▶ ***RESEARCH REPORT***

A Universal Pass/Refer Criterion for DPOAEs: Is it Possible?

By Laurel A. Christensen, PhD

What is the pass/refer criterion for your distortion product otoacoustic emission (DPOAE) system? If you use one of the hand-held DPOAE devices available on the market, you might not know the answer to this question. These devices have been designed so that the pass/refer is printed on the screen of the unit and/or on the print-out following a test. Therefore, it might be the case that someone using the equipment does not know the particular pass/refer criterion for their unit. Moreover, if they are aware of the pass/refer criterion, they may not know how this criterion was derived.

How can DPOAE measurements using different DPOAE systems on the same infant differ by more than 3 dB? The answer is that there are currently no measurement or calibration standards for these devices. For this reason, it is important to use data collected for each individual brand and model of equipment to determine appropriate pass/refer criterion.

I recently had the opportunity to use several DPOAE systems on the same day in one hospital to test newborns. As a novice with most of these systems, the first thing I noticed was that, although every system was measuring DPOAEs usually with the same test characteristics (i.e., f1, f2, f1/f2 ratio and presentation levels), every system used a different *criterion* for determining if an infant passed the test. Additionally, the DPOAEs of the different devices on the same newborn were not the same and often were not within 3 dB of each other. The goal of this paper is to explain these differences and to give the reader a better understanding of pass/refer criteria for DPOAE systems.

Laurel A. Christensen, PhD, is research audiologist at Etymotic Research, Elk Grove Village, IL, and an adjunct associat professor at Northwestern U, Evanston, IL & Rush U, Chicago, IL.

Normative Data

The best way to show the differences between DPOAE systems is to display available normative data for different DPOAE systems on the same graph. Fig. 1 shows normative data for DP amplitude and noise floor (NF) collected on school-age and adult subjects for six different DPOAE systems. The data for four of the devices shown in Fig. 1 (Biologic Scout, Madsen Celesta, GSI 60 and Starkey DP2000) are from a 1996 study conducted at Vanderbilt Univ. by Hornsby, Kelly and Hall.[1] In their study, normative data were established for these DPOAE systems. The authors found significant differences in DP amplitudes among the devices and concluded that normative data collected with the particular brand of DPOAE device used in the clinic must also be used in the analysis and interpretation of DPOAE data for patients. Data from the CUBDIS system and the ER-10B probe in Fig. 1 are from Gorga and colleagues[2] and data from the ERO-SCAN are from Christensen.[3] (*For specific information on these normative data sets, the reader is referred to the original sources.)*

Hearing care professionals are accustomed to calibrated equipment so that an audiogram obtained at one clinic will be equivalent to an audiogram obtained at another clinic. Thus, if the patient has a flat 40 dB HL hearing loss as plotted on an audiogram at a clinic in Illinois, the results should be the same when this patient is retested at another clinic in Wyoming. This is not the case for DPOAE systems unless the same brand and model of system is used. Each system may give a different result, and thus a different pass/refer criterion is required for every system.

What's Responsible for Differences in DP Amplitude and Noise Floor (NF)?

▶ *Probe Design & DP Amplitude*: Probably the most significant source of DP measurement differences is in

