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A Critical Appraisal of Nonconformity of New Hearing Aids with American National Standards Institute Standards

Évaluation critique de la non-conformité de nouveaux appareils auditifs aux normes de l'*American National Standards Institute*

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Abstract

Some studies have found an alarming rate of hearing aids' nonconformity with American National Standards Institute standards, but research in this area is limited. This study reports a comprehensive assessment of the compliance rate of hearing aids of various brands and styles. The Audioscan Verifit-1 analyzer was used to examine the compliance of 62 new hearing aids with the S3.22-2014 standard of the American National Standards Institute. Audioscan Verifit-2 and Aurical test systems were also used to determine the potential influence of hearing aid test systems on the compliance rate. With the Verifit-1 test system, most hearing aids (96.8%) were found to be out of specification for the equivalent input noise measure. Compared to equivalent input noise, the compliance rates for output sound pressure level, high-frequency average at 50 dB, and total harmonic distortion were higher and did not differ between brands and styles. The type of analyzer had a considerable impact on the measured equivalent input noise compliance rate: Compared to the Verifit-1, the Verifit-2 and Aurical test systems indicated a higher compliance rate (> 90% versus ~ 5%). However, there were no differences in compliance rates across the analyzers for the rest of the tests. This study reveals that hearing aids mostly comply with the standard. There is a need to establish clinically reproducible and easily accessible testing protocols for the quality control of hearing aids at various stages of use.

Abrégé

Certaines études indiquent qu'un nombre alarmant d'appareils auditifs ne sont pas conformes aux normes de l'*American National Standards Institute*, mais les recherches sur cette question demeurent limitées. La présente étude a évalué de façon exhaustive le taux de conformité d'appareils auditifs de différents modèles et fabricants. Le système d'analyse Verifit-1 d'Audioscan a été utilisé pour déterminer la conformité de 62 nouveaux appareils auditifs à la norme S3.22-2014 de l'*American National Standards Institute*. Des tests ont également été réalisés à l'aide des systèmes Verifit-2 d'Audioscan et Aurical afin de déterminer l'influence potentielle des systèmes d'analyse utilisés sur le taux de conformité. Les résultats des tests réalisés à l'aide du système Verifit-1 ont indiqué que la plupart des appareils auditifs (96,8 %) étaient non conformes pour le bruit équivalent en entrée. Comparés au taux de conformité du bruit équivalent en entrée, les taux de conformité pour le niveau de pression acoustique de sortie, pour la valeur moyenne du niveau de pression acoustique de sortie pour un niveau de pression acoustique d'entrée de 50 dB aux hautes fréquences et pour la distorsion harmonique totale étaient plus élevés et ne différaient pas selon les fabricants ou modèles. L'impact du type de système d'analyse sur les taux de conformité concernant le bruit équivalent en entrée était considérable. Spécifiquement, en comparaison au système Verifit-1, les taux de conformité obtenus avec les systèmes Verifit-2 et Aurical étaient supérieurs (> 90 %, versus ~ 5 %). Cependant, aucune différence n'a été constatée concernant les taux de conformité entre les différents appareils d'analyse pour les autres mesures. Cette étude révèle que, de façon générale, les appareils auditifs respectent les normes établies. Il existe un besoin de mettre au point des protocoles reproductibles en clinique pour contrôler la qualité des appareils auditifs aux différents stades d'utilisation.

To ensure a successful clinical outcome and patient compliance, hearing aids (HAs) must provide specified performance (Gallagher & Woodside, 2018; McCormack & Fortnum, 2013; Mueller, 2005; Yong et al., 2019). Manufacturers, therefore, generally examine the performance of each HA before dispatch and provide information about key measures such as maximum output sound pressure level (OSPL) with a 90 dB input (Max OSPL 90), high-frequency average OSPL with a 90 dB input (HFA-OSPL 90), HFA @ 50 dB, equivalent input noise (EIN), and total harmonic distortion (THD), that can be used for performance validation (Levitt et al., 1990). The American National Standards Institute (ANSI) has developed recommendations for evaluating HA performance (ANSI, 1992). As HA technology advances and new features are introduced, the ANSI requirements are typically reaffirmed, updated, or removed every 5 years (Blaeser & Struck, 2019; Ravn & Preves, 2015). In the United States, the Food and Drug Administration has described HA performance (as stated in the ANSI standard S3.22 2014) as a quality control provision (Frye, 2005; U. S. Food and Drug Administration, 2021). If HAs fail to meet ANSI standards, manufacturers may face penalties, including forced market withdrawal; although, more commonly, HAs are returned to the manufacturer if ANSI standards are not met (Frye, 2005).

ANSI defines a standard set of criteria and tests that enable industry-wide consensus among HA professionals and manufacturers (ANSI, 1992; Struck, 2015). ANSI S3.22 2014 includes electroacoustic tests to characterize the performance and evaluate the reliability of air conduction HAs (Bentler et al., 2016). Standard tests used for the performance assessment of HAs include Max OSPL 90, HFA-OSPL 90, HFA @ 50 dB, EIN, and THD (ANSI, 1992; Frye, 2005; Lewis et al., 2010; Valente et al., 2008). The Max OSPL90 represents the highest output level that the HA can deliver, HFA-OSPL 90 is the average HA output in dB SPL at 1000, 1600, and 2500 Hz, with a 90 dB SPL input and the HFA@50 dB is the average output of HA in dB SPL at 1000, 1600, and 2500 Hz, with the 50 dB SPL input with the gain control setting in the reference test setting. The EIN, or circuit noise of the HA, is considered within specification if the measured noise is within 3 dB of the value specified by the manufacturer (ANSI, 2014). The THD is the ratio of the power of total harmonics generated with respect to the power of the fundamental/standard input signal.

Previous research raised concerns about the poor compliance of HAs with ANSI standards, reporting that more than 30% of HAs did not meet ANSI specifications (Callaway & Punch, 2008; Townsend & Olsen, 1982). According to one study, none of the HAs tested were within the permitted tolerance for all ANSI criteria (Holder et al., 2016). It was stressed that the performance of a HA may fall short of expectations particularly in the presence of excessive background noise, feedback, and/or poor sound quality (Abrams & Kihm, 2015). Recent advancements in digital technology have enabled the inclusion of advanced processing algorithms and functionalities in HAs, further accentuating the need for homogeneity of quality control measures used at the manufacturers' and clinical sites (Bentler & Duve, 2000).

