

Genesis AI – Engineered From The Inside Out To Be Waterproof



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The all-new rechargeable Genesis AI product line was engineered from the inside out with the goal of creating a waterproof hearing aid. Our industry-leading improvements to the design assure reliability of the device throughout the entire product lifespan while our continuous dedication to quality and reliability ensures our products can withstand even the most rigorous environments.

Pro8 HydraShield™ technology for improved quality and reliability

Starkey hearing aids are medical-grade hearing healthcare devices that are built for superior sound quality and to encourage our hearing aid wearers to live a more active lifestyle. In addition, Starkey was the first in the industry to introduce on-ear sensors, coupled with health and wellness features that inspired an evolution in the benefit hearing aids could provide beyond aural rehabilitation.

The ability to track physical activity came with the responsibility to ensure the hearing aids can withstand the heat, sweat, and varied environments they are subjected to. While most hearing aids today are designed to withstand wear and tear associated with being in constant contact with the wearer's skin, in or around the ear, Starkey hearing aids continue to push the limits of the lifestyles the wearers maintain.

Since its introduction close to two decades ago, nanocoating technology has become a hearing aid industry standard that protects the device by acting as a first layer of defense from liquids, oils, and solids that may degrade the components of the hearing aids over time.

With Genesis AI, multiple ingress protection barriers were put in place for both standard and custom products to ensure reliability of the product throughout its lifespan.

Starkey's Pro8 HydraShield technology consists of an elaborate design and additional layers of protective barriers specifically targeting ingress and corrosion, offering additional protection in even the harshest environments.

What is Pro8 Hydrashield?

Pro8 Hydrashield is our proprietary approach to quality design improvements for our rechargeable products. Thorough testing was carried out to ensure Pro8 Hydrashield improvements protect our rechargeable devices from moisture ingress to make them waterproof.

The all-new Genesis AI RIC RT and mRIC R case design benefited from a ground-up re-imagination of quality design compared to our legacy RIC products. Moisture ingress to the battery is the largest concern with rechargeable products, therefore a completely encapsulated lithium-ion battery compartment was instituted, as well as silicone seals for the charging contacts. An Ethylene Propylene Diene Monomer (EPDM) compression seal was also added to the RIC receiver connection for an added layer of moisture ingress protection.

Due to their inherent differences in design, our custom rechargeable hearing aids and standard rechargeable hearing aids have slightly different waterproof* design elements. However, they both boast more robust circuit sealing, full sealing of case parts, enclosed lithium-ion batteries, internal and external protective coating, and hydrophobic and oleophobic protection of the microphone and receiver ports.

Testing above and beyond IP68

IP Rating

Ingress Protection (IP) ratings were developed by the International Electrotechnical Commission (IEC) in 1989 to provide a quality standard for classification of degrees of protection by electrical equipment at a rated voltage. The ratings grade the resistance of enclosure of an electronic device against the intrusion of dust or liquids and has been readily adopted by the hearing aid industry as a standard measure of quality.

The IP rating consists of two parts: the first number indicates the level of protection against solid objects, such as dirt or dust and the second number indicates the level of protection against liquids, like water and moisture. The highest IP rating that is applicable for hearing aids is IP68. The “6” means that the enclosure of the hearing aid body is completely protected from dust and the “8” means that the enclosure is watertight when submerged in liquids (usually at a depth of 1 m for over 30 minutes). This typically means that the device will continue to work when exposed to day-to-day wear such as the occasional splash of water, snow, rain, humidity, windblown dust, and so on.

All Genesis AI hearing aids received IP68 ratings, tested both internally and by an independent external laboratory. All Genesis AI hearing aids are submerged in liquid at a depth of 1 m for over 30 minutes for IPX8 (Fig. 1 & 2). For IP6X, the devices are tested in an air-tight dust chamber.¹

While the IP rating system defines criteria by which to test and achieve ratings for solid and liquid ingress protection, it does not provide guidelines as to what is considered truly “Waterproof”, thus leading to a need for additional testing beyond the IP68 specifications.

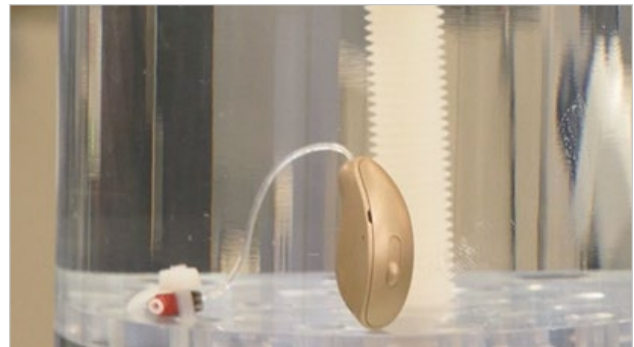


Figure 1: IPX8 test for mRIC R at a depth of 1 m for over 30 minutes.