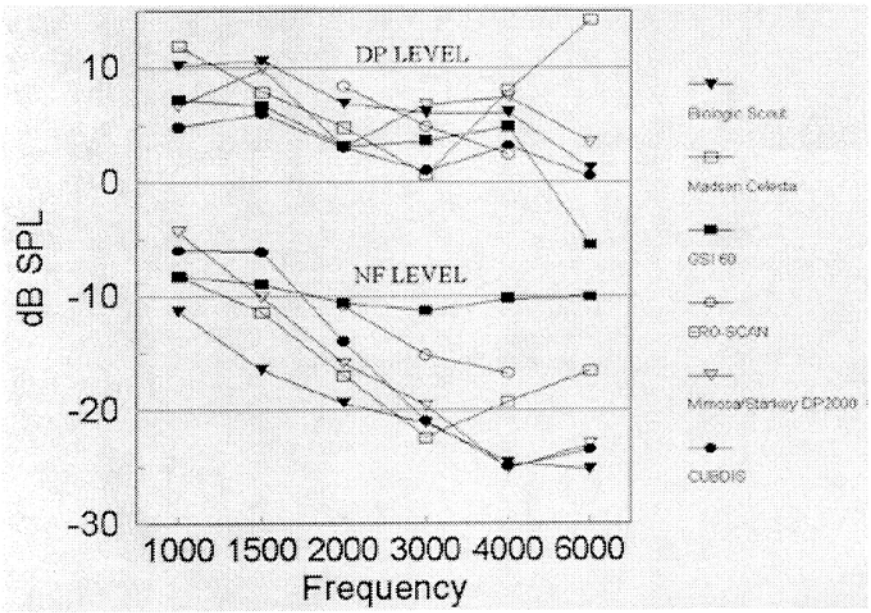

Fig. 1. *Normative data for DPOAE systems. Data included on this graph were collected at presentation levels of f1=65 dB SPL and f2=55 dB SPL at an f2/f1 ratio of 1.22 (with the exception of the CUBDIS data which was collected at presentation levels of f1=65 dB SPL and f2=50 dB SPL at an f2/f1 ratio of 1.2). Although the frequencies at which the data were collected were not identical, the data are plotted for comparison in this graph at the f2 frequencies of 1000, 1500, 2000, 3000, 4000 and 6000 Hz. Thus, if a DPOAE system tested the f2 frequencies 1093, 1562, 1968, 3093, 3937 and 6250 Hz, these data points were plotted at 1000, 1500, 2000, 3000, 4000 and 6000 Hz. Data from Hornsby et al.[1], Gorga et al.[2] and Christensen.[3]*

the design of the probe microphone used in the system. Probe microphone designs vary from instrument to instrument and each of these designs has a different microphone frequency response. This variation in the frequency responses of the microphones will account for some of these measurement differences.

Another factor related to probe design that might account for DP differences was examined by Siegel[4] in 1995. His study examined the cross-talk between the sound source and the probe microphone in several OAE systems. Results indicated that the amount of leakage from the probe tube to the microphone will influence OAE recordings.

A third factor contributing to DP differences, especially in the high frequencies, is the presence of standing waves in the ear canal.[5] Standing waves occur because the microphone of the OAE probe is at different distances (usually from 15-20 mm) from the eardrum. Standing waves can cause the calibration of the primary tones to be off by as much as +/- 20 dB.[5] Therefore, the presentation levels at the eardrum for the various instruments may be different, causing the measured DPOAEs to differ.

► *Test Subjects and DP Amplitude*: The subject population used to collect the normative data will contribute to the differences in the DP measurements. For example, if individuals with noise exposure and tinnitus were included, the normative data could be affected by these factors even if the subjects had normal hearing. In addition, the definition of normal hearing (thresholds of 15 dB HL or better vs. thresholds of 25 dB HL or better) for the subjects can have an effect on the normative data. Finally, normative data should be collected on the specific population that will be tested. Published normative data on newborns is scarce. Fig. 2 shows some normative data collected on newborns for three DPOAE test systems (Sonamed-Clarity System[6], Intelligent Hearing Systems-SmartOAE[7] and Etymotic Research/MAICO ERO-SCAN[8]).

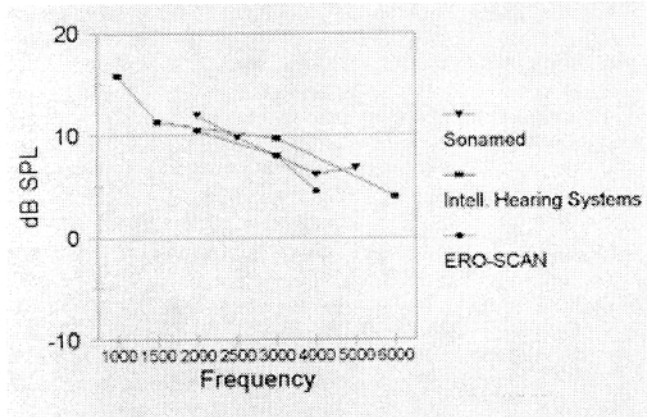

Fig. 2. *Newborn normative data (DP Amplitude).*[6,7,9]

► *Noise Floor*: The differences between units in the measured noise floor are also due to a variety of factors. These factors include the electrical noise of the microphone, the test environment in which the data were collected, the averaging time at each frequency during testing, the isolation properties of the eartip and probe, and whether a manufacturer limits the noise floor to a certain number.