This study examines the compliance of HAs with ANSI standard S3.22-2014 using three analyzers with different frequency ranges. A separate series of experiments were carried out that closely mimicked the experimental conditions used by Holder et al. (2016). Previous research has focused primarily on the measurements of behind-the-ear HAs; this study expands the research by including HAs with receiver-in-canal, in-the-ear, completely-in-canal, and behind-the-ear styles. Notably, HAs can have a bandwidth ranging from 100 to 10000 Hz, but the frequency response range of HA analyzers such as the Verifit-1 is up to only 8000 Hz. Consequently, three distinct analyzers were used in this study (Verifit-1: 100–8000 Hz, Verifit-2: 100–12500 Hz and Aurical: 100–10000 Hz).

Methods

The Institutional Review Board at Bloomsburg University of Pennsylvania approved this study (IRB# 2017-42). Measurements were performed at Bloomsburg University's Speech and Hearing Clinic, on digital HAs that were received between 2017 and 2020. All electroacoustic measurements were performed according to the instructions provided in the HA test system manuals. All measurements were made in a quiet HA dispensing room in the clinic. The room was not acoustically treated. Included electroacoustic measurements were Max OSPL 90, HFA-OSPL 90, and HFA @ 50 dB, measured at a full-on gain; EIN and THD were measured at the reference test gain. The current standard (ANSI S3.22-2014) was used for tolerance measurements in this study. The ANSI S3.22-2014 model specifies a 2 cc acoustic coupler tailored to fit a HA with a specific acoustic impedance. The measured levels were compared with the manufacturers' specifications plus tolerances provided by ANSI. If the measured levels were within tolerances, the HA was classified as compliant. The ANSI compliance rate for an electroacoustic measurement was defined as the proportion of HAs with measured values within the tolerance specified by the manufacturer. The gain settings and tolerances used for the ANSI measurement are listed in **Table 1**.

Table 1

Hearing Aid Gain Setting and Tolerance Levels for Each ANSI Standard Parameter

Parameter	Definition	Gain setting	Tolerance
Max OSPL 90	The maximum value of the OSPL 90 curve	FOG	+ 3 dB
HFA-OSPL 90	Average high-frequency average output saturation sound pressure level	FOG	± 4 dB
HFA @ 50 dB	Average of the full-on gain at the HFA frequencies	FOG	± 5 dB
EIN	SPL of an external noise source at the input that would result in the same coupler SPL as that caused by all internal noise sources in the hearing aid	RTS	+ 3 dB
THD	The ratio of the sum of the powers of all the harmonics to the power of the fundamental	RTS	+ 3%

Note. ANSI = American National Standards Institute; EIN = equivalent input noise; FOG: full-on gain; HFA = high-frequency average, meaning the average of values at 1000, 1600, and 2500 Hz; Max = maximum; OSPL 90 = output sound pressure level with a 90 dB input; RTS = reference test setting; SPL = sound pressure level; THD = total harmonic distortion.

Testing was completed according to the publicized protocol and the test mode recommended by the manufacturers. The calibration of the test box microphone was completed before measurement. The coupler connection, positioning, and measurement were performed as recommended in the manual, using 2 cc HA-1 and HA-2 couplers and a new HA battery. Investigators conducted the tests strictly following the manufacturer's protocols to minimize measurement errors, calibrated each analyzer according to the manual, and evaluated HAs in three separate analyzers. New batteries were used for each HA.

Compliance Rate Assessment Using Verifit-1

One of the goals of this research was to reexamine the findings of Holder et al. (2016), who found that none of the included HA satisfied all the ANSI requirements. Therefore, in the first part of this study, the ANSI compliance rate of 62 new HAs was examined using an Audioscan Verifit-1 analyzer, which is the same model that Holder et al. used. Rather than focusing on only one type of style, in this work, four different styles (completely-in-canal, in-the-ear, receiver-in-canal, behind-the-ear) from five different brands were included to have a more comprehensive evaluation (Palmer, 2009). The selected HAs represent the most commonly used models at the Bloomsburg University Speech and Hearing Clinic.

Compliance Rate Assessment Using Three Different Analyzers

In the second part of this study, the possible influence of various analyzers with different frequency ranges on the ANSI compliance rate was investigated. A different set of 20 new HAs was examined using three different analyzers: Audioscan Verifit-1 (up to 8000 Hz), Audioscan Verifit-2 (version 4.2; up to 12500 Hz), and Aurical Freefit HA test system (up to 10000 Hz). To control the variability due to style and coupling method within the test box, all 20 HAs were receiver-in-canal style. The sample size of 20 was sufficient to have adequate power measured using G*power analysis. The frequency responses of the HAs included in this study were 100–7500 Hz (n = 1), 100–7800 Hz (n = 2), 100–9600 Hz (n = 15), and 100–10000 Hz (n = 2).

Statistical Analysis

Data were analyzed using IBM SPSS Statistics for Windows (version 26), and Microsoft Excel for Mac (version 2016). Descriptive statistics were performed to calculate the mean and standard deviations or median and interquartile range (IQR: Q1–Q3) for the HA outputs across the ANSI specifications. A frequency distribution analysis was performed to determine the percentage of HAs that met the ANSI specifications. As the data followed a nonnormal distribution, the Kruskal-Wallis test was conducted to compare different groups. The Fleiss kappa was used to determine if the three analyzers agreed on whether or not each HA met the ANSI requirements.

