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Standard Practice for Describing System Output of Implantable Middle Ear Hearing Devices[1]

This standard is issued under the fixed designation F2504; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This practice defines means for describing system performance (*ex vivo*) and, in particular, system output of an implantable middle ear hearing device (IMEHD) by measuring a physical quantity that is relevant to the insertion gain and output level of the IMEHD when implanted in the patient.

1.2 This practice is similar to headphone calibration on an artificial ear in which the sound pressure level (in decibel sound pressure level (SPL)) measured in the artificial ear can be converted to patient hearing level (in decibel hearing level (HL)) using a known transfer function, as defined by ANSI 3.7. These measurements can then be used to predict system parameters relevant for patient benefit such as functional gain, maximum output, and variability. Measurements defined in this practice should be useful for patients, clinicians, manufacturers, investigators, and regulatory agencies in making comparative evaluations of IMEHDs.

1.3 The values given in SI units are to be considered the standard.

1.4 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ANSI Standards:*[2]

ANSI 3.6 Specification for Audiometers

ANSI 3.7 Method for Coupler Calibration of Earphones

ANSI 3.22 Specification of Hearing Aid Characteristics

3. Terminology

3.1 Refer to the block diagram of Fig. 1 for a clarification of the mathematical notations used in this section.

3.2 In the following definitions, these symbols are used for physical quantities:

3.2.1 E = electrical drive signal (voltage or current)

3.2.2 p = sound pressure

3.2.3 v = vibration velocity

3.3 All transfer functions are denoted by the symbol H, with the following subscripts indicative of the type of transfer function:

3.3.1 A = IMEHD-aided

3.3.2 E = electrical

3.3.3 H = hearing level

3.3.4 S = sound field sound pressure

3.3.5 T = tympanic membrane (ear drum) sound pressure

3.3.6 U = unimplanted

3.3.7 V = vibration of stapes

3.4 *Definitions:*

3.4.1 *coupling, n*—points and methods of attachment.

3.4.2 *displacement, n*—integral of velocity measured in nanometres.

3.4.3 *ear-canal sound pressure, p_T, n*—sound pressure produced in the ear canal, at the tympanic membrane, by a sound field stimulus, specified in units of pascals.

3.4.4 *equivalent hearing level, L_H, n*—ratio of an equivalent sound pressure, p_Q, relative to the sound field pressure, p_{RETSPL}, at 0° incidence that is just detectable monaurally by a normally hearing individual, as defined in ANSI S3.6, Table 9, expressed in decibels: $L_H = 20 \cdot \log_{10}(p_Q/p_{RETSPL})$.

3.4.5 *equivalent sound pressure, p_Q, n*—unimplanted input sound field pressure needed to produce a stapes velocity equal to that produced by a specified IMEHD input in the IMEHD-aided condition: $p_Q = E \cdot H_{ES}$.

3.4.5.1 *Discussion*—The equivalent sound pressure is the product of the equivalent sound pressure transfer function, H_{ES}, and the IMEHD output transducer electrical input E: $p_Q = E \cdot H_{ES}$. The equivalent sound pressure can be expressed as equivalent sound pressure level in units of decibels, SPL_{eq}, calculated as $20 \cdot \log_{10}(p_Q/2 \cdot 10^{-5}$ Pa).

3.4.6 *equivalent sound pressure level, L_Q, n*—logarithmic representation of equivalent sound pressure, $L_Q = 20 \cdot \log_{10}(p_Q)$.

[1] This practice is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.37 on Implantable Hearing Devices (IHDs).

