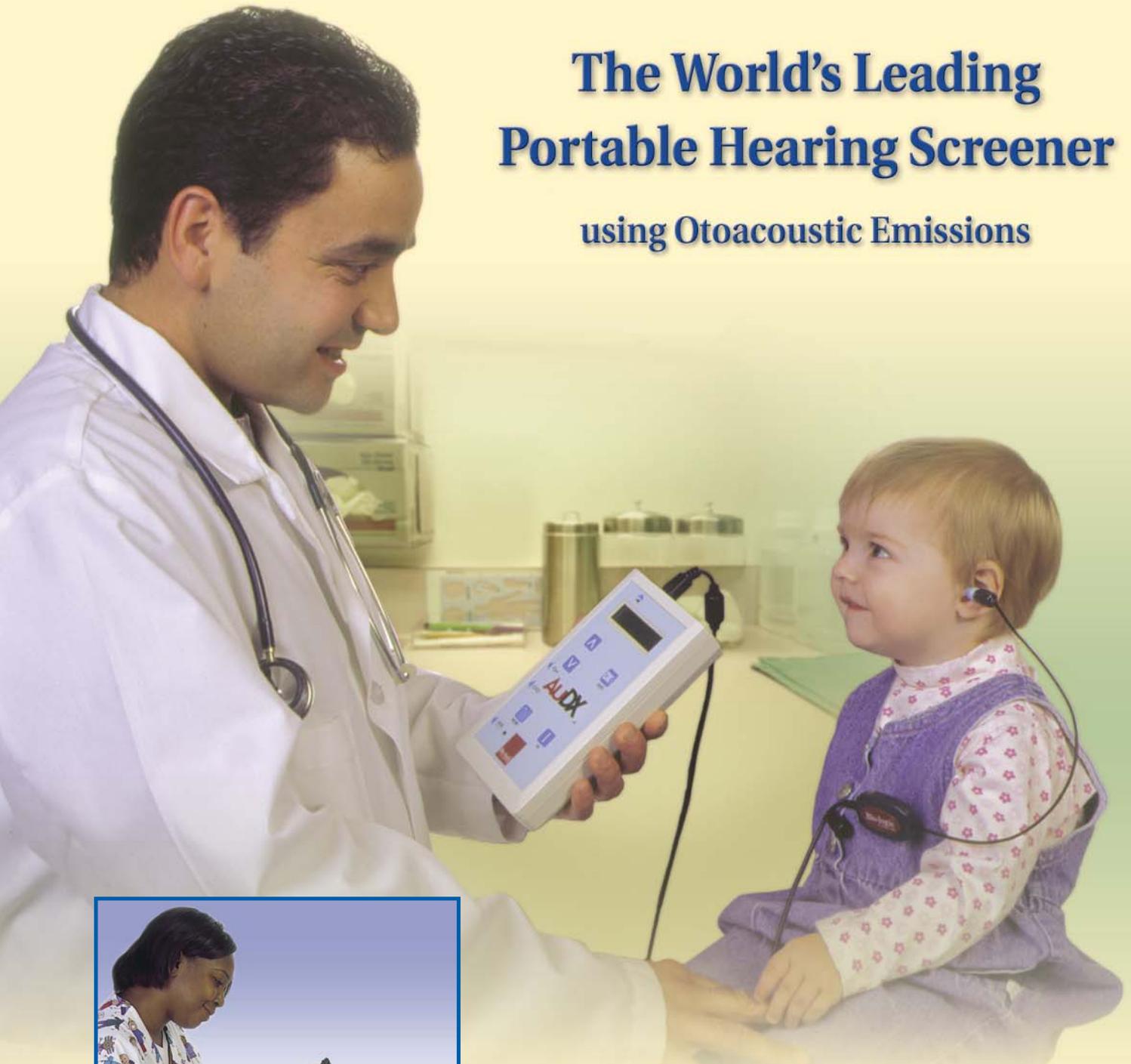


The World's Leading Portable Hearing Screener

using Otoacoustic Emissions



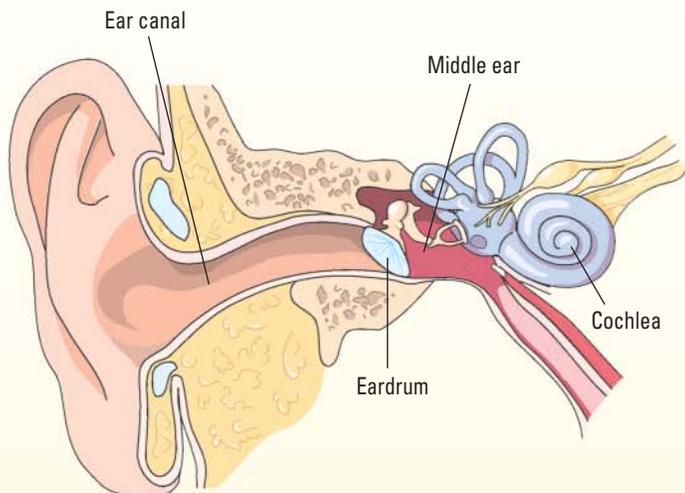
*Early Hearing Detection & Intervention Programs,
Pediatricians, Audiologists, and School Nurses use AuDX*

Bio-logic Systems Corp is an
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The World's Leading Portable OAE Screener...



