ±2½ dB) with headset transducer
- 300-3300 Hz (flat within ±2½ dB) with hearing aid transducer

Maximum Sound Pressure Level:
- 140 dB with hearing aid transducer
- 130 dB with headset transducer

Acoustic Gain: 70 dB

Acoustic Signal-to-Noise Ratio: 60 dB measured at maximum sound pressure level output

Volume Control Range: 50 dB

Dynamic Range: 30 minimum (at lowest volume setting)

From *Educational Amplification Response Study* (EARS), pp. 142, 143, 144

ACOUSTICAL SUMMARY

Mode	HAIC Gain–dB	HAIC Range–Hz	HAIC MPO–dB
insert earphones	67	310–3800	142
TDH 39 earphones	38	300–10000	––

H. C. ELECTRONICS, INC.
PHONIC EAR BINAURAL AUDITORY TRAINER MODEL 219

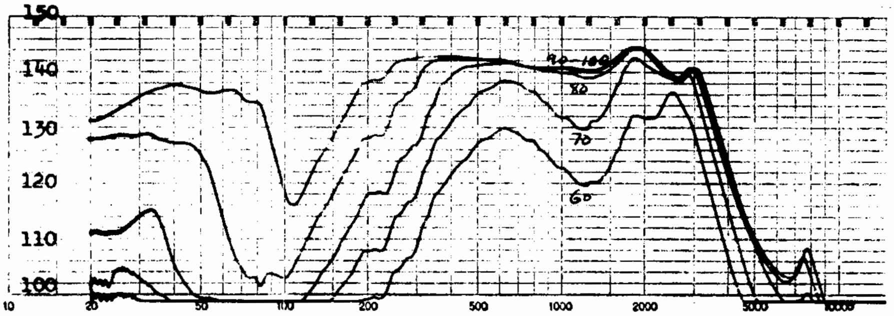

Figure 1—Series of curves with insert type earphone. Inputs of 60, 70, 80, 90, & 100 dB. Right gain control set at maximum.

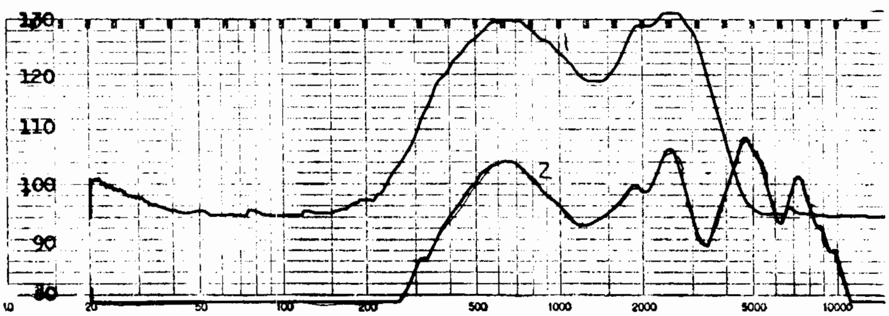

Figure 6—Comparison of insert type earphone (curve 1) and TDH-39 muff type earphone (curve 2). Input of 60 dB. Left ear volume control set at maximum.

some difference in the maximum output. While the frequency range of this unit is quite similar to that reported by the manufacturer, it does not appear that the unit meets the manufacturers claim of ±3 dB throughout the range.

Example III. Enclosed are excerpts from the manufacturers specification sheet for the Eckstein Brothers, Model 31 2-channel desk type amplifier and data sheets from the EARS study. For this particular unit the manufacturer does not report the acoustical gain or make any statement about the smoothness of the frequency response curve. There does not seem to be much relationship between the reported frequency response and the frequency range calculated by HAIC procedures.

Example IV. Enclosed are excerpts from the manufacturers specification sheet for the Phonic Ear, Model HC 219 binaural auditory trainer, along with some of the data sheets from the EARS study. It is interesting to note while looking at the manufacturers specification sheet that, as far back as 1968, we begin to see manufacturers comparing auditory training units to hearing aids, while at the same time not subjecting them to the measurement standards for hearing aids. Comparison of this data shows that the manufacturers statements about the flatness of the frequency response curve with earphones or with hearing aid transducers are not borne out by actual measurement. We can also observe that many units have reported or measured MPO's in excess of 132 dB (see also appendices B, C, and G).

