

Phonak Field Study News.

A 90-day journey into the performance of Phonak Audéo Life™

Phonak Audéo Life was put through a 90-day test trial on active participants through the Phonak Audiology Research Center (PARC) in order to assess real-world usage under harsh conditions.

Miller, A.F., December 2022

Key highlights

- Participants in this study shared stories of wearing hearing aids in water, around water, during exercise, and during other 'harsh' activities
- 95% of Audéo Life hearing aids passed electroacoustic testing at the 90 day mark, with 100% passing following replacement of the acoustic receiver.
- 95% of participants preferred the Phonak Charger Case Go™ for charging Audéo Life compared to the previous-generation Charger Case Combi.

Considerations for practice

- Audéo Life is a solution for individuals who want a robust hearing aid they can wear in or around water, while exercising, or in humid environments.
- Audéo Life provides additional protection from moisture. Care should be taken when wearers are in water as retention may become an issue.

Introduction

Audéo Life is a waterproof (up to 50 cm) and sweatproof receiver-in-canal (RIC) hearing aid introduced globally in May, 2022. Audéo Life boasts several key modifications to the housing and design which make it waterproof and sweatproof. These housing updates include:

- Audéo Life has 4 microphone ports to protect both microphones from the effects of direct water pressure.
- A pin-less receiver port means fewer points of entry in the housing for moisture to enter, with the added benefit of no tools needed to change a receiver, while using existing SDS 4.0 receivers.
- All seams and seals have been reinforced with silicone gaskets and beading to protect from water intrusion.
- Parylene (a plastic polymer coating) now encapsulates the internal circuitry. This material is often used to protect sensitive electronic equipment in hostile environments, like implantable medical devices and spacecraft.
- Audéo Life has no charging pins! It is the first Phonak hearing aid to utilize inductive charging, once again reducing the number of possible entry points for moisture in the hearing aids.

Virtually every behind-the-ear (BTE) hearing aid on the market has an assigned Ingress Protection Code, or IP rating. For Phonak RIC and BTE hearing aids, that number is IP68. The left number indicates how protected the hearing aid is from dust, and a /6/, the highest rating in that category, means the hearing aids survived 8-hours in a dust chamber with no ill effect on the hearing aid. The /8/ on the right means the hearing aids are water resistant, and survived immersion in 1 meter of water for 60 minutes and still functioned. One thing to keep in mind is that all of the tests for an IP rating are done with fresh water only. Audéo Life takes IP68 *further*, with repeated mechanical tests proving it can withstand not only fresh water, but also salt water, pool water, and even sweat. This is important, because salt and other chemicals change the physical properties of water, making it more damaging to electronics.

In addition to the laboratory testing of the housing, we wanted to understand how Audéo Life would perform when used by people who were active and would expose the hearing aids to harsh conditions. Furthermore, what would the participants in the study have to say regarding their experience using hearing aids around water? Although we do not generally recommend it, for this study participants were also asked to wear the hearing aids while showering and bathing.

The primary objective of this study was to confirm that for adults with mild to severe hearing loss, Phonak Audéo Life functioned as expected in terms of electroacoustic performance after three months of daily wearing compared to baseline hearing aid performance testing. Additional objectives for the study included understanding participant experiences using hearing aids while exercising, swimming, or doing other activities in or around water, and determining how confident participants felt wearing Audéo Life in a variety of harsh, real-world environments. The inductive charger (Phonak Charger Case Go) was also assessed regarding ease of use.

Methodology

Participants

Study participants consisted of 19 self-reported "active" participants. Seventeen of the participants were experienced hearing aid users and two were first-time hearing aid users. The ages of the participants ranged from 28 years-old to 86 years-old, with the mean age being 70 years. Participants were required to be within the mild to severe hearing loss range (N2-N4 per IEC 60118-15) (Bisgaard et al., 2010). Figure 1 shows the average audiograms of the participants.

