



# Use of a Quality System to Improve Product Performance

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## ABSTRACT

The NATURA™ 9-channel DSP hearing aid and the EXPRESSfit™ programming system from **SONIC innovations** were launched in September 1998. One year after the launch in the American market, the hearing aid and fitting system were released to the world-wide marketplace. Using information and analysis from a Quality System, several improvements in the hardware, software, and fitting system have been incorporated into the product during the first year of production. These include, but are not limited to, enhancement of calibration procedures, incorporation of alternate components, revised specifications for the NATURA product, and refined algorithms in the EXPRESSfit software. Data are presented to show the effect of these quality improvements on product performance, overall sound quality, and consumer preference ratings.

## INTRODUCTION

The Quality System of **SONIC innovations** is certified against the ISO 9001 standard and the European Medical Device Directive, allowing the Company to ship CE-marked products. The company's Quality System mandates systematic monitoring of product quality and efforts to continuously improve product performance. Extensive pre-launch and post-launch clinical testing of NATURA demonstrated outstanding user benefits<sup>1</sup> and identified some areas for product refinement. Typical for the industry, some of the changes are hardware driven, such as incorporating redesigned components and transducers. However, other changes are software driven, such as improved calibration and programming procedures. Because **SONIC innovations** uses an "Optimized Platform" in its DSP design<sup>2</sup>, the software changes can be applied to any device manufactured since product launch to achieve the improvements described.

## HARDWARE IMPROVEMENTS

### Programming Reliability

NATURA hearing instruments utilize a new "flex strip" programming system. This system offers the advantage of a single cable to program all hearing aids styles, as compared to other systems that require a different cable for every size battery. However, early in the product life of NATURA, programming reliability using this system did not meet expectations. Since the product launch in 1998, programming hardware [see Figure 1] has been modified (1) to increase flex strip thickness, (2) provide a molded "gripper," (3) to improve contact with the programming pins inside the hearing aid, and

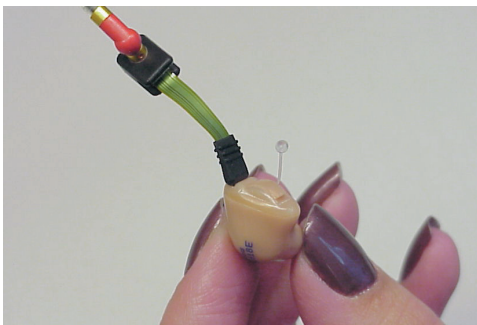


Figure 1. Flex strip programming system

(4) to increase tension on the flex strip and prevent it from shifting during programming by redesigning the battery door.

### Transducers and Specifications

NATURA hearing aids were released initially with undamped

receivers. Follow-up work, including clinical evaluation, revealed that sound quality could be improved with damped receivers. The major change was elimination of a secondary peak near 5 kHz that was responsible for a complaint of "harshness." Another change was improved mid-frequency emphasis, which also enhances sound quality (see Figure 2 comparing mean performance with undamped and damped receivers). The NATURA product specifications changed with

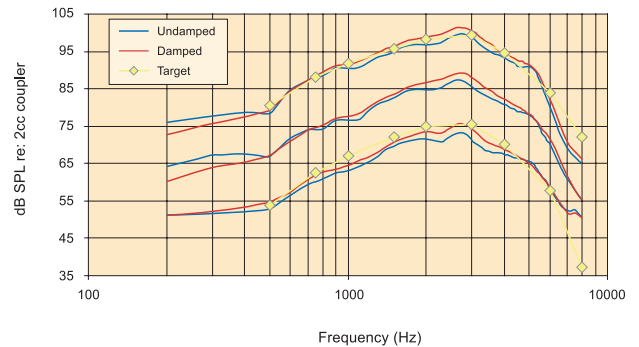


Figure 2. NATURA ITE Coupler Response (20 devices)

the transition to damped receivers. The output of the NATURA hearing instruments were reduced, on average, about 3 dB. However, the gain, bandwidth, THD, EIN, and battery drain specifications remain unaltered.