Review of this data reveals that there is some disparity between the performance of earphone and hearing aid type transducers. My impression is that manufacturers tend to make them look more alike in terms of response characteristics than the situation warrants. The EARS study clearly shows that these two types of transducers tend to vary significantly in frequency range, gain, and MPO. The industry seems to know that teachers of the hearing impaired tend to prefer hearing aid type transducers and that the sale of their units may be predicated upon offering that option whether or not it is appropriate for an individual child.

The second study that I will cite as evidence for the need of standards for auditory training units is the paper published by Matkin and Olsen entitled *Induction Loop Amplification Systems: Classroom Performance* (1970). These authors made electro-acoustic measurements on six different brands of ILA equipment located in ten classrooms in the Chicago area. They do not specify the manufacturers of the ILA equipment, but did conclude that performance was highly inconsistent across systems. Their study was complicated by the fact that "while specifications for electro-acoustic measurement of hearing aids are currently available, there are no such procedural guidelines for the measurement of auditory training units. This accounts, in part, for the marked differences among performance data provided by various manufacturers of induction loop amplification systems" (p. 239). In order to accomplish the study they had to decide upon methods to employ in the measurement of performance. Their objective was to determine through measurements of acoustic gain and frequency response, the similarities or differences among these systems. It should be pointed out that these measurements were not obtained in the laboratory, but in the classroom situations where they had been installed by manufacturers representatives.

In terms of gain they found that the six systems ranged from a low of 30 dB gain to a high of 65 dB gain. Obviously, such factors as loop placement and size of the room might be variables that would effect gain. The point is, however, that these units were sold and installed by manufacturers purporting to be interested in the amplification needs of severely hearing impaired youngsters, but apparently little attention was paid to performance characteristics after installation.

Variability of frequency response characteristics was also noted. The authors state "at the present time, manufacturers do not provide frequency response data for ILA systems when used with a wearable hearing aid. This proved true even in those instances in which the ILA system and a stock of hearing aids were sold as a package to the school by a particular company" (p. 242). It would seem on the basis of the results of this study that the purchaser of ILA systems would be completely in the dark as to the actual acoustical characteristics of the system he was purchasing (see Figure 1 on page 77). If specification sheets do report electro-acoustic data, it is probably not done according to ANSI specifications and is probably done under laboratory conditions that may bear no resemblance to actual function when installed. The authors also investigated the similarity between acoustic gain values and frequency response curves for the receivers when in the microphone mode and the telephone mode. They found four ILA systems where the change in gain from microphone to telephone was 5 dB or less, however, the other classroom systems varied up to 30 dB. They also found considerable variability in the frequency response characteristics of the microphone and telephone modes (see Figure 2 on page 77). One can conclude after reading this study that amplification offered by ILA systems is quite variable and that it is sold and installed without the same due care given to desireable electro-acoustic characteristics that is applied in the selection of individual hearing aids for children. The authors conclude that "to complicate matters further, even individuals with a fair degree of sophistication find it difficult to abstract practical information from manufacturers equipment manuals and specifications sheets as presently written. Standardization in the reporting of technical data is needed if one is to make meaningful comparisons of the performance and ease of operation of

From Matkin & Olsen (1970), pp. 242 & 243

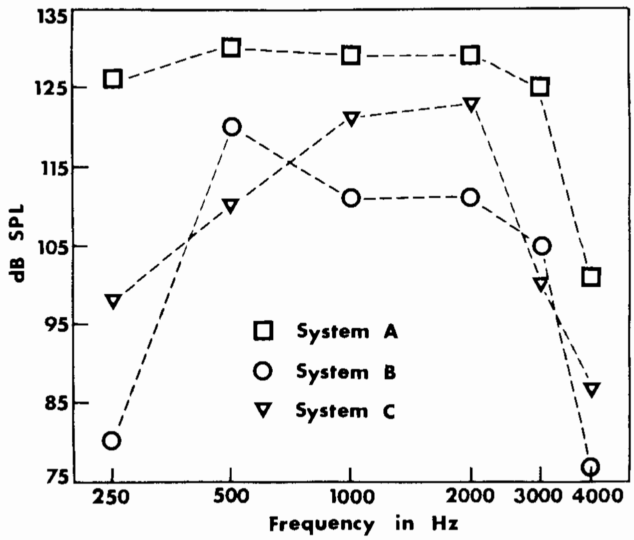

Figure 1—A comparison of frequency response curves for three different ILA systems.

