Normative Data For Five FDA-Approved Distortion Product OAE Systems

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INTRODUCTION

Like aural immittance measures in the 1970s and the auditory brainstem response (ABR) in the 1980s, otoacoustic emissions (OAE) have, in the 1990s, ushered in a new era of auditory research and clinical potential.

Although first described back in 1978,[1] OAE have only recently begun to gain widespread acceptance by clinicians. To a large extent, the lag in clinical application of OAE was related to the dearth of user-friendly and Food and Drug Administration-approved systems for OAE measurement.[2] A device for recording OAE in response to transient stimuli (TEOAE) was introduced in 1988 by Otodynamics, Ltd. This company holds the exclusive license for TEOAE instrumentation until 1999. However, within the past 5 years, five manufacturers have developed and obtained FDA approval for clinical *distortion product* otoacoustic emissions (DPOAE) devices. In order of their appearance in the marketplace, the systems are the Virtual 330, the Etymotic Research/Mimosa Acoustics CubDis, the Madsen Celesta, the Grason Stadler Inc. 60, and the Biologic Scout (manufacturers' addresses are listed in the Appendix).

As these different DPOAE instruments are purchased for application in various patient populations, clinicians require normative DPOAE databases. Optimally, DPOAE databases would be collected systematically for each of the five systems from a single sizable and well-defined subject sample. Comparative databases would permit cross-clinic comparison of DPOAE and would facilitate meaningful clinical interpretation of DPOAE findings. The purpose of this study was to develop normative adult databases for the five DPOAE systems, using a rather conventional test protocol.

METHODS

We measured DPOAE in a group of young adults age 21 to 28 years. All subjects had hearing thresholds of 15 dB HL or better for audiometric test frequencies of 500 Hz through 8000 Hz. In addition, all subjects had normal (Type A) tympanograms. None of the subjects reported tinnitus or exposure to excessive levels of sound. The environment for DPOAE measurement was a quiet, but not sound-treated, room with an average ambient noise level of 56 dBC. The data were collected by three graduate students in audiology who had received classroom instruction on OAE topics and clinical experience in OAE measurement.

We analyzed the cubic distortion product ($2f_1$-f_2) following simultaneous stimulation with two primary tonal stimuli (f_1 and f_2). This measure was defined as DPOAE amplitude. We presented the two stimuli with an f_2/f_1 ratio of 1.22. Stimuli pairs (f_1 is the lower frequency and f_2 is the higher frequency) were presented across a frequency region of 500 Hz to 6000 Hz. We used two different stimulus intensity protocols. For one protocol, the two stimuli were at an intensity level of 65 dB SPL (L_1=L_2=65 dB SPL). For the other protocol, L_1 was 65 dB SPL and L_2 was 55 dB SPL.

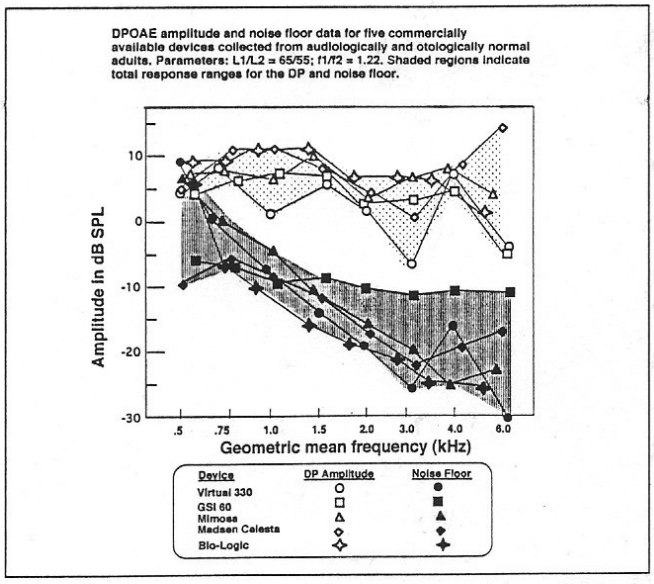

Figure 1. Composite DPgrams for five commercially available devices. For each device, DP amplitudes and noise floors averaged from a series of audiometrically normal adults are plotted as a function of the geometric mean of the stimulus frequencies (f_1 and f_2). Note the disparity of DP data among devices for some of the test frequencies.

