VANDERBILT UNIVERSITY MEDICAL CENTER

# Newborn Hearing Screening: A Comparison of the Vivosonic Aurix and Vivosonic Integrity G2 Automated ABR Hearing Screening

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## INTRODUCTION

Today, newborn hearing screening (NBHS) is a test completed in many parts of the world. One of the most common methods for conducting NBHS is through an automated auditory brainstem response (ABR) hearing screening system. Time and resources dedicated to conducting NBHS are important factors to consider in any newborn hearing screening program. Therefore, equipment manufacturers are often testing new technology to maintain and improve efficient NBHS testing procedures, test results, and ease of use with screening equipment.

Vivosonic Inc. recently developed new hardware for the Vivosonic Integrity system which is designed for use with both automated ABR screening and diagnostic ABR testing. Conventionally, separate equipment is required to complete screening and diagnostic ABR.

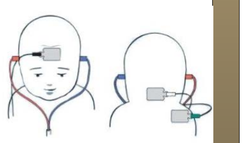
## PURPOSE

The purpose of this project was to validate that the newborn hearing screening result and screening performance using the Vivosonic Integrity G2 hardware is equivalent to or better than the current clinically available Vivosonic Aurix hardware.

## METHODS

All infants admitted to the Vanderbilt University Medical Center newborn nursery, except for those who decline due to religious beliefs, receive a newborn hearing screening prior to discharge. English-speaking parents of these infants were offered enrollment in the study at the time of the clinical screening. Informed consent was obtained before testing.

PROTOCOL:
Order of clinical vs. research tests and right vs. left test ear was pseudorandomized using a Latin Square method to avoid bias. The order of right vs. left ear first was determined based on the baby's position in the crib. A total of 99 babies were enrolled in the study (53 male, 47 female).



- Infant was prepped for clinical screening by cleaning the skin and applying electrodes to the forehead, nape, and shoulder.
- The research G2 or clinical Aurix electrode leads were connected to the sensors.
- The first test (either G2 or Aurix) was completed and information regarding the baby's sleep state and position was documented during the test period. For the G2 test, only one ear was tested. Additionally, the earphone was removed from the ear for an additional test in order to create a control "dry" run. The order of test or dry run completed first was determined by Latin Square.
- To complete the second test, the electrode leads and earphones were changed to the other hardware configuration. The second test was completed, and the test data and infant's state was recorded.
- If the infant did not pass the clinical screening in the ear which was ***not*** tested by G2 hardware, a G2 test was completed on that ear if infant's sleep state allowed.

## METHODS

All data was digitized with no identifiable health information recorded. Two types of data were generated:

1) data entered by the tester on the data sheet during the data collection
2) log files of the sub-averaged data sent from the Link to the PC

The comparison tests were performed for stimulus presence. The primary data that was analyzed was the result of the test, confidence percentage, and time to decision. These results were based not only on hearing sensitivity of the infant, but on infant state during the test and it is important to note that the noisier states, such as squirming, sucking and crying, were not always consistent during the test or between systems. Therefore, comparisons were made on an aggregate as well as an individual subject basis. The sensitivity of the G2 system was then determined using the control "dry" (i.e. stimulus absent) data.

Data was analyzed for 80 of the 99 enrolled subjects. Reasons for discarding data included issues with the insert earphones, the use of headphones for diagnostic screening, or problems with software.

## RESULTS

### Result of Test (Stimulus Present)

Table 1: Results from both systems when the ear tested, and baby states are the same between systems

| State | Aurix | | | | G2 | | | |
|---|---|---|---|---|---|---|---|---|
| | Pass | Refer | Total | % Pass | Pass | Refer | Total | % Pass |
| Asleep | 34 | 3 | 37 | 91.9% | 35 | 2 | 37 | 94.6% |
| Awake | 3 | 0 | 3 | 100.0% | 3 | 0 | 3 | 100.0% |
| Squirming | 1 | 0 | 1 | 100.0% | 1 | 0 | 1 | 100.0% |
| Sucking | 19 | 1 | 20 | 94.4% | 16 | 4 | 20 | 80.0% |
| Total | 57 | 4 | 61 | 93.4% | 55 | 6 | 61 | 90.2% |

There was no statistical difference in results with stimulus present (see Table 1 above). However the largest differences were noted for noisy test results as the G2 hardware demonstrated a slightly higher noise level during testing due to differences in hardware filter (see Figure 1 below).