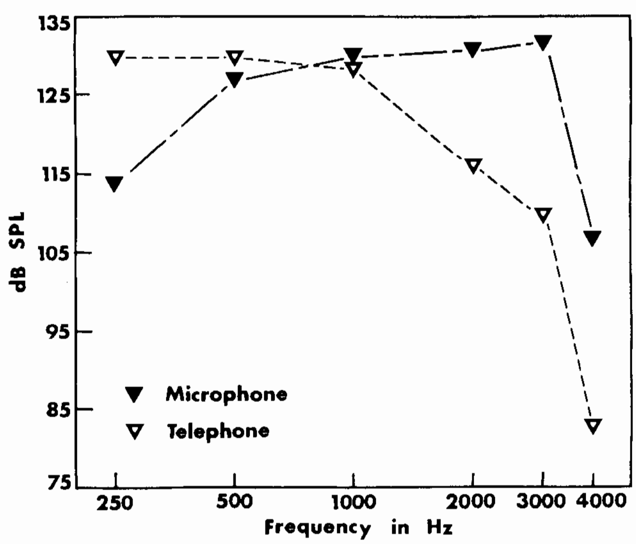

Figure 3—Performance of differences in microphone and telephone modes of operation for one ILA system.

various ILA systems" (p. 244).

In preparing this paper I made an informal survey of audiologists involved with classroom programs for hearing impaired children in the metropolitan Detroit community. Most of these audiologists are employed by large county-wide public school systems, one is employed by a private school for the deaf, and some are used on a consultant basis (usually after the fact). These people were unanimous in indicating the need for standards in the manufacture, reporting of electro-acoustical characteristics, installation, repair, and durability of auditory training units. All reported that it is very difficult to make judgements regarding the purchase of new equipment because of the lack of standardization of relevant characteristics. One of these school systems serves 175 severely hearing impaired children and has about 200 auditory training units in use or in reserve. The 200 units represent three different manufacturers and are of the ILA or FM wireless varieties. While units from one company are above average in conformance, stability, and durability, the others are a constant source of difficulty. They vary from manufacturers specifications, reveal considerable intra-model variability, and are subject to frequent breakdown. All are capable of MPO's exceeding 132 dB. Such differences are not apparent by reading specification sheets or advertising claims. This school system employs four full-time audiologists and one full-time electronics technician (this is the optimal situation, but extremely rare). The technician's sole responsibility is keeping the auditory training units in proper repair. The Lutheran School for the Deaf in Detroit provides education for 55 severely hearing impaired children. The audiologist on staff indicates that during the 1974-75 school year 368 auditory training unit repairs were provided and that 387 repairs to personally owned hearing aids were necessary. These statistics would indicate that both types of units are approximately equally susceptible to damage. He further reports that if the school did not have someone like him on staff and the necessary electro-acoustic equipment to evaluate performance, the units would be placed back in service under the assumption that the manufacturer had provided appropriate and responsible service. Approximately two years ago the Lutheran School for the Deaf purchased new auditory training units for their educational program. They were generally pleased with their final decision, but in the process evaluated five ILA or FM systems. Each manufacturer submitted some units for a trial evaluation under the supervision of the audiologist. You might be interested in some of his comments about the systems. Based upon electroacoustic analysis he reports "Sample #1 is unacceptable due to distortion . . . . Sample #2 (left channel only) shows good low frequency and smoother response, but relatively poor response above 2000 Hz. . . . Poor quality control in these samples." "Controls are poorly designed on receiver;

functions fuzzy. Poor acoustic signal quality on RF; slightly better on hearing aid microphone. Excessive distortion on both. Poor service record: Two units failed during trial." "Excessive distortion through RF system. Cross talk is present but minimal." It should be kept in mind that sales representatives usually do not provide any of these services to the purchasers of their equipment; either the school system provides it through their own personnel, or by consultation, or it is not done. Teachers and administrators cannot provide these services because of lack of relevant training, time, or instrumentation.

Bastian (1974) reports on two school programs that sought audiological expertise after purchasing FM wireless and RF loop equipment, because performance problems obviously existed and no satisfaction had been received from manufacturers or sales personnel. Their analysis revealed many unexpected nulls in the loop classroom; environmental microphone input produced excessive harmonic distortion; poor frequency response; and excessive variability between channels. Units were sent for repair and re-evaluated. Several units had to be returned again because repairs were inadequate. This experience was followed by a questionnaire survey of the 277 teachers for hearing impaired children in Michigan, which revealed performance as inadequate and service as unreliable, and, in some instances, non-existent.