For four of the five devices, we recorded DPOAE amplitude and the noise floor in the adjacent frequency region of the distortion product ($2f_1$-f_2) for a total of six frequency pairs per octave. One of the devices permitted the presentation of only two frequency pairs per octave. The ➤

TABLE 1. Biologic Scout (N=30 Ears)

GM	Type	Mean	Median	S.D.	95%-ile	5%-ile
488	DP	2.39	2.9	6.51	4.82	-0.04
	NF	-5.49	-4.15	6.06	-3.23	-7.75
634	DP	10.48	11.4	5.18	12.41	8.55
	NF	-4.83	-3.4	5.95	-2.61	-7.06
805	DP	10.04	6.55	5.79	12.20	7.88
	NF	-7.52	-3.5	8.94	-4.18	-10.86
1001	DP	11.26	9.0	5.62	13.35	9.16
	NF	-12.06	-31.1	12.7	-7.32	-16.81
1269	DP	10.54	6.9	8.66	13.78	7.31
	NF	-10.42	-2.3	9.06	-7.03	-13.8
1586	DP	11.76	9.4	5.26	13.72	9.79
	NF	-17.05	-14.3	7.41	-14.28	-19.82
2002	DP	7.39	1.6	6.94	9.98	4.80
	NF	-18.28	-18.7	6.36	-15.91	-20.66
2514	DP	5.44	0.5	5.84	7.62	3.26
	NF	-20.14	-12.0	5.68	-18.02	-22.26
3173	DP	7.46	4.9	5.03	9.34	5.58
	NF	-20.57	-25.1	6.41	-18.17	-22.96
4003	DP	7.35	1.6	6.00	9.59	5.11
	NF	-25.44	-29.0	7.47	-22.65	-28.23
5029	DP	5.16	4.1	5.30	7.14	3.18
	NF	-26.89	-25.0	7.34	-24.15	-29.63
6347	DP	2.37	-6.0	8.15	5.41	-0.68
	NF	-25.61	-16.1	7.58	-22.78	-28.44
8007	DP	-7.63	-7.6	11.14	-3.47	-11.79
	NF	-22.68	-7.6	10.66	-18.7	-26.66

Biologic Scout Protocol

Size of Token: 2048
Rate of Clock: 50,000
Calibrate Stimulus: c:2K.lls
Distortion Product Frequency: 2*F1/F2
F2/F1 Ratio: 1.22
F2 frequency end (Hz): 500.0
L2 level: 55dB SPL
Averaging time (seconds): 16.0
S/N Ratio (dB): 10

Sweeps per Set: 50
CheckFit Stimulus: c:2K.ils
Parameter Protocol File: *.1st
Artifact Limit: 3.0 mPa

F2 frequency begin (Hz): 8000.0
L1 level: 65 dB SPL
Points per Octave: 3
Noise (dB): -10
Repeat: 1

actual measurement parameters used for each device are listed below the normative data tables that follow. The above parameters were held constant across devices. However, we followed manufacturer recommendations for additional settings for efficiently recording optimal DPOAE amplitudes while also minimizing noise floor levels. Thus, the configurations or test set-ups which usually incorporated criteria for acceptance of a DP data point and for definition of an acceptable noise floor level varied among devices according to manufacturer recommendations. Algorithms for processing DP amplitudes and noise floors also varied among manufacturers.

We also plotted the DPOAE amplitude as a function of either the geometric mean of the two stimulus frequencies or as a function of the f_2 frequency, as recommended by the manufacturer. In either case, this plot is referred to as a DPgram. Finally, we always performed replicated DPgrams to ensure that the DPOAE data were repeatable.

