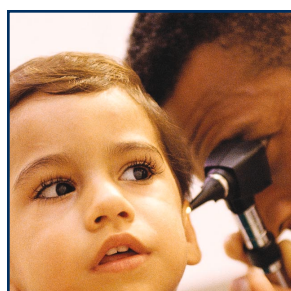


# ERO•SCAN™

OAE TEST SYSTEMS



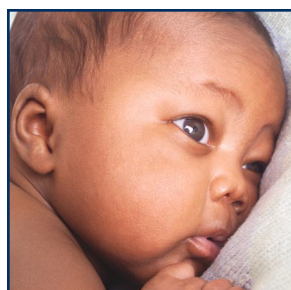
**Head Start & School Screening**



**Pediatrics**



**Otolaryngology & Audiology**



**Newborn Screening**

*Reliable, Quick, Cost-effective OAE Testing*

TRUSTED TECHNOLOGY



# What are OAEs?

*In 1977,  
Dr. David Kemp  
discovered that  
the cochlea was  
capable of  
producing sound.  
These sounds  
are known as  
Otoacoustic  
Emissions (OAEs).*

Otoacoustic emissions are low-level sounds generated by the outer hair cells of the cochlea (inner ear) in response to auditory stimuli. OAEs are present in nearly all normal-hearing ears. Absent OAEs indicate hearing loss and/or middle ear pathology.

The ERO•SCAN measures two types of OAEs, Distortion Product Otoacoustic Emissions (DPOAEs) and Transient Otoacoustic Emissions (TEOAEs). DPOAEs are generated by simultaneous stimulation of the outer hair cells by presenting two pure tones of different frequency through the OAE probe. TEOAEs are generated when the ear is stimulated by clicks or tonebursts. DPOAEs and TEOAEs are equally reliable in the 1.5 kHz to 4 kHz range. TEOAEs are more reliable for frequencies below 1.5 kHz while DPOAEs are more reliable for frequencies above 4 kHz.



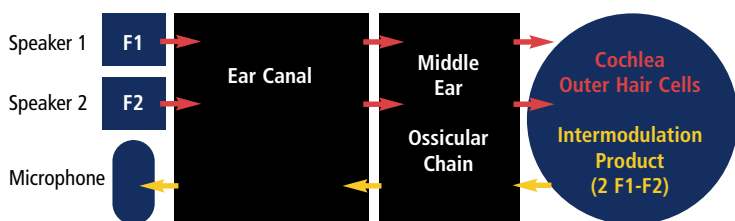
## HOW IS AN OAE DETECTED?

An OAE probe with eartip is inserted into the ear canal and sealed. The acoustic signal is presented from the probe. The signal travels through the ear canal, the middle ear, and finally reaches the cochlea where the outer hair cells are excited and the emission is generated. The emission travels back through the middle and outer ears and is detected by a highly sensitive microphone in the OAE probe.

Emissions are very soft sounds that must be separated from environmental and biological sounds. Computer averaging and noise reduction techniques are used to separate the emissions from the noise.

Note that both the stimuli and the emission must travel from the outer ear through the middle ear before reaching the cochlea and then back along the same pathway. For this reason, OAE tests detect middle ear pathology and cochlear hearing loss.

## Pathway of OAE Transmission:



## ERO•SCAN System Parts and Accessories



ERO•SCAN



Cradle



Printer



Headphones



Cable



Database Software  
(optional accessory)



Printer Paper



Probe Tips



**Print out from optional database software for full page customized reporting capabilities and data transfer to patient management software**

**Print out from printer that comes with all versions of ERO•SCAN**

.....  
**ERO•SCAN MAICO**  
 .....  
 OTOACOUSTIC EMISSIONS TEST  
 Right 27-Mar-98 05:55 PM  
 DP 4 sec avg U7.62

NAME:	F2	P1	P2	DP	NF	SN
2.0	65	55	-9	-13	4	
3.0	65	55	3	-19	22	
4.0	65	55	1	-20	21	
5.0	66	55	-4	-20	16	

F2 P1 P2 DP NF SN  
 2.0 65 55 -9 -13 4  
 3.0 65 55 3 -19 22  
 4.0 65 55 1 -20 21  
 5.0 66 55 -4 -20 16

F2 P1 P2 DP NF SN  
 2.0 65 55 -9 -13 4  
 3.0 65 55 3 -19 22  
 4.0 65 55 1 -20 21  
 5.0 66 55 -4 -20 16

Level (dB) NF -DP

**Right : Pass**

**4 frequencies (default)**

.....  
**ERO•SCAN MAICO**  
 .....  
 OTOACOUSTIC EMISSIONS TEST  
 Right 09-May-03 11:59 AM  
 DP Custom 1 sec avg U7.62

NAME:	F2	P1	P2	DP	NF	SN
2	66	56	19	-12	31	
4	65	55	7	-15	22	
6	65	55	6	-18	24	
8	69	60	-1	-14	14	
10	70	55	-1	-15	14	
12	58	59	4	-13	16	

F2 P1 P2 DP NF SN  
 2 66 56 19 -12 31  
 4 65 55 7 -15 22  
 6 65 55 6 -18 24  
 8 69 60 -1 -14 14  
 10 70 55 -1 -15 14  
 12 58 59 4 -13 16

Level (dB) NF -DP

**Right**

**6 frequencies (advanced options)**

Maico Diagnostics ERO•SCAN

DPOAE Distortion-Product Otoacoustic Emission Test Report

**Right Ear : Pass**

Patient Name: Bob Smith  
 Patient ID: SI031965  
 Date of Birth: 01/02/02  
 Sex: Male

Test Number: Test Date: 11/16/97 03:03 PM  
 Tester: TKL Physician: Ranikan  
 Test Mode: CustomA Avg. Time: 1  
 Firmware: 5.92

F2	P1	P2	DP	NF	SNR
1.5	64	55	-2	-10	8
2.0	67	57	7	-12	19
3.0	66	53	5	-13	18
4.0	63	53	7	-18	25
5.0	63	54	2	-18	20
6.0	64	54	-6	-18	12

Notes:

**Left Ear : Pass**

Patient Name: Bob Smith  
 Patient ID: SI031965  
 Date of Birth: 01/02/02  
 Sex: Male

Test Number: Test Date: 11/16/97 03:03 PM  
 Tester: TKL Physician: Ranikan  
 Test Mode: CustomA Avg. Time: 1  
 Firmware: 5.92

F2	P1	P2	DP	NF	SNR
1.5	65	55	-2	-10	8
2.0	65	56	11	-11	22
3.0	67	54	9	-13	21
4.0	65	54	10	-18	28
5.0	63	56	9	-18	27
6.0	66	55	11	-18	29

Notes:

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Eartips



Printer AC Power Supply



Printer Rechargeable Battery  
(optional accessory)



AA batteries  
UM-3/R6 Alkaline



Remote Probe



Carrying Case  
(optional accessory)

# Head Start & School Screening

*The MAICO ERO•SCAN is ideal for school screening because it can quickly identify a possible hearing loss and signal referral for more comprehensive audiometric testing.*

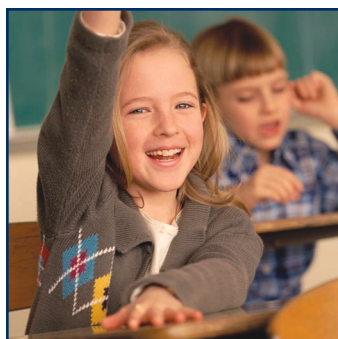
## The Goals for School Hearing Screening

*To identify hearing loss that may influence communication, development, health or academic performance.*

AND

*To identify outer and middle ear disorders.*

*Currently, otoscopy, pure-tone audiometry and tympanometry are used to accomplish these goals.*

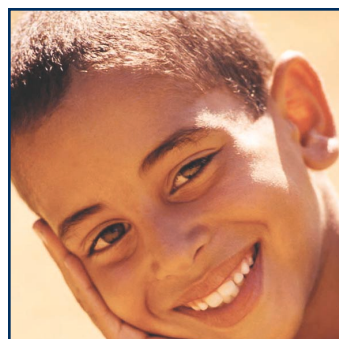


### ADVANTAGES OF OAEs

- OAEs accomplish both goals of screening using only one test
- No response is required from the child. Pure tone audiometry requires a response e.g., raