



Advanced Bionics Technology and Reliability Report 2011

Advanced Bionics is committed to providing superior and reliable cochlear implant systems to its customers. Over its 17-year history, AB has remained focused on enhancing the technology and reliability of its internal and external devices, resulting in cochlear implant systems that are unrivaled worldwide in performance and dependability. Individuals who choose the Harmony™ HiResolution™ Bionic Ear System (Harmony) will experience more hearing and less downtime than with any other cochlear implant.

Unsurpassed Technology

AB has a record of innovative “first” technologies aimed at enhancing hearing performance so that today’s recipients are able to hear in challenging listening environments and to appreciate music. Many of these innovations remain unmatched. As a result, the Harmony system represents the best in contemporary implantable hearing technology.

Technology “Firsts”

- Bipolar-paired electrode designed to focus stimulation toward the hearing nerve
- Multiple independent current sources for sound processing flexibility and control
- Both pulsatile and analog stimulation to the same implant
- Multiple sound processing strategies for the same implant
- Multiple program slots in the same processor
- Both volume and sensitivity controls
- Back-telemetry system to monitor the status of the implant and electrode
- Windows®-based programming software for easy device fitting
- Powerful rechargeable battery technology for high-speed digital signal processing
- Perimodiolar electrode array
- Fine temporal resolution
- Fine spectral resolution
- Adaptive front-end algorithm for hearing in noise

Constant Improvement through a Robust Quality Assurance System

A dependable Quality Assurance (QA) system is important to our goal of constantly improving our products. At AB, the QA system comprises a variety of functions focused on delivering the best and most reliable hearing to Harmony recipients. One important component of the QA system is customer feedback. All clinician and recipient issues are logged into a database and analyzed for trends. Another key component is the detailed analysis of returned product to determine root causes of any potential failure. Both of these components are used to improve product designs and manufacturing processes to produce a cochlear implant system that delivers the utmost in performance and reliability. By continuously monitoring and integrating manufacturing processes and feedback from recipients, the QA system responds quickly to any issues, complaints, or suggestions that can lead to improvements in quality and reliability.

To illustrate, the QA system recently led to a new molding process that improves protection to the area where the electrode connects to the HiRes 90K™ implant, thereby improving the robustness of the implantable components. Another example is our improvement of the battery latches on the Platinum Series™ body-worn processor to make it better suited for energetic children.



Most recently, it was the diligence of the QA system that identified a very rare electronic failure mode that could occur only after the device was activated for a brief period of time. Although the incidence of the failure mode was very low (only 2 instances in over 28,000 implanted devices), the QA system identified the nature of the failure after the devices were returned. The root cause involved potential direct current (DC), which is a known failure mode in cochlear implant systems.^{1,2} AB determined that the issue merited a voluntary recall of unimplanted devices because of the potential for permanent hearing damage if left unaddressed. Although the overall reliability of the HiRes 90K implant was not affected significantly by this issue, AB believed the recall was an ethical imperative to prevent even a remote possibility for harm. The QA system subsequently initiated changes to manufacturing processes to ensure that the issue never recurs.

These modifications are only a few examples of AB’s dedication to the safety and well-being of its recipients, irrespective of the impact on its business. We strive to make trust, responsibility, and transparency hallmarks of our communications with our customers. Similarly, customer feedback and reporting is a cornerstone to the success of the QA process. As a result, tens of thousands of patients worldwide who hear the rich world of sound with Harmony are benefiting from AB’s best ever Total System Reliability—the reliability of both the internal and external devices combined—for more days of uninterrupted hearing.

High Implant Reliability

The AB cochlear implants that are implanted today demonstrate very high reliability with a 99.8% one-year cumulative survival rate (CSR), a measure that defines the likelihood of a device continuing to function over time. That remarkable number reflects manufacturing changes implemented by the QA system in 2004 and 2005, which further improved the HiRes 90K implant reliability.

