vivosonic


# Aurix™

Newborn Hearing Screening System

www.vivosonic.com

# Aurix™

Newborn Hearing Screening System

## The Next Level in Hearing Screening

Early detection of hearing loss in infants is critical for the normal development of speech, language, learning, and social skills. Aurix is an advanced hearing screening system that identifies potential hearing loss with accuracy and efficiency. It is a fully Automated ABR system which detects the presence or absence of an auditory brainstem response in newborns and infants.

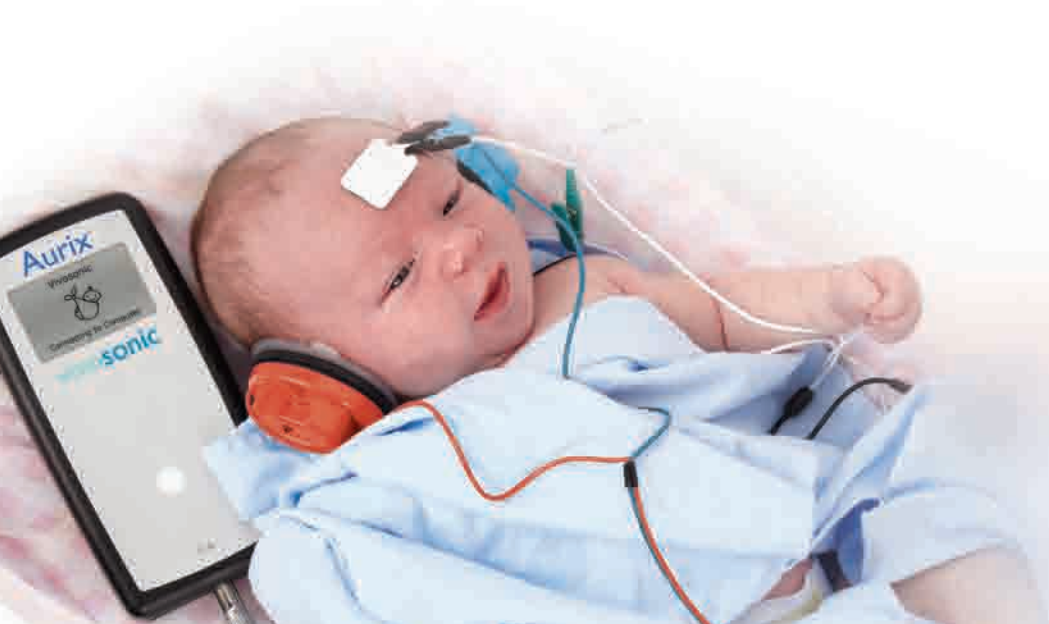
### *Aurix allows you to focus on the patient while reducing test time and the impact on hospital resources*

Aurix provides more reliable screening results in awake and premature babies, resulting in:

- Reduced need for rescreens caused by an awake or stirring baby;
- Less variability in test time allowing for scheduling with greater accuracy;
- Wireless communication between the Aurix Link™ and the computer allows screeners to comfort newborns by holding or feeding during testing;
- Premature infants can be tested in their incubator or NICU bed.

### *Aurix improves technical reliability in all screening environments*

Much like Vivosonic's Integrity™, our patented Kalman filter helps Aurix to tune out electromagnetic noise. This helps reduce the number of abandoned tests and virtually eliminates the need for specialized screening environments.




vivosonic

www.vivosonic.com

# The Aurix System

*Complete Aurix System (cart optional)*


### Aurix Link™

Used to obtain data from the patient. Completely wireless, tests can be conducted at the bedside using the Link, or via the Aurix computer.

### Sound Stimulator

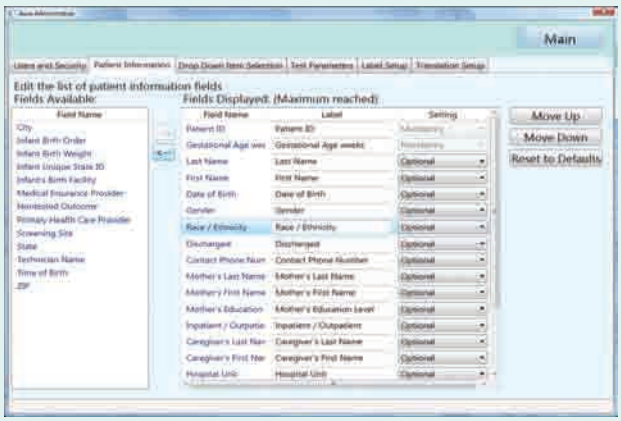
Advanced technology delivers the stimulus, while simultaneously monitoring test conditions to deliver optimal results.


## Hearing Screening as easy as 1-2-3

The Vivosonic Aurix takes hearing screening to the next level. Developed with input from policy makers, clinicians and parents - it is the next step in Automated ABR screening technology.

Easy to use, and simple to understand, the Aurix conducts infant hearing screenings in 3 simple steps: Create a record, perform the test and then print the result.

Built using the same technology as our Integrity Non-Sedated ABR, Aurix has demonstrated excellent reliability, particularly in less than ideal screening situations.