Deriving a Pass/Refer Criterion

As discussed above, pass/refer criteria need to be based on normative data for each unit. Excellent work on the establishment of normative data was published by Gorga and colleagues[9] using the Biologic Scout and the Etymotic Research ER10-C probe microphone. In this study, the distributions of DPs and NFs were established for a large group of normal-hearing and hearing-impaired individuals (1267 ears of 806 subjects). From these distributions, statistical decision theory was used to determine the probability that a result was from an ear with normal hearing or an ear with hearing loss. The results of Gorga's study indicated that the distributions of the DPOAEs from normal and impaired ears overlap and no single pass criterion can be established that will result in perfect performance. That is, there is no minimum DP amplitude or signal-to-noise ratio (SNR) level that can be chosen at each frequency that, if met or exceeded, will perfectly identify every individual with normal hearing and every individual with hearing impairment. Therefore, a pass/refer criterion must be set with the goals of the program in mind.

For newborn hearing screening, the goal is often to pick the pass/refer criterion that will minimize referrals of newborns with normal hearing (false positives), yet maximize the likelihood that newborns with actual hearing loss will be identified (test sensitivity). *A pass criterion that* minimizes *referrals simultaneously* increases *the number of children with mild hearing loss who might be missed. Establishing a pass/refer criterion is a trade-off. If a criterion is set to pick up every child with even*

minimal hearing loss, many babies with normal hearing will have to be referred (false positives) and the cost of the screening program will increase.

An Example of Establishing a Pass/Refer Criterion

The decision that a DPOAE exists is based on detecting a signal with a level significantly above the background noise level. Using OAEs, the signal-to-noise ratio (SNR) is often used to make the pass/refer decision. To determine if the SNR is an actual emission instead of noise requires a statistical decision, because the random noise level in the DPOAE filter channel can be expected to exceed the average of the random noise levels in adjacent filter channels—used as the reference for comparison—roughly half the time.

► *Example:* The EROSCAN DPOAE system's primaries at f1 and f2, DPOAE at 2f1-f2 and noise floor sound pressure levels are estimated via a digital signal processor and discrete Fourier transform (bin resolution = 31 Hz). The device estimates the noise floor based on the four closest frequency bins to the emission bin. The noise floor is limited at -18 dB SPL. For the EROSCAN, the statistical decisions were based on extended measurements in a DB-100 "Zwislocki" coupler (the DB-100 coupler was used as a "patient equivalent" for an ear with significant hearing loss) of the noise distributions in both the DPOAE filter channel (DP level) and the rms average of the four adjacent channels (N level). From these measurements, cumulative frequency distributions and probability theory were used to estimate the *miss rate,* defined as the percentage of ears with hearing loss that will be missed using the given pass/refer criteria.

Fig. 3 shows the SNR cumulative probability distribution for 2000 Hz. This distribution would indicate that there is a 10% probability of measuring a 7 dB SNR at one frequency in a patient with a hearing loss ranging from moderate to profound. Simply stated this means that 10% of the time, when testing an infant with a moderate-to-profound hearing loss, an "emission" of 7 dB at one frequency may be seen, caused only by the variability of the noise levels in the DPOAE bin and the adjacent bins. If a pass criterion of 7 dB SNR at one frequency was set, 10 babies out of every 100 with a hearing loss would be missed and incorrectly identified as "normal hearing." A criterion such as this would produce a very low referral rate; however, this low referral rate would be at the expense of missing babies with hearing loss.