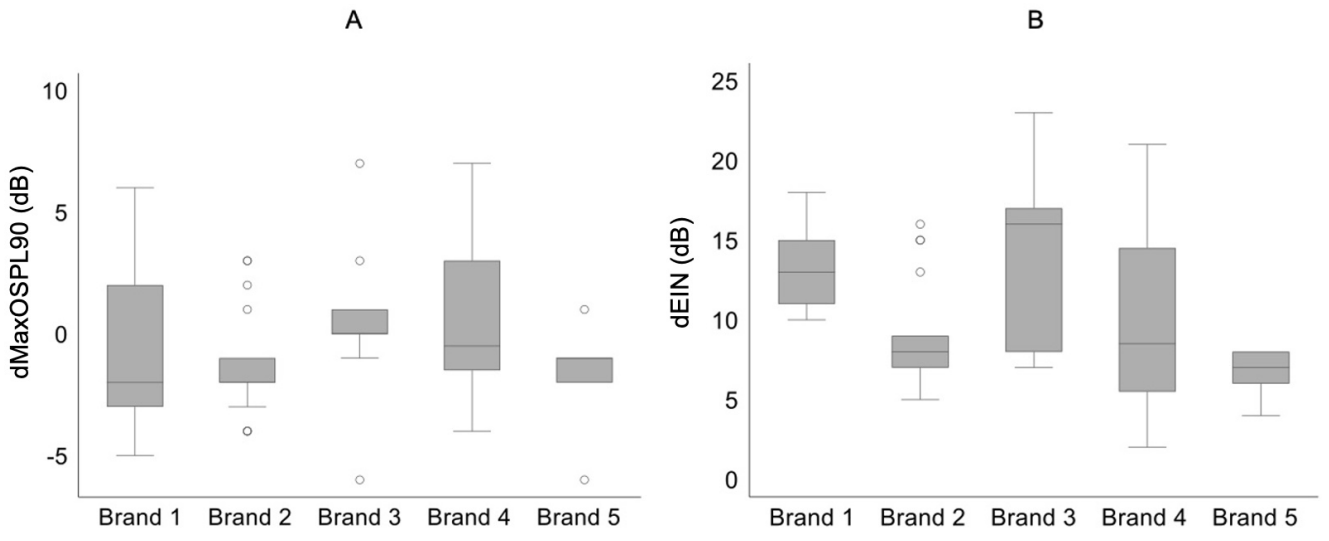
Results

Assessment of the ANSI Compliance Rate Using Verifit-1

Figure 1A represents the deviation of the measured Max OSPL90 (dMaxOSPL90) from the manufacturer-specified values. The number of HAs for Brands 1, 2, 3, 4, and 5 was 13, 22, 9, 12, and 6, respectively.

The median measured Max OSPL90 was 115.0 (IQR: 113.0–119.0), and there was no difference across different brands (p = .513, **Table 2**). It can be seen that Brands 1 and 4 have a relatively broader range of dMaxOSPL90.

Figure 1



Compliance rate for different hearing aid brands using the Verifit-1 analyzer

Note. Panel A: Deviation of the measured Max OSPL90 (dMaxOSPL90) from the manufacturer-specified value. Panel B: Deviation of the measured EIN from the manufacturer-specified EIN (dEIN). Max OSPL90 = maximum output sound pressure level at 90dB input; EIN = equivalent input noise.

A negative dMaxOSPL90 suggests that the HA saturates with distortion; conversely, with a positive dMaxOSPL90, high performance can be achieved without distortion or saturation. The output of noncompliant HAs (Brands 1, 3, and 4) was higher than the manufacturer's specification with $M = 3.25$ dB ($SD = 0.95$, minimum = 2 dB; maximum = 4 dB). Regarding the conformity of the measured Max OSPL90 with ANSI standards, the overall compliance rate was 93.5% (**Table 3**). Notably, for two brands (2 and 5), there were no incidents of noncompliance with respect to Max OSPL90, and the lowest compliance rate by a brand was 84.6% (Brand 1), although the difference in compliance rate was not statistically significant across brands (**Table 3**).

If the performance of a HA is within ± 4 dB of the manufacturer's specification, it is deemed to be consistent with the ANSI specification for HFA-OSPL90. Brands 3 and 5 had a 100% compliance rate for the HFA-OSPL90 measurement, and Brands 1, 2, and 4 had compliance rates of 92.3%, 95.5%, and 83.3%, respectively ($p = .513$, **Table 3**). The median measured HFA-OSPL 90 was 111.5 dB (IQR: 108.0–116.0), and there was no difference among different brands ($p = .115$, **Table 2**). Of 62 HAs, four not in compliance for HFA-OSPL90 were from Brands 1 ($n = 1$), 2 ($n = 1$), and 4 ($n = 2$). After applying the tolerance levels, three HA had higher values (maximum deviation +3 dB), and one had lower values (−1 dB) than the manufacturer's specification.

If a HA's output is within ± 5 dB of the manufacturer's specification, it is considered ANSI compliant for HFA@50 dB. Brands 3 and 5 had a 100% compliance rate and Brands 1, 2, and 4 had compliance rates of 84.6%, 77.3%, and 66.7% ($p = .226$, **Table 3**). The median HFA@50 dB was 46.5 dB (44.0, 52.0), and there was no statistically significant difference across brands ($p = .381$, **Table 2**). Four noncompliant HAs had higher values (maximum deviation +6 dB), and seven had values lower (maximum deviation −7 dB) than the manufacturer's specification.

The deviation of the measured EIN from the manufacturer-specified EIN (dEIN) is shown in **Figure 1B** for each brand. The median measured EIN was 34.0 dB (IQR: 33.0–36.0; **Table 2**). In four of the five brands included in this work, none of the HAs complied with the ANSI specification for EIN. Only 16.7% of Brand 3's HAs met the EIN test tolerance specified in the ANSI standard (**Table 3**). The median EIN specified by the company was 25.0 dB (IQR: 22.0–26.0), which was considerably lower than the measured EIN ($Mdn = 34.0$ dB [33.0–36.0], **Table 2**). The EIN represents the level of environmental input noise needed to generate an output voltage equal to the voltage of the device's internal noise; therefore, if a HA has an excessively high EIN, the noise can be noticeable to listeners with low thresholds. It can be seen in **Figure 1B** that for all brands, the EIN values are considerably higher than the manufacturer-specified values.

Table 2

ANSI Test Parameters Across Different Brands Measured With the Verifit-1 Analyzer