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[2] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

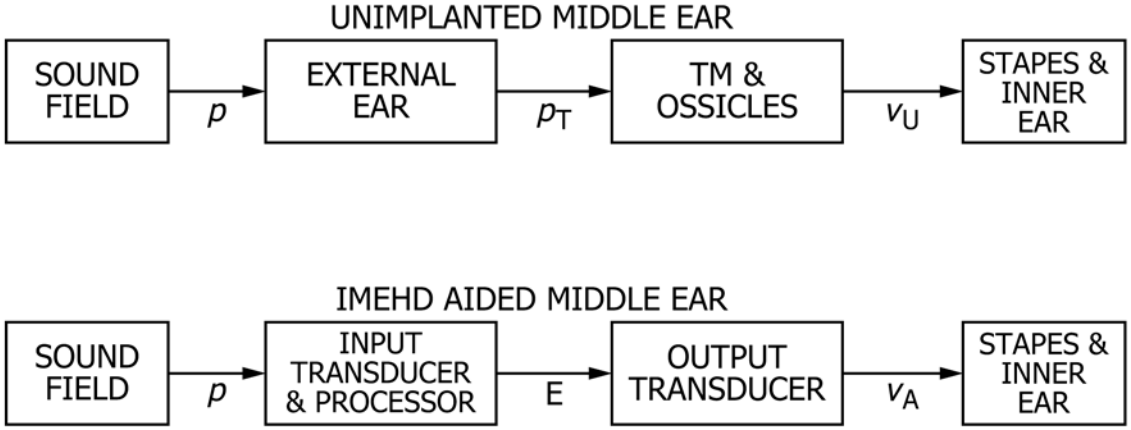


FIG. 1 Signal Flow in the Unimplanted and IMEHD-Aided Middle Ear

3.4.7 *hearing level (HL), L, n*—ratio of the input sound field pressure, p_S, relative to the sound field pressure p_{RETSPL} at 0° incidence that is just detectable monaurally by a normally hearing individual, as defined in ANSI S3.6, Table 9, expressed in decibels as: $L = 20 \cdot \log_{10}(p_S/p_{RETSPL})$.

3.4.8 *IMEHD electrical input at threshold* $E_{threshold}$, *n*—electrical input to the IMEHD output transducer at threshold of audibility.

3.4.9 *IMEHD harmonic distortion, n*—harmonic distortion of the stapes velocity IMEHD-aided analogous to ANSI S3.22, Section 6.11S, from sinusoidal inputs of the frequencies 500, 800, and 1600 Hz; input levels shall be E_{max} – 20 dB.

3.4.10 *IMEHD output transducer, n*—electromechanical output transducer of the IMEHD.

3.4.11 *IMEHD output transducer frequency range, n*—using the equivalent sound pressure transfer function, H_{ES}, draw a horizontal line at the average for 1000, 1600, and 2500 Hz, then subtract 20 dB, or divide by 10; the lower and the upper bounds of the frequency response range are where the average line crosses the transfer function curve.

3.4.12 *IMEHD output transducer input, E, n*— electrical input to the IMEHD output transducer, specified in volts or amperes, as appropriate for the particular device.

3.4.13 *IMEHD system frequency range, n*—using the insertion gain transfer function (velocity), H_{VV}, draw a horizontal line at the average for 1000, 1600, and 2500 Hz, then subtract 20 dB, or divide by 10; the lower and the upper bounds of the frequency response range are where the average line crosses the transfer function curve.

3.4.14 *input sound field pressure,* p_S, *n*—sound stimulus measured in the free field and presented to the listener in either the IMEHD-aided or unimplanted condition, specified in units of pascals.

3.4.15 *maximum electrical transducer input,* E_{max}, *n*—maximum electrical output of the sound signal processor, specified as peak-to-peak or root mean square value, specified in volts or amperes, as appropriate for the particular device.

3.4.16 *maximum equivalent sound pressure,* $p_{E,max}$, *n*—equivalent sound pressure that corresponds to the maximum electrical output E_{max} of the implant electronics, $p_{E,max} = E_{max} \cdot H_{ES}$.

3.4.17 *maximum equivalent sound pressure level,* $L_{E,max}$, *n*—logarithmic representation of the maximum equivalent sound pressure $L_{E,max} = 20 \cdot \log_{10}(p_{E,max}/2 \cdot 10^{-5}$ Pa).

3.4.18 *sound pressure at threshold,* $p_{threshold}$, *n*—stimulus sound field pressure at the threshold of audibility.