For each device, we established normative databases for both the stimulus intensity protocols described above. In this paper, we report only data collected when the intensity of the f_2 frequency

APPENDIX

Manufacturers of the five FDA-approved DPOAE systems, listed alphabetically, are:

Bio-Logic Systems, Inc.
Mundelein, IL
TEL: (708) 949-5200 or
(800)323-8326, ext. 700

Grason Stadler, Inc.
1 Westchester Drive
Milford, NH 03055
TEL: (603) 672-0470

Madsen Electronics
5600 Rowland Road, Suite 275
Minnetonka, MN 55434
TEL: (800) 362-3736

Mimosa Acoustics
P.O. Box 1111
Mountainside, NJ 07092-0111
TEL: (908) 518-071
Fax: (908) 789-9575

Virtual Corporation
521 SW 11th Street, Suite 400
Portland, OR 97205
TEL: (503) 226-3000

TABLE 2. Etymotic Research (N=36 Ears)

GM	Type	Mean	Median	S.D.	95%-ile	5%-ile
585	DP	6.78	7.4	5.74	8.72	4.83
	NF	6.28	7.1	6.68	8.54	4.02
683	DP	10.77	9.3	4.18	12.18	9.36
	NF	5.05	7.2	6.94	7.39	2.70
781	DP	8.68	5.8	6.05	10.73	6.63
	NF	0.43	0.8	6.10	2.49	-1.63
878	DP	6.64	4.8	6.93	8.98	4.29
	NF	0.49	1.8	6.40	2.66	-1.67
1025	DP	9.45	9.7	6.40	11.62	7.28
	NF	-2.56	0.4	7.60	0.01	-5.13
1171	DP	6.93	4.4	7.71	9.54	4.32
	NF	-4.78	-2.3	8.59	-1.87	-7.68
1367	DP	8.44	3.7	7.35	10.93	5.95
	NF	-8.12	-4.9	7.99	-5.41	-10.82
1562	DP	10.62	5.8	6.50	12.45	8.06
	NF	-10.55	4.7	6.83	-8.24	-12.86
1806	DP	7.81	8.2	5.81	9.77	5.84
	NF	-12.86	-9.1	6.46	-10.68	-15.05
2050	DP	5.76	3.8	5.76	7.71	3.81
	NF	-14.93	-13.5	5.7	-13.01	-16.86
2343	DP	2.86	0.2	5.63	4.76	0.95
	NF	-16.82	-13.0	6.11	-14.75	-18.89
2685	DP	1.98	-0.3	6.36	4.16	-0.17
	NF	-17.72	-8.7	7.06	-15.34	-20.11
3027	DP	4.69	4.4	4.21	6.12	3.27
	NF	-18.84	-17.1	6.08	-16.78	-20.89
3417	DP	6.56	3.4	5.04	8.27	4.86
	NF	-20.16	-11.5	8.95	-17.13	-23.18
3857	DP	7.19	5.9	3.97	8.53	5.85
	NF	-23.76	-16.8	7.02	-21.39	-26.14
4345	DP	7.49	6.2	4.66	9.06	5.91
	NF	-25.27	-22.85	6.10	-23.51	-27.64
4931	DP	6.53	3.5	5.03	8.23	4.83
	NF	-26.31	-24.5	4.01	-24.96	-27.67
5566	DP	4.81	3.6	5.67	6.73	2.89
	NF	-23.97	-14.7	6.14	-21.90	-26.05
6298	DP	3.51	1.3	5.87	5.49	1.52
	NF	-25.34	-24.1	3.59	-24.13	-26.56
7080	DP	-2.81	-5.0	9.14	0.29	-5.90
	NF	-25.77	-24.5	2.83	-24.81	-26.72
7958	DP	-4.74	-6.1	9.96	-1.36	-8.11
	NF	-24.13	-16.5	4.01	-22.72	-25.48
8935	DP	-9.28	-8.3	8.99	-6.24	-12.32
	NF	-23.40	-19.5	3.90	-22.08	-24.72