## Robust administration tools put you in control

The Aurix system will grow with your screening program, or fit seamlessly into your existing one. A secure administrator interface allows Program Managers to customize the screening software to obtain only the data you want or need, while hiding the rest.

Aurix is fully compatible with industry database software like Oz Systems℠ and Hi*Track.

# Aurix™

Newborn Hearing Screening System

## Product Specifications

| | |
|---|---|
| Intended use | • Vivosonic Aurix is indicated for use in the recording and analysis of human auditory brainstem response data necessary for the screening for hearing loss;<br>• The Vivosonic Aurix is indicated for newborns and infants from 34 weeks gestational age to 6 months. |
| Digital Signal Processing (DSP) method | The Kalman Weighted method, a patented method using a Linear Minimum Mean-Square Error Filter, also called the Kalman Filter (US Patents 7,286,983 and 6,778,955), is used to estimate ABR response signals recording and a time-averaging method. (Li 2002) |
| Test procedure | Non-invasive. |
| Patient participation /response | Not required - screening is objective. |
| Diagnostic environment | Aurix will perform in a variety of environments (hospital, ambulatory, or home). A soundproof room is typically not required. |
| Compliant transducers and cables | Compliant with the requirements of EN60601-1-2:2001 Sections 36.201, 36.20<br>Sound stimulator attached to 150 cm cable. |
| Compliant accessories | Compliant with the requirements of EN60601-1-2:2001, Sections 36.201, 36.202:<br>• Amplifier - #11003;<br>• Electrodes - #100001;<br>• Sound Stimulators - #11002;<br>• EarDomes™ - #100004;<br>• Link - wireless interface module - #11001. |
| ABR Electrode type | Single use disposable electrodes with following characteristics:<br>• Rectangular Ag/AgCl adhesive hydro gel;<br>• Circular tabs for electrical connection;<br>• Comply with ANSI/AAMI EC 12:2000 standard. |
| Amplifier filters | For ABR: 30± 10 Hz – 3 kHz ± 300 Hz<br>Slope: 12 dB/octave. |
| Stimulation type | Alternating click. |
| Stimulation rate | Greater than 37.7 stimulations per second. |
| Output level | Selectable between 30 and 35 dB nHL. |
| Frequency bands and bandwidth of reception | The receiver operates in 79 bands separated by 1MHz, centered at 2402 MHz through 2480 MHz with a bandwidth of +/- 20 parts per million. |
| Frequency characteristics of the modulation and the effective radiated power of transmission | For all frequencies:<br>Modulation Type: IQ Modulation<br>Frequency Characteristics (where center frequency F0 = 2F1-F2):<br>Average delta F1 Modulation = 165 kHz (+10/-25 kHz)<br>Maximum delta F2 Modulation = 125 kHz<br>Effective Radiated Power: +1 dBm (+/- 3dB) |
| Amplifier gain | For ABR: 10 × $10^3$. |

| | |
|---|---|
| Resolution | Analog-to-digital (A/D) conversion (in recording channels): 24 bit. |
| Automatic checking procedures | The measurement of:<br>• Electrode contact quality;<br>• Headphone seal quality;<br>• Acoustic noise;<br>• EM interference too high. |
| Power source | The Link is powered by battery pack. The battery pack is charged through a charger that is safety tested. |
| Electrical path to the patient | In ABR test: from the Link through the amplifier and electrodes. There is no electrical hazard to the patient, as the Link is battery-operated. |
| Regulatory compliance | The products gained the following regulatory clearances and approvals:<br>• USA: FDA clearance under 510(k) K080060;<br>• European Union: CE Registration No. DE/CA09/0170/1207 to 1212;<br>• Health Canada Medical Device License 81824. |
| Environmental conditions for transport and storage | • Ambient temperature of -40C to +70C;<br>• Relative humidity of 10% to 100%;<br>• Atmospheric pressure range of 500 hPa to 1060 hPa. |
| Radio frequency related specifications software | RF Output Power rating: 4 dB mW maximum<br>Operating frequency range: 2.400 – 2.4835 GHz<br>Modulation Types: GFSK Integrity™ control software |
| Printers (optional) | Dymo Writer |
| Screening decision-making | Fully Automated:<br>• Pass: Outcome indicates a consistent ABR was detected;<br>• Refer: No ABR was detected during the screening time;<br>• Incomplete: Testing was stopped before an outcome could be determined. |
| Computer | • Laptop Computer;<br>• Touch screen (optional);<br>• Windows Operating System;<br>• Bluetooth Connectivity;<br>• USB Ports;<br>• LAN and Wireless Networking;<br>• Global power capabilities (110V to 240V).<br>*(Please note: computer may not be exactly as shown)* |
| Software | • Easy to use, intuitive interface;<br>• Color Graphic User Interface (GUI);<br>• Fully compatible with Oz Systems℠ and Hi*Track databases;<br>• XML export allows for database conversion to a number of popular formats including excel and text. |
| Device cart (optional) | Laptop Mobile WorkSpace |


vivosonic

www.vivosonic.com

Phone: +1 (416) 231-9997
Fax: +1 (416) 231-2289

E-mail: sales@vivosonic.com

Address: 120-5525 Eglinton Ave. W.
Toronto, ON M9C 5K5 Canada


For more information on Aurix, visit us online or contact your local distributor: