



The HiResolution™ Bionic Ear System from Advanced Bionics (AB) is designed to provide cochlear implant recipients with natural and effortless hearing. Through a combination of high-fidelity, front-end signal processing (T-Mic™, AutoSound™) and innovations in stimulus delivery (current steering, high stimulation rates), HiRes Fidelity 120™\* sound processing provides high-resolution temporal and spectral information to AB implant recipients. With the addition of the ClearVoice™\* strategy, HiRes Fidelity 120 users are able to hear speech in noisy environments without compromising their ability to hear in quiet surroundings. When ClearVoice is selected, AB implant recipients do not need to switch programs when the listening environment changes.

The next innovation in HiResolution™ sound processing, HiRes™ Optima is designed to improve battery life without compromising listening benefit for HiRes Fidelity 120 users. HiRes Optima takes advantage of current steering and a unique power management scheme to lower the voltage required to power the implant, thereby reducing battery consumption. As a result, battery life is longer when HiRes Optima is selected.

AB conducted a regulatory clinical trial to demonstrate that speech understanding in quiet and noisy environments using HiRes Optima was not inferior to HiRes Fidelity 120 sound processing. Battery life was also compared for the two strategies. The following summarized data show that battery life is substantially improved without compromising speech understanding when HiRes Optima is used compared to HiRes Fidelity 120.

## Study Design

The clinical study investigated the benefits of HiRes Optima in 36 adults who were unilateral (n = 20) or bilateral (n = 16) recipients of a CII/HiRes 90K implant (minimum of one year of use in each implanted ear) and who demonstrated at least moderate speech perception abilities. Participants were comprised of 19 women and 17 men. Subjects used either HiRes Optima or HiRes Fidelity 120 for one week, after which they used the opposite strategy for one week (randomized crossover design). At the end of each week, participants were assessed using the AzBio sentence test in quiet (60 dB SPL), in speech-spectrum noise (60 dB SPL, SNR = +5 dB), and in multi-talker babble (60 dB SPL, SNR = +8 dB). Subjects completed an acceptability questionnaire after using HiRes Optima. Battery life was tracked throughout the study.

## Subjects

Subjects were 36 adults (17 men, 19 women) with postlingual onset of severe-to-profound hearing loss who had used HiRes Fidelity 120 for at least six months and who had moderate speech perception abilities (defined as a word recognition score of at least 50% in quiet). All subjects had been implanted with a CII/HiRes 90K™ implant and used a Harmony™

behind-the-ear processor throughout the study. Demographics are summarized in Table 1.

Table 1. Demographics of Study Population

Variable	Mean	Range
Age at first implant	54 years	22 to 84 years
Age at time of study	60 years	27 to 86 years
Duration of severe-to-profound hearing loss at time of implant (unilateral subjects)	7 years	< 1 to 32 years
Duration of severe-to-profound hearing loss at time of first implant (bilateral subjects)	7 years	< 1 to 12 years

## HiRes Optima does not Compromise Speech Understanding in Quiet and Noise

Sentence scores in quiet, in speech-spectrum noise (SSN), and in multi-talker babble (MTB) with HiRes Optima were not inferior than with HiRes Fidelity 120 (Figure 1). Individuals attained comparable scores with both strategies (Figure 2-4).

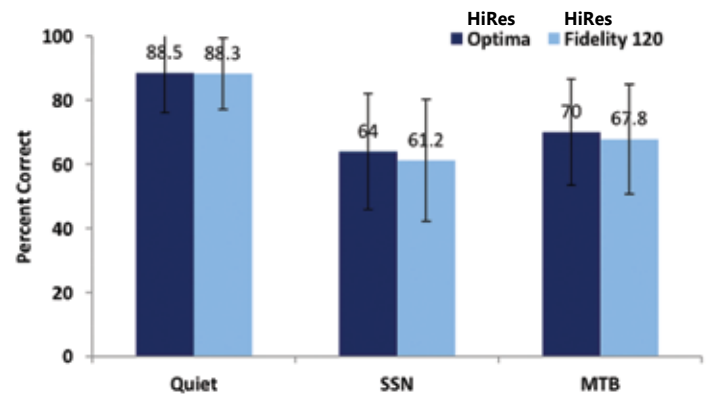


Figure 1. Means and standard deviations of AzBio sentence scores in quiet, speech-spectrum noise, and multi-talker babble for HiRes Optima and HiRes Fidelity 120. Non-inferiority p-values for all three test conditions were < .0001, indicating that results with HiRes Optima were not inferior than with HiRes Fidelity 120.