3.4.19 *stapes velocity (IMEHD-aided),* v_A, *n*—translational velocity of the stapes when driven by the IMEHD output transducer, specified in units of mm/s.

3.4.20 *stapes velocity (unimplanted),* v_U, *n*—translational velocity of the stapes when driven by sound input to the middle ear specified in units of mm/s.

Transfer Function

3.4.21 *acousto-electric transfer function,* H_{SE}, *n*—electrical input to the IMEHD output transducer *E* produced by a sound field, divided by the input sound field pressure p_S: $H_{SE} = E/p_S$.

3.4.21.1 *Discussion*—H_{SE} will depend on the particular gain settings used, for example, full-on gain or minimal gain. The gain should be reported whenever that transfer function is used.

3.4.22 *acousto-vibrational transfer function (IMEHD aided),* H_{SVA}—stapes velocity (IMEHD aided) divided by the input sound field pressure: $H_{SVA} = v_A/p_S$.

3.4.22.1 *Discussion*—This quantity can be measured directly or computed from the product of the electro-vibrational transfer function, H_{EV}, and the acousto-electric transfer function, H_{SE}, measured in the IMEHD-aided condition: $H_{SVA} = v_A/p_S$.

3.4.23 *acousto-vibrational transfer function (unimplanted),* H_{SVU}, *n*—stapes velocity (unimplanted) when driven by the input sound field, divided by the input sound field pressure: $H_{SVU} = v_U/p_S$.

3.4.23.1 *Discussion*—This quantity can be measured directly or computed from the product of the middle-ear transfer function, H_{TV}, and the ear-canal transfer function, H_{ST}, measured in the unimplanted condition: $H_{SVU} = v_U/p_S = H_{ST} \cdot H_{TV}$.

3.4.24 *ear-canal pressure transfer function, H_{ST}, n*—ear canal sound pressure, p_T, produced by the input sound field pressure, p_S, in the unimplanted case, divided by that input sound field pressure: $H_{ST} = p_T/p_S$; this quantity is unitless (**1, 2**).[3]

3.4.25 *electro-vibrational transfer function, H_{EV}, n*—stapes velocity (IMEHD-aided) when driven by the IMEHD output transducer, divided by the transducer input: $H_{EV} = v_A/E$.

3.4.26 *equivalent sound pressure transfer function, H_{ES}, n*—unimplanted sound field pressure needed to produce a stapes velocity equivalent to that produced by an electrical IMEHD input in the IMEHD-aided condition, divided by the IMEHD input.

3.4.26.1 *Discussion*—If the electrical IMEHD input produces a linear change in stapes velocity with a change in input electrical stimulus, the equivalent sound pressure transfer function, H_{ES}, can be computed as the quotient between the vibro-electric transfer function (IMEHD-aided), H_{EV}, and the vibro-acoustic transfer function (unimplanted), H_{SVU}: $H_{ES} = (v/E)/(v/p_S) = H_{EV}/H_{SVU}$.

3.4.27 *insertion gain transfer function (sound field), H_{SS}, n*—ratio of the equivalent sound pressure produced in the IMEHD-aided case with a given electrical input to the IMEHD output transducer and the input sound field pressure used as input in the IMEHD-aided case required to produce the same IMEHD output transducer electrical input: $H_{SS} = p_E/p_S$; this ratio is unitless.

3.4.27.1 *Discussion*—With a linear sound signal processor, the insertion gain (sound field) can be computed from the product of the equivalent sound pressure transfer function, H_{ES}, and the electro-acoustic transfer function, H_{SE}: $H_{SS} = p_E/p_S = H_{SE} \cdot H_{ES}$. H_{SS} will depend on the particular gain settings used, for example, full-on gain or minimal gain. The gain should be reported whenever that transfer function is used.

3.4.28 *insertion gain transfer function (velocity), H_{Vv}, n*—ratio of the stapes velocity (IMEHD-aided) and the stapes velocity (unimplanted) produced by a given input sound field: $H_{VV} = v_A/v_U$; the ratio is unitless and can be expressed in decibels as $20 \cdot \log_{10}(H_{Vv})$.