Parameter	Brand 1 (*n* = 13) median (Q1–Q3)	Brand 2 (*n* = 22) median (Q1–Q3)	Brand 3 (*n* = 9) median (Q1–Q3)	Brand 4 (*n* = 12) median (Q1–Q3)	Brand 5 (*n* = 6) median (Q1–Q3)	Total (*N* = 62) median (Q1–Q3)	*p* value
Measured Max OSPL 90	116.0 (114.0–121.0)	114.0 (113.0–117.0)	117.0 (115.0–125.0)	115.5 (114.0–118.0)	118.0 (114.0–119.0)	115.0 (113.0–119.0)	.513
Manufacturer Max OSPL 90	116.0 (116.0–119.0)	115.0 (115.0–116.0)	118.0 (115.0–123.0)	115.0 (114.0–115.0)	120.0 (115.0–123.0)	115.0 (115.0–119.0)	.03
dMax OSPL 90	−2.0 (−3.0–2.0)	−2.0 (−2.0– −1.0)	0.0 (0.0–1.0)	−0.5 (−1.5–3.0)	−1.0 (−2.0– −1.0)	−1.0 (−2.0–1.0)	.117
Measured HFA-OSPL 90	113.0 (111.0–115.0)	109.0 (108.0–114.0)	115.0 (111.0–118.0)	111.5 (109.5–115.0)	115.5 (110.0–116.0)	111.5 (108.0–116.0)	.115
Manufacturer HFA-OSPL 90	114.0 (113.0–114.0)	109.0 (109.0–110.0)	114.0 (109.0–117.0)	109.5 (109.0–111.0)	115.0 (109.0–117.0)	110.0 (109.0–114.0)	.036
Measured HFA @ 50 dB	48.0 (45.0–50.0)	45.0 (42.0–51.0)	48.0 (48.0–55.0)	45.5 (44.0–53.5)	54.0 (46.0–55.0)	46.5 (44.0–52.0)	.381
Manufacturer HFA @ 50 dB	51.0 (45.0–51.0)	45.0 (44.0–46.0)	47.0 (45.0–54.0)	50.0 (45.0–55.5)	54.0 (45.0–54.0)	46.0 (45.0–52.0)	.195
Measured EIN	35.0 (33.0–36.0)	34.0 (32.0–34.0)	34.0 (34.0–37.0)	34.0 (31.5–38.0)	32.0 (31.0–33.0)	34.0 (33.0–36.0)	.15
Manufacturer EIN	23.0 (21.0–23.0)	26.0 (25.0–26.0)	18.0 (18.0–26.0)	25.0 (21.5–26.0)	25.5 (25.0–26.0)	25.0 (22.0–26.0)	< .001
dEIN	13.0 (11.0–15.0)	8.0 (7.0–9.0)	16.0 (8.0–17.0)	8.5 (5.5–14.5)	7.0 (6.0–8.0)	8.5 (7.0–14.0)	.001
Harmonic distortion measured 500 Hz	0.0 (0.0–1.0)	1.0 (0.0–1.0)	1.0 (0.0–1.0)	1.0 (1.0–2.0)	1.0 (0.0–1.0)	1.0 (0.0–1.0)	.073
Manufacturer harmonic distortion 500 Hz	0.5 (0.5–0.6)	3.0 (3.0–3.0)	2.0 (2.0–3.0)	3.0 (2.0–3.0)	3.0 (3.0–3.0)	3.0 (2.0–3.0)	< .001
Harmonic distortion measured 800 Hz	1.0 (0.0–1.0)	1.0 (1.0–1.0)	1.0 (0.0–1.0)	1.0 (0.0–1.0)	1.0 (1.0–1.0)	1.0 (0.0–1.0)	.405
Manufacturer harmonic distortion 800 Hz	0.6 (0.6–0.6)	3.0 (3.0–3.0)	2.0 (2.0–3.0)	3.0 (2.0–3.0)	3.0 (3.0–3.0)	3.0 (2.0–3.0)	< .001
Harmonic distortion measured 1600 Hz	0.0 (0.0–1.0)	1.0 (0.0–1.0)	1.0 (0.0–1.0)	0.0 (0.0–1.0)	1.0 (0.0–1.0)	1.0 (0.0–1.0)	.425
Manufacturer harmonic distortion 1600 Hz	1.2 (0.9–1.2)	3.0 (3.0–3.0)	2.0 (2.0–3.0)	2.5 (2.0–3.0)	3.0 (3.0–3.0)	3.0 (1.2–3.0)	< .001

Note. ANSI = American National Standards Institute; dEIN = deviation of the measured EIN from the manufacturer-specified EIN; dMax = deviation of the measured maximum from the manufacturer-specified maximum; EIN = equivalent input noise; HFA = high-frequency average, meaning the average of values at 1000, 1600, and 2500 Hz; Max = maximum; OSPL 90 = output sound pressure level with a 90 dB input; Q1–Q3 = range from first to third quartile.

Table 3

ANSI Compliance Rates for Hearing Aids From Five Different Brands

Parameter	Brand 1 (*n* = 13)	Brand 2 (*n* = 22)	Brand 3 (*n* = 9)	Brand 4 (*n* = 12)	Brand 5 (*n* = 6)	Total (*N* = 62)	*p* value
Max OSPL 90 (< +3 dB)	11 (84.6%)	22 (100.0%)	8 (88.9%)	11 (91.7%)	6 (100.0%)	58 (93.5%)	.400
HFA-OSPL 90 (± 4 dB)	12 (92.3%)	21 (95.5%)	9 (100.0%)	10 (83.3%)	6 (100.0%)	58 (93.5%)	.513
HFA @ 50 dB (± 5 dB)	11 (84.6%)	17 (77.3%)	9 (100.0%)	8 (66.7%)	6 (100.0%)	51 (82.3%)	.226
THD (< +3%)	13 (100.0%)	20 (90.9%)	8 (88.9%)	11 (91.7%)	6 (100.0%)	58 (93.5%)	.743
EIN (< +3 dB)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (16.7%)	0 (0.0%)	2 (3.2%)	.072

Note. Variance allowances from the ANSI standard are shown with each parameter. ANSI = American National Standards Institute; EIN = equivalent input noise; HFA = high-frequency average, meaning the average of values at 1000, 1600, and 2500 Hz; Max = maximum; OSPL 90 = output sound pressure level with a 90 dB input; THD = total harmonic distortion.

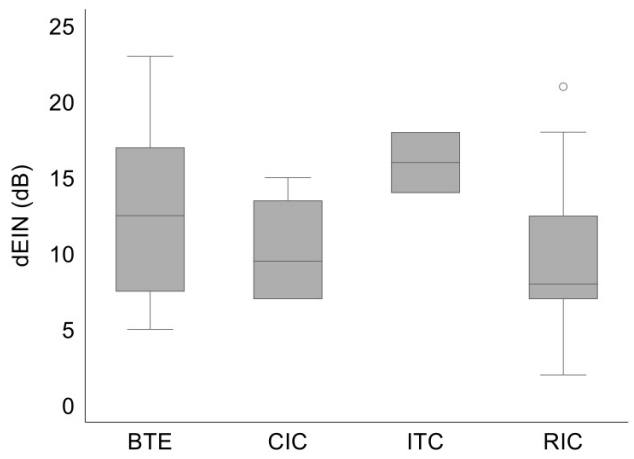
A HA is considered in compliance with the ANSI standards specified for THD if it does not exceed the manufacturer's specification by 3% (**Table 1**). In the case of Brands 1 and 5, all HAs were compliant at all three frequencies: 500 Hz, 800 Hz, and 1600 Hz. Whereas in the case of Brand 2, two HAs were out of specification: one at 500 Hz and a different one at 800 Hz. One HA from each of Brands 3 and 4 was out of specification at 500 Hz. Two of the brands (1 and 5) were within the specification for THD, and the compliance rates for Brands 2, 3, and 4 were 90.9%, 88.9%, and 91.7% ($p = .743$, **Table 3**). Overall, 45 of the 62 HAs met all benchmarks except EIN. When EIN test compliance was included, none of the HA met the ANSI requirements.

