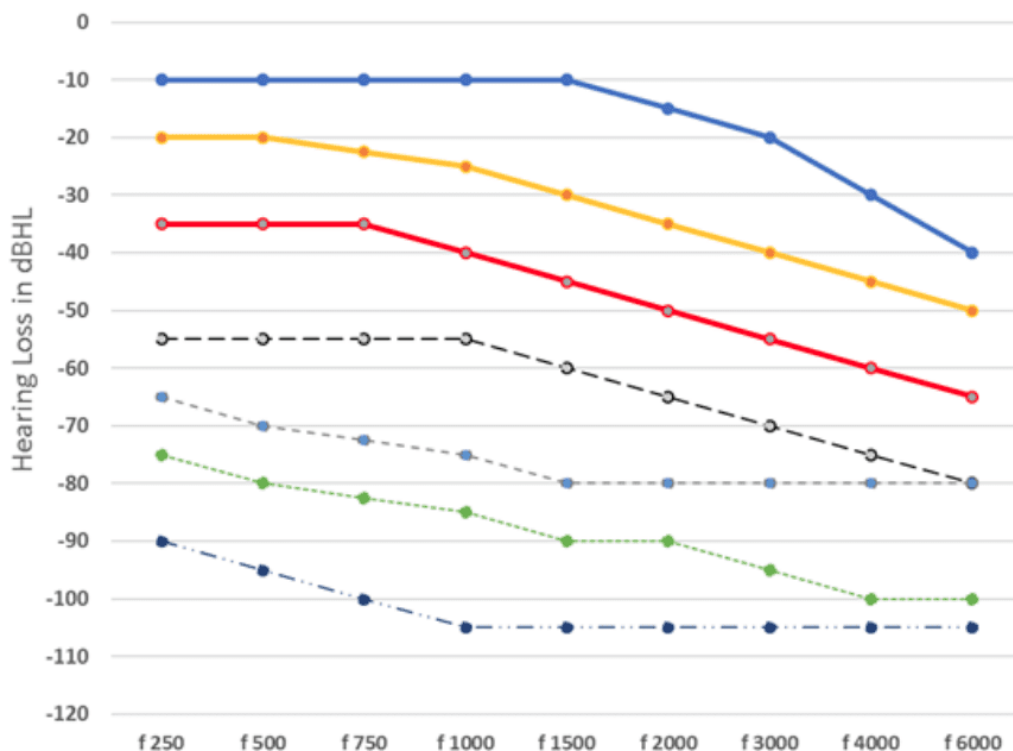


## Real World Evidence on Gain and Output Settings for Individuals with Mild-to-Moderate Hearing Loss

Jul 14, 2020 | Over the Counter, Personal Sound Amplification, Research | ★★★★★



### Research | July 2020 Hearing Review

What a large data set says about the gain/output requirements for OTC hearing devices

By Thomas J. Tedeschi, AuD, Christine Jones, AuD, and Elizabeth Stewart, AuD

Based on the audiograms of over 28,000 adults, this study shows that commercially-available hearing aids programmed according to parameters typical of those used for individuals with mild-to-moderate hearing loss yield output and gain levels that are well within the recommended limits (110 dB SPL output and 25 dB gain) specified by a recent Consensus Paper issued by the four national professional organizations representing hearing healthcare providers.

On August 2017, Congress passed the *Over-the-Counter Hearing Aid Act (OTC Act)*.<sup>1</sup> The law requires the US Food and Drug Administration (FDA) to promulgate regulations for a new category of over-the-counter (OTC) hearing aids that would be available to adults

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with perceived mild-to-moderate hearing impairment without the involvement of a licensed hearing care professional. The OTC Act gives the FDA up to 3 years to set forth draft proposed regulation, and 180 days after the closing of the Public Comment period to publish the Final Rule. Since May 2019, the OTC Hearing Aid rule-making has been added to the FDA's short-term agenda, indicating that the Administration is currently working on a Proposed Regulation (it's possible the timeline will be delayed by the FDA's necessary attention to the Covid-19 pandemic).

Both the Congressional mandate and a prior 2016 **National Academies of Sciences, Engineering, and Medicine (NASEM) report**<sup>2</sup> suggest that OTC hearing aids need to be regulated with parameters that provide reassurance of safety and effectiveness. If such safety and efficacy parameters are not carefully defined, these devices will not serve their intended benefit and could create an influx of products that could harm, instead of benefit, individuals with hearing impairment.

