Auditory Function Screening Device, Newborn

Health problem addressed
Devices that allow hearing impairments to be detected quickly so that any speech and language deficiencies can be addressed with early intervention programs. If hearing impairments are not detected early in life, social, emotional, and intellectual development (e.g., speech and language acquisition, academics) can be affected. Permanent childhood hearing loss is the most common defect that can be diagnosed at birth.

Product description
Devices consisting of a main testing system with a display screen and ear tips, earmuffs, or electrodes; the unit can be table- or cart-mounted.

Principles of operation
Once the ear probe(s) or electrodes are in place, infant screening tests are performed using either auditory brainstem response (ABR) or otoacoustic emissions (OAEs). ABR, an electrophysiologic assessment, is used to measure the auditory system’s response to sound. A soft click (usually 35 to 50 decibels [dB]) is presented to the ear(s) via earphones or probes. OAE is a screening method based on measuring the integrity of the outer hair cells in the cochlea (inner ear). A soft click (usually 25 dB) is presented, and a small microphone measures the acoustic response that is returned from the baby’s ear via a probe in the ear canal.

Operating steps
For OAE screening the screener places a miniature earphone and microphone in the infant’s ear. Sounds are played, and a response is measured. If the infant hears normally, an echo is reflected into the ear canal and is measured by the microphone. If there is no hearing loss, no echo can be measured. For ABR testing, sounds are played into an infant’s ears. Electrodes are placed on the baby’s head to detect responses. This measures how the hearing nerve responds to sounds and can identify infants with a hearing loss.

Reported problems
Users may experience difficulty inserting probes into the ear canal. Improper probe fitting can increase the referral rate. Proper insertion technique is easily learned, but the operator usually needs some instruction. Some units have alarms for improper probe placement. Proper earphone placement and electrode impedances during setup and continuous monitoring during testing are important. Obstruction in earphones (tips or muffs) or myogenic interferences should be monitored during automatic checks.

Use and maintenance
User(s): Audiologist; medical staff
Maintenance: Medical staff; technician; biomedical or clinical engineer
Training: Initial training by manufacturer and manuals

Environment of use
Settings of use: Hospital; clinic
Requirements: Stable power source

Product specifications
Approx. dimensions (mm): 195 x 70 x 30
Approx. weight (kg): 0.25
Consumables: NA
Price range (USD): 2,995 - 22,000
Typical product life time (years): 7
Shelf life (consumables): NA

Types and variations
Units may be table- or cart-mounted.