The audiological staff at Michigan State University reports that they have been asked to evaluate a newly purchased system (beginning of 1974-75 academic year) in one of the neighboring school districts. The school system purchased new FM auditory training equipment from manufacturer's representatives without seeking prior professional consultation. The system is not functioning adequately, units vary considerably from one another and from manufacturer's specifications, some MPOs exceed 140 dB (manufacturer reports maximum as 135 dB), and they report great difficulty in locating the sales representative or securing necessary information and help from the manufacturer. At the time they were called in they found that 38 of the 70 purchased units were not functioning and had been out of commission for some time while the school had been trying to receive service from the sales representative. Of the remaining 42 units evaluated with appropriate B & K instrumentation, only 26 were found to be functioning satisfactorily. This evaluation has just been completed so I can not share with you the outcome, but we may presume that the educational progress of many children has been compromised for 2 years. Audiologists further report that repair services of both auditory training units and hearing aids is poor. The whole matter of standards for repair has not been addressed by either ANSI, HAIC, or probably the FDA. A soon to be published paper by Warren & Kasten entitled "Efficacy of Hearing Aid Repairs by Manufacturers and by Alternative Repair Facilities", indicates that of 41 hearing aids examined following repair by either the manufacturer or an independent repair laboratory, only 39% were found to match manufacturer's specifications for a new hearing aid of the same model within reasonable tolerances. My personal experience as Director of the Hearing Clinic of the Department of Audiology at Wayne State University from 1960 to 1964 indicates to me that most manufacturers of hearing aids make little attempt to acoustically verify conformance of repaired hearing aids to specifications. Interviews with audiologists would seem to indicate that the repair record of manufacturers of auditory training units is not better. Adult hearing aid users frequently complain that their hearing aid sounds and performs differently in substantial respects after repair. One never hears those comments from small children, but we must not assume that greater care is given to the repair of children's hearing aids. It is for this additional reason that it is far more important to direct some attention to requiring manufacturers to adhere to standards in the manufacture and repair of hearing aids and auditory training units for children than is true for any other age group. It is a difficult enough job for an audiologist to decipher manufacturers specification sheets to allow meaningful comparisons among options and determining the extent to which manufacturers claims are supported by actual performance. Unfortunately, most school systems in the United States today do not employ audiologists. The fact that they urgently require these services and that some progress is being made is beside the point, but it does point out that in most school systems decisions about the purchase of auditory training equipment, whether it meets manufacturers specifications, and whether it continues to do so after some use are decisions made by uninformed laymen with respect to this technology. Most teachers of the hearing impaired are not academically or experientially prepared to deal with electro-acoustic characteristics of amplification systems, and certainly not prepared to translate manufacturers specifications into some kind of common nomenclature for comparison purposes. To make matters worse, decisions about appropriate amplification may be made by directors of special education, purchasing agents, or others more distant from the problem. The availability of instrumentation and appropriate personnel for determining electro-acoustic characteristics of hearing aids and auditory training units is sparse in the schools, therefore there is no easy way to determine whether products meet specifications, if indeed, there is any awareness of the importance of it. Since the industry is not required to provide specific electro-acoustic data for each installation, the purchaser has only the word of the salesperson to rely upon. My audiological colleagues consistently reported to me that auditory training units presently available in the marketplace range from acceptable systems to "junk". For the most part auditory training units are sold by salespeople who have no relevant training or background in hearing loss, electronics, or acoustics. While they may basically understand the function of the system they are selling they are grossly unaware of whether the system they deliver conforms to manufacturer's specifications; or whether placing the system in a classroom causes changes in characteristics; cannot answer straight forward questions such as, "What is the gain of the instrument when the volume control is set at half rotation?; do not provide adequate instructions in the use of the equipment (EARS reports that only 49% of teachers received instructions) and have little knowledge of the importance of periodically evaluating the response characteristics of the system.

If we have any concern at all for hearing impaired children it is mandatory that we regulate what is sold, how it is sold, how it is serviced, and the quality of repairs, no matter what label the device carries. In the meantime, audiologists will continue to press for adequate professional supervision of amplification equipment and the children who use it. But one does not take the place of the other.