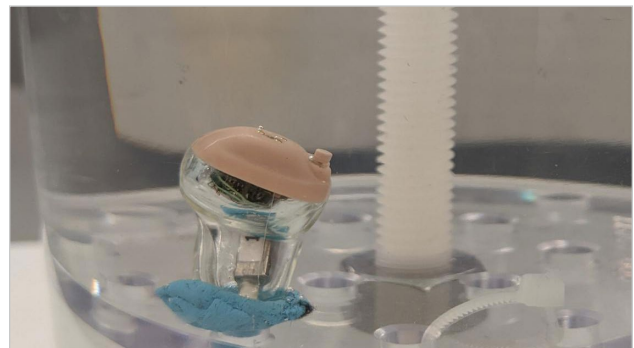


Figure 2: IPX8 test for ITC R at a depth of 1 m for over 30 minutes.

Starkey's dedication to quality and reliability

In addition to the IP68 standardized tests, Starkey standard and custom rechargeable hearing aids, are tested beyond what is required by the IP requirements.

Starkey rechargeable products are subjected to specialized tests to achieve waterproof* protection, and extended accelerated aging tests to ensure the devices are robust enough to withstand exposure and handling through the years the device is worn.

Hearing aids are subjected to an accelerated aging^{2,3} high humidity test in an environmental chamber at 95°F and 95% relative humidity for 21 days. The high humidity test simulates accelerated aging over the course of 5 years. All Genesis AI rechargeable products pass the high humidity test, continuing to function up to specifications.

To simulate liquids with high salt concentration like sweat, chlorinated water, and humid environments, hearing aids are tested in a highly corrosive environment with salt spray for 48 hours⁴. All Genesis AI products pass the Salt Mist test and continue to function up to specifications following the test.

Additionally, due to the customization carried out during the production of our custom rechargeable products, standard processes are in place for every custom build. Due to this, all initial custom build processes are analyzed through a quality check performed with the custom aids submerged in water and analyzed for moisture ingress.

Extended reliability tests

The standard Genesis AI products underwent a series of extended reliability tests in addition to the tests described above. These tests replicate difficult environments hearing aids face in the real world and validate that Starkey hearing aids will not only survive varied states of moisture conditions in the short term, but will continue to function as expected for the lifetime** of the device. For these additional tests, powered hearing aids are subjected to real-life handling, such as intermittent automated switch activation (user control short press), and charge cycles while in the environmental test chambers. During the tests, the battery voltage is continuously monitored wirelessly to observe for anomalies.

High Humidity +

Hearing aids are heavily exposed to the presence of moisture and humidity due to their location in the ear canal or over and behind the ear. The extended reliability test in a High-Humidity chamber exposes hearing aids to 95% relative humidity and at 95° F. The accelerated aging test parameters were calculated using the Arrhenius Peck equation (*Equation 1*) to simulate 5 years real-life use.

Twenty-two Genesis AI RIC RT and twenty-two Genesis AI mRIC R devices were subjected to 365 insertion/removal cycles on the charger and 182 switch presses per test run. Each test run is the full battery life cycle; 51 hours for RIC RT and 41 hours for the mRIC R. Based on the Arrhenius equation, the Genesis AI RIC RT devices were tested through 10 full test runs and Genesis AI mRIC R devices were tested through 13 full test runs. All devices continued to perform with no deviation in battery life. Also, not only did battery life continue to outperform industry standards, 100% of the devices tested passed all the post-test functional performance specifications evaluation after each and all test runs.

$$\text{Acceleration factor} = \left[\frac{\text{Humidity}_{\text{low}}}{\text{Humidity}_{\text{high}}} \right]^{-2.66} \times \left[e^{\left(\frac{E_a}{K} \right) \left(\frac{1}{T_1} - \frac{1}{T_2} \right)} \right]$$

Equation 1: Arrhenius Peck equation used in accelerated aging tests

Salt Mist (Salt Fog) +

Starkey was the first in the industry to introduce fitness and activity tracking on-board the hearing aid to encourage hearing aid users to lead an active lifestyle. The Salt Mist chamber used to test the hearing aids simulates highly corrosive conditions that could be attributed to an active lifestyle through the years the devices are worn. Powered hearing aids were subjected to similar switch activation and insertion/removal cycles on chargers, like in the High Humidity + test.

Each test run in the Salt Mist chamber was the full battery cycle for each style: 51 hours for the RIC RT and 41 hours for the mRIC R, and the battery voltage was continuously monitored wirelessly to look for any anomalies in battery life. Both the Genesis AI RIC RT devices and the Genesis AI mRIC R devices were subjected to 5 continuous test runs and were evaluated after each run. Twenty-two Genesis AI RIC RT devices and twenty-two Genesis AI mRIC R devices were tested with 100% pass rate with no deviation in battery life for either style. Also, all devices tested passed the post-test functional performance specifications evaluation after all test runs.