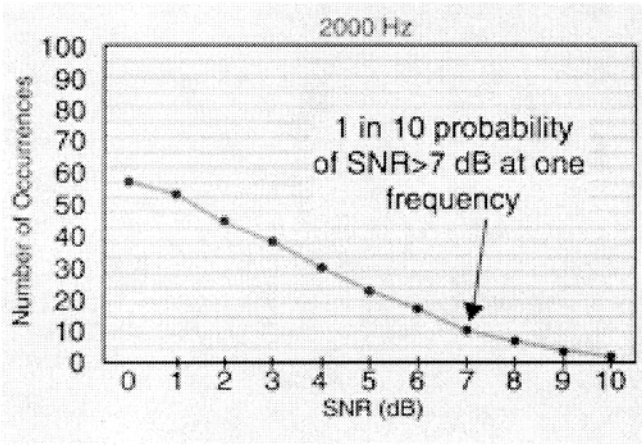

Fig. 3. *SNR cumulative probability distribution.*

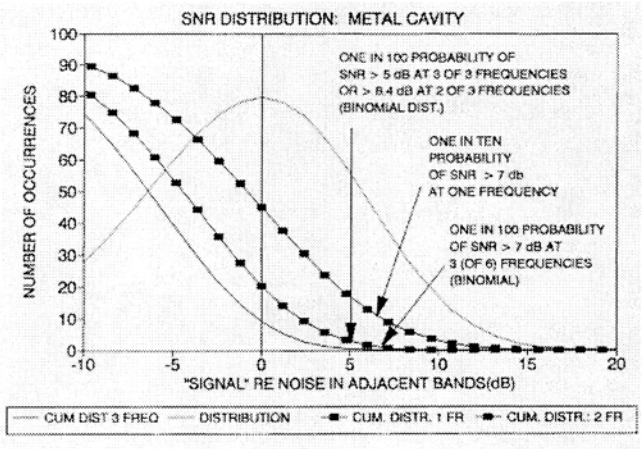

Fig. 4. *Probability of missing moderately severe hearing loss Distribution was of Gaussian form with a standard deviation of 6 dB.*

Results of similar measurements gave SNR distributions at 2000, 3000 and 4000 Hz. These were collapsed across frequencies and one SNR distribution was determined. This distribution can be seen in Fig. 4. Applying binomial probability theory, SNR cumulative probability distributions were derived for two and three frequencies. These distributions, along with the cumulative probability distribution for one frequency, are also seen in Fig. 4. The distributions show the probability of obtaining a certain SNR at two out of two frequencies or three out of three frequencies. From these curves, a criterion of 5 dB SNR was chosen for the three frequencies. The three-frequency curve in Fig. 4 indicates that this criterion (Pass = SNR of 5 dB at three of three frequencies) will miss an ear with hearing loss ranging from moderate to profound 1 out of 100 times. Thus, it follows that significant bilateral hearing loss will be missed 1 out of 10,000 times with this criterion. In addition, by the binomial distribution, two of three frequencies at >8.4 dB or three.of six frequencies at >7 dB should also ensure less than a 1% probability of missing an infant with significant hearing loss.

Pass/Refer Criterion

The example above was based on data from one DPOAE unit. Table 1 shows the default pass/refer criterion for several DPOAE systems available on the market. In this table, the unit's default pass/refer criteria are displayed. Many of these DPOAE systems offer users the option of setting their own pass/refer criteria. This is indicated by the word "customizable" in the table. Four of the devices in this table do not set any default criteria for a pass/refer, but instead leave this decision up to the user. It should be recognized that none of the pass/refer criterion shown can be considered "product advantages," per se; the table simply gives the reader an idea of how diverse the pass/refer criteria are for the different DPOAE systems. Normative data from manufacturers or published data sets are provided in Figs. 1 and 2 when they were available to the author. On one device (GSI 70), normative data was considered proprietary and thus was not available. *(The reader is referred to J.W. Hall's textbook[10] on otoacoustic emissions and Gorga and colleagues[9] for more normative data sets.)*

Conclusions

Is a universal pass/refer criterion for DPOAE systems possible? At this time, the answer is no. When measuring the same ear with different DPOAE systems, different results will be produced by the different systems. Until standardization of DPOAE systems and/or calibration is

Table 1. Pass/Refer Criteria For Several DPOAE Screeners

DPOAE System	Pass/Fail Criteria
Biologic AuDX	*DPMin*: -7, -8, -5, -6 dB SPL at 2k, 3k, 4k,and 5k Hz respectively *MinSNR*: 6 dB at all test frequencies *Overall Test Pass*: 3/4 test frequencies have to meet above criteria Customizable on AuDXII and AuDXPlus
Etymotic Research ERO-SCAN	*DPMin*: -5 dB SPL at 2k, 3k, and 4kHz *MinSNR*: 5 dB at all test frequencies *Overall Test Pass*: 3/3 test frequencies have to meet above criteria Customizable
Grason-Stadler GSI-60 avail.	No Default Pass/Refer Criterion
Grason-Stadler GSI-70	*DPMin*: -3, -3, -5 dB SPL at 2k, 3k, and 4k Hz, respectively *MinSNR*: 10 dB at all test frequencies *Overall Test Pass*: 3/3 test frequencies have to meet above criteria Customizable on GSI70 Multiple Patient Version
Intelligent Hearing Systems SmartOAE	No Default Pass/Refer Criterion
Starkey DP2000	No Default Pass/Refer Criterion
Sonamed Clarity System	*DPMin*: -5 dB SPL from 2000-5000 Hz *MinSNR*: 5 dB from 2000-5000 Hz *MaxNF*: 10(1-2K), 5(2-4K), 0(4-8K) *Replicability* (dB separation) = 3 *Overall Test Pass* - User specifiable. Customizable
Madsen-Celesta	No Default Pass/Refer Criterion *DPMin*: Distortion Product minimum amplitude *MinSNR*: Minimum signal-to-noise ratio *MaxNF*: Maximum allowable noise floor