Most auditory training units are capable of delivering sound pressure levels in excess of 132 dB into the ear of hearing impaired children, most of whom have little residual hearing. There is some evidence accumulating (Jerger, 1975) that high MPO amplification devices may prove injurious to that precious residual hearing. We also have the situation that has occurred in Peoria, Illinois, where a number of children reportedly sustained substantial loss of their residual hearing. While there are many variables involved, considerable attention has been focused on one common fact, that they all wore the same type of auditory training unit. I do not know the outcome of this matter, but my understanding is that it is presently in the courts.

If it is important that certain frequency response characteristics might be desirable for an individual hearing loss configuration then it is equally important that the same care and attention be paid to the characteristics of auditory training units when matched to the residual hearing of the children that wear them. If it is important to know what the frequency response characteristics of a new hearing aid are for later comparison in order to determine whether changes have occurred, then it is equally important that the same information be available for auditory training units. If it is important that there be an ANSI standard for hearing aids, then it is no less important that there be a standard for auditory training units. We must remember that these units are being worn by children who have significant hearing losses and resultant language and communication problems. We cannot, to the same extent that we can with adults, rely upon these children to tell us that there is something wrong with the auditory training unit, or that this auditory training unit is not as beneficial as the one worn yesterday, or that the newly purchased units are not as good as the old ones. We cannot continue to operate in the dark, making choices without comparable data, or having instrumentation installed without knowing its electro-acoustic properties or not knowing its stability over time. It would seem that the greatest potential for harm is in the area of amplification for children because they have limited residual hearing, have much to lose developmentally, and because they have no effective voice in determining what is harmful or beneficial to them. The least we can do is to devote as much time and attention to the quality of the amplification systems that we ask them to wear as we do with hearing aids that adults wear. We definitely need to address ourselves to the establishment of minimal standards for auditory training units with the same precision and strictness that the Federal Communications Commission exerts over the FM transmitter and the FM receiver.

We should also be aware, even though I do not know if this occurs at the present time, that the development of the wireless microphone and hearing aid-FM receiver combination have much wider application than simply being used as auditory training units in a public school program. Great improvements in communication would be obtained by hearing impaired adults if the industry were to advertise them to the general public. I can imagine many of my patients being delighted at being able to communicate with their mate who is in another part of the house or out of doors without having to use the conventional hearing aid microphone system. Think of the application in noisy work places where control of the S/N ratio is critical for understanding.

There is some indication that members of the hearing aid industry conference believe that there is a need for standards that apply to auditory training units as well as hearing aids. The following is a quote from Mr. Hyman Goldberg, who, in 1968 was chairman of the hearing aid Research Committee of the Hearing Aid Industry Conference. The following quote was his final statement in a speech presented before the EARS workshop on auditory training units. He said "In summation, the value of any EAS can be measured only through the establishment of standards of performance. The parameters of acoustic output level, frequency response, distortion, field strengths, noise levels, spillover, and degree of maintenance must be adequately defined before the EAS user can properly evaluate any system" (EARS, p. 17).

RECOMMENDATIONS

1. That the definition of hearing aid, as printed in the Federal Register of April 21, 1976 be altered by deleting "wearable" thus including any devices commonly labeled as auditory training units under the definition.

It appears that the proposed ANSI standard (S3.22, 1976) would be equally applicable to auditory training units as hearing aids. It might be modified so that instrument arrangements for measurement of wireless microphone-receiver combinations, ILA systems, etc., are understood. Some attention then should be given by ANSI writing groups or this panel of the FDA, to the development of a supplement specifically for auditory training units (preferrably hearing aids capable of external microphone input) covering such things as utilization of additional input levels for measurement of gain and harmonic distortion since the decibel input to the teachers (external) microphone is considerably higher than the input to a hearing aid microphone; requirements for potential similarity and difference of acoustical responses of two transducers driven by the same amplifier; development of tolerances for variations in gain between the teachers microphone and the environmental microphone. Certain other suggested changes might be equally applicable to conventional hearing aids, for example, calibration and color-coding of volume controls, specification of some type of indicator that provides a warning when the battery has deteriorated to the point of reduced gain or high distortion, development of a more stringent requirement for measuring the frequency response curve in the telephone mode, and some standard for an induction loop or RF loop installed in a classroom (or elsewhere) for use in conjunction with hearing aids or auditory training units.