HiRes 90K™ Implant Reliability³

Years Implanted	1	2	3	4	5
CSR before 2005 modifications	99.4	98.6	97.9	96.9	96.3
CSR after 2005 modifications	99.8	99.5	99.2	98.9	98.6

Implant Reliability Reporting

Advanced Bionics believes in the importance of measuring and reporting device reliability in a full and transparent manner. For this reason, AB adheres to a more conservative interpretation of the industry reliability standard than other cochlear implant manufacturers.⁴

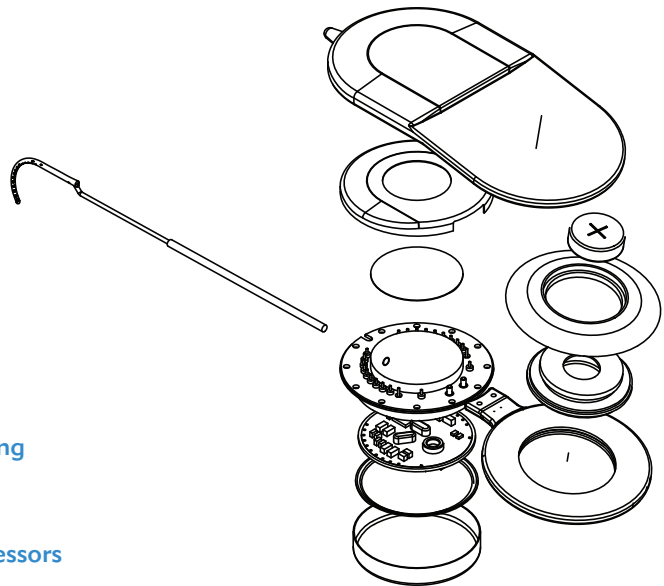
AB counts all devices removed for non-medical reasons as failures according to global consensus.^{5,6} AB’s CSR includes all “soft” failures,^{7,8} *in situ* failures, and electrode issues that other manufacturers may exclude in their reporting. AB also provides a Failure Analysis Report for every explanted device clearly stating whether the device is counted against the CSR. We believe these criteria should be followed by all manufacturers.



High Impact Resistance

When individuals choose the HiRes 90K implant for themselves or their child, they have chosen the most advanced implant on the market with the industry’s highest case impact resistance.⁹ Recipients have peace of mind knowing that AB implants are built for active lifestyles.

- Small size ideal for very young children
- Low-profile, comfort forming shape
- Durable, lightweight titanium case that can withstand impact
- Broadband data transmission with high-precision gold coil and platinum shielding
- Removable magnet for MRI compatibility
- Multiple current sources for full-spectrum coverage
- Soft, flexible HiFocus™ electrodes for neural targeting
- Neural Response Imaging diagnostics
- Intellilink™ safety feature to match implants to processors



High Processor Reliability

Advanced Bionics sound processors are known industry-wide for their reliability. Built to survive real-world conditions, today’s robust Harmony processor features advanced water protection with a Xylex® case that resists water penetration and a special coating on the internal electronics that provides a waterproof barrier.

AB’s Harmony processor also features event-logging capabilities. This important diagnostic feature captures and records events and unexpected conditions. This technology allows the QA system to analyze stored data and use the findings to make ongoing improvements.

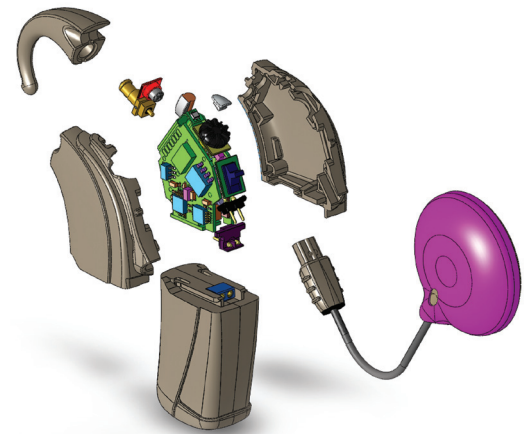
Sound Processor Reliability Reporting

Consistent with its policy to report Total System Reliability, AB publishes sound processor reliability data. The low return rates for the Harmony™ and Platinum Series™ processors set the benchmark for external reliability. The Mean-Time-Between-Failure (MTBF) durations for the two processors clearly demonstrate their robustness over time.