Figure 2 represents the dEIN, that is, the difference between the measured and specified EIN values for HAs of different styles. It can be seen that all styles had a positive deviation from the specified value. The median values for behind-the-ear, completely-in-canal, in-the-ear, and receiver-in-canal types of HA were 12.5 dB (IQR: 7.5–17.0), 9.5 dB (7.0–13.5), 16.0 dB (14.0–18.0), and 8.0 dB (7.0–12.5) respectively ($p = .204$). Other parameters of interest are presented in **Table 4** for HAs of different styles.

Comparison of ANSI Compliance Rates Using Three Different Analyzers

According to the findings described in the preceding section, HAs have poor conformity with ANSI standards for EIN. To rule out the possible influence of the analyzer on the assessment of EIN, we examined the HA output using different analyzers. HA output was compared with three analyzers for a different set of 20 new receiver-in-canal HAs. The Max OSPL90 compliance rate calculated by different analyzers did not vary significantly ($p = .765$, **Figure 3A**, **Table 5**). The compliance rates with respect to HFA-OSPL90, HFA @50 dB, and THD were also not different between analyzers (all $p > .05$, **Table 5**). However, the three analyzers showed a substantial difference in the EIN compliance rate (**Table 5** and **Table 6**). It can be seen that Verifit-1 has the highest positive deviation from the manufacturer-specified values (**Figure 3B**). The median EIN output was highest in the Verifit-1 at 30.5 dB (IQR: 27.0–32.0) followed by the Aurical at 27.6 dB (25.0–28.1) and the Verifit-2 at 24.5 dB (22.0–26.0; $p < .001$). EIN compliance rate was only 5% in the Verifit-1 and 95% and 90% for the Verifit-2 and Aurical, respectively ($p < .001$, **Table 5**).

Figure 2



Values of dEIN for hearing aids of different styles using the Verifit-1 analyzer

Note. dEIN = deviation of the measured equivalent input noise from the manufacturer-specified value; BTE = behind the ear; CIC = completely in canal; ITC = in the canal; RIC = receiver in canal.

To determine the agreement between the three analyzers, we performed Fleiss kappa analysis. The Fleiss kappa values were interpreted according to the recommendations of Landis and Koch (1977). A substantial agreement between the analyzers was noted for Max OSPL90, $\kappa = .73$ (95% CI [.72,.74]), $p < .01$ and moderate agreements were observed for HFA-OSPL 90 $\kappa = .56$ (95% CI [.55,.57]), $p < .01$, HFA@50 dB, $\kappa = .51$ (95% CI [.50,.52]), $p < .01$; and THD, $\kappa = .48$ (95% CI [.47,.49]), $p < .01$. Poor or no agreement was found for EIN $\kappa = -.29$ (95% CI [−.30, −.28]), $p = .02$.

When the Verifit-1 was used, only 14 of the 20 HAs met all the ANSI criteria except EIN (when EIN was included, none were compliant). In other words, according to the assessment made using Verifit-1, the majority of HAs were out of compliance with at least one ANSI criterion. Using the Verifit-2, 16 out of 20 HAs met all the standards, including EIN. EIN was over tolerances for one HA of the four that did not meet the guidelines. Using the Aurical, 16 out of 20 HAs met all the standards, including EIN. EIN was outside the limits for two of the four HAs that did not match the criterion. Notably, when both the Verifit-2 and Aurical assessments were considered, 14 of the 20 HAs satisfied all of the ANSI requirements. The rest (6 HAs) were out of compliance for at least one parameter on either the Verifit-2 or the Aurical. The number of HAs that met each norm on all three analyzers was as follows: MaxOSPL 90 (18/20), HFA 90 (17/20), HFA 50 (16/20), THD (19/20), and EIN (1/20). When using only the Verifit-2 and Aurical analyzers with a frequency response of 10 kHz or above for EIN, 18/20 HA satisfied the ANSI criterion for EIN.

Discussion

Compliance with ANSI standards is desired to ensure that the sound output of HAs falls within the clinically prescribed range (Sabin et al., 2020). This study has clarified several aspects of the reported noncompliance of HAs (Holder et al., 2016; Lewis et al., 2010). Using the Verifit-1 analyzer, our analysis revealed that approximately 4% of HAs met the ANSI tolerance requirement for EIN. Notably, even after excluding EIN, our study found that only 45 of the 62 HAs met the remaining ANSI benchmarks (Max OSPL 90, HFA-OSPL 90, THD, and HFA@50 dB). This noncompliance of HAs brings the manufacturers' quality control procedures into doubt, creating a serious concern of introducing inefficiencies in the process due to the rejection of noncompliant HAs and suboptimal patient satisfaction.

Taking the investigation further, we discovered no difference in compliance rates amongst various brands and styles of HAs (behind-the-ear, completely-in-canal, in-the-ear, and receiver-in-canal). However, surprisingly, the compliance rate for EIN was found to be greater than 90% when Verifit-2 and Aurical analyzers were used. To a great extent, these results clarify previous findings, implying that observed noncompliance of HAs with ANSI standards may be due to the limitations of the Verifit-1 analyzer (Holder et al., 2016; Lewis et al., 2010). Therefore, a more comprehensive testing framework is needed to allow accurate measurements in clinical settings.

The findings of our research and those of the aforementioned studies are alarming from a patient care perspective. According to a study by Abrams and Kihm (2015), one of the most common reasons patients stops wearing or return their HAs is the poor performance of the devices. Patient satisfaction plummets when the HAs deliver background noise or do not deliver the desired sound output. From a clinical standpoint, hearing healthcare professionals should verify the performance of HAs to ensure fewer return visits for adjustment.

As stated above, with the Verifit-1 analyzer, noncompliance with ANSI specifications was observed across brands and styles, primarily concerning EIN. EIN is one of the quality control criteria recommended by the ANSI. The presence of high levels of EIN may contribute to fitting failure of HAs. Internal noise in this context is the noise generated by the HAs anywhere in the processing path that is not present in the initial acoustic input. Internal noise may