3.4.28.1 *Discussion*—With a linear sound signal processor and IMEHD, that is, a processor whose electrical output E is proportional to the input sound field pressure, p_S, and an IMEHD whose vibrational output is proportional to its electrical output, the insertion gain (sound field), H_{SS}, will equal the insertion gain transfer function (velocity), H_{VV}.

3.4.29 *maximum insertion gain transfer function (sound field), $H_{SS,max}$, n*—maximum insertion gain transfer function (sound field) that can be achieved with the implant electronics.

3.4.30 *middle-ear transfer function, H_{TV}, n*—stapes velocity (unimplanted) produced by an ear-canal sound pressure, divided by the ear-canal sound pressure, in units of mm/s/Pa: $H_{TV} = v_U/p_T$.

3.5 *Acronyms:*

3.5.1 *IHD*—implantable hearing device

3.5.2 *IMEHD*—implantable middle-ear hearing device

3.5.3 *LDV*—laser Doppler vibrometry

3.5.4 *SPL*—sound pressure level

4. Summary of Practice

4.1 This practice involves the use of human temporal bones and laser Doppler interferometry measurements of middle ear structures velocities, to test for the *ex-vivo* performances of IMEHD. Once a procedure for measuring system output has been defined, several characteristics of the IMEHD can be specified. Detailed instructions for measuring and reporting these characteristics are given below. The important characteristics are:

4.1.1 *For Transducers:*

4.1.1.1 Equivalent sound pressure transfer function,

4.1.1.2 IMEHD output transducer frequency range, and

4.1.1.3 IMEHD harmonic distortion.

4.1.2 *For the System:*

4.1.2.1 Maximum insertion gain transfer function (sound field) (see full-on gain in ANSI S3.22, paragraph 3.7),

4.1.2.2 Maximum equivalent sound pressure level (see OSPL90 in ANSI S3.22, paragraph 3.5), and

4.1.2.3 IMEHD system frequency range.

5. Significance and Use

5.1 IMEHDs are alternatives to air conduction hearing aids. They are similar to air conduction hearing aids in that they process incoming sound by applying frequency shaping and compression to create an analog, vibratory audio frequency output. IMEHDs differ from hearing aids in that they do not create an airborne acoustical output signal with an electroacoustical output transducer in the external ear canal, but rather a mechanical stimulation that results in the vibration of the cochlear fluid. Therefore, the IMEHD output signal is not readily accessible after implantation in the way hearing aid output is accessible with real-ear probe microphone measurements. Different devices will use different methods of coupling to the ossicular chain or cochlea. This makes it difficult to design a uniform model of the middle ear in the way the 2-cm^3 coupler is used as a model of the external ear canal with conventional hearing aids.

5.2 This practice provides uniformity of data collection practices, thus allowing IMEHD *in vitro* performances to be evaluated and readily compared. Once clinical data are available, the performance specifications can be augmented with corresponding transfer functions or results from measurements in patients.

5.3 The temporal bone is a well-accepted model that relates closely to the biomechanics of the living middle ear, which is readily relatable to hearing level. Laser Doppler vibrometry provides accurate velocity measurements in the ranges required for human hearing.

[3] The boldface numbers in parentheses refer to the list of references at the end of this standard.

6. Procedure

6.1 *Procedure Setup*—The basic procedure is to define a method for the measurement of the insertion gain and maximum output of the IMEHD based on temporal bone measurements of sound-induced stapes velocity before implantation and measurements of IMEHD-induced stapes velocity after implantation.