Mimosa Acoustics/Etymotic Research Cubdis Protocol

Maximum F2 in Hz: 8935.5
Sound pressure for F1 (P1) in dB SPL: 65
Number of points per octave tested: 6
Averaging time in seconds: 4.0

Minimum F2 in Hz: 537.1
Sound pressure for F2 (P2) in dB SPL: 55
F2 to F1 ratio: 1.22
Gain set for microphone at preamp: 40

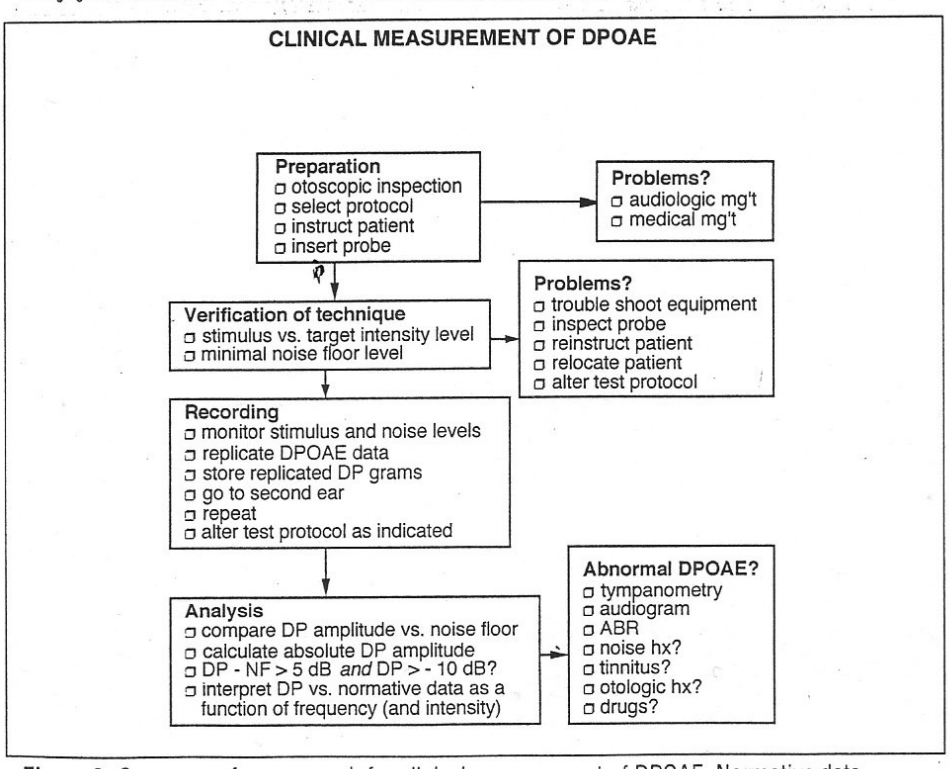

Figure 2. Summary of an approach for clinical measurement of DPOAE. Normative data presented in this paper are used in the Analysis portion of the figure. Many other important factors, however, must be considered before and after DPOAE analysis for accurate measurement and meaningful clinical interpretation of DPOAE.

was lower by 10 dB than the intensity level of the f_1 frequency, specifically, L_1=65 dB SPL and L_2=55 dB SPL. Our rationale for this decision was based on published evidence that DPOAE measures are more sensitive to cochlear dysfunction when this relationship exists in f_2 and f_1 intensity levels (L_2 lower than L_1 by 10 dB to 15 dB).[3-6] As an aside, with this relative intensity difference, it appears that the cochlea is maximally stimulated at the frequency region represented by f_2.

RESULTS

DPOAE data for the five devices are displayed in Tables 1-5. Data include the test frequency (the geometric mean or GM between the f_1 and f_2 frequencies). At each test frequency, descriptive statistics for DP amplitude and the corresponding noise floor are indicated in dB SPL, such as the mean, median, and measures of variability. A summary of important test protocol parameters for the DPOAE device is provided along with each table. Details on device operation and parameters not included here are available from the manufacturers (see Appendix).