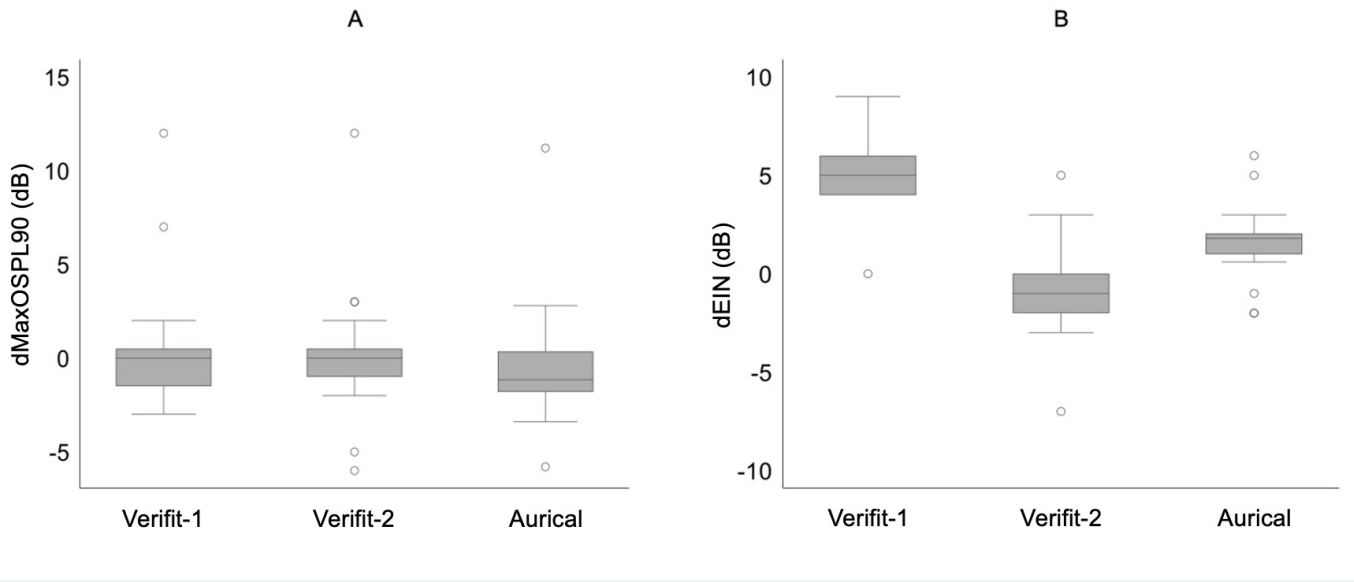
Table 4

ANSI Test Parameters Measured for Different Hearing Aid Styles

Parameter	BTE (*n* = 12) median (Q1–Q3)	CIC (*n* = 4) median (Q1–Q3)	ITE (*n* = 2) median (Q1–Q3)	RIC (*n* = 44) median (Q1–Q3)	Total (*N* = 62) median (Q1–Q3)	*p* value
Measured Max OSPL 90	127.0 (125.5–131.5)	111.5 (110.0–112.5)	115.0 (114.0–116.0)	114.0 (113.0–117.0)	115.0 (113.0–119.0)	< .001
Manufacturer Max OSPL 90	130.5 (126.5–135.0)	112.5 (110.0–115.0)	119.0 (119.0–119.0)	115.0 (115.0–116.0)	115.0 (115.0–119.0)	< .001
dMax OSPL 90	−1.5 (−4.0–0.5)	−2.0 (−3.5–1.0)	−4.0 (−5.0– −3.0)	−1.0 (−2.0–2.0)	−1.0 (−2.0–1.0)	.126
Measured HFA-OSPL 90	118.5 (116.0–125.5)	107.0 (104.0–110.0)	113.0 (113.0–113.0)	109.0 (109.0–112.5)	110.0 (109.0–114.0)	< .001
Manufacturer HFA-OSPL 90	118.5 (116.0–125.5)	107.0 (104.0–110.0)	113.0 (113.0–113.0)	109.0 (109.0–112.5)	110.0 (109.0–114.0)	< .001
Measured HFA @ 50 dB	54.0 (50.5–63.0)	35.0 (33.0–41.0)	43.5 (42.0–45.0)	46.0 (44.0–49.0)	46.5 (44.0–52.0)	< .001
Manufacturer HFA @ 50 dB	55.5 (48.0–66.0)	36.5 (35.0–38.0)	45.0 (45.0–45.0)	45.0 (45.0–51.0)	46.0 (45.0–52.0)	< .001
Measured EIN	34.0 (32.0–38.0)	32.5 (32.0–34.5)	37.0 (35.0–39.0)	34.0 (33.0–36.0)	34.0 (33.0–36.0)	.51
Manufacturer EIN	23.0 (18.0–25.5)	23.0 (21.0–25.0)	21.0 (21.0–21.0)	25.0 (23.0–26.0)	25.0 (22.0–26.0)	.04
dEIN	12.5 (7.5–17.0)	9.5 (7.0–13.5)	16.0 (14.0–18.0)	8.0 (7.0–12.5)	8.5 (7.0–14.0)	.204
Harmonic distortion measured 500 Hz	1.0 (1.0–2.5)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	1.0 (0.0–1.0)	1.0 (0.0–1.0)	.02
Manufacturer harmonic distortion 500 Hz	2.5 (2.0–4.5)	1.8 (0.6–3.0)	0.7 (0.7–0.7)	3.0 (2.0–3.0)	3.0 (2.0–3.0)	.416
Harmonic distortion measured 800 Hz	1.0 (0.0–1.5)	0.0 (0.0–0.5)	0.0 (0.0–0.0)	1.0 (1.0–1.0)	1.0 (0.0–1.0)	.105
Manufacturer harmonic distortion 800 Hz	2.0 (2.0–3.0)	1.8 (0.6–3.0)	0.8 (0.8–0.8)	3.0 (2.0–3.0)	3.0 (2.0–3.0)	.244
Harmonic distortion measured 1600 Hz	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	1.0 (0.0–1.0)	1.0 (0.0–1.0)	.005
Manufacturer harmonic distortion 1600 Hz	2.0 (1.0–2.5)	2.0 (1.0–3.0)	0.9 (0.9–0.9)	3.0 (2.0–3.0)	3.0 (1.2–3.0)	.006

Note. BTE = behind the ear; CIC = completely in canal; ITE = in the ear; RIC = receiver in canal; dEIN = deviation of the measured EIN from the manufacturer-specified EIN; dMax = deviation of the measured maximum from the manufacturer-specified maximum; EIN = equivalent input noise; HFA = high frequency average, meaning the average of values at 1000, 1600, and 2500 Hz; Max = maximum; OSPL 90 = output sound pressure level with a 90 dB input; Q1–Q3 = range from first to third quartile.

Figure 3



Hearing aid compliance rate with three different analyzers

Note. Panel A: deviation of the measured Max OSPL90 (dMaxOSPL90) from the manufacturer-specified values. Panel B: deviation of the measured EIN from the company specified EIN (dEIN). Max OSPL90 = maximum output sound pressure level at 90dB input; EIN = equivalent input noise.

