ENVIRONMENTAL HEARING INSTRUMENT PROTECTION THE ISOLATE™ NANOTECH WAY

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Abstract

Hearing instruments spend most of their service life under environmental conditions which are quite hostile for electronics. The results of this exposure range from reduced performance to complete functional breakdowns. The recent use of advanced protection technologies has addressed a number of known environmental aggressors, such as aggressive substances, temperature changes and moist environments. The introduction of nanocoating technologies together with traditional protection methods has proven effective and has added reliability and performance consistency, as well as reducing repair and service frequency. This paper discusses the challenges posed by the environmental operating conditions of hearing instruments and how they are addressed by protective technologies such as iSolate nanotech. Qualification of hearing instrument reliability via environmental testing, including the IP test system, is also discussed.

Good product design takes into account the conditions under which the product will operate. For example, an ordinary wristwatch does not have to be waterproof, as it is not intended to be used underwater. In contrast, it is critical that a diver's watch does not allow water to enter the case at water depths in which the watch will be worn. Protection of the delicate watch mechanism during immersion must be built into the design for the diver's watch, but not for the ordinary watch.

Hearing instruments are also used in conditions that would be damaging for the sensitive electronics that they contain, and their design should take this into account. ReSound understands the importance of robust hearing instrument performance and has developed protective technologies.

THE LIFE OF A HEARING INSTRUMENT

Hearing instruments must consistently work while in close proximity to the human body. This is especially challenging for delicate electronic instruments. Factors such as temperature, environmental humidity, exposure to perspiration, cerumen, particulates, greases and oils, and grooming products can all have significant impact on hearing instrument performance. In addition, exposure to bacteria and fungi can pose a health threat, as conditions for them to grow on hearing aid surfaces are favorable. Table 1 summarizes some of these conditions and what the consequences can be for hearing instrument performance.

Table 1

Exposure	Possible consequence for hearing instrument
Temperature changes combined with humidity (water vapor)	Condensation resulting in short-circuits and migration
Moisture from bathing, precipitation, etc	Short-circuits, battery failure, battery leakage
Salt deposits due to dried perspiration	Short-circuits, when salts are re-wetted
Cerumen and dead skin in ear canal	Blockage of microphone and receiver, discoloration and brittleness of hearing instrument materials
Microbes	Can multiply on instrument leading to cross-contamination
Solvents (hair products, cleaners, perfumes, etc) on surface or inside instrument	Tension cracks, denaturing and discoloration of surfaces, blockage of microphone and receiver, short-circuits

The presence of moisture in hearing instruments is particularly serious, as it interacts with other factors. For example, although hearing instruments most often will be operating in an environment near 37 degrees C (98 degrees F), ambient temperature variations still occur when the user removes their hearing instruments or enters an environment with an extreme temperature change. Combined with humid ambient air, such temperature variations can cause condensation inside the hearing instrument. This means that the electronic components, battery and contact points get wet, ultimately leading to corrosion and device failures.

Figure 1: Condensation and conductive sediments can make up an electrolyte solution that under a DC voltage can lead to formation of a conductive path. Known as electro-migration, this process can lead to short-circuits or current leakage. The photo shows the migration of copper on a printed circuit board.

The Zinc-Air batteries necessary to power hearing instruments today pose their own challenges for long-term performance. For one thing, this type of battery requires a supply of oxygen in order to operate, so any condition that prevents this supply, such as moisture covering the oxygen inlets, will shut down the hearing instrument. Battery performance can also vary with humidity and temperature changes. Zinc-Air batteries can also leak. The leakage typically happens after usage if the battery is exposed to deep discharge or the battery has been exposed to liquids from an external source, such as rainwater or sweat.
The main effect is expansion and/or leakage of the alkaline electrolyte of the battery into the battery compartment of the hearing instrument. The electrolyte, an aqueous solution of potassium hydroxide, is a very good conductor which will wreak havoc once it comes into contact with a conducting surface such as the battery contacts. As with perspiration, once dried up, it will leave behind a residue that can be re-activated as a conductor if exposed to moisture. The leakage may also lead to a short circuiting of the battery with a complete loss of functionality or the aforementioned liquids blocks the battery air ventilation holes, thereby hindering the normal functioning of the battery.