2. That the FDA direct its attention to a requirement that repaired hearing aids or auditory training units conform to original specifications within appropriate tolerances. Some consideration might be given to certifying or licensing repair facilities that wish to engage in the repair of these units. It would also be worthwhile to require periodic electroacoustic calibration of amplification devices used in educational programs.

3. That personnel involved in the sale and installation of amplification systems for use in school programs be required to be licensed in those states presently having hearing aid licensing laws. Since these people usually do not engage in the testing of hearing or the taking of ear impressions some might argue that they should not be included. Obviously, there are some problems involved, but we cannot escape that fact that they are engaged in the sale of health related prosthetic products designed to provide the same benefits as provided by hearing aids. It would seem logical that the purchasers of these devices should have the same recourse to law as that provided to the individual citizen and that sellers should have to meet some minimal level of knowledge and competency.

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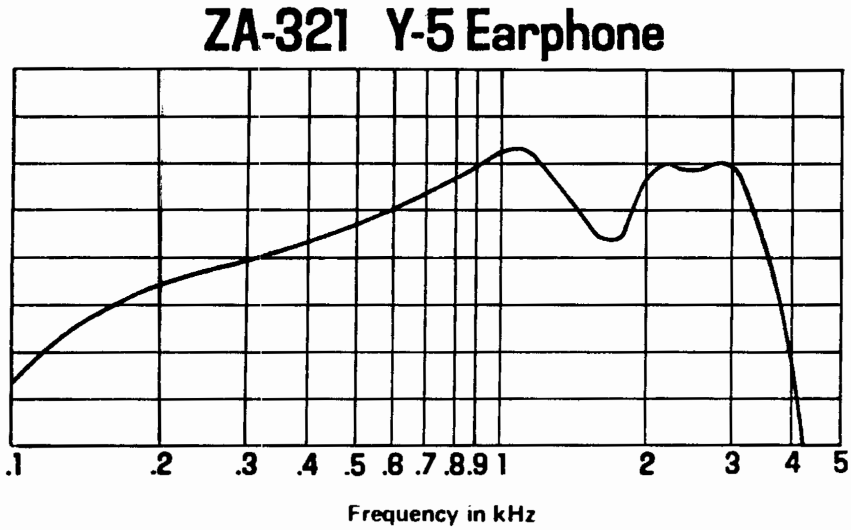
APPENDICES

A. **Response Characteristics of ZENITH FM AUDITORY TRAINING UNIT, MODEL ZA-321 as Reported on Manufacturers Specification Sheet.**

PRELIMINARY SPECIFICATIONS ZA-321 Y-5 EARPHONE



Z89 Silver Oxide	Battery	ZM401 Mercury
74dB	Peak Acoustic Gain	68dB
70dB	HAIC Acoustic Gain	66dB
134dB	Peak Acoustic Output	133dB
133dB	HAIC Acoustic Output	132dB

ZA321 HAIC Frequency Range—135Hz to 3500Hz

B. **Response Characteristics of TELEX WIRELESS TRAINER, MODEL TLR-1 (Student Receiver) as Reported on Manufacturers Specification Sheet.**

The minimum acoustic gain and output in FM mode shall be the same as that in the hearing aid mode.

Acoustic gain: 77db peak
HAIC gain: 66 db
Max. output: 143 db
HAIC output: 130 db
HAIC response: 130 to 3200 Hz

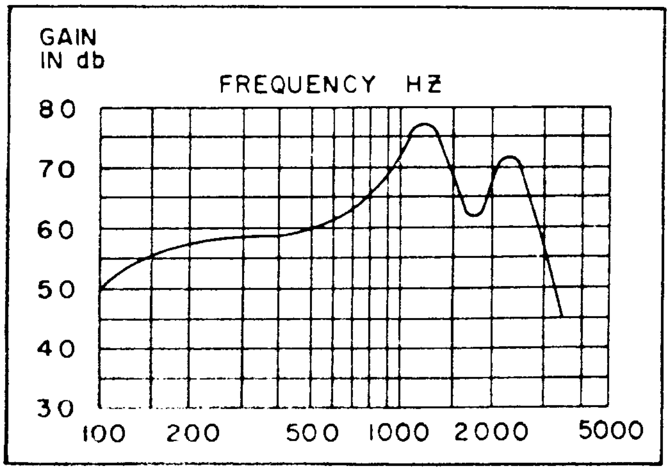


FIGURE 2. FREQUENCY RESPONSE, TLR-1

C. **Response Characteristics of ECKSTEIN BROS. AUDITORY TRAINERS, MODELS 40, 41 and 43 as Reported on Manufacturers Specification Sheet.**

PSEUDO BINAURAL MODEL 40

A single channel high fidelity auditory trainer with balance control to provide binaural output. Incorporates a wide range low distortion amplifier with built-in microphone, volume and two-position pitch control. Powered by internal lifetime rechargable battery.