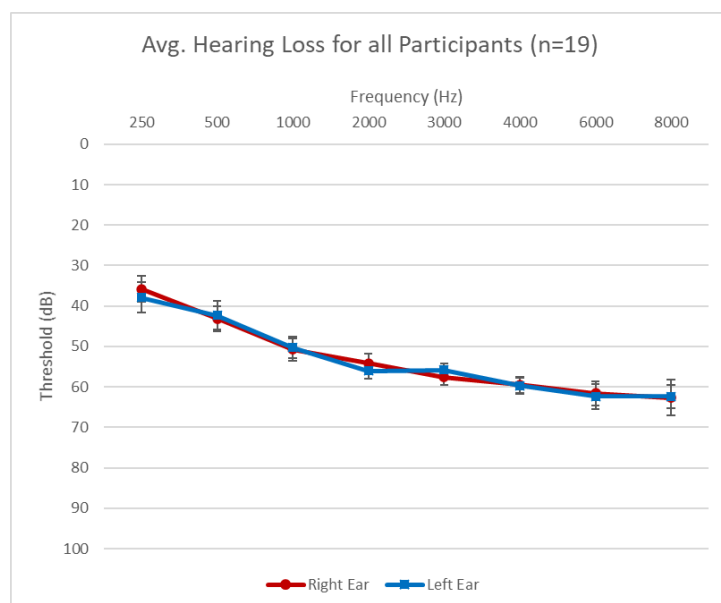


Figure 1. Average Audiogram of participants. Error bars indicate one Standard Error.

Equipment

Participants were fitted with Phonak Audéo Life (Audéo P-RL) rechargeable hearing aids with dome properties and receiver strength based on the recommendations from Phonak Target Fitting software. Participants were provided with the Phonak Charger Case Go: the compatible, portable, battery-powered induction charger. Additionally, the Charger Case Go does not require titanium posts on the

hearing aid to match precisely with a snug fit to the charging port on the charger, therefore it may be easier to insert and remove the hearing aids from the charger.

Procedure

The study consisted of three lab appointments, spaced 45 days apart, at PARC in Aurora, IL. Participants were encouraged to "use and abuse" the hearing aids by wearing them as much as possible, even in adverse conditions. Adverse conditions consisted of exercise, gardening, running, swimming, walking for exercise, water activities on a lake, and showering/bathing. The participants were also asked questions regarding the Charger Case Go and were given an assignment during one of the 45-day intervals to assess the charging capabilities of the on-board charger on the Charger Case Go. Performance of the hearing aids was measured three times. The first time was prior to the participant fitting at Visit 1 (baseline). The subsequent measurements were taken at Visit 2 and Visit 3. If the devices matched ANSI specifications, it was considered a 'pass'. If the devices did not pass ANSI specifications, the researcher was allowed to replace the CeruShield™ and re-test the device.

Clinical Investigation Plan	Visit 1 (Day 1)	Visit 2 (Day 45)	Visit 3 (Day 90)
Audiogram	x		
ANSI electroacoustic Text Box Measurements	x	x	x
Fitting of hearing aids, including feedback thresholds, pairing to cell phone	x		
Speech Mapping	x		
First Comments		x	x
In Lab comparison between Charger Case Go and the Charger Case Combi	x		
Review Homework: Charge aids with on-board charge for 4 consecutive nights		x	

Table 1. Clinical investigation plan showing the procedures carried out at each of the three clinical visits.

Results

As seen in Figure 2, 100% of the hearing aids passed the electroacoustic evaluation at Visit 2 (after 45-days of wear-time), and 95% passed the same testing after another 45 days of wear-time (90-days total wear-time). Two hearing aids failed the evaluation. These hearing aids were on the same participant, and a failed receiver was found to be the cause for both of the failures. Once the receiver was replaced, the devices resumed normal function. One device could not be tested at Visit 3 because the hearing aid was

lost when the subject dove into a lake (see the Discussion section for more on this).

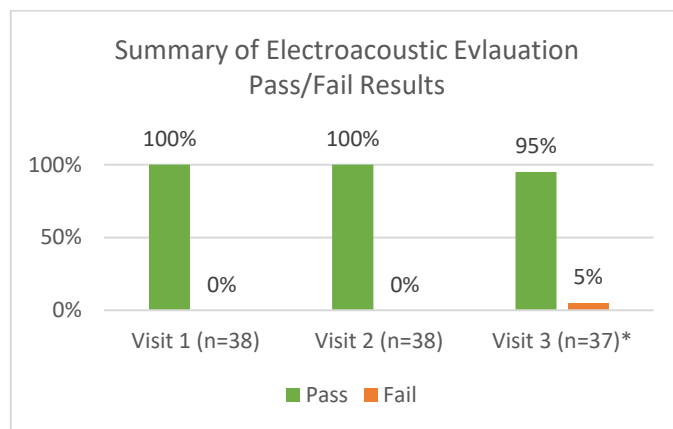


Figure 2. Summary of the electroacoustic evaluation tests per Visit. * There was one less hearing aid tested at Visit 3 than at Visit 2 due to hearing aid loss.