PROTECTING THE HEARING AID

The conventional approach to protecting hearing instruments from environmental exposure has been to seek out areas and/or spots where visible damage occurred and coat with a suitable material. The rationale for this approach is that by encapsulating the problem point, the area would be protected. Certain areas, such as all electrical contacts for the battery springs and contacts for audio or programming inputs, could not be encapsulated. These metallic surfaces had to be protected by depositing another, less corrosion-sensitive metal, such as gold, to protect from corrosion.

The usage of conformal coatings for encapsulation of critical components, such as the integrated circuits, is critical and necessary for the functioning of these circuits. Apart from protecting from aggressive substances, the coating also shields the integrated circuit from light, an exposure that could disturb the functioning of the circuit. Figure 2 shows an example of such a coating that protects the integrated circuit (IC) on a printed circuit board.

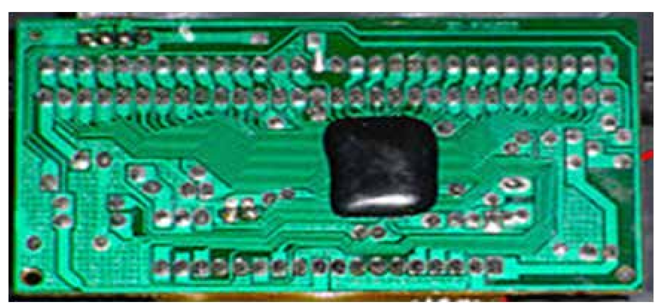


Figure 2: Printed circuit board with glob-top protected IC

Because these coating materials often are epoxy-based, they can potentially introduce other problems such as free ions, which can damage the delicate workings of the IC. In addition, such materials cannot be used on surfaces where it is desired to establish electrical contact.

Materials other than those that are epoxy-based continue to be used for protection of targeted components. The protective materials include an assortment of waxes, lacquers, and silicones. Like the epoxy-based materials, these coatings are not conductive and thus cannot be used in places where electrical contacts are necessary.

Metallic surfaces, such as contact points (battery contacts, DAI & programming contacts) have traditionally been protected against corrosion by applying a non-corrosive metallic protection layer, typically gold. A reasonably thick layer with no pinhole openings is necessary to obtain sustained protection.

The mechanical design of the hearing instrument itself is also an important way of hindering or delaying the ingress of particulates and liquids that can interfere with the functioning of the device or be the cause of a long-term reliability problem. Adding acoustically transparent filters to transducer openings is an obvious part of this approach.

A DIFFERENT APPROACH TO PROTECTION

The emergence of nanocoating technologies has completely changed the way we think of coating and protection of hearing instruments. No longer is such protection limited to targeted areas. By applying a coat that will act globally and enter every cavity and add to every surface - internally as well as externally - we obtain an added layer of protection.

Does nanocoating make other forms of protection obsolete? The answer is that some degree of local and partial protective coatings will still be used, but only where the combined effect is beneficial or where there is a specialized need, such as protecting the integrated circuits.

NANOCOATING – WHAT IS IT?

"Nano" is the standard metric prefix referring to 10^{-9}. It is used in conjunction with various technologies that deal with the study of controlling matter on an atomic and molecular scale.

Generally, nanotechnology deals with structures that are 100 nanometers or smaller in size in at least one dimension, and involves developing materials or devices within that size range. Good examples of nanotechnologies are integrated circuits, which currently are on the order of 45 nanometers in feature size (smallest dimension of a transistor), micro-mechanics and nanocoatings.

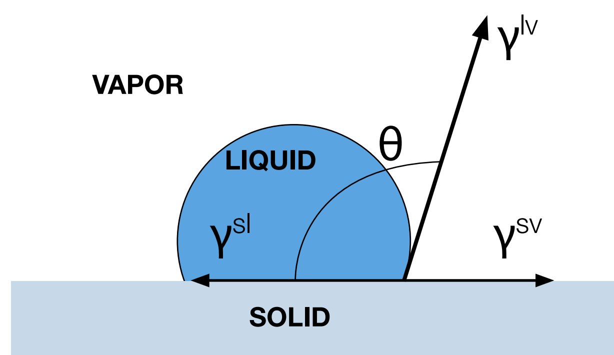
The thickness of the nanocoating protecting layer used by ReSound is typically in the range 60 - 80 nanometers. This corresponds to 1/1000 of the thickness of an average human hair. One nanometer equals 1×10^{-9}m or 1 billionth of a meter.