In August of 2018, representatives of the major US hearing healthcare associations established a working group which developed a **Consensus Paper**<sup>3</sup> providing recommendations on how to regulate the new category of OTC hearing aids. The Consensus Paper's Working Group supported efforts aimed at making hearing care solutions more accessible; at the same time, the Associations strongly advocated that any solutions presented to consumers be safe and effective, and include safeguards that optimize consumers' awareness and use of appropriate treatment.

More specifically, the Consensus Paper recommends that the maximum output speech pressure level (OSPL90) for the OTC Hearing Aid category be no greater than 110 dB SPL as measured in a **2cc coupler**,<sup>4</sup> and that a gain limit be defined at 25 dB (HFA full-on gain, as measured at an input level of 50 dB SPL per **ANSI specifications**<sup>5</sup>), based on the National Acoustic Laboratories NAL-NL2 formula which is the most widely used formula worldwide for the calculation of gain for adults.<sup>4</sup>

These standards, however, are not universally accepted by all groups and for all types of amplification products. In January 2017, the Consumer Technology Association (CTA) published CTA Standard 2051, entitled *Personal Sound Amplification Performance Criteria*.<sup>6</sup> This standard includes technical performance metrics and associated target values for consumer products that provide personal sound amplification and/or enhancement to a user. Per the CTA standard, the maximum output level OSPL 90 shall not exceed 120 dB SPL when measured in a 2cc coupler. The CTA also states that for maximum gain, the requirement is for the manufacturer to report the gain; however, there is not a gain limit defined *per se*.

In October 2018, the FDA authorized the marketing of a new device, the Bose Self-Fitting Hearing Aid, designed for individuals over the age of 18 with perceived **mild-to-moderate hearing impairment**.<sup>7</sup> The FDA made it clear that this device must comply with applicable federal and state laws regarding the sale of hearing aids, including state laws that might require hearing aids to be purchased from or dispensed by a licensed hearing aid dispenser. However, the Bose Hearing Aid followed the electroacoustic specifications as recommended by CTA Standard 2051,<sup>6</sup> and therefore set a max output of 120 dB SPL and no limit on gain on a device intended for individuals with perceived mild-to-moderate hearing loss.

### Insights from Real World Data

The goal of this article is to derive hearing aid gain and output settings appropriate for individuals with mild-to-moderate hearing loss by taking a more practical approach; specifically, by assessing the electroacoustic response of a current commercially available hearing aid (device) that has been used in over 1,000,000 fittings around the world. The

gain and output of this device were measured using the two most common prescriptive gain approaches available in this device.

This analysis focused primarily on hearing aid fittings for mild-to-moderate hearing loss to ensure that results were representative of the hearing loss configuration targeted by the OTC legislation. To maintain consistency with the Associations' Consensus Paper, we utilized ASHA's classifications of mild and moderate hearing loss as 26-40 dB HL and 41-55 dB HL, respectively. Bisgaard et al<sup>8</sup> used a vector quantization analysis method on a database of 28,244 audiograms to derive standard audiograms for different degrees of hearing loss, shown in Table 1 and Figure 1.