The results of the charger comparison show 18 out of 19 participants would choose the new Charger Case Go over the Charger Case Combi (which is used for other Phonak rechargeable hearing aids). Additionally, 100% of chargers passed the home trial test of using the on-board charge to charge the hearing aids for at least 3 consecutive charges. The first comments from the participants make it apparent that Phonak Audéo Life held up well for all activities mentioned.

Figure 3, below, summarizes the activities in which participants engaged during the course of the study.

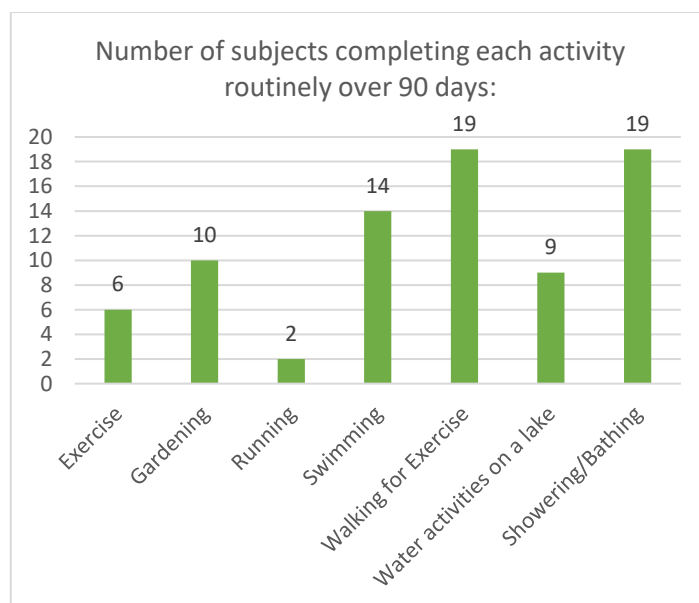


Figure 3. Activities conducted by participants. (n= 19 total participants).

The tables below provide selected comments from the participants for several adverse conditions where the hearing aids were worn.

First Comments: Hearing Aid Performance While Exercising or Sweating:
Wore while walking the dog; no issues at all. Heard great and enjoyed streaming. Very hot/humid outside and there was no issue with the performance of the aids, even when wet with sweat.
Worked great while bike riding and walking. Liked streaming pod casts while exercising.
Marathon runner. Ran during all training runs and the actual marathon. Devices worked great. Streaming was consistent and even when sweaty/wet the performance did not decline that he was aware of. Sounded great. Previously, took out hearing aids and put in earbuds but when they would get sweaty, music was crackly, and the buds were uncomfortable. These were fine.
Liked that the possibility of damaging the hearing aids with water/sweat was not an issue. It was great not to have to remember to remove them to shower or to do "sweaty" exercise.

Table 2. First Comments regarding hearing aid performance while exercising or sweating.

First Comments: Hearing Aid Performance While Showering or Bathing	
Positives	Negatives
14 participants indicated they enjoyed not having to worry about forgetting to take out devices.	The same 14 participants indicated that although it was reassuring, in the end they did not 'like' wearing devices in the shower. The reasons included: Ears felt 'gross/wet'; uncomfortable - water is LOUD; ear canals felt waterlogged after showering; was afraid of losing devices while washing hair; did not enjoy/ had to dry out ear canals after shower anyway so hearing aids came out after all.
Could hear small child when in the shower, which was nice because typically there is a small amount of concern that a cry would not be heard.	
Liked being able to hear while in the shower.	
Liked that the possibility of damaging the hearing aids with water/sweat was not an issue. It was great not to have to remember to remove them to shower or to do "sweaty" exercise.	