HOW DOES NANOCOATING PROTECT THE HEARING INSTRUMENT?

To understand how nanocoating works we have to introduce the term "contact angle". Consider a liquid droplet at rest on a flat, solid surface. A cross-sectional view of the droplet is given below. Its shape is characteristically lenticular (lentil shaped). The angle θ formed by the solid surface and the tangent line to the upper surface at the end point is called the contact angle. The contact angle is a result of the interface/ surface tensions (surface free energies) between liquid and solid surrounded by vapor, and is measured according to the Young's equation given below:

Young's Equation

$$\gamma^{sv} = \gamma^{sl} + \gamma^{lv} \cos\theta$$



θ is the contact angle

γ^{sl} is the solid/liquid interfacial free energy

γ^{sv} is the solid surface free energy

γ^{lv} is the liquid surface free energy

Figure 3: Young's equation describes the contact angle, an indication how hydrophobic the surface is.

Increasing the contact angle will make the water droplet bead up more; decreasing the contact angle will cause the droplet to spread out and eventually, when the angle becomes 0 degrees, the water droplet will adhere completely to the host material.

Two other important terms we need to introduce at this point are “wetting” and ”wettability”. The latter term is defined as the degree to which a solid will wet, meaning that the liquid will maintain contact with the solid. If a drop spreads out indefinitely, then the contact angle approaches 0 degrees, and total wetting occurs. The implications of wetting of a solid, such as contact points, and solder points on electronic components, are significant. Corrosion, migration, and short circuiting are a few of the consequences. Increasing the contact angle as much as possible will seriously reduce the surface wetting and thus the related problems.

By nanocoating a surface you greatly increase the contact angle over the contact angle of the base material, thereby facilitating beading of liquids and reducing wetting. When serious beading occurs, the droplets will either roll of the surface or they can be easily removed.

Contact angles obtained by ReSound iSolate nanotech typically run in the 120 –130 degree range. This is considered to be highly hydrophobic. A hydrophobic surface is defined as a surface that will form a droplet with a contact angle greater than 100 degrees.

When hearing instruments – including all internal components – are nanocoated, any liquid resulting from condensation or introduced from outside beads up and rolls away. Figure 4 illustrates this protection mechanism with a nanocoated hearing instrument microphone.

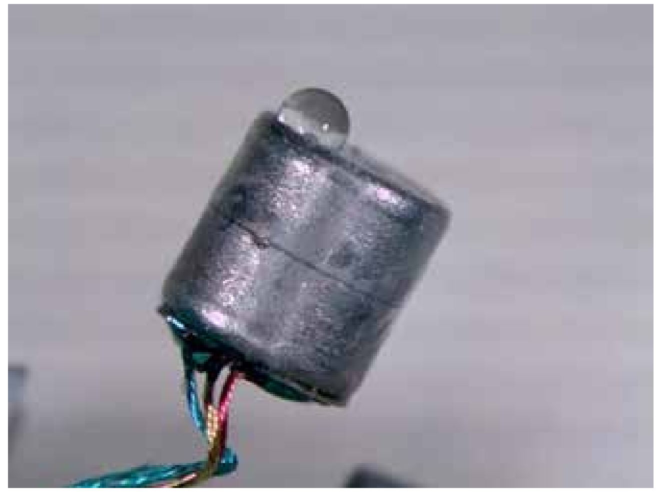


Figure 4: Nanocoated microphone unit with beaded water droplet.

The increased contact angle resulting from the nanocoating process also gives improved protection against other substances such oils and waxes, referred to as “oleophobicity”. This mechanism is important in relation to protecting a hearing instrument from the effects of cerumen as well as making it difficult for fingerprints and other particulates to adhere to the outer surfaces of a hearing instrument.

HOW IS NANOCOATING APPLIED?

The iSolate nanotech coating process is done by applying a plasma (electrically charged monomer molecules) under vacuum conditions to finished hearing instruments. Doing this under vacuum conditions allows for the coating material to enter the hearing instrument, thereby coating every exterior as well as interior surface. When the electrically charged monomer molecules attach to the surface of the various materials in the hearing instrument, they chemically combine with each other and form a polymer film. This polymer film is molecularly bound to the host surface making the coating inseparable from the host surface. The thickness of this polymer film is 60 -80 nanometers.