These normative data are appropriate for clinical analysis of DPOAE with adult patients, assuming DPOAE are recorded with an equivalent test protocol. With some DPOAE devices, the user can enter data representing the range of normal findings for DP and noise floor for each test frequency. Then, the normative region is displayed as the DPOAE, i.e., DPgrams, are recorded for a patient. This approach facilitates on-line analysis of DPOAE data clinically. At least one manufacturer (Grason Stadler) has included these normative data within DPOAE devices distributed from the factory.

COMMENTS

The importance of using normative data collected with the particular DPOAE device that you are using in a clinical setting is highlighted by inspection of Figure 1. There were distinct, and statistically significant, differences among devices in DP amplitude. The differences were especially evident in certain frequency regions. Disparity among the devices was greatest for the highest test frequencies.

This finding may be related to variable effects of ear canal acoustics. For

TABLE 3. Grason Stadler, Inc. 60 (N=38 Ears)

GM	Type	Mean	Median	S.D.	95%-ile	5%-ile
562	DP	4.39	4.0	5.96	6.35	2.44
	NF	-6.13	-3.5	3.31	-5.04	-7.22
625	DP	3.69	-3.0	6.31	5.77	1.62
	NF	-6.24	-6.0	2.29	-5.48	-6.99
687	DP	5.71	0.5	6.79	7.94	3.48
	NF	-6.26	-5.0	2.46	-5.46	-7.07
781	DP	5.32	5.0	6.38	7.41	3.22
	NF	-7.74	-2.0	2.36	-6.96	-8.51
875	DP	5.76	-1.0	7.7	8.29	3.23
	NF	-7.08	-8.5	2.12	-6.38	-7.78
968	DP	7.66	9.0	7.1	9.99	5.33
	NF	-7.11	-5.0	3.09	-6.09	-8.12
1093	DP	7.0	7.0	7.52	9.47	4.53
	NF	-8.24	-9.5	2.17	-7.52	-8.95
1250	DP	7.37	6.5	6.43	9.48	5.26
	NF	-8.5	-10.0	2.55	-7.66	-9.34
1375	DP	7.47	2.0	7.82	10.04	4.90
	NF	-9.11	-11.0	2.76	-8.20	-10.01
1562	DP	6.58	5.0	6.40	8.68	4.48
	NF	-9.05	-11.0	2.58	-8.21	-9.9
1750	DP	5.71	5.0	6.12	7.72	3.7
	NF	-10.68	-11.0	2.65	-9.81	-11.56
1968	DP	2.92	-6.5	7.51	5.39	.45
	NF	-10.76	-12.0	3.13	-9.73	-11.79
2218	DP	2.76	1.5	6.37	4.86	.67
	NF	-10.93	-12.0	2.82	-9.1	-10.95
2500	DP	4.53	3.5	6.21	6.57	2.48
	NF	-12.89	-11.5	2.89	-11.94	-13.85
2781	DP	3.26	4.0	4.46	4.73	1.8
	NF	-13.45	-14.0	2.9	-12.49	-14.4
3093	DP	3.79	1.0	4.89	5.40	2.18
	NF	-11.37	-12.5	2.89	-10.42	-12.32
3500	DP	4.34	3.0	4.75	2.78	5.9
	NF	-11.71	-13.0	2.36	-10.94	-12.94
3937	DP	4.76	1.0	6.28	2.70	6.83
	NF	-10.58	-12.0	2.62	-9.72	-11.44
4406	DP	4.55	1.0	6.25	6.61	2.50
	NF	-9.71	-12.5	3.38	-8.60	-10.82
4968	DP	2.14	-2.5	7.63	4.68	-0.41
	NF	-8.32	-8.5	2.25	-7.57	-9.07
5562	DP	-0.74	-2.5	7.4	1.70	-3.17
	NF	-9.55	-12.0	3.52	-8.39	-10.71
6250	DP	-4.97	-9.5	7.05	-2.47	-7.11
	NF	-10.39	-8.5	3.34	-9.3	-11.49