Specialized corrosion and ingress stress test

Starkey hearing aids are also subjected to a battery of tests to stress various parts of the hearing aid, so that potential weaknesses and failures can be investigated and improved upon. Corrosion and ingress stress tests are targeted, short-term aggressive tests to ensure the ability to test the design to failure so that comparisons and continuous refinements can be made to improve product quality.

In some of these tests, the hearing aids were evaluated without the nanocoating applied to understand the worst-case scenario if this first layer of defense is breached as is often the case after years of use.

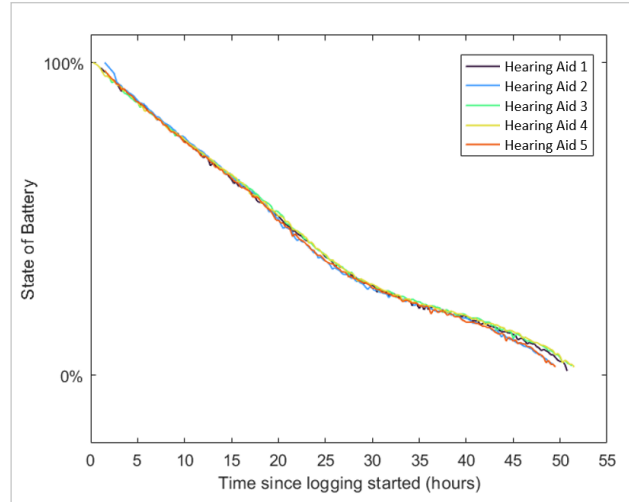


Figure 3: Results of the targeted sweat drip test showing 5 Starkey Genesis AI hearing aids achieving 100% pass rate with no failures.

Targeted Sweat Drip Test

In the targeted sweat drip test, standard hearing aids without nanocoating protection are oriented in a variety of positions to simulate different handling situations and use cases to expose each of the potential ingress seams, while an artificial sweat solution is dripped onto the hearing aid every second continuously throughout the day (Fig. 2). The hearing aid's battery voltage is monitored during the process to catch any abnormalities or defects in the system. Starkey's Genesis AI hearing aids achieved a 100% pass rate with no failures on its full charge cycle of over 50 hours.** (Fig. 3)

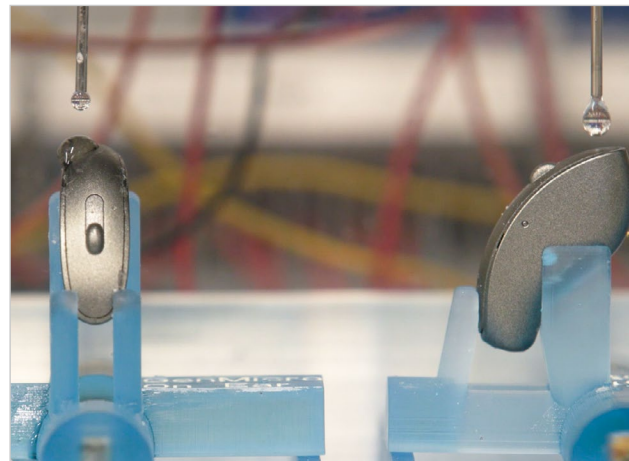


Figure 2: Targeted sweat drip test with artificial sweat solution dripped onto hearing aid continuously throughout the day.

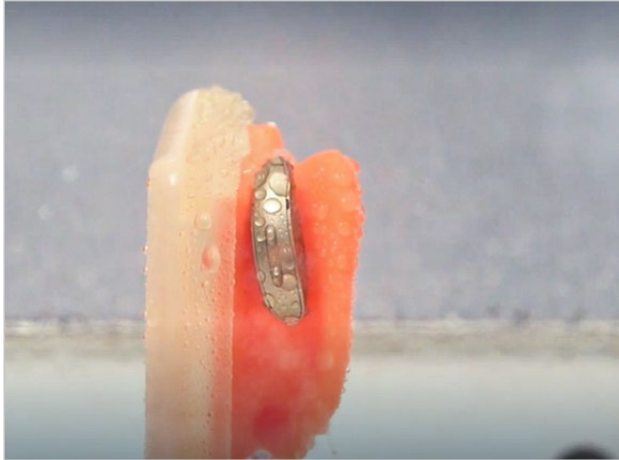


Figure 4: Rain Spray test to simulate hearing aid being exposed to a rain shower.