Table 3. First Comments regarding wearing the hearing instruments while showering and bathing.

First Comments: Hearing Aid Performance While Swimming/ Water Activities	
Positives	Negatives
People in her PT Swimming group were very curious about her wearing the aids in the water. Really liked being able to communicate more in the pool.	Dove into the lake with the devices in, and the next time he thought about them, he reached up and one was gone.
Wore in therapy pool. Was nice to converse with the other people in the pool and doing the water aerobics. Mentioned that she is usually not able to converse with others in the pool. Will be a 'shame' to go back to her own aids. She had no trouble hearing even when aids were wet. No "lag time" worked great.	
No issues at the pool. Felt it was nice to "hang with the young girls at the pool" and "hear all the gossip!" Felt part of the group and with own aids she would have had to take them out or worry that they would get wet. Also felt it was safer and was able to communicate.	Had to make sure the devices were still in ears occasionally.
Likes using in the water. She is part of a community w/ outdoor pool. Very social. Likes being in the water with the devices in. Can socialize in the pool and lounge on her pool noodle and visit. If she had her personal aids on, she would have to be ultra-careful to not get them wet. Others told her she was hearing much better. Performance was GREAT even with WET devices: she was surprised they wouldn't need to 'dry out' in order to hear from them.	

Table 4. First Comments regarding hearing aid performance while swimming/during water activities.

First Comments: Otherwise not captured by other Questions
Overall, she liked that she could completely FORGET about the hearing aids.
Felt so calm and less stressed. Really felt these are the best hearing aids she ever used in a study or ever. When asked "I that because of sound quality or the low stress of worrying about wearing them in pool, etc.?", participant answered "I think both."
Commented that he liked not having to THINK about the devices. Easy to wear. No problems with the pool and he could hear his kids/grandkids.
Performance of hearing aids stayed stable even with showering and exercising. No issues with performance at all. No crackling sounds.

Table 5. First Comments unrelated to other categories.

Discussion

This study's main objective was to learn from real people wearing Audéo Life for 90 days in active conditions, over the summer. The results shed light not only on that data, but also on the feelings of the novel enjoyment the participants

experienced while "using and abusing" these devices. The anecdotal comments from the tables above give a written summary; but to hear the excitement in the voices of the participants as they globally seemed to have re-found this joy at not having to worry about their hearing aids was exciting. Notwithstanding the positive outcomes, however, there were 2 hearing aids which did ultimately fail the electroacoustic evaluation at the 90 day appointment. Troubleshooting determined the receivers had failed on both devices (weak response). These two hearing aids were worn by the same participant, and prior to running the test, the CeruShield filters were replaced due to observable evidence of cerumen filling them. Once the receivers were replaced, the hearing aids returned to normal function. Additionally, one participant lost a hearing aid during a day boating on a lake. Regarding this particular participant, it is important to keep in mind that he was fit with the largest domes available and there was still hesitation regarding him leaving with the hearing aids due to the loose fit of the domes in his ear canals. Custom molds may have been the best option for retention.

Conclusion

The results of the study indicate favorable results for Audéo Life maintaining their performance after 90 days of use by active participants in harsh conditions. Additionally, most participants preferred the new Charger Case Go over the Charger Case Combi, and the preferred charger was able to pass the evaluations of our participants using the onboard battery to charge their hearing aids for at least 3 consecutive nights. The comments in Table 5 are exceptionally interesting and further studies may be helpful to determine the amount of anxiety reduction when wearing waterproof* Audéo Life hearing aids compared to traditional IP68-rated hearing aids. Additionally, it is unclear if abundant cerumen producers should be counseled regarding changing the CeruShield wax filters more frequently.

References

Bisgaard, N., Vlaming, M. S. M. G., & Dahlquist, M. (2010). Standard Audiograms for the IEC 60118-15 Measurement Procedure. *Trends in Amplification*, 14(2), 113-120.

* Up to 50 cm

Authors and investigators

Internal Investigator /Author

Anne F. Miller, Au.D.



Anne is a Research Audiologist with Sonova. She has been with Sonova since 2013 and previously worked in Phonak Technical support, Phonak Validations and has gained extensive pediatric and adult clinical experience during her positions at a variety of

large hospital systems and private practices.