Table 5

ANSI Compliance Rates for 20 Receiver-in-Canal Hearing Aids Using Three Different Analyzers

Parameter	Verifit-1 (*n* = 20)	Verifit-2 (*n* = 20)	Aurical (*n* = 20)	Total (*N* = 60)	*p* value
Max OSPL 90 (< +3 dB)	18 (90.0%)	19 (95.0%)	19 (95.0%)	56 (93.3%)	.765
HFA-OSPL 90 (± 4 dB)	18 (90.0%)	18 (90.0%)	19 (95.0%)	55 (91.7%)	.804
HFA @ 50 dB (± 5 dB)	18 (90.0%)	17 (85.0%)	18 (90.0%)	53 (88.3%)	.851
EIN (< +3 dB)	1 (5.0%)	19 (95.0%)	18 (90.0%)	38 (63.3%)	< .001
THD (< +3%)	19 (95.0%)	20 (100.0%)	19 (95.0%)	58 (96.7%)	.596

Note. Variance allowances from the ANSI standard are shown with each parameter. ANSI = American National Standards Institute; EIN = equivalent input noise; HFA = high-frequency average, meaning the average of values at 1000, 1600, and 2500 Hz; Max = maximum; OSPL 90 = output sound pressure level with a 90 dB input; THD = total harmonic distortion.

come from various sources, including the microphone, the analog-to-digital converter, the digital-to-analog converter, and the receiver; however, the microphone is the most common source of internal noise (Chong & Jenstad, 2017; Lee & Geddes, 1998; Ohlenforst et al, 2017). EIN becomes a problem when it becomes audible to the listener. Patients with better low- and mid-frequency hearing levels may be more vulnerable to EIN, depending on which frequencies have the most noise energy (Nabelek et al., 2006). According to the research, individual patients consider varying levels of background noise tolerable, so if a patient has a lower tolerance to background noise and the HA is producing EIN, the patient may be dissatisfied with the HA (Chong & Jenstad, 2017; Cox et al., 2016; Lewis et al., 2010). Furthermore, it should be noted that a high-frequency hearing loss configuration produces higher noise levels in the HAs compared to a flat configuration (Rawool, 1998), and the internal level at which the noise is perceived to be audible also depends on the audiometric configuration (Agnew, 1996).

Notably, little research has been done on how the analyzer used to examine compliance affects the ANSI test results (Ravn & Preves, 2015). To investigate the possible effect of the analyzers on the ANSI test results, three different analyzers were used in this work. Our findings revealed that the performance of the HA tested using the three analyzers differed significantly for EIN. The EIN is dictated by the bandwidth of the HAs (ANSI, 1992). Of

Table 6

ANSI Hearing Aid Test Parameters Obtained Using Different Analyzers

Parameter	Verifit-1 (*n* = 20) median (Q1–Q3)	Verifit-2 (*n* = 20) median (Q1–Q3)	Aurical (*n* = 20) median (Q1–Q3)	Total (*N* = 60) median (Q1–Q3)	*p* value
Measured Max OSPL 90	115.0 (114.0–116.0)	115.0 (114.0–116.0)	114.3 (113.2–115.3)	114.8 (113.8–115.9)	.387
Manufacturer Max OSPL 90	115.0 (115.0–115.0)	115.0 (115.0–115.0)	115.0 (115.0–115.0)	115.0 (115.0–115.0)	1.000
Measured HFA-OSPL 90	109.5 (107.5–112.0)	109.0 (108.5–111.5)	108.7 (107.8–109.5)	109.0 (108.0–111.0)	.393
Manufacturer OSPL 90	109.0 (109.0–112.0)	109.0 (109.0–112.0)	109.0 (109.0–112.0)	109.0 (109.0–112.0)	1.000
Measured HFA @ 50 dB	46.0 (45.5–48.5)	46.0 (46.0–48.5)	45.2 (44.2–46.0)	46.0 (45.0–47.5)	.022
Manufacturer HFA @ 50 dB	45.0 (45.0–47.0)	45.0 (45.0–47.0)	45.0 (45.0–47.0)	45.0 (45.0–47.0)	1.000
Measured EIN	30.5 (27.0–32.0)	24.5 (22.0–26.0)	27.6 (25.0–28.1)	27.0 (24.0–30.0)	< .001
Manufacturer EIN	26.0 (25.0–26.0)	26.0 (25.0–26.0)	26.0 (25.0–26.0)	26.0 (25.0–26.0)	1.000
Harmonic distortion measured 500 Hz	1.0 (1.0–2.0)	1.0 (1.0–1.0)	1.3 (1.1–1.8)	1.0 (1.0–1.8)	.067
Manufacturer harmonic distortion 500 Hz	3.0 (3.0–3.0)	3.0 (3.0–3.0)	3.0 (3.0–3.0)	3.0 (3.0–3.0)	1.000
Harmonic distortion measured 800 Hz	1.0 (1.0–1.0)	1.0 (1.0–2.0)	1.4 (1.1–1.8)	1.0 (1.0–1.8)	.162
Manufacturer harmonic distortion 800 Hz	3.0 (3.0–3.0)	3.0 (3.0–3.0)	3.0 (3.0–3.0)	3.0 (3.0–3.0)	1.000
Harmonic distortion measured 1600 Hz	1.0 (1.0–2.0)	1.0 (1.0–1.0)	1.4 (1.1–1.6)	1.0 (1.0–1.6)	.057
Manufacturer harmonic distortion 1600 Hz	3.0 (3.0–3.0)	3.0 (3.0–3.0)	3.0 (3.0–3.0)	3.0 (3.0–3.0)	1.000
Max OSPL 90 difference between measured and manufacturer	0.0 (−1.5–1.5)	0.0 (−1.0–6.0)	−1.8 (−2.3– −1.5)	−1.0 (−2.0–0.0)	< .001
OSPL 90 difference between measured and manufacturer	0.0 (−1.0–4.0)	0.0 (−1.0–4.0)	−2.0 (−4.0– −1.2)	−0.1 (−2.7–1.0)	< .001
HFA @ 50 dB difference between measured and manufacturer	0.0 (−1.5–1.0)	1.0 (−0.5–2.0)	−0.9 (−4.3– −0.3)	0.0 (−1.7–1.0)	.007
EIN difference between measured and manufacturer (dEIN)	5.0 (4.0–6.0)	−1.0 (−2.0–0.0)	1.8 (1.0–2.0)	2.0 (−1.0–4.0)	< .001
HD 500 difference between measured and manufacturer	−2.0 (−2.0– −1.0)	−2.0 (−2.0– −1.5)	−1.6 (−1.9– −1.3)	−1.9 (−2.0– −1.0)	.053
HD 800 difference between measured and manufacturer	−2.0 (−2.0– −1.0)	−2.0 (−2.0– −1.0)	−1.5 (−1.8– −1.2)	−1.8 (−2.0– −1.0)	.211
HD 1600 difference between measured and manufacturer	−2.0 (−2.0– −1.0)	−2.0 (−2.0– −2.0)	−1.4 (−1.9– −0.6)	−2.0 (−2.0– −1.0)	.007

Note. ANSI = American National Standards Institute; EIN = equivalent input noise; HFA = high frequency average; HD = harmonic distortion; Max = maximum; OSPL 90 = output sound pressure level with a 90 dB input.

the HAs that were noncompliant on the Verifit-1, most were compliant with the Verifit-2 and the Aurical. Fleiss kappa analysis confirmed a significant discrepancy. Most current digital HAs have extended frequency responses up to 10000–12000 Hz. If HAs with extended frequency responses were tested using analyzers that have limited analyzing bandwidth up to 8000 Hz, the frequencies beyond 8000 Hz and harmonics of the HAs at higher frequencies might be counted towards the noise (Florentine et al., 1987; Martin, 2009; Moore et al., 2010).