Sound Processor Reliability¹⁰

Processor Type	Monthly Return Rate	MTBF
Harmony Behind-the-Ear	0.98 %	5.3 years
Platinum Series Body-Worn	0.46 %	6.4 years

- **Static resistant**
- **Advanced water protection**
 - Xylex®-polymer case resists water penetration
 - Special coating provides water barrier
 - Three-year warranty
- **Dust resistant**
- **Protected microphone port**
 - Prevents dirt penetration
- **Corrosion resistant**
 - Platinum contact coated in transparent epoxy
 - Additional dummy battery anode to reduce power pin corrosion
- **Diagnostic Tools**
 - Internal event logging
 - Device performance and reliability trend monitoring
 - Information tracking for design improvements over time
- **16-bit processing for sound fidelity**
- **Programmable wide Input Dynamic Range**
- **Powerful dual-loop automatic gain control for hearing in noise**



The Best Choice Today...The Best Choice Tomorrow

When individuals choose a cochlear implant, they also choose a company that will be with them for a lifetime. AB offers unmatched technical and clinical support, the most advanced cochlear implant technology available today, and a system that constantly works to improve the reliability and performance of its products. AB's comprehensive QA system continually implements improvements in reliability and safety. In cooperation with Phonak under the Sonova Group, AB will continue to deliver Total System Reliability, innovative hearing healthcare solutions, unsurpassed service, and a lifelong commitment to recipients and their families



References

1. Waltzman S, Roland JT Jr, Waltzman M, Shapiro W, Lalwani A, Cohen N. (2004) Cochlear reimplantation in children: soft signs, symptoms and results. *Cochlear Implants International*, 5(4):138-145.
2. Kane J, Mann E. (2007) ENT devices: cochlear implants. In *Medical Device Epidemiology and Surveillance*, ed. S Brown, R Bright, D Tavis, John Wiley & Sons: New York.
3. As of January 2011, and does not include Vendor B devices.
4. ISO 5841-2 (2000) Implants for surgery—cardiac pacemakers. International Organization for Standardization (ISO), Geneva, Switzerland.
5. European Consensus Statement on Cochlear Implant Failures and Explantations. (2005) *Otology and Neurotology*, 26(6):1097-1099.
6. Battmer RD, Backous DD, Balkany TJ, et al. (2010) International classification of reliability for implanted cochlear implant receiver stimulators. *Otology and Neurotology*, 31(8):1190-1193.
7. A “soft” failure is an uncommon event where a device malfunction is suspected based upon user performance/adversive symptoms, but cannot be proven through *in vivo* tests or evaluation of the explanted device.
8. Balkany TJ, Hodges AV, Buchman CA, et al. (2005) Cochlear implant soft failures consensus development conference statement. *Otology and Neurotology*, 26:815–818.
9. Holtkamp V. (2004) Cochlear Implants under Impact Loading: Evaluation of Accident Scenarios, Determination of Load Limits, and Development of a Standardizable Test Procedure. Ph.D. Dissertation, Hannover Medical School.
10. Return rates reflect average monthly return rates over a three-month period for confirmed failures from October 4, 2010 to January 4, 2011. MTBF is a measure of hardware reliability calculated over a 90-day period. MTBF indicates in statistical terms the working lifetime of a given device—the longer the time, the more reliable the product.



“There is no greater honor than the trust our recipients and their families place in us. We will continue to stay focused on developing high-quality, reliable devices that our adult and pediatric patients can rely on each and every day for their hearing.”

—Dr. Gerhard Roehrlein, CEO and CTO