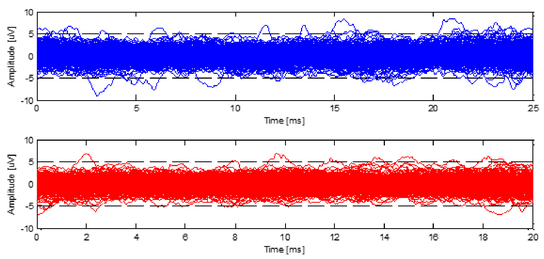



Figure 1: Raw data from subject 31 for G2 (blue) and Aurix (red). All responses are sub-averages of 16 sweeps.

### Test Time to Decision (Stimulus Present)

Table 2: Average time to pass for both systems when the ear tested, and baby states are the same between systems

| State | Aurix | G2 |
|---|---|---|
| | Average Time to Pass (seconds) | Average Time to Pass (seconds) |
| Asleep | 93 | 128 |
| Awake | 97 | 215 |
| Squirming | 112 | 440 |
| Sucking | 218 | 173 |
| Total | 123 | 133 |

There was no statistical difference in test time (see Table 2 above).

## RESULTS

### Test Sensitivity (Stimulus Absent)

Table 3: Results from G2 dry runs

| State | G2 | | | |
|---|---|---|---|---|
| | Pass | Refer | Total | % Refer |
| Asleep | 0 | 42 | 42 | 100% |
| Awake | 1 | 1 | 2 | 50% |
| Squirming | 0 | 7 | 7 | 100% |
| Sucking | 0 | 24 | 24 | 100% |
| Total | 1 | 74 | 75 | 98.7% |

Compared to Aurix sensitivity of 98%, sensitivity with G2 hardware is equivalent (see Table 3 above).

## DATA SHEETS

**Vivosonic™ Integrity™ Screener Data Sheet**

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Patient's Study ID:** | | | | | | | | | | |
| Patient Sex: | | | | | | | | | | |
| Location : | | | | | | | | | | |
| Date of Test: | | | | | | | | | | |
| Infant Position | ☐ Lying flat on back<br>☐ Lying on side<br>☐ Held in arms<br>☐ Other position (specify) | | | | | | | | | |
| Impedance: Shoulder | | | | | | | | | | |
| Impedance: Forehead | | | | | | | | | | |
| Impedance: Nape | | | | | | | | | | |
| Ear: circle ear tested first | **Right** | | | **Left** | | | **Dry** | | | |
| Start of Test (hh:mm) | | | | | | | | | | |
| Patient State (**S**)tart (**M**)id (**E**)nd | S | M | E | S | M | E | S | M | E | |
| Asleep | | | | | | | | | | |
| Awake Quiet | | | | | | | | | | |
| Feeding | | | | | | | | | | |
| Sucking | | | | | | | | | | |
| Squirming | | | | | | | | | | |
| Crying | | | | | | | | | | |
| Result | ☐ Pass<br>☐ Refer<br>☐ Inc. | | | ☐ Pass<br>☐ Refer<br>☐ Inc. | | | ☐ Pass<br>☐ Refer<br>☐ Inc. | | | |
| Test Duration (m:ss) | | | | | | | | | | |
| Confidence percentage | | | | | | | | | | |
| Name of Tester | | | | | | | | | | |
| Signature | | | | | | | | | | |
| **Notes and Observations On Reverse** | | | | | | | | | | |

## SUMMARY

As hypothesized, both hardware systems showed equivalent performance with ABR screening.

As both systems are equivalent, one benefit to the combined hardware (screening and diagnostic ABR) is that a newborn hearing screening program would only need to purchase one piece of equipment in order to be able to complete both hearing screening and diagnostic follow-up testing. This may be a critical advantage in areas with limited budgets or resources for follow-up testing. It may also lend itself for future teleaudiology opportunities in areas with non-licensed screening personnel rather than audiologists.

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