Rain Spray Test

The Rain Spray test simulates rain shower on a hearing aid as it is worn on the ear (*Fig. 4*). This is a novel test with ten rotating nozzle heads that spray water continuously as it moves in a 180° arch around the artificial ear and hearing aid setup. The hearing aid's acoustic response to specific input tones is analyzed in real-time as a measure of device functionality. Additionally, after the device is removed from the Rain Spray test chamber, the device is analyzed further for acoustic, wireless, switch (user control), and charging performance. All devices tested had a 100% pass rate in the post Rain Spray chamber battery of tests, continuing to function up to specification requirements.

Salt Brine Immersion

This test focuses on isolating different ingress paths of Starkey Genesis AI RIC hearing aids, such as charge contacts, that are susceptible to failure when exposed to sweat and humidity after prolonged use. Genesis AI hearing aids are immersed in a salt brine solution for one hour. Moisture sensitive indicators are carefully positioned in the targeted areas inside the hearing aid during the build process to monitor for any moisture ingress. The devices tested showed no signs of ingress in the targeted areas after being immersed in a salt brine solution.

Sub-assembly Immersion

While the external housing of the device provides the first layer of defense, Starkey developed novel tests to isolate and evaluate the robustness of different sub-systems and circuit components. Genesis AI RIC hearing aids have added layers of silicone seals and gaskets to further protect the interior components should the external layers of protection be breached. To test these improvements, the external housing of the device is removed while the spine and circuitry are immersed in an artificial sweat solution. With the new Pro8 Hydrashield technology, the device's battery life lasted longer in the artificial sweat solution compared to control devices without the design improvements (*Fig 5*).

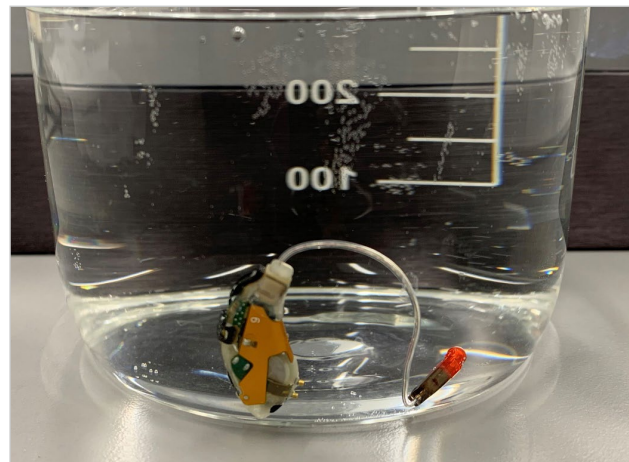


Figure 5: Sub-assembly of a Genesis AI RIC device immersed in an artificial sweat solution.

Waterproof,* but not invincible

Despite innovative strides to make hearing aids 100% impervious to intrusion, the reality is that hearing aids will always be subjected to some level of environmental damage. This is largely because hearing aids consist of multiple functioning parts, like the receiver, that are exposed to slightly different conditions (e.g., moisture and wax in the ear canal versus showers or debris on the body of the hearing aid). The best way to support the lifespan of a hearing aid is to encourage patients to practice good maintenance such as:

1. Wiping down hearing aids with a clean, dry cloth
2. Using a dehumidifier for excess moisture exposure or after immersion
3. Regularly using a brush to clean the receiver
4. Changing the wax guard as needed

We do not recommend activities like swimming or showering with the devices, mostly due to comfort and retention of the devices for the user. Genesis AI rechargeable standard hearing aids were designed and engineered from the inside out to be waterproof* to whatever life may bring: heavy perspiration, falling into a body of water, getting stuck in a rain shower without an umbrella, or simply residing in a humid environment.

Conclusion

Starkey's Genesis AI hearing aids provide unprecedented waterproof* protection to both standard and custom rechargeable devices. Our rigorous battery of tests exceeds the IP68 requirements for maximum durability and reliability for any lifestyle. Starkey's continued dedication to quality and reliability remains a top priority to continue helping patients hear better and live better for years to come.

References

1. IEC 60529, Degrees of protection provided by enclosures (IP Code)
2. ASTM F1980, Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
3. IEC 60068-2-78 ,Environmental Testing: Damp heat, steady state
4. MIL-STD-810, Method 509.5, Salt Fog

Author Biography



Ganesh Borra, M.S. is the Director of Mechanical R&D Engineering at Starkey. Ganesh leads the team that designs, develops and tests the mechanical and electro-mechanical systems, sub-systems, and components for all Starkey hearing aids. This includes developing new industrial designs and formulating novel test methods tailored to ever-changing customer and market needs. Ganesh has over 12 patents across complex electro-mechanical systems, hardware firmware integration, autonomous machines, mechanical assemblies, and design methods.

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* Up to 1 m

** Lifetime is estimated by five years of use

*** 51 hours for Genesis AI RIC RT and 41 hours for Genesis AI mRIC R