6.2 *Components of the Test System:*

6.2.1 *Test Model—Human Temporal Bone:*

6.2.1.1 *Temporal Bone Pre-Selection*—Fresh or fresh-frozen temporal bones shall be used. Fresh temporal bones shall be kept moist and used within seven days of harvesting or be frozen within 24 h of harvesting for later testing (**3**). Thawed bones shall be used within six days. Fresh or thawed temporal bones shall be stored at 5°C in isotonic saline with 1:10 000 thimerosal (or antibacterial equivalent). Once removed from storage, all measurements, including qualification, shall be made within one 8-h period. The middle and inner ears shall be inspected to be morphologically intact and with normal-appearing tympanic membrane and middle ear. Diseased ears or overtly abnormal structures or evidence of a conductive defect, or combination thereof, shall disqualify bones from testing. Temporal bones with indicated leaks of perilymph also shall not be used in the study. Microscopic visual inspection, surgical observation, or physical measurements shall be used to ascertain the absence of perilymph leakage.

6.2.1.2 An acoustic probe consisting of a speaker and a probe microphone shall be placed in the ear canal, with the tip of the probe microphone located at a distance of 2 to 3 mm of the center of the eardrum.

6.2.1.3 The facial recess shall be opened to gain laser light access to the stapes. Vibration either of the stapes footplate, the stapes head, or the posterior crus of the stapes shall be measured with laser Doppler vibrometry (LDV). The angle of incidence of the LDV laser shall not exceed 60° normal to the stapes footplate. Appropriate corrections shall be attempted for experimental angle of incidence.

6.2.1.4 *Qualification Criteria for Temporal Bone*—The temporal bone shall be considered acceptable for testing only if the middle ear transfer function, H_{TV}, between 0.25 to 4.0 kHz falls within the range defined by normative data in Fig. 2 and Table 1. This measurement shall be made before the IMEHD output transducer is implanted. Ear canal SPL for this measurement shall be between 80- and 100-dB SPL. If the temporal bone does not meet qualification criteria, it shall not be used for the testing.

6.2.1.5 *IMEHD Output Transducer Placements*—The IMEHD output transducer shall be implanted in the same way it is implanted in an actual patient and attached in a manner that most closely approximates that in the implanted patient after healing. The IMEHD output transducer shall be driven with an electrical input signal (constant voltage or constant current, as appropriate for the particular device) and vibrations shall be measured from the same location used for the qualification measurements.

6.2.2 *Experimental Apparatus:*

6.2.2.1 *Equipment Configuration*—The temporal bone test setup has two major parts, as shown in Fig. 3. The open boxes of the figure depict the experimental temporal bone. The filled boxes depict the measuring and IMEHD output transducers and instrumentation. All measurement instrumentation shall be calibrated at least annually.

6.2.2.2 A signal generator/analyzer produces a swept or multitone signal that drives the speaker and creates a sound in the auditory ear canal to allow sound-induced velocity measurements of the middle-ear transfer function, H_{TV}, either to quantify the baseline behavior used in computations of gain or to test the normality of the temporal bone. The stimulus sound pressure within the ear canal is measured with the microphone. The stapes velocity induced by the sound is measured by LDV, preferably at the stapes footplate. The middle-ear transfer function, H_{TV}, is computed, and the acceptability of the temporal bone is determined in this manner.