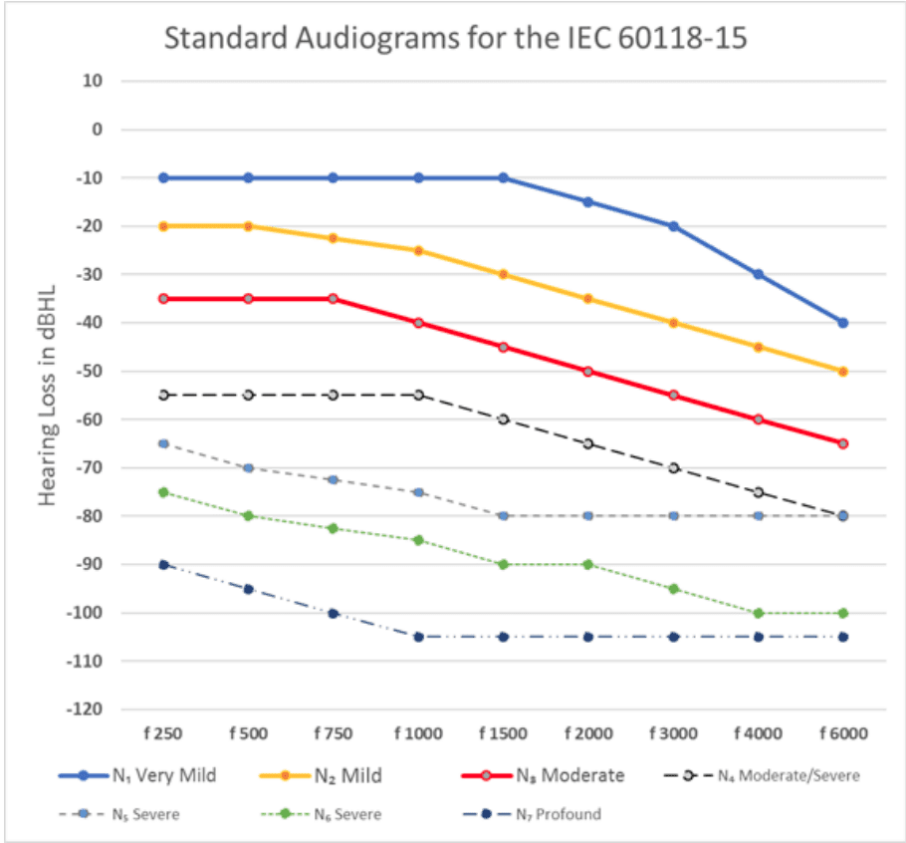


Figure 1. Standard audiograms in graphic form (ie, same data as Table 1).

		Frequency (Hz)									
No.	Category	250	375	500	750	1000	1500	2000	3000	4000	6000
N <sub>1</sub>	Very Mild	10	10	10	10	10	10	15	20	30	40
N <sub>2</sub>	Mild	20	20	20	22.5	25	30	35	40	45	50
N <sub>3</sub>	Moderate	35	35	35	35	40	45	50	55	60	65
N <sub>4</sub>	Moderate/Severe	55	55	55	55	55	60	65	70	75	80
N <sub>5</sub>	Severe	65	67.5	70	72.5	75	80	80	80	80	80
N <sub>6</sub>	Severe	75	77.5	80	82.5	85	90	90	95	100	100
N <sub>7</sub>	Profound	90	92.5	95	100	105	105	105	105	105	105

Table 1. Standard Audiograms for the IEC 60118-15 Measurement Procedure derived from a dataset of 28,244 audiograms. For each level of hearing loss (N1-N7) dB HL are reported for different frequencies ranging from 250 Hz to 6,000 Hz.

Phonak Audéo M90-R receiver-in-canal (RIC) hearing aids were utilized for electroacoustic analysis. Hearing aids were programmed as binaural fittings using Phonak Target fitting software (v6.2). The measurements were completed per the American National Standards Institute (ANSI) S3.22-2009 hearing aid specification standard using Otosuite software (Otometrics) installed on a laboratory computer connected to an Aurical hearing instrument test box (Natus) with a 2cc coupler. Only the maximum output for a 90 dB SPL input (OSPL 90 MAX) and the maximum full-on gain for a 50 dB SPL input

(FOG 50 MAX) were examined, as these measures were most relevant to the recommendations set forth in the Associations' Consensus Paper.

All measurements were performed at full-on gain based on Phonak's proprietary fitting formula, Adaptive Phonak Digital (APD), utilizing an omni-directional microphone setting with all noise reduction features deactivated. Four hearing loss configurations were utilized, representing mild (N<sub>2</sub>), moderate (N<sub>3</sub>), Moderate/Severe (N<sub>4</sub>), and Severe (N<sub>5</sub>) hearing losses from the configurations identified by Bisgaard et al<sup>8</sup> and reported in Table 1.

The results of ANSI measures obtained using the APD fitting formula are shown in Table 2. Maximum OSPL 90 for mild (N<sub>2</sub>) and moderate (N<sub>3</sub>) configurations are under 100 dB SPL. Full-on maximum gain for mild and moderate configurations were under the 25 dB recommendation put forth in the Consensus Paper.