GSI 60 Protocol

Octaves tested: 500-8000 Hz
L1: 65 dB SPL
Points per octave measured: 6
Single frame noise level: Absolute Noise> 35 dB SPL
Test rejection conditions:
*test time> or = 400 frames or > or = 12.8 seconds
*L1 out of tolerance > or = 20 frames
*L2 out of tolerance > or = 20 frames
*noise level exceeded > or = 50 frames

F1/F2 ratio: 1.22
L2: 55 dB SPL
Sampling rate: 16000 Hz
L1 or L2 tolerance: + or - 5 dB
Test acceptance conditions:
*Minimum accepted frames > or = 10
*Absolute average noise < o r= -6 dB
AND
*DP amplitude–average noise floor > or = 10 dB SPL
*Averaged absolute noise < or = -12 dB SPL

stimulus frequencies above 5000 Hz, DPOAE measurement may be confounded by interference from standing waves.[7] Standing wave influences are likely to vary among devices as they are related, in part, to the distance of the microphone from the tympanic membrane. The effects of "internal coupling (cross-talk) between the sound source and probe microphone,[8]" that is leakage of stimulus energy from within the silicone tubing in the probe assembly to the microphone used to detect the DPOAE, may contribute to measurement artifacts and may have a negative influence on the accuracy of DPOAE recordings. Differences in the extent of this problem among devices are likely to have contributed to the disparity in DP amplitude values.

A complete review of techniques and strategies for analysis and interpretation of DPOAE in clinical populations is far beyond the scope of this paper. There are, as Figure 2 illustrates, many important steps in DPOAE measurement before the analysis of DPOAE amplitude values and noise floor levels as a function of test frequency. The most straightforward DPOAE outcome is the finding of DP amplitudes well within normal limits for all test frequencies, with corresponding noise floor values that are below the upper limit for normal. In contrast, there are many possible explanations for abnormally depressed DP amplitudes, ranging from middle ear dysfunction to equipment malfunction, or, of course, cochlear dysfunction involving outer hair cells. For a more detailed discussion of DPOAE measure-

TABLE 4. Madsen Celesta (N=22 Ears)

GM	Type	Mean	Median	S.D.	95%-ile	5%-ile
500	DP	4.68	5.5	4.85	6.83	2.53
	NF	-9.55	-8.0	4.84	-7.40	-11.69
700	DP	10.00	11.5	5.26	12.33	7.67
	NF	-5.82	-0.5	5.99	-3.16	-8.47
1000	DP	11.23	11.5	6.23	13.99	8.46
	NF	-8.05	-6.0	4.28	-6.15	-9.94
1500	DP	7.27	2.5	7.68	10.68	3.87
	NF	-11.64	-3.0	7.62	-8.26	-15.01
2000	DP	4.23	3.0	4.94	6.42	2.04
	NF	-17.05	16.5	3.72	-15.4	-18.7
3000	DP	0.50	-4.0	4.14	2.33	-1.33
	NF	-22.36	-23.5	3.65	-20.75	-23.98
4000	DP	8.27	6.0	5.58	10.75	5.80
	NF	-18.64	-15.5	3.62	-17.03	-20.24
6000	DP	14.00	5.0	8.32	17.69	10.31
	NF	-17.14	-18.0	2.68	-15.95	-18.32

Madsen Celesta Protocol

F2/F1 ratio: 1.22
F2 level: 55 dB SPL
Reject sweeps: 2 standard deviations
Intervals per octave: 2
F1 level: 65 dB SPL
Accept sweeps: 200
Frequencies tested: 500-8000 Hz

TABLE 5. Virtual Corporation 330 (N=38 Ears)