AuDX delivers sounds into the ear canal and measures the OAE response produced by outer hair cells in the cochlea.

An otoacoustic emission (OAE) is a response generated by structures (outer hair cells) in the healthy cochlea to sounds presented into the ear canal. AuDX presents a soft pair of tones (distortion product OAE) or a click (transient-evoked OAE) through a probe placed in the patient's ear canal. A tiny, sensitive microphone in the probe measures the OAE. AuDX automatically compares the response to normal data and assigns a "pass" or "refer" result to the screening. The presence of "passing" OAEs is highly correlated with normal hearing and middle ear function. OAE screening can be used for patients of all ages, newborns through geriatrics.

**Easy to clean,
durable Ear Probe!**



Why professionals choose AuDX®:

- Fast, accurate results
- Objective test – no patient response required
- No interpretation required – Pass/Refer result provided
- Choice of infrared wireless or serial label printer
- Operates on rechargeable lithium battery or AC Power
- Over 25 years of experience with hearing product design and manufacturing
- 24/7 Technical Support

...for Newborn Hearing Screening

Three to four babies out of every 1000 are born with hearing loss, making it the most frequently occurring birth disorder.

The American Academy of Pediatrics¹, Joint Committee on Infant Hearing² and National Institutes of Health³ recommend screening infants for hearing loss using either otoacoustic emissions (OAE) or auditory brainstem response (ABR). Either method alone or in combination is acceptable for detecting hearing loss.

1 American Academy of Pediatrics (1999) Newborn and infant hearing loss: Detection and intervention. Task Force on Newborn and Infant Hearing. Pediatrics 103(2):527-530.

2 Joint Committee on Infant Hearing (2000) Position Statement: Principles and guidelines for early hearing detection and intervention programs. American Journal of Audiology 9:9-29.

3 National Institutes of Health (1993) Summary of the NIH Consensus: Early identification in infants and young children. National Institutes of Health Consensus Developmental Conference.



Diagnosis of hearing loss should be completed by 3 months of age so that appropriate habilitation can begin before the infant is six months old.

Is an OAE Test Reimbursable?

Yes, the CPT code for an OAE screening is 92587 (evoked otoacoustic emission, limited). According to the American Speech-Language-Hearing Association (2005), the national average for reimbursement for this CPT code is \$61.00.

Based on this reimbursement level, and assuming a modest usage rate of 10 screenings per week, the cost of an AuDX I unit will be recouped in less than 6 weeks.

...for the Medical Home

Significant hearing loss can develop after the newborn period, so birth screening is not enough. Regular hearing screening is important throughout childhood.

Routine Hearing Screening

The American Academy of Pediatrics¹ recommends hearing screening throughout infancy and childhood by testing for hearing loss at ages 3, 4, 5, 10, 12, 15 and 18.

The National Institutes of Health (NIH) initiative, Healthy People 2010², set the following target goals:

- increase the proportion of persons who have a hearing examination on schedule;
- increase the number of persons who are referred by their primary care physician for hearing evaluation and treatment;
- reduce noise-induced hearing loss in children and adolescents aged 17 years and under.

These goals underscore the importance that the NIH places on identifying and preventing hearing loss.

1 American Academy of Pediatrics Committee on Practice and Ambulatory Medicine. Recommendations for preventive pediatric health care. Pediatrics 1995; 96:373-374

2 Healthy People 2010: Volume II (second edition). www.healthypeople.gov.



Late Onset of Hearing Loss

The Joint Committee on Infant Hearing¹ recommends biannual hearing screening for children with the following risk indicators:

- Parental or caregiver concern
- Family history of childhood hearing loss
- Findings associated with a syndrome known to include hearing loss or neurodegenerative disorders
- Contraction of infection associated with hearing loss (i.e. bacterial meningitis)
- In-utero infection (cytomegalovirus, herpes, rubella, syphilis, and toxoplasmosis)
- Neonatal indicators (hyperbilirubinemia resulting in transfusion, persistent pulmonary hypertension resulting in mechanical ventilation and conditions requiring extracorporeal membrane oxygenation)
- Head trauma

1 Joint Committee on Infant Hearing (2000) Position Statement: Principles and guidelines for early hearing detection and intervention programs. American Journal of Audiology 9:9-29.

Otitis Media

Otitis Media (OM) results in periods of temporary hearing loss during the critical years of language and speech acquisition and can result in developmental language delays.

- OM accounts for 24.5 million visits to doctors' offices per year.
- Approximately 61 to 83% of all children will have otitis media (OM).
- Children having persistent OM in the first 3 years of life are more likely to continue to have OM through the first years of school.
- The American Academy of Pediatrics¹ and the Agency of Health Care Policy and Research² recommend that patients with otitis media persisting more than 3 months be evaluated for hearing loss.