Usually, HAs with EIN levels beyond tolerances from the manufacturer's specifications are considered out of compliance and sent for repair or replacement. However, as our findings indicate, considerable variability in EIN is possible when assessments are made using different analyzers, making it plausible to erroneously classify some of the HAs as out of specification for EIN (ANSI, 1992). Other factors that may increase EIN are a leak between the HAs, coupler connection, and microphone connection; open vents; ambient noise levels in the environment leaking into the test chamber; and vibrations of other equipment placed on the same table/platform. All these variables were controlled in this study, but in clinical settings this may not always be the case. Furthermore, Holder et al. (2016), who reported similar findings using the Verifit-1, cross-checked EIN levels obtained from Verifit-1 with the Fonix 8000 test box system (Frye, 2005) to rule out the impact of test box isolation on EIN measurement. In particular, the noise isolation provided by Verifit-1 was 25 dB, and for Fonix 8000, it was 45 dB at 1000 Hz. The authors concluded that noncompliance is because the measurement protocols cannot be replicated in the clinical setting or the HAs are not designed to have lower EIN levels. Such factors can therefore contribute to the apparent anomalies in the performance assessment of HAs, underscoring the need for testing protocols that can be homogeneously implemented in different test settings (Lewis et al., 2010).

Furthermore, even if EIN levels are high, they are not directly linked to patients' perceptions of HAs noise sensitivity (Kates et al., 2018; Lee & Geddes, 1998; Lopez-Poveda et al., 2017; Nabelek et al., 2006; Ohlenforst et al., 2017). Because the EIN is an average of noise levels at specific frequencies and does not account for all frequencies on the audiogram, internal noise from the HAs cannot be reliably reflected by the EIN in real-world situations, and any noise introduced into the HAs after the application of the gain is not accurately represented in the EIN (Kates et al., 2018). The clinical application of EIN levels is further limited, as the individual's perception of HAs noise depends on lower-level gain, compression, circuit noise, venting, and the individual's auditory thresholds. Additionally, the perception depends on the spectral shape of the noise and cannot be represented by a single value.

A variety of other factors can influence HA testing in clinics. Although HAs and the software used to fit them have advanced technologically, the quality management of the fitting process has not. Some manufacturers have a test mode and precise measurement setup with their HAs, but not all have this, making it difficult to replicate test results in the clinical setting. Such challenges defeat the purpose of the ANSI standard for HA quality assurance. In the absence of a clinically replicable protocol, professionals may classify HAs that are not meeting the specifications as defective and return them to the manufacturer. This may not be a time-efficient practice for the dispenser, the patient, or the manufacturer.

Ambient noise is another factor that can affect the reliability of ANSI tests. In the study by Holder et al. (2016), after finding that the EIN measurements were significantly out of specification in both test boxes used, they contacted representatives from the HA companies. They found that the manufacturers' measurements were conducted in an anechoic chamber. Because measurement in the anechoic chamber cannot be repeated in a regular clinical setting, such discrepancies violate the fundamental principle of quality control. If quality management is the goal, the testing process and procedure must be well-publicized and applicable to the clinical environment. Future research comparing measurements taken in a sound-treated environment with those taken in a quiet room could help determine whether ambient noise affects EIN levels; however, using anechoic chambers in clinical settings may not be feasible.

Verification and quality control measures of the HAs should be replicable across settings and quality. Although performing ANSI measurements of HAs before fitting is considered best practice, only 67% of hearing health professionals own a HA analyzer, and only a portion of them perform the measurements (Mueller, 2005). When polled regarding the utility of verifying the HAs before fitting, dispensers indicated the absence of compelling scientific evidence to support the benefits of performing all HA fitting protocols (Kochkin et al., 2010). Notably, many audiologists believed the ANSI compliance test to have limited practical benefit, be time-consuming, and produce inconsistent results with different HA analyzers (Holder et al., 2016; Walden et al., 2000). Although our results support the fact that differences in analyzer and testing setup may lead to some inconsistency, it is important to conduct an ANSI

compliance test to avoid the problems that patients might face during use. The prudent approach is to standardize testing procedures and configurations, ensuring that they are highly repeatable and independent of the testing location.

Our study has certain limitations that should be acknowledged before generalizing our findings. First, this study is a single-centre study and does not have any data or perspective from HA users to gauge the real impact of HA noncompliance with standards. Second, we have found that the type of analyzer can affect the test results; however, solely on the basis of the current study, we cannot conclusively ascribe the reasons for such deviations. More controlled experiments are needed to fully elucidate the factors that might influence the reliability of tests using different analyzers. The different styles and different brands were not equally represented in the sample. Furthermore, it is also important to examine the variability in results obtained when conducting repeated measurements on the same HAs using the same analyzer. Because the ANSI standard contains multiple parameters, it would be helpful if the parameters were weighted with respect to their clinical significance. A homogeneous, easy and accurate testing standard and test setup are necessary to avoid spurious rejections or dispense of substandard HAs.

Conclusion

When using the Verifit-2 or Aurical analyzers, our findings indicate that HA noncompliance rates are lower than those previously reported. Rates of noncompliance for EIN were found to be exceptionally high with the Verifit-1 analyzer. Given that extended frequency ranges of HAs can contribute erroneously to EIN, failure to meet the standard EIN levels should not be the sole criterion for rejection of HAs, especially if using the Verifit-1 analyzer. Because EIN is a function of bandwidth, the observed noncompliance of a HA with EIN may not necessarily indicate a problem with the HA; rather, it could be an error due to the analyzer's restricted frequency response. Manufacturers are encouraged to provide clinically replicable quality control protocols to avoid the unnecessary rejection of HAs due to noncompliance with ANSI standards. There is also a need to establish more uniform and easily accessible testing protocols to assess and validate the efficacy of HAs.

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Disclosures

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