Maximum power output: 135 db. SPL
Maximum acoustic gain: 75 db.

Pitch Control: Two-position switch which provides flat response or high frequency emphasis

Balance control: Continuously variable—for adjustment of output to each ear as required

Frequency response: With Type CA headset, 100-7500Hz, ± 3 db.
With Type U headset, 100-5500 Hz, ± 3 db.

MODEL 41 TRUE BINAURAL

A dual channel true binaural auditory trainer incorporating two high fidelity amplifiers each with its own built-in microphone, volume and two-position pitch control. Provides truly directional amplification with wide-frequency response and low distortion. Powered by built-in lifetime rechargable battery.

Maximum power output: 135 db. SPL—each channel.

Maximum acoustic gain: 75 db.—each channel.

Pitch control: Two-position selector for each ear providing flat response or high frequency emphasis.

Frequency response: With Type CA headset, 100-7500 Hz, ± 3 db.
With Type U headset, 100-5500 Hz, ± 3 db.

MODEL 43 MASTER TRUE BINAURAL

A deluxe dual channel true binaural auditory trainer featuring dB-calibrated controls for each channel. Provides accurate control of gain, frequency response and maximum power output for each ear. Offers the ultimate in high fidelity directional amplification. Ideally suited to those with severe high frequency losses and problems related to discrimination or recruitment. Powered by built-in lifetime rechargable battery.

Maximum power output: 135 db. SPL—each channel.

Maximum gain: 75 db.—each channel

Maximum power output limiter: 105 to 135 db. in 5 db steps.

Pitch control 0-18 db/octave attenuation of frequencies below 1000 Hz (2000 Hz crossover frequency available on request.)

Input accessory jacks: Incorporated for each channel for external microphones, tape or phono playback units or induction loop pickups.

Frequency response: With Type CA headset, 100-7500 Hz. ± 3 db.
With Type U headset, 100-5500 Hz. ± 3 db.

CA headset—earphones with circumaural cushions
U headset—hearing aid type receiver

D. Response Characteristics of BIOCOUSTICS, MODEL 70 FM RECEIVER as Reported on Manufacturers Specification Sheet.

MODEL 70 RECEIVER

RF SECTION

Dual conversion, crystal controlled superheterodyne
32 narrow band plug-in modules select channel; one module provided with each receiver
Adjacent channel rejection 60 dB
Wide band discriminator for minimum distortion

AUDIO SECTION

Maximum power outputs: full, -10 dB, or -20 dB. Settable by internal switch
Frequency response from flat (100-6000 Hz) to 50 dB down at 100 Hz (ref. 6000 Hz). Nine curves settable by internal switches
Maximum acoustic gain 66 dB
Total Harmonic Distortion (electrical) less than 2% at maximum volume setting; Total Harmonic Distortion (acoustic) less than 4% with 125 dB spl @1000 Hz into high output transducer
Compression: attack time 4 msec; release to program 120 msec; release to noise 10 minutes; range 40 dB at input/1 dB at output
Internal microphone with separate gain control
Auxiliary input: impedance 1 megohm; sensitivity 1 volt rms for 10 dB compression; connector is 2.5 mm phone plug
Extended frequency response (100-5800 Hz, 124 dB mpo) miniature transducers with Y-cord standard; high output (137 dB) and single ear options available
Ear balance settable to 20 dB down by internal control

E. Response Characteristics of EFI, MODEL TRAVELEAR II as Reported on Manufacturers Specification Sheet.

MODEL 150, 152 FM TRAVELEAR RECEIVERS

Maximum power: binaural: variable down from 132db SPL
Monaural: variable from 132db SPL for -40db, then -24db differential adjustment for each ear from MPO
Frequency response: 150 Hz to 8 KHz ± 3 db.
Distortion: total system less than 5% @ 130db
Squelch: automatically eliminates white noise when teacher mic is off

