



Advanced Bionics



2012 Reliability Update

Total System Reliability Reporting

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Industry Leadership

Advanced Bionics is committed to the continual development and improvement of high-quality products that deliver the best possible hearing performance in all listening environments. Working with Phonak under the Sonova Group, AB is uniquely positioned to deliver future innovations that will continue to lead the industry.

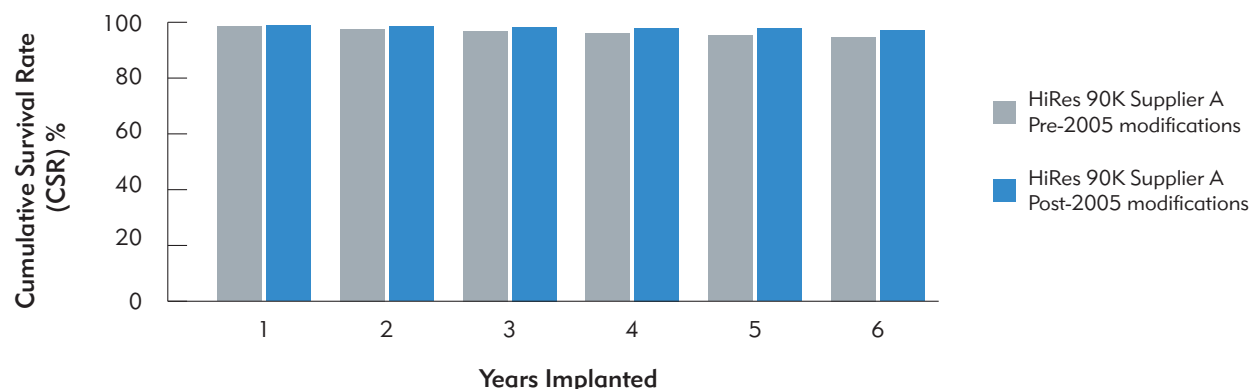
As part of our mission to put patients first and safeguard their well-being, AB's incredibly responsive Quality Assurance System ensures high product reliability, swiftly identifies any potential product issue, and employs remedial corrective actions irrespective of the impact on its business.

Trust, responsibility, and transparency have remained hallmarks of AB's communications with patients and professionals over its 19-year history. AB's reliability reporting is another example of its steadfast dedication to providing the industry with clear and accurate information.

High Implant Reliability and Truth in Reporting

AB cochlear implants that are implanted today demonstrate high reliability with a 99.8% one-year cumulative survival rate (CSR) measured as dictated by the international standard.¹ AB adheres to the most conservative interpretation of the industry reliability standard, counting all devices removed for non-medical reasons as failures according to global consensus.^{2,3} AB's CSR includes all "soft" failures,^{4,5} *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 indicating whether the device is counted against the CSR.

HiRes 90K™ Implant Reliability⁶



Years Implanted	1	2	3	4	5	6
HiRes 90K Implant Since 2005	99.83%	99.54%	99.23%	98.94%	98.69%	98.08%



Only AB's Advanced Implant Offers:

- Built Kid Tough™ durable, lightweight titanium case that can withstand impact
- 16 independent current sources for the most flexible stimulus delivery
- The most fine timing information with 83,000 pps
- Most spectral resolution with up to 120 spectral bands
- Soft, flexible HiFocus™ electrodes for neural targeting
- Intellilink™ safety feature to match implants to processors
- Untapped potential for future advancements in technology

High Processor Reliability and Transparency in Reporting

Built to survive real-world conditions, Advanced Bionics sound processors are known industry-wide for low return rates setting the benchmark for external reliability. AB publishes sound processor reliability data consistent with its policy to report Total System Reliability fully and transparently.

Sound Processor Reliability⁷

Processor Type	Return Rate	MTBF
Harmony Behind-the-Ear	0.96%	5.5 years
Platinum Series Body-Worn	0.46%	7.0 years

Only AB's Harmony Sound Processor Offers:

- T-Mic™ natural microphone placement for focused hearing
- 16-bit processing for unparalleled sound fidelity
- Programmable wide Input Dynamic Range
- HiRes Fidelity 120™* for industry leading hearing performance and music perception
- ClearVoice™* sound processing for optimized hearing in difficult listening situations

Neptune — The Newest Innovation from AB

Across the industry, the Neptune™ sound processor continues to make a big splash with patients and professionals as the world's first and only swimmable sound processor. Also the industry's first freestyle™ design, the Neptune processor is designed for all ages, lifestyles, activities, weather and terrain. New to the market, Neptune has been developed under the Quality Assurance System to the same standards of durability for which AB is known. AB will publish a reliability update on Neptune when available.

Hear Your Best with AB

From corporate integrity to high Total System Reliability to leadership in innovation, AB is the company that patients and professionals can trust for the best possible hearing performance.

AdvancedBionics.com

References

1. ISO 5841-2 (2000) Implants for surgery—cardiac pacemakers. International Organization for Standardization (ISO), Geneva, Switzerland.
2. European Consensus Statement on Cochlear Implant Failures and Explantations. (2005) *Otology and Neurotology*, 26(6):1097-1099.
3. 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.
4. 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.
5. Balkany TJ, Hodges AV, Buchman CA, et al. (2005) Cochlear implant soft failures consensus development conference statement. *Otology and Neurotology*, 26:815–818.
6. As of May 1, 2012.
7. Return rates reflect average monthly return rates over a 90-day period for confirmed failures prior to May 1, 2012. MTBF indicates in statistical terms the working lifetime of a given device—the longer the time, the more reliable the product.

**Not approved for pediatric use in the United States.*