ASTM INTERNATIONAL

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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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.5 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

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,

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UNIMPLANTED MIDDLE EAR

SOUND FIELD → p → EXTERNAL EAR → p_T → TM & OSSICLES → v_U → STAPES & INNER EAR

IMEHD AIDED MIDDLE EAR

SOUND FIELD → p → INPUT TRANSDUCER & PROCESSOR → E → OUTPUT TRANSDUCER → v_A → STAPES & INNER EAR
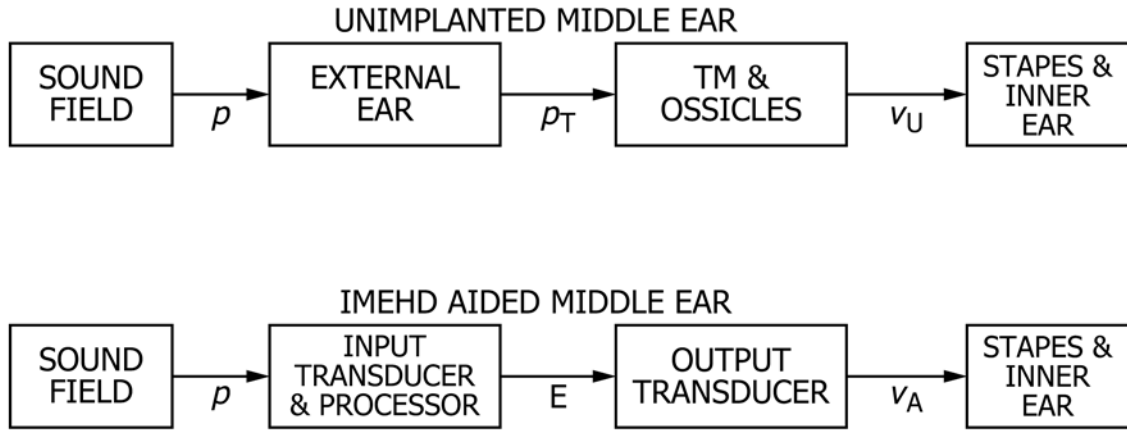
FIG. 1 Signal Flow in the Unimplanted and IMEHD-Aided Middle Ear

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, $L_Q = 20 \cdot \log_{10}(p_Q)$.

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