Compared to prior art of coating, nanocoating brings with it the advantage of coating areas of the hearing instrument that were not possible before. This is truly a process that brings coating from being targeted to global protection.

Specialized manufacturing equipment is used to provide hearing instruments with the iSolate nanotech nanocoating. The central component of the manufacturing equipment is the processing chamber (Figure 5) which will hold a number of hearing instruments in a custom designed fixture for simultaneous processing. The processing chamber has an integral electrical coil that will subject small organic molecules (the monomer gas) to an ionizing electrical field under low pressure conditions thereby creating the plasma. The entire process is referred to as Plasma Deposition.

Figure 5: Hearing instruments mounted in fixture being loaded into the processing chamber.

HEARING INSTRUMENT ENVIRONMENTAL TESTING

To ensure robust long-term performance, it is necessary to include qualification testing as part of hearing instrument design. This type of testing serves to verify the protective properties of the various protective measures applied to the hearing instruments, as well as to identify any weak product points which can be improved. ReSound performs a thorough protocol of environmental tests. Some of these tests are in accordance with international standards, while others are specific proprietary measures designed to address previously mentioned areas of concern. Replication of the various conditions to which hearing instruments are exposed and accelerating the impact of these exposures is a primary goal. Ideally, it would be a time limited test that would emulate the exposures experienced by the hearing instrument over its useful lifetime. Such a test - the ReSound AST (Accelerated Screen Testing) – is a 5-week process that yields results that are predictive of long-term performance of the hearing instrument. The following tests from the AST are of particular interest when evaluating the efficacy of the Isolate™ NanoTech coating:

- Salt Mist and Humidity (IEC60068-2-11 & IEC60068-2-3)
- Temperature Cycling (IEC60068-2-4)
- Damp Heat, Cyclic (IEC60068-2-30)

Checking the hearing instrument performance at regular intervals during the AST testing and inspecting for impact of the various exposure from the testing is an important part of quality assurance. As mentioned earlier, looking for signs of corrosion, migration, blockage of sound inlets (microphone ports) and build-up of debris, is a crucial part of the verification process.

Figure 6 shows the difference in debris build-up on the microphone inlet screen for non-nanocoated (left) vs. nanocoated (right) devices that went through the AST test.

The AST test is designed to give an indication of the lifetime performance of the hearing instrument and point out potential areas of trouble that should be addressed in the design. Other tests of importance for hearing instruments include testing for biocompatibility (ISO 10993) and toxicity to ensure that nanocoated hearing instruments can be worn next to the skin without causing irritation or allergic reactions. The iSolate nanotech coating technology is in compliance with the RoHS (Restriction of Hazardous Substances) directive.

Nanocoating may also play an important role in reducing the growth of microbes on hearing instrument surfaces. The very nature of the technology will render the hearing instrument surface an unfriendly host for microbes.

A further benefit could be that the hearing instrument itself will retain its appealing cosmetic appearance for a longer period. Maintaining and caring for the hearing instrument is easier and less time-consuming, which can ultimately contribute to increased end user satisfaction.

IP RATINGS AND HEARING INSTRUMENTS

As discussed, moisture and humidity can have severe effects on hearing instrument performance, and manufacturers continually look for ways to qualify and prove the ability of their products to withstand this type of exposure. To this end, it has become common in the hearing instrument industry for manufacturers to report “ratings” for Ingress Protection (IP) for their products. Use of these ratings was first introduced in the hearing instrument industry by a manufacturer that introduced a fully-sealed waterproof hearing instrument. Existing tests for hearing instruments did not meet the need to ensure a waterproof device, forcing the manufacturer to look outside the industry for a more suitable test to prove the value of the new design. The IEC60529 IP test system is intended to rate the degree of protection provided by enclosures for electrical equipment under normal conditions of use. Today, this system is used by many hearing instrument manufacturers to suggest the robustness of both new and existing products to the effects of exposure to dust and water. Although the test conditions do not resemble the real working conditions of a hearing instrument, the IEC60529 standard does guarantee that test conditions will be documented, consistent and reproducible. Although this allows comparison across different products which are tested according to the standard, it is of interest to consider whether it provides information regarding long-term performance as implied by information provided to consumers and hearing care professionals.

WHAT ARE IP RATINGS?