GM	Type	Mean	Median	S.D.	95%-ile	5%-ile
500	DP	5.77	3.4	7.90	7.49	3.17
	NF	10.53	13.5	7.39	12.46	7.61
560	DP	5.63	-5.0	5.22	7.49	3.77
	NF	5.98	3.8	6.17	8.01	3.95
630	DP	8.03	9.4	5.22	9.75	6.32
	NF	3.70	4.3	5.78	5.60	1.80
700	DP	8.53	8.0	6.56	10.68	6.37
	NF	0.76	2.2	5.92	2.70	-1.19
800	DP	6.41	6.3	7.15	8.76	4.05
	NF	-0.13	1.3	6.10	1.9	-2.17
890	DP	3.31	5.2	6.47	5.43	1.18
	NF	-2.81	1.5	6.09	-0.81	-4.81
1000	DP	0.18	-2.5	6.46	2.31	-1.94
	NF	-6.73	-6.6	6.04	-4.74	-8.71
1120	DP	2.39	-4.2	8.84	5.29	-0.52
	NF	-13.04	-9.6	5.54	-11.22	-14.86
1260	DP	5.04	3.0	7.59	7.53	2.54
	NF	-13.72	-12.6	6.09	-11.71	-15.72
1410	DP	6.95	-2.5	7.83	9.52	4.38
	NF	-13.12	-10.2	5.53	-11.3	-14.94
1580	DP	5.99	3.8	6.20	8.03	3.95
	NF	-14.45	-11.1	6.00	-12.48	-16.42
1780	DP	4.51	0.4	8.20	7.20	1.81
	NF	-16.86	-11.6	4.99	-15.21	-18.5
2000	DP	2.57	-0.9	7.02	4.88	0.27
	NF	-18.83	-14.3	5.62	-16.99	-20.68
2250	DP	1.04	-1.3	6.51	3.18	-1.10
	NF	-20.92	-9.1	6.75	-18.7	-23.14
2520	DP	-2.27	-7.4	6.35	-0.18	-4.36
	NF	-24.12	-12.95	5.42	-22.34	-25.9
2830	DP	-5.18	-19.0	10.53	-1.72	-8.64
	NF	-24.54	-22.3	5.16	-22.84	-26.24
3180	DP	-8.18	-12.0	9.00	-5.23	-11.14
	NF	-24.94	-17.5	5.58	-23.14	-26.81
3570	DP	-0.48	-5.8	10.64	3.01	-3.98
	NF	-20.76	-9.1	4.24	-19.36	-22.15
4000	DP	6.08	-1.5	11.47	9.85	2.31
	NF	-16.04	-11.8	4.55	-14.55	-17.54
4490	DP	6.20	0.2	10.29	9.58	2.82
	NF	-15.44	-13.3	4.06	-14.11	-16.78
5040	DP	2.57	1.2	10.48	6.01	-0.88
	NF	-18.88	-17.9	4.1	-17.53	-20.53
5660	DP	-3.39	-4.0	11.00	0.22	-7.01
	NF	-27.16	25.15	4.03	-25.83	-28.48
6350	DP	-4.9	-5.9	9.79	-1.68	-8.12
	NF	-30.75	-30.0	3.58	-29.57	-31.93
7120	DP	-4.76	-7.5	8.25	-2.04	-7.47
	NF	-30.23	-26.5	4.5	-28.76	-31.71
8000	DP	-9.14	-11.4	10.32	-5.75	-12.53
	NF	-29.88	-26.9	3.48	-28.74	-31.02

Virtual 330 Protocol

Level of F1: 65 dB SPL
Frequency range: 500-8000 Hz
Distortion product plotted as F1*F2
Time averages: 16
Noise retries: 4
Level of F2: 55 dB SPL
Octave step size 1/6
Ratio of F2 to F1: 1:22
Spectral averages: 0
Noise tolerance: 10 dB

ment, analysis, and interpretation, the reader is referred to *The Audiologists' Desk Reference*, Volume I.[9]

The recent introduction of a variety of clinical FDA-approved DPOAE devices to audiologists is sure to lead to systematic investigation and documentation of both screening and diagnostic applications and to refinement of techniques for measurement and analysis. Nonetheless, DPOAE are in our experience already assuming a unique and very important role in clinical audiologic test battery.

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