

Clinical Validation of the Edge AI Family



Maddie M. Olson, Au.D., Sarah Rosen Iverson, Au.D., & Sian C. Halvorsen, Au.D. Hear better. Live better.

INTRODUCTION

Several types of clinical studies are conducted in the laboratory and in the field with normal-hearing and hearing-impaired participants, prior to releasing a new hearing aid family, including prototype evaluations, usability studies, and fit and comfort studies. When a product family has met all acceptance criteria of the preliminary studies and is confirmed to perform as expected, it is ready for product and feature validation studies. The purpose of the validation study is to ensure the hearing aids provide clinical benefit, provide adequate amplification, perform as expected for the hearing aid user, and are safe and effective.

The Edge AI validation study covered a variety of clinical outcomes, including an investigation of the accuracy of the e-STAT 2.0 fittings using real-ear measures, an evaluation of sound quality and listening effort in a variety of environments, and an assessment of new features, such as the Deep Neural Network (DNN) noise reduction algorithm and the Balance Assessment feature. This poster aims to summarize the primary clinical outcome measures, including the overall usability of the product family, the streaming sound quality, speech intelligibility, and perceived benefit and satisfaction.

METHODS

Participants (n=57)

- Mean age = 72 years (46-87 years; 37 male and 20 female)
- Average loss: mild sloping to severe sensorineural hearing loss
- Devices:
 - 32 fitted with Edge AI RIC products (RIC RT, RIC 312, or mRIC R)
 - 16 fitted with Edge AI ITE/ITC R
 - 11 fitted with Edge AI CIC
- Average wear time = 49 days or approximately 7 weeks
- Results shown for n=43-46 due to excluding CROS fittings and individuals not completing every study session

Design

- Participants were fitted with hearing aids and had three follow-up appointments, each two weeks apart.

Fitting	1 st Follow-Up	2 nd Follow-Up	3 rd Follow-Up
• Usability • Real-ear measures	• Fine-tuning as needed • Streaming Sound Quality	• Edge Mode+ and DNN Noise Reduction • Balance Assessment	• Subjective Questionnaires • Aided Speech Intelligibility

RESULTS

Speech Intelligibility

Figure 1. Box plot of the speech intelligibility in noise results for all directional products (n=33). plotted as percent of sentences correct. The X symbol represents the mean performance.

- IEEE sentences¹ presented in an 8-speaker array at participant’s SNR50 from 0° azimuth, with uncorrelated 4-talker babble at 67 dBA from 7 surrounding speakers.
- Conditions: 1) unaided, 2) aided (omni microphones + noise reduction disabled), and 3) aided + noise management (directional microphones + DNN noise reduction enabled)
- Aided benefit was achieved for both aided conditions (RMANOVA p<0.0001, post-hoc paired t-test, Unaided:Aided p=0.017, Unaided:Aided+NM p<0.0001).
- **The Aided + Noise Management performed significantly better than the Aided condition, demonstrating the utility of directional microphones and DNN noise reduction features** (post-hoc paired t-test, Aided:Aided+NM p<0.001).

Streaming Sound Quality

Figure 2. Sound quality ratings while streaming a music (n=45) and audiobook (n=44) clip from an iOS or Android smartphone. One rating provided per participant, using either the default or adjusted equalizer settings.

- First, participants listened to a music and an audiobook clip at their prescribed (default) streaming gains. Sound Quality was rated on a scale from (1) ‘Very Poor’ to (7) ‘Very Good’ for each audio sample.
- Second, if participants rated the sound quality as less than (7) ‘Very Good’, they had the opportunity to manipulate the streaming equalizer in the My Starkey app to their preference.
- **When combining the ratings from the default and adjusted equalizer conditions, 73.3-75% rated each clip as ‘Very Good’ sound quality.**

Overall Usability

Figure 3. Box plot of the System Usability Scale (SUS) results. Participants (n=46) rated the usability of the Edge AI hearing aids, charger (if applicable), and mobile application (if applicable).

- Participants evaluated all aspects of the hearing aids and charger and were encouraged to use Edge Mode+ and fine-tune acoustic and streamed inputs via My Starkey.
- After approximately 7 weeks, the System Usability Scale (SUS) questionnaire was administered.
- **The average SUS score was 78.48, which exceeds the recommended “average” benchmark score of 68².**

RESULTS

Benefit Questionnaires

Figure 4. Benefit Score of APHAB RIC, Rechargeable Custom, & CIC Products (n=44-45)

Figure 5. Mean DOSO Results RIC, Rechargeable Custom, & CIC Products (n=43-46)

- A benefit score for the Abbreviated Profile of Hearing Aid Benefit³ (APHAB) was calculated (Unaided – Aided). A higher score indicates greater perceived aided benefit. (Fig. 4).
- **The minimal clinically important difference (MCID)² (≥ 5 pt. improvement on BN, EC & RV, or ≥ 22 pt. improvement on BN, EC, or RV) was met for 93.3% (42/45) of participants, indicating meaningful aided benefit was achieved.**
- The Device Oriented Subjective Outcome⁴ (DOSO) questionnaire was administered for the participant’s own hearing aids and after trialing Edge AI hearing aids (Fig. 5).
- **Average results are higher across all five subscales, with significantly higher scores for the Listening Effort and Speech Cues subscales when using Edge AI** (Wilcoxon Signed-Rank Test, LE: z=-2.6, p<0.01. SC: z=-3.4, p<0.01).

CONCLUSIONS

When validating a new hearing aid prior to launch, it is crucial to investigate the patient experience with the product. The validation study for the Edge AI hearing aid family indicates:

- Significant aided benefit in noise with directional microphones and noise reduction compared to when noise management features are disabled.
- Good to very good streaming sound quality, and the ability to fine-tune streamed inputs.
- Above average usability scores for Edge AI hearing aids.
- 93.3% of participants meet the MCID for APHAB, and 2/5 subscales on the DOSO are significantly higher when compared to their own hearing aids, indicating significant perceived aided benefit and satisfaction.

Edge AI hearing aids were found to be easy to use and improve patient’s listening experiences in clinically meaningful ways.

REFERENCES

¹ Campbell, J.P., & Reynolds, D.A. (1999, March 15-19). *Corpora for the evaluation of speaker recognition systems*. IEEE International Conference on Acoustics, Speech, and Signal Processing, Phoenix, AZ, USA.

² Bangor, A., Kortum, P.T., & Miller, J.T. (2008). An empirical evaluation of the system usability scale. *Intl. Journal of Human-Computer Interaction*, 24(6), 574-594.

³ Cox, RM (1997). Administration and Application of the APHAB. *The Hearing Journal*, 50(4), 32-48.

⁴ Cox, R.M., Alexander, G.C., & Xu, J. (2014). Development of the Device-Oriented Subjective Outcome Scale (DOSO). *Journal of the American Academy of Audiology*, 25(8), 727-736.