IEC60529 specifies “degrees of protection provided by enclosures”, hereafter referred to as IP codes. The term IP itself is an abbreviation of Ingress Protection. This is a measure of the degree of protection against ingress of solid foreign objects or water into the equipment, but also the degree of protection of persons against access to hazardous parts inside the enclosure. This way of describing the intent of the IP coding implies that the equipment should be functioning and be in a normal condition of use when testing of the equipment takes place according to the test procedures and conditions defined in the standard.

The IP testing procedures are designed to give a snapshot of the designed enclosure’s ability to withstand certain exposures, as defined in the IEC 60529 standard, but will not give any indication of long-term effects from the exposures. Thus an IP test does not predict future reliability and performance of the tested device, in this case the hearing instrument.

The IP code is described as IPXX, where the first X (number) refers to protection against solid objects and the second X (number) is against water. The protection test levels are as indicated in table 2 on the next page.

IP (1st)	Meaning for Protection of Equipment Against Solid Objects	Tested by	Meaning for Protected Against Access to Hazardous Parts)	IP (2nd)	Protection Against Water with Harmful Effects	Tested by	Meaning for Protection from water
0	No Protection	None	No protection	0	No protection	None	None
1	Solid objects 50 mm	50mm dia. Sphere applied with 50N force	Accidental touch by back of hand	1	Vertically Dripping	Drip box for 10 min.	Falling drops of water, condensation
2	Solid objects 12.5mm	12.5mm dia. sphere applied with 3N force	Accidental touch by fingers	2	Dripping – 15° tilted	Drip box, 2.5 min. per side	Direct light streams of water up to 15° from the vertical
3	Solid objects 2.5mm	2.5mm dia. Steel rod applied with 3N force	Accidental touch by tool	3	Spraying	Oscillating tube ± 60°, 10 min., 10l/min.	Direct sprays of water, up to 60° from the vertical
4	Solid objects 1mm	1mm dia. Steel wire applied with 1N force	Accidental touch by small wire	4	Splashing	Oscillating tube ± 180°, 10 min., 10l/min.	Water sprayed from all directions, limited ingress
5	Dust-protected (limited ingress, no harmful deposit)	Dust chamber with or without underpressure	Accidental touch by small wire	5	Jetting	6.3mm dia. Nozzle from 2.5 to 3m distances, 12.5l/m for 3 min.	Low pressure water jets from all directions, limited ingress
6	Dust-tight (totally protected against dust)	Dust chamber with under-pressure	Accidental touch by small wire	6	Powerful jetting	12.5mm dia. Nozzle from 2.5 to 3 m distance, 100l/ min. for 3 min.	Strong jets of water, limited ingress
				7	Temporary immersion	Immersed in tank with water 0.15m above top and 1m above bottom. For 30 min.	Protected against the effects of temporary immersion in water
				8	Continuous immersion	Water-level and time as specified by manufacturer	Protected against the effects of continuous immersion in water

Table 2: Ingress Protection test levels according to IEC60529

TESTING ACCORDING TO THE IP STANDARD

Fully-sealed hearing instruments are tested according to an IP68 test code level, indicating – according to the table above – that pass criteria would be no dust and no water entering the hearing instrument. The exposures are made up of talcum particles, emulating dust and clean water. Obviously these exposures do not represent real life exposures; however, they are well-defined for repetitious testing. Testing is predominantly done by 3rd party independent test laboratories.

Test results are presented in a report that states findings and observations as to whether the device under test met the intended criteria for the test. In the IP68 case, the criteria would be no dust (talcum) and no water inside the hearing instrument. Test laboratories perform the tests and report observations, but do not grant IP ratings or issue certifications for the tested device. The requestor, in this case the hearing instrument manufacturer, can state that an IPXX test has been performed, that the tested device met the test criteria, and that the tested device performed according to the design intent for the device.

As previously mentioned, it has become common practice in the hearing instrument industry to test and qualify both new and existing hearing instrument designs using the IP test code system. Most designs have been tested using the IP57 test requirement, which allows for limited ingress of dust and water, as long as it does not interfere with the normal functioning of the device. The interpretation of results from such IP57 tests have led to a variety of "rating" and "certification" claims from hearing instrument manufactures. It should be noted that these are not supported by the 3rd party test laboratories nor is this practice consistent with the intent of the IEC60529 standard.

NANOCOATING AND IP RATINGS

With the widespread reporting of IP test results, it is of interest to know how nanocoated ReSound hearing instruments perform when tested according to an IP57 test. Because ReSound hearing instruments are not a fully sealed waterproof design, a certain amount of dust and water is expected to enter the device during test.