1 Wright P.F., Thompson J & Bess FH (1991) Hearing, speech, and language sequelae of otitis media with effusion. Pediatric Annuals 20(11), 617-18.

2 Stool SE, Berg AO & Berman S (1994) Managing otitis media with effusion in young children: quick reference guide for clinicians. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services, AHCPH publication 94-0623.

...for Providers of World Class Care

Frequently Asked Questions

1. How long does an OAE screening with AuDX take?

Test time is very fast – about 10 seconds per ear if the patient is quiet and cooperative; slightly longer for "refer" results.

2. Who should administer the test?

Since AuDX provides a pass or refer result, any trained staff member, under the supervision of a health-care professional, can easily perform the AuDX screening.

3. What patient preparation is required?

The ear probe must be placed securely in the ear canal and the patient must be relatively quiet for the few seconds that it takes to perform the test. No other preparation is needed.

4. What does a "refer" result mean on AuDX?

A "refer" result means that the OAEs are absent or small compared to normal data. Assuming good test conditions and technique, possible causes of a refer result are:

- Excessive debris in the ear canal such as vernix (newborns) or cerumen
- Middle ear fluid or other middle ear abnormalities (e.g. otosclerosis, etc.)
- Cochlear hearing loss greater than 25-30 dB HL

If a reliable OAE screening cannot be achieved or a refer result persists on repeat screenings despite good test conditions and apparently normal middle ear function, the patient should be referred to an audiologist or otologist for further evaluation.

5. Why do I need OAEs if I have Tympanometry?

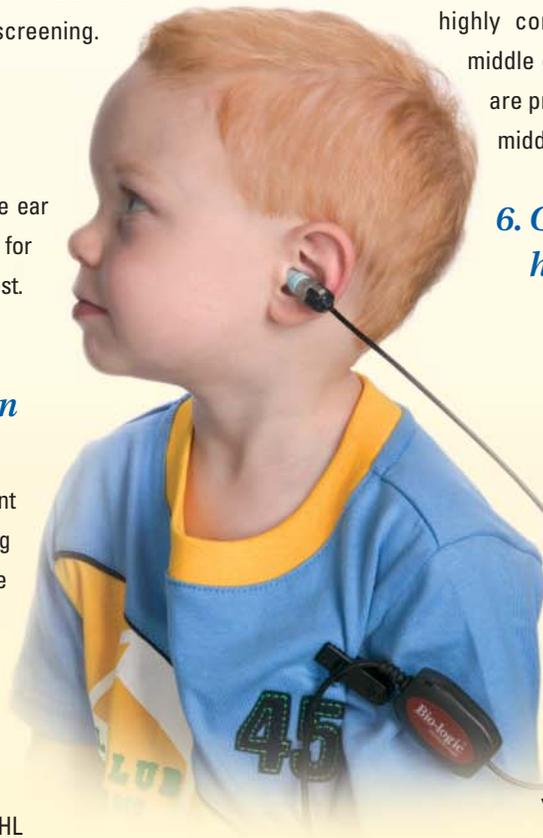
Tympanometry is a powerful tool for assessing middle ear function. However, it provides no information about cochlear function or hearing. OAEs are affected by both hearing loss and middle ear dysfunction. For children with OME, for example, it is important to monitor their OAEs to verify the return to normal when the middle ear condition appears resolved. Passing OAE screening results are highly correlated with normal hearing and normal middle ear function; whereas normal tympanograms are present in hearing impaired ears as long as the middle ear is healthy.

6. Can I screen a patient who has otitis media?

The presence of middle ear fluid almost always blocks transmission of the OAE causing a "refer" result. OAEs are very useful for tracking the resolution of middle ear fluid and the return of hearing to normal. A "pass" result on an OAE screening is highly correlated with normal middle ear function and normal cochlear function (i.e. normal hearing).

7. Can I screen a patient who has PE tubes?

Yes, most ears with PE tubes in combination with a healthy middle ear and normal cochlear function will achieve a "pass" result on AuDX. However, in some ears, the added weight of the PE tube in the eardrum can affect the OAE and cause a "refer" result. In that case, referral for further evaluation may be required.



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#203206 (20)	#203206(20)	#203331 (20)
#203218 (100)	#203219 (100)	#203353 (100)

Installing a Disposable Eartip
The disposable eartip is installed by slipping it over the metal tube assembly and pushing it with a gentle twist so that it slips completely over the plastic collar near the body of the probe. A properly installed eartip should extend approximately 1/16 inch over the end of the probe tube assembly.

Probe Tips

- Patented Infant TreeTip® with graduated tip for secure fit for virtually all newborns
- Smallest – Premie TreeTip 3mm
- Foam tip offers a better fit for varying shapes and sizes of ear canals



Printer Labels

- 300 self-adhesive labels/roll
- Results from both ears on one label

* U.S. Patent No. 6,258,043

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