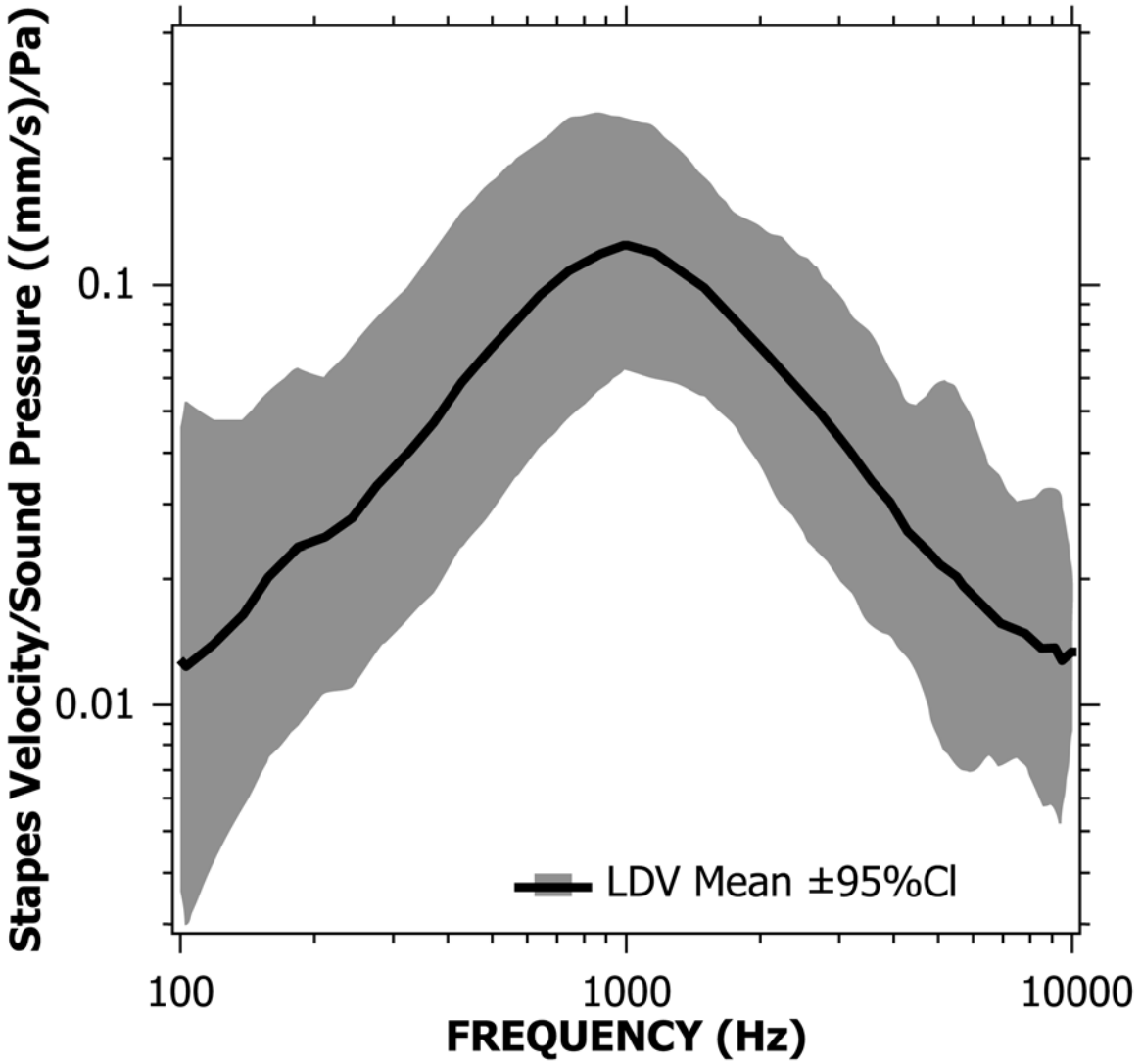
6.2.2.3 The computation of device gain and performance also requires measurements of the electro-vibrational transfer function, H_{EV}, a measure of the stapes velocity produced by direct mechanical drive of the middle ear. For these measurements, the signal generator/analyzer produces a signal that acts as input to the driving transducer. This transducer is coupled in a device-specific manner to the ossicular chain or stapes. The velocity of the stapes evoked by the driving transducer is measured by LDV, preferably at the stapes footplate. The ratio of the measured velocity to the electrical input to the driving transducer is the electro-vibrational transfer function, H_{EV}.

6.2.2.4 *Velocity Measurements*—The computation of performance parameters listed in 3.4 requires measurements of stapes velocity (IMEHD-aided) and stapes velocity (unimplanted). To measure stapes velocity IMEHD-aided, drive the IMEHD output transducer with a signal generator, monitor the IMEHD output transducer input, and measure stapes velocity by LDV. To measure stapes velocity unimplanted, create an acoustic stimulus in the ear canal with the ear canal speaker, monitor the ear canal sound pressure with the ear canal microphone, and measure stapes velocity by LDV. For each measurement and each test frequency, an estimate of the noise floor shall be documented. Measurements shall only be accepted if they are at least 10 dB above the noise floor.