The dust test (IP5X) leaves traces of dust inside the instrument, but it does not interfere with the functioning of the instrument. During the immersion test (IPX7), water does enter the hearing instrument and does interfere with the functioning of the instrument during the test. This is mainly due to the fact that the functioning of the Zinc-Air battery is obstructed, as the air supply to the battery is cut off due to the immersion in water. In addition, the hearing instrument transducers are blocked by the water during immersion, and will not be able to receive or emit sound.

Following the tests, the hearing instruments have been inspected, a new battery has been inserted and the instruments were found to operate normally. The conclusion that can be drawn from these tests is that the nanocoat protection that has been applied to all exterior and in particular all internal parts does protect all critical parts to such a degree that normal functioning will resume once a functioning power source (a new battery) is inserted. This kind of performance is at least on par with other manufacturer's products that have undergone the IP57 test. In other words, passing the IP57 test suggests that if you accidently drop your hearing instrument in the bathtub once, you should expect it to work once you replace the battery. It does not indicate that the hearing instrument will continue to function if you regularly drop it in the bathtub. The additional environmental tests described earlier show how iSolate nanotech also provides long-term protection from exposures.

RELEVANCE OF IP TESTS FOR HEARING INSTRUMENTS

For any hearing instrument manufacturer using the IP test system to qualify their products, it is relevant to question the validity of claiming that the hearing instrument meets the IP test result pass criteria when the device did not function during the test. In fact, testing according to IP57 is inappropriate, as the test conditions are not suitable for its intended use (submersion into water) and the claimed degree of protection is not maintained under normal conditions of use (operational while submerged). As all hearing instrument manufacturers are using Zinc-Air batteries, this conclusion would apply to all hearing instruments, even those that are fully sealed and have been tested according to the IP68 test code.

The more important point here is to provide hearing instruments to end-users that will perform under all real life conditions (diving is not one of these scenarios) and continue to do so over its projected lifetime.

Although testing according to the IP test system is of limited value for qualifying long-term robustness of hearing instruments, consistency with hearing industry practice has led ReSound to conduct IP57 tests on all products. This not only accommodates certain commercial requirements to have performed such a test, but also allows hearing care professionals to compare results across manufacturers. Results for all ReSound hearing instruments have been as reported above: the hearing instrument performs as intended with a fresh battery inserted following the test.

ReSound continues to place high emphasis on environmental testing to ensure long-term product robustness. Not only does the IP testing system not represent real-life conditions, it also lacks the long-term predictive element that would indicate how reliable the hearing instrument would be over its lifetime.

SUMMARY

The use of nanocoating brings with it significant benefits for the hearing instrument user. Nanocoating has become an integral part of the hearing instrument design, but cannot stand alone in the defense against the environmental aggressors. The optimum way to ensure long-term functioning of hearing instruments involves a multifaceted line of defense: mechanical design techniques, conformal coatings for critical components, precious metals for contact points, suitable lacquers for conducting traces and passive components on PCBs and hybrids, always with a globally added layer of nanocoating.

Known issues related to the environmental operating conditions of hearing instruments are successfully addressed with the application of iSolate nanotech coating technology, thereby affording the hearing instrument user the greatest opportunity for improved reliability.

Comprehensive reliability testing that emulates real-life conditions is critical to ensure that full performance of the hearing instrument will be present for the lifetime of the product.

Testing according to the IEC60529 IP code system has been introduced to the hearing instrument industry; because it is a test system intended for the electrical equipment industry and delivers only a snapshot of a device's performance, it does not add valuable information on long-term reliability of hearing instruments. Contrary to popular belief, the IP code system is not a protection system, but merely a way of testing a given hearing instrument design under adverse and unrealistic (for hearing instruments) conditions. ReSound does conduct IP57 code testing to accommodate market requests for competitive comparison, and to be consistent with what has become industry practice.

Hearing instrument design at ReSound focuses on coping with the real-life exposures that its users will experience to maintain full performance over the hearing instrument's lifetime. To package this robust performance into small and cosmetically appealing instruments is a top priority for the design group at ReSound.

REFERENCES

1. IEC60529; Degrees of protection provided by enclosures (IP Code); Edition 2; 1989 consolidated with amendment 1: 1999

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