	Maximum Output		Gain Performance	
	(OSPL 90 MAX)		(FOG 50 HFA)	
Mild (N <sub>2</sub> )	84.7	dB SPL	9.2	dB
Moderate (N <sub>3</sub> )	99.7	dB SPL	24.6	dB
Moderate Severe (N <sub>4</sub> )	103.3	dB SPL	35.8	dB
Severe (N <sub>5</sub> )	115	dB SPL	50.8	dB

Table 2. Output and gain settings measured on a Phonak Audeo M90-R programmed with a commercial fitting formula. These results represent the settings applied in over 1,000,000 hearing aids fitted to different degrees and configuration of hearing losses.

Interestingly, the maximum OSPL 90 for the moderate/severe configuration was also within the consensus-recommended limit of 110 dB SPL. Only the severe type hearing loss exceeded the 110 dB SPL. However, output was still well under the CTA Standard of 120 dB SPL utilized by Bose.

These results suggest that the proprietary fitting formula used in this investigation complies with recommended gain and output settings. However, the revised version of the prescriptive formula from the National Acoustic Laboratories (NAL-NL2) is the most widely used fitting rationale in the United States, and the same as the one used by the Associations' Consensus Paper. Thus, electroacoustic measures were repeated using the same hearing loss configurations, but with the hearing aids programmed using the NAL-NL2 fitting formula. All other parameters of the hearing aid fittings were kept constant.

The results of ANSI measures obtained using the NAL-NL2 fitting formula are shown in Table 3. Again, the measured maximum OSPL 90 is below 100 dB for the mild (N<sub>2</sub>) and moderate (N<sub>3</sub>) configurations, and below the recommendation of 110 dB SPL—even when configured for the moderate/severe (N<sub>4</sub>) hearing loss. The maximum OSPL 90 for the severe (N<sub>5</sub>) hearing loss configuration exceeded the 110 dB SPL recommended limit by only 1.4 dB, and was well under the 120 dB SPL limit currently utilized by an FDA-approved device. Gain performance for mild and moderate hearing losses also complied with the 25 dB limit recommended by the Associations' Consensus Paper.

	Maximum Output		Gain Performance	
	(OSPL 90 MAX)		(FOG 50 HFA)	
Mild (N <sub>2</sub> )	70.9	dB SPL	9.6	dB
Moderate (N <sub>3</sub> )	97.5	dB SPL	21.7	dB
Moderate Severe (N <sub>4</sub> )	104	dB SPL	42.4	dB
Severe (N <sub>5</sub> )	111.4	dB SPL	49.9	dB

Table 3. Output and gain settings measured on a Phonak Audeo M90-R programmed with NAL-N2 fitting formula for different degrees and configuration of hearing losses.

It should be noted that the results shown in Table 2 and Table 3 were based on settings appropriate for long-term hearing aid users. It is anticipated that the majority of the early adopters to OTC hearing aids will be new users or individuals with little or no experience with professionally fitted hearing devices.<sup>9</sup> Lower levels of amplification are typically prescribed for new hearing aid users to allow for acclimatization. Thus, the data presented here likely overestimate the gain that first-time hearing aid users would experience with these devices.

## Conclusions

Recall that the purpose of this article was to provide insights from objective measurements of commercially-available hearing aids, programmed according to real-world audiograms and fitting protocol. This was achieved by examining hearing aid gain and output parameters based on the fitting requirements for a standard set of audiograms based on the research of over 28,000 patients and utilizing the NAL-NL2 fitting protocol, as well as a proprietary manufacturer fitting formula.

Based on an examination of objective outcomes, we conclude that commercially-available hearing aids programmed according to parameters typical of those used for individuals with mild-to-moderate hearing loss yield output and gain levels that are within the recommended limits specified in the Associations' Consensus Paper. It was also noted that, in fact, the recommended limits proposed in the Consensus Paper are higher than the levels prescribed in professionally fitted devices for long-term hearing aid users with mild and moderate hearing loss.

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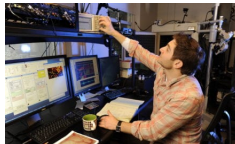
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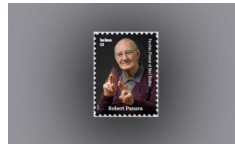
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