Acoustic gain: 70db in both wireless and hearing aid modes
Microphones: electret with variable range control
Base tone adjustment: 3 position, flat, -9db, -18db
Binaural Adjustment: -24db in each ear from MPO
Automatic gain control: automatically adjusts output for constant level

MODEL 550 FM TRAVELEAR MICROPHONE

Frequency: crystal controlled in 72-76 MHz band
Microphone: electret, respone 20-16,000 Hz flat
Modulation: wide band FM
Signal to noise ratio: -75db
Frequency response: 50 Hz to 10KHz ± 3 db.

F. Response Characteristics of MAICO, MODEL MT-6 as Reported on Manufacturers Specification Sheet.

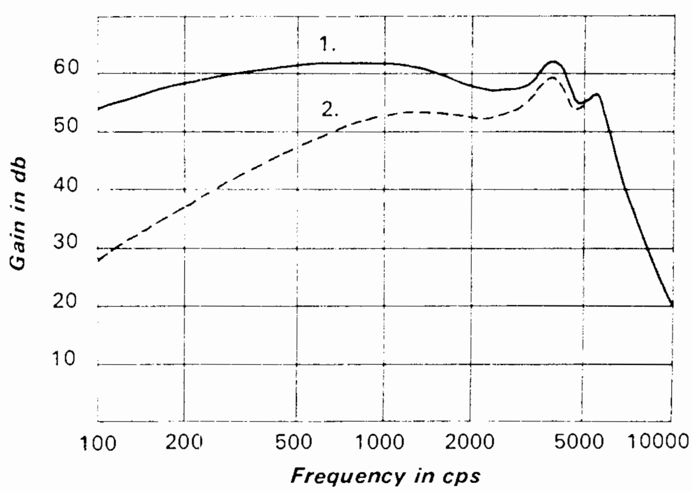
SPECIFICATIONS

Frequency Range: 50 to 6000 cps
Acoustical gain at 1000 cycles: 63 db

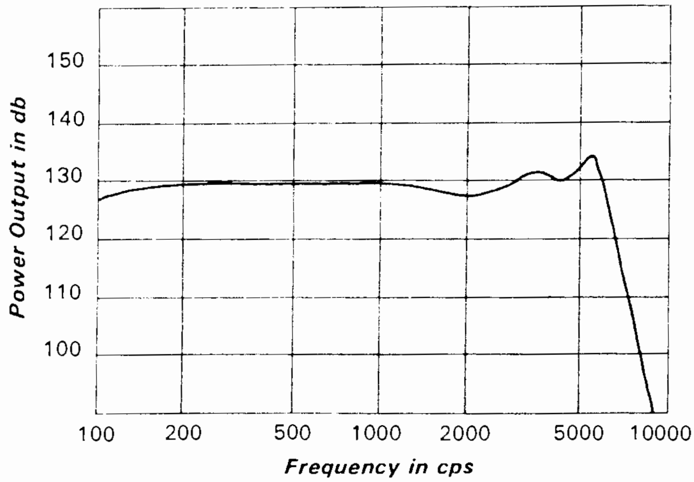
Model MT-6 Response Showing Maximum Clockwise and Counterclockwise Tone Settings.

Key:

1. Fully Clockwise setting 2. Fully Counterclockwise setting



Model MT-6 Power Output



G. Response Characteristics of HC ELECTRONICS, MODEL HC 255 FM PHONIC EAR MONAURAL SYSTEM as Reported on Manufacturers Specification Sheet.

Frequency response: 300-5300 Hz (headset)—300-4000 Hz (transducer)
Maximum output: 128 dB SPL (headset)—138 dB SPL (transducer)
Acoustic gain: 50 dB (headset)—60 dB (transducer)
Distortion: less than 5% THD at maximum volume setting with 60 dB acoustic input
Compression: Dynamic gain control*—Compression incorporated in the Transmitter
- Attack Time: 3 ms
- Overshoot: .5 dB
- Undershoot: 0 dB
- Recovery time: 130 ms
- Undershoot: 6 dB
- Measured with 70-90-70 dB SPL acoustic input sequency at 1000 Hz

Signal-to-noise Ratio: 50 dB measured at maximum SPL