

GSI AUDIOscreeener™

OAE AND ABR HEARING SCREENING



VIASYS[®]
HEALTHCARE
Excellence For Life

GSI AUDIOScreener™

THE PROBLEM

Hearing loss is the most common birth defect in the United States, affecting one million children (up to five of every thousand babies born). Yet most hearing-impaired children are not identified until 1 to 3 years of age – which is well beyond the critical period (6 months) for healthy speech and language development.

In addition, 3 out of 4 children experience otitis media (ear infections-the most common illness in babies and young children) by the time they are 3 years of age. An ear infection can cause temporary hearing, speech and language problems. If left untreated, these problems can become permanent.

However, if a hearing-impairment is identified and treated in its early stages, studies have shown that the child's speech and language skills will be comparable to his or her normal-hearing peers. For these reasons, hearing screening at birth and routinely throughout childhood is extremely important.



THE SOLUTION

THE SOLUTION IS ROUTINE HEARING SCREENING WITH OAE AND ABR TECHNOLOGY

Recent improvements in hearing screening standards have led to the advancement of hearing screening technology. Otoacoustic Emissions (OAE) and Auditory Brainstem Response (ABR) have become the standard of care for hospital newborn hearing screening programs. In addition, more and more physician offices are using the technology to screen children of all ages throughout adolescence.

THE GSI AUDIOSCREENER PROVIDES THE BEST SOLUTION FOR HEARING SCREENING WITH OAE AND ABR

- DPOAE, ABR and TEOAE
- Simple to Use Interface
- Objective Screening
- Time and Cost Savings
- High-Volume Screening
- Portability and Versatility



TECHNICAL FEATURES

OAE SOFTWARE FEATURES:

- DPOAE and TEOAE available for complete OAE screening
- Automatic Operations for quick and easy screening
 - Probe fit and calibration
 - 5 frequency pairs available - DPOAE
 - 5 frequency bands available - TEOAE
 - Pass criteria set to NIH 2000 protocol (configurable)
- Programmable test frequencies for more highly trained personnel (i.e. audiologist)
- Set the environment to *Noisy*, *Normal* or *Quiet* to get the most accurate results
- Real-time graphic test progress is available for monitoring
- Simple and detailed test reports are available for accurate reporting
- All test information is saved and stored for easy retrieval

ABR SOFTWARE FEATURES:

- Automatic Operations for quick and easy screening
 - Impedance test
 - Probe fit and calibration
 - Testing of up to 8 stimulus conditions per test
 - Pass criteria set to NIH 2000 protocol (configurable)
- Ability to create a latency intensity function
- Manual peak V scoring
- Manual threshold search
- Real-time graphic test progress is available for monitoring
- Click and tone pip stimulus available
- Stimulus rate of 32 to 62 stimuli per second
- Stimulus level of 0 to 98 dB SPL



It is now recognized that early intervention is critical to speech and language development in hearing-impaired infants and children. Available interventions include fitting a hearing aid before six months or performing a cochlear implant as early as one year of age. Selection of the proper plan requires accurate, detailed information about the hearing loss. This makes it critical that hearing clinicians have an objective, reliable method for measuring hearing loss in neonates and infants. **Hearing screening with OAE and ABR is the first step to early intervention.**



CONTINUUM OF CONFIDENCE

From the integrity of **VIASYS Healthcare** to the reliability of the data from our equipment, the GSI AUDIOscreeener is the most reliable, portable hearing screening system in the market.

COMPANY

With more than a century of combined experience, our trusted brands, Grason-Stadler, Nicolet and Toennies have provided **innovative technologies** for diagnostic audiology, neurodiagnostic, peripheral vascular and hand-held Doppler equipment.

EXPERIENCED SUPPORT

Our more than 220 trained regional and in-house representatives provide **unmatched customer support**. We're committed to helping you get the most out of your VIASYS diagnostic and monitoring systems.

HARDWARE

As with all our products, GSI Audioscreener is designed to achieve the perfect balance of **simplicity, ease of use, and flexibility**.

SUPPLIES

To complement the performance offered by all of our systems, we offer a full line of quality electrodes and supplies.

Excellence in life, excellence in design, and excellence in support: VIASYS Healthcare provides premier equipment, supplies, and services to help you offer the **quality of care** your patients expect.



BENEFITS

THREE MODELS

Choose the model to fit the screening needs of your hospital, office, or practice – OAE Only (includes DPOAE and TEOAE), ABR Only, Combination unit.

REQUIRES NO INTERPRETATION OF DATA

Only a single button push is necessary to initiate an OAE or ABR screening, producing a quick and clear *Pass* or *Refer* result.

OBJECTIVE AND ACCURATE SCREENING

Perform objective and accurate hearing screening that has been clinically proven to be highly specific and sensitive with a minimal refer rate.

TIME SAVINGS

OAE screening only takes 20 seconds per ear – saving valuable testing time while producing an additional cost-saving benefit.

PORTABILITY AND VERSATILITY

The GSI AUDIOscreeener is a hand-held, battery-operated hearing screening device designed to test newborns, children, adults and all difficult-to-test patients

HIGH-VOLUME SCREENING

The GSI AUDIOscreeener is designed for use by minimally trained staff (i.e. technician or volunteer), allowing for rapid and easy high-volume screening across multiple locations

PROBES OR COMFORT CUPS™

The GSI AUDIOscreeener can be used to perform an ABR test with probes inserted into the patient's ear canal or with the GSI COMFORT CUPS secured over the patient's ear.

WIRELESS DATA TRANSMITTAL

Up to 300 patient records can be either wirelessly transmitted, via infrared port, to and from a desktop computer, or to a printer for clear, concise, easy-to-read, full page reports.