## SOFTWARE IMPROVEMENTS

### Enhanced Calibration Procedures

At the launch of NATURA custom products, the internal calibration of the hearing instruments was at nine points corresponding to the nine channels in the programming system. With the launch of the BTE in 1999, internal calibration was changed to twenty-five points, covering the same bandwidth

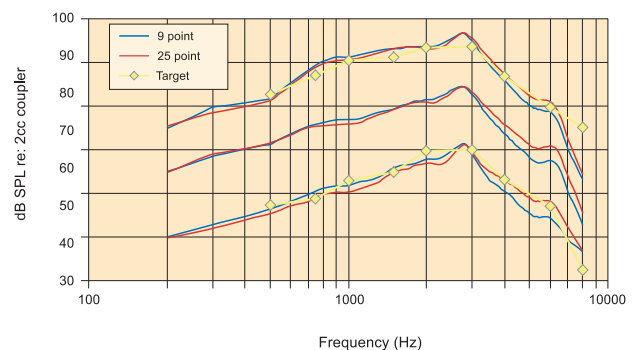


Figure 3. NATURA ITC Coupler Response (18 devices)

as the earlier nine-point procedure. "Twenty-five point calibration" was introduced to the custom product line later in 1999. The change improves the programming system accuracy, especially in the frequency range above the primary resonance peak [see Figure 3 comparing performance with nine-point and twenty-five point calibration].

### EXPRESSfit Fitting Algorithm

An extensive laboratory investigation re-evaluated NATURA's performance following the receiver change and calibration enhancements. Incremental improvements to sound quality (see Results section) were attained with enhanced low-frequency performance, improved control of high-frequency output, and increased gain in the mid frequencies [see Figure 4 comparing mean performance before and after changes].

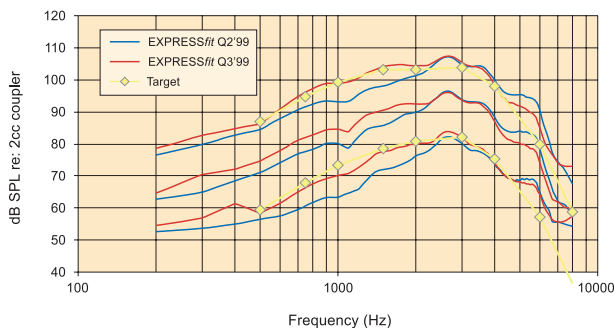


Figure 4. NATURA BTE Fitting Targets (20 devices)

sound quality ratings were 6.5 for CIC, 6.2 for ITC, 6.0 for ITE, and 5.7 for BTE. As shown in Figure 5, the changes in ratings were overwhelmingly positive, indicating a strong preference for the modifications. The most beneficial effects were seen for the ITE and BTE hearing instruments.

### SUMMARY

The NATURA hearing instruments were launched one year ago by **SONIC innovations**, a company committed to producing quality products. Based on feedback from our Quality System, hardware changes improved programming reliability and sound quality. Software changes improved calibration control and programming system accuracy. The cumulative effect is enhanced sound quality for the entire NATURA hearing instrument product line. Because the calibration and fitting algorithm changes are software driven in an "Optimized Platform," the beneficial effects of these improvements, including natural, lifelike hearing, are retroactive to devices manufactured from product launch.

### REFERENCES

1. Bray, V., Nilsson, M., Ghent, R., & Johnson, J. (1999). Results from a Clinical Evaluation of a New DSP Hearing Aid Using an Optimized Platform. Poster presented at the American Academy of Audiology, Miami Beach, Florida.
2. Bray, V., Ghent, R., Nilsson, M., & Johnson, J. (1998). An "Optimized" Platform for DSP Hearing Aids. Poster presented at the Conference on Advanced Signal Processing Hearing Aids - Cleveland, Ohio.

Presented at the Hearing Aid Amplification for the New Millennium National Acoustic Laboratories Conference in Sydney, Australia, on November 15-19, 1999.

### RESULTS

A controlled 60-day field trial of NATURA device performance with 28 satisfied users evaluated the new receivers, enhanced calibration procedure, and revised fitting algorithm. Using a counterbalanced protocol, changes in performance, based on a listening task, were rated on a seven-point satisfaction scale in four areas: "own voice," "music," "speech," and "environmental sounds." Following modifications, mean

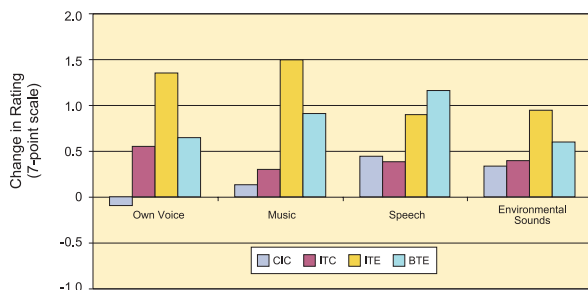


Figure 5. Change in Sound Quality Rating