6.2.2.5 *System Tests*—The implanted IMEHD system is tested by separating the IMEHD output transducer from the IMEHD electronics. The system response is evaluated by combining the measured electro-vibrational transfer function, H_{VE}, with the acousto-electric transfer function, H_{SE}, the IMEHD output transducer with the measurements of the IMEHD electronics. If the IMEHD electronics are tested separately, its output shall be terminated with an impedance that approximates the actual transducer (see 3.4.21, 3.4.22, and 3.4.27).

6.3 *IMEHD Output Transducer Testing*—No fewer than five qualified temporal bones shall be studied. Report the number of qualified temporal bones used. The variability of these measurements, as a function of frequency across temporal bones, shall also be reported.

6.3.1 *Range of Test Frequencies*—Transfer functions shall be measured over the range of frequencies that will be processed by the IMEHD electronics, but at least for the range



NOTE 1—The plot units on the ordinate of mm/s/Pa are equivalent to the RMS velocity in mm/s produced by a 94-dB SPL sound pressure.

FIG. 2 Magnitude of Normal Temporal-Bone Stapes Velocity Measurements Normalized by the Sound Pressure Measured in the Ear Canal

TABLE 1 Mean and Estimated 95 % Confidence Interval from Ten Published Studies of Stapes Velocity in Temporal Bones Including Nine LDV Studies (4-12) and One Study of Round-Window Displacement (13)[A]

NOTE 1—The means from each study were averaged to produce the mean of the group. The 95 % confidence interval is estimated by assuming that the standard deviation of the ten means is the standard error mean of the population.

Frequency, Hz	Mean Value, mm/s/Pa	Upper Limit, mm/s/Pa	Lower Limit, mm/s/Pa
125	0.015	0.048	0.004
250	0.030	0.074	0.012
500	0.073	0.180	0.029
1000	0.125	0.250	0.062
2000	0.071	0.138	0.037
3000	0.043	0.094	0.020
4000	0.029	0.060	0.014
6000	0.018	0.047	0.007

[A] Rosowski, J. J., Huber, A. M., Ravicz, M. E., and Goode, R. L., "Are Temporal Bones Useful Models of Human Middle-Ear Mechanics?" *Abstracts of the Twenty-Seventh Meeting of the Association for Research in Otolaryngology 2004*, p 275.

250 to 4000 Hz. If, for example, discrete frequencies are measured using single tones or multitones, information for at least three lines/oct shall be collected.

6.3.2 *IMEHD Output Transducer Input*—The amplitude of the electrical input signal during tests shall be within the range of amplitudes that can be produced with the actual IMEHD system.

7. Keywords

7.1 electromechanical hearing; hearing implant; IHD; implantable hearing aid; implantable middle ear hearing device; IMEHD; laser interferometry; middle ear; middle ear implant; system output; system performance; temporal bone; transfer function; vibrational transducer; vibratory implant