established, it is important to use data collected for each individual brand and model of equipment.

When a manufacturer does not establish a default pass/refer criterion, the arbitrary use of a pass/refer criterion such as 3 dB at 3 frequencies or 6 dB SNR at 3 frequencies is not recommended. A further discussion and example of the use of these arbitrary criteria can be found in Gorga et al.'s recent (1999) study.[11] According to Gorga and colleagues, application of these arbitrary criteria can lead to low sensitivity rates—especially for infants with mild hearing loss. In these cases, normative data should be collected for the particular unit, or a published database for the unit should be consulted.

Pass/Refer criteria built into the DPOAE systems by the manufacturer can be used, but care should be taken by the user to determine how these criteria were established and what normative database was used. In addition, the protocol used to collect these data must be carefully followed. For instance, if the data were collected with f1 = 65 dB SPL and f2 = 55 dB SPL at a f1/f2 ratio of 1.22, then these test characteristics must be used in testing. In addition, there are other issues that should be considered about these data, such as the criteria for normal hearing, test environment and subject selection. Finally, the pass/refer criterion must meet the goals of the program and therefore might need to be changed based on these goals. ◆

References

1. Hornsby B, Kelly T & Hall J: Normative data for five FDA-approved distortion product OAE systems. *Hear Jour* 1996; 49 (9): 39-46.
2. Gorga MP, Neely ST, Bergman B, Beauchaine KL, Daminski JR, Peters J & Jesteadt W: Otoacoustic emissions from normal-hearing and hearing-impaired subjects: Distortion product responses. *Jour Acoust Soc Amer* 1993; 93: 2050-2060.
3. Christensen LA: School-age hearing screening using otoacoustic emissions. Paper presented at the American Speech Language Hearing Association Annual Convention, San Francisco, CA, 1999.
4. Siegel JH: Cross-talk in otoacoustic emission probes. *Ear & Hear* 1995: 16: 150-158.
5. Siegel JH: Ear-canal standing waves and high-frequency sound calibration using otoacoustic emission probes. *Jour Acoust Soc Amer* 1994; 95: 2589-2597.
6. Dolphin W: Manufacturers' forum-Sonamed Corporation. In J.W. Hall III's (ed.) *Handbook of Otoacoustic Emissions*. San Diego: Singular Publishing Group, 2000.
7. Miskiel E: Manufacturers' forum-Intelligent Hearing Systems. In JW Hall III's (ed.) *Handbook of Otoacoustic Emissions*. San Diego: Singular Publishing Group, 2000.
8. Christensen LA & Killion MC: A pass/refer criterion for screening newborns using DPOAEs. Paper presented at the International Evoked Response Audiometry Study Group XVI Biennial Symposium, Tromso, Norway, 1999.
9. Gorga MP, Neely ST, Ohlrich B, Hoover B, Redner J & Peters J: From laboratory to clinic: A large scale study of distortion product otoacoustic emissions in ears with normal hearing and ears with hearing loss. *Ear & Hear* 1997; 18, 440-455.
10. Hall, J.W. III: *Handbook of Otoacoustic Emissions*. San Diego: Singular Publishing Group, 2000.
11. Gorga MP, Neely ST & Dorn PA: DPOAE test performance for a priori criteria and for multifrequency audiometric standards. *Ear and Hear* 1999; 20: 345-362.

Correspondence can be addressed to HR *or Laurel A. Christensen, PhD, Etymotic Research, 61 Martin Lane, Elk Grove Village, IL 60007-1307; e-mail: l_christensen@etymotic.com.*

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