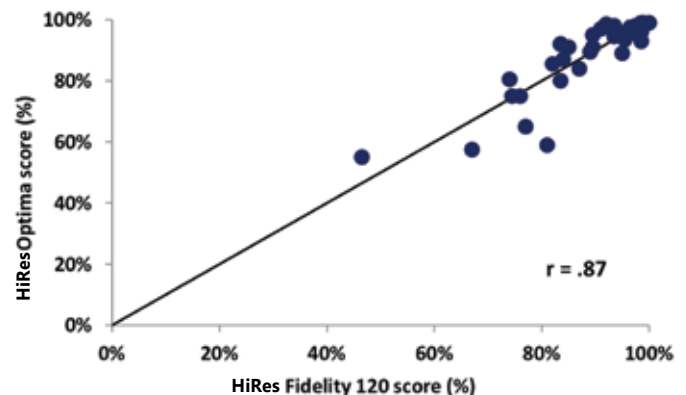


Figure 2. Individual-subject sentence perception scores in quiet for HiRes Optima vs. HiRes Fidelity 120. A Pearson correlation coefficient  $r = .87$  indicates comparable scores between the two strategies. The straight line represents a perfect correlation where  $r = 1.0$ .

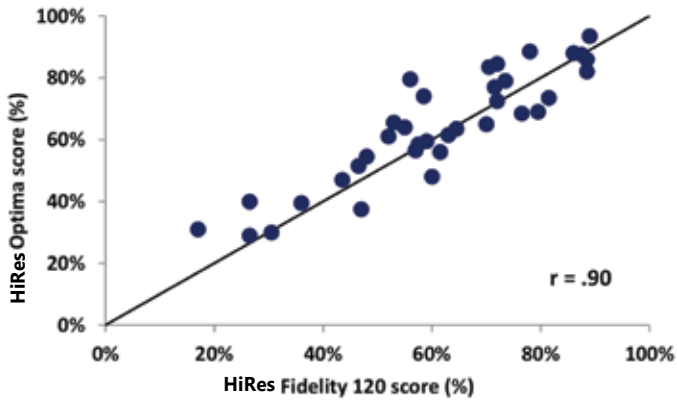


Figure 3. Individual-subject sentence perception scores in speech-spectrum noise for HiRes Optima vs. HiRes Fidelity 120. A Pearson correlation coefficient  $r = .90$  indicates comparable scores between the two strategies.

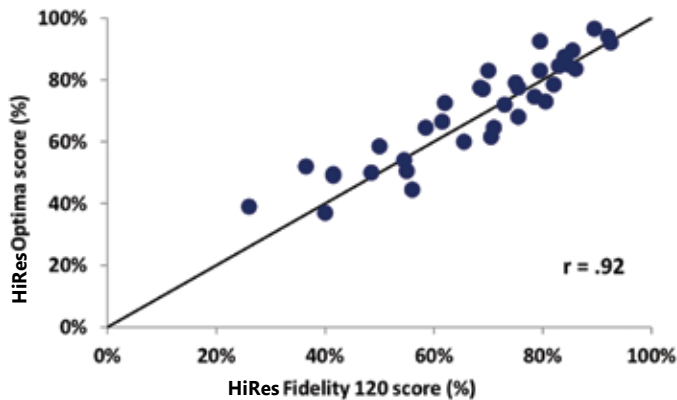


Figure 4. Individual-subject sentence perception scores in multi-talker babble for HiRes Optima vs. HiRes Fidelity 120. A Pearson correlation coefficient  $r = .92$  indicates comparable scores between the two strategies.

## HiRes Optima is Acceptable for Daily Listening

All participants (100%) reported that HiRes Optima was an acceptable sound processing strategy for everyday use. These subjective responses, in combination with the objective speech test results, indicate that using HiRes Optima does not compromise everyday listening benefits in experienced users of HiRes Fidelity 120 sound processing.

## HiRes Optima Improves Battery Life

Battery use was tracked by the Harmony™ processor memory throughout the study. Average battery life improvement was 53%, ranging from 25% to 109% for individual Harmony processors.

## Summary

This clinical study shows that HiRes Optima is an effective innovation in HiResolution sound processing that provides the same high-performance hearing as HiRes Fidelity 120 while prolonging battery life. The results demonstrate that:

- HiRes Optima does not compromise speech understanding in quiet or noisy environments
- All subjects (100%) like and would use HiRes Optima
- Battery life is improved substantially

HiRes Optima represents just one of the many pioneering HiResolution sound processing options that have been developed to provide uncompromised hearing performance for AB recipients in the last ten years. HiRes Optima will be an optional programming feature for users of HiRes Fidelity 120 sound processing, and can be programmed for use by any AB recipient with CII or HiRes 90K implants.

These data served to support regulatory approval of HiRes Optima in the United States.  
\*Not approved for pediatric use in the United States.

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## Participating U.S. Sites

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 House Ear Clinic, Los Angeles, CA  
 Midwest Ear Institute, Kansas City, MO  
 Tampa Bay Hearing and Balance, Tampa, FL  
 Washington University, St. Louis, MO