TOTAL SCREENING ACCURACY

Real ear calibration for OAE and ABR promotes total screening accuracy, unlike competitor systems whose stimuli can vary by many dB.

REDUCE THE INCIDENCE OF FALSE POSITIVES

Limited OAE and ABR diagnostic data is gathered to help ensure that no child with a hearing impairment goes undetected and to reduce the incidence of false positives (children with normal hearing who receive Refer results). Data can be read by a staff audiologist or be emailed to a consulting audiologist.

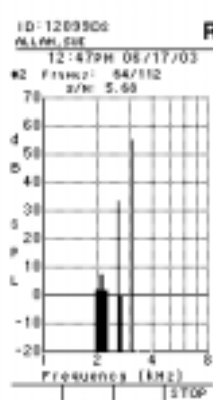
UNPARALLELED CUSTOMER SERVICE

The GSI AUDIOscreeener is supported by more than 60 years of customer service as well as technical support.

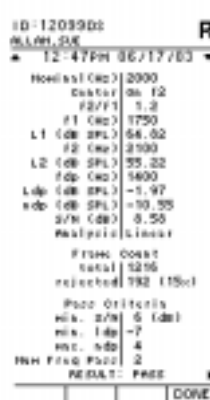
DPOAE TEST PROGRESS



GRAPH DPOAE TEST PROGRESS



NUMERIC DPOAE TEST RESULTS



GSI AUDIOscreeener™

OAE and ABR Hearing Screening

PRODUCT SPECIFICATIONS

GENERAL SPECIFICATIONS

L x W x H: 19.7 cm x 10.2 cm x 4.5 cm
Shipping Weight: 0.57 Kg
Test Types: Distortion Product Otoacoustic Emissions, Transient Evoked Otoacoustic Emissions and Auditory Brainstem Response
Screening Methods: Presence/Absence (DPOAE & ABR), Level (DPOAE & TEOAE), or Latency (ABR)
Display: Pass/Refer/Noise or Graphical
Reports: Simple or Detailed
ABR tests: Using Comfort Cups or Probe – protocols included
Storage: Up to 300 patients
Data Transfer: Infrared to computer or printer

DPOAE OPERATING SPECIFICATIONS

Frequency Range: 2,000 Hz to 6,000 Hz, $\pm 2\%$
Frequency Resolution: 50Hz
Level Measurement Accuracy: ± 1 dB SPL
Dynamic Range: 96 dB
Test Time: Varies dependent on parameters selected
Automated pass criteria:
DPOAE SNR and/or DPOAE Level

TEOAE OPERATING SPECIFICATIONS

Frequency Range: 250 Hz to 5,250 Hz, $\pm 2\%$
Frequency Resolution: 50Hz
Level Measurement Accuracy: ± 1 dB SPL
Dynamic Range: 96 dB
Test Time: Varies dependent on parameters selected
Automated pass criteria:
TEOAE SNR and TEOAE Reproducibility

ABR OPERATING SPECIFICATIONS

Stimulus types: Click 100 μ sec width, Blackman window tone pips (500Hz, 1KHz, 2KHz, 4KHz)
Stimulus Polarity: Rarefaction, Condensation, Alternating
Stimulus Rate: 32 to 62 per second
Stimulus Intensity: 0 to 100dB in 5dB steps
Level Measurement Accuracy: ± 1 dB SPL
Input Frequency Range: 30Hz to 3,000Hz
Waveform latency Delay: ± 0.2 msec
Common mode Rejection: 108 dB
Gain: 43 dB
Automated Impedance Testing
Automated Pass criteria: ABR Fsp

POWER

Power AC Adaptor: 100-240VAC
Line Frequency Range: 50 to 60 Hz

BATTERY

NiMH 2150 mAh
Operating life: Approximately 24hrs
Recharge time: Approximately 2hrs

SYSTEM CONFIGURATION

Each AUDIOscreeener™ comes with AUDIOtrac™, a Windows based patient database software package.

SYSTEM REQUIREMENTS FOR AUDIOtrac

Windows Operating system (95, 98, 2000, ME, XP, or NT)
CD-ROM Drive
5 Mb or more available space on Hard drive
3.5", 1.44 Mb floppy disk drive
An Infrared port (IrDA) set to COM 1.
For systems that do not have an IrDA as standard a special IrDA is provided.
Screen resolution 800x600 or larger

ENVIRONMENTAL

Temperature:
Storage: 0°C to 50°C
Operating: 10°C to 40°C
Humidity: up to 95%, (non-condensing)

ALARMS

Low Battery, Dead Battery
Database Error
Internal Circuit Error

QUALITY SYSTEM

Manufactured, designed, developed and marketed by VIASYS Healthcare Inc. NeuroCare Group under ISO 13485, ISO 9001 certified quality system.

COMPLIANCE / REGULATORY STANDARDS

Designed, tested and manufactured to meet the following domestic (USA), Canadian, European and International Standards:

UL 2601-1 Standard for Safety Medical Equipment
IEC 601-1-2 Medical Electrical Equipment CISPR 11 (EN55011)
IEC 1000-4-2, IEC 1000-4-3, IEC 1000-4-4, IEC 1000-4-5 EN 61000-4-11 IEC 10000-4-8
ANSI S3.6-1996 IEC 60601-2-26 IEC 60601-2-40 IEC 60645-3
CSA C22.2, No. 601-1
CE 0344 – the CE mark on this product indicates that it conforms with the 93/42/EEC Medical Device Directive

VIASYS HEALTHCARE

Grason-Stadler • Medelec • Nicolet • TECA

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