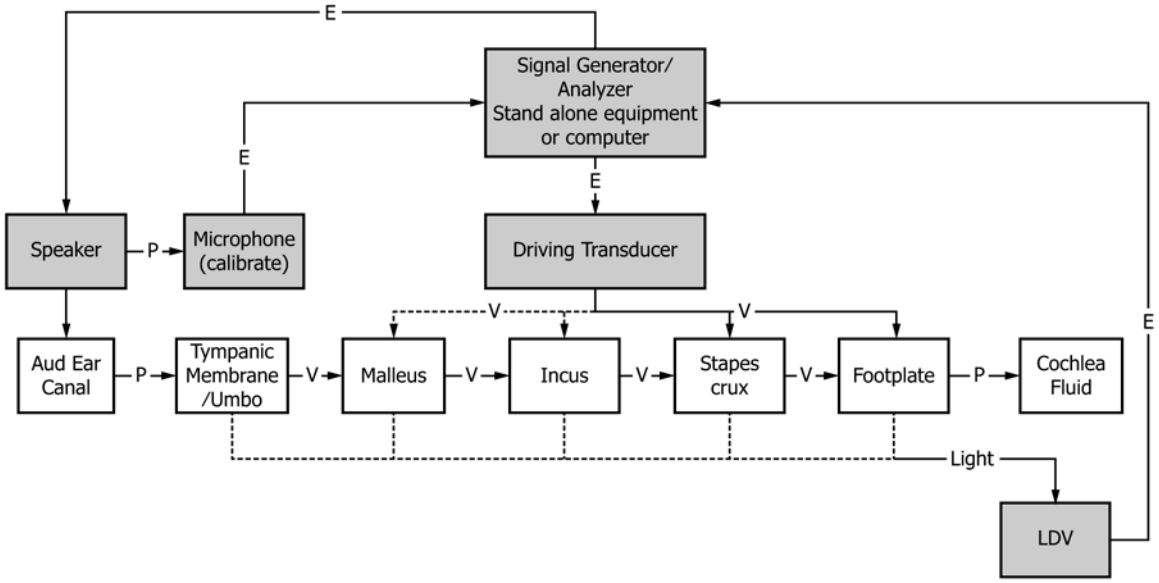


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FIG. 3 Temporal Bone Equipment Test Setup

REFERENCES

(1) Shaw, E. A. G., "Transformation of Sound Pressure Level from the Free Field to the Ear Drum in the Horizontal Plain," *Journal of the Acoustical Society of America* , Vol 56, 1974, pp. 1869–1860.

(2) Vaillancourt and Shaw, E. A. G., "Transformation of Sound Pressure Level from the Free Field to the Ear Drum Presented in Numeric Form," *Journal of the Acoustical Society of America*, Vol 78, No. 3, p. 1122.

(3) Good, R. L., et al, "New Knowledge About the Function of the Human Middle Ear; Development of an Improved Analog Model," *American Journal of Otology*, Vol 15, 1994, pp. 145–154.

(4) Aibara, R., Welsh, J. T., Puria, S., and Goode, R. L., "Human Middle-Ear Sound Transfer Function and Cochlear Input Impedance," *Hearing Research*, Vol 152, 2001, pp. 100–109.

(5) Asai, M., et al, "Analysis of the Best Site on the Stapes Footplate for Ossicular Chain Reconstruction," *Acta Otolaryngologica*, Vol 119, 1999, pp. 356–361.

(6) Gan, R., et al, "Mass Loading on the Ossicles and Middle Ear Function," *Annals of Otology, Rhinology and Laryngology*, Vol 110, No. 5:1, 2001, pp. 478–485.

(7) Goode R., et al, "New Knowledge About the Function of the Human Middle Ear: Development of an Improved Analog Model," *American Journal of Otology*, Vol 15, No. 2, 1994, pp. 145–154.

(8) Hato, N., et al, "Acoustic Role of the Buttress and the Posterior Ligament in Human Temporal Bones," *Otolaryngology-Head and Neck Surgery*, Vol 124, No. 3, 2001, pp. 274–278.

(9) Hato, N., et al, "Three-Dimensional Stapes Footplate Motion in Human Temporal Bones," *Audiology & Neurootology*, Vol 8, No. 3, 2003, pp. 140–152.

(10) Kurokawa, H., and Goode, R., "Sound Pressure Gain Produced by the Human Middle Ear," *American Journal of Otology*, Vol 113, 1995, pp. 349–355.

(11) Nishihara, S., et al, "Effect of Changes in Mass on Middle Ear Function," *Otolaryngology-Head and Neck Surgery*, Vol 109, No. 5, 1993, pp. 899–910.

(12) Voss, S. E., et al, "Acoustic Response of the Human Middle Ear," *Hearing Research*, Vol 150, 2000, pp. 43-69.

(13) Kringlebotn, M., and Gundersen, T., "Frequency Characteristics of the Middle Ear," *Journal of the Acoustical Society of America*, Vol 77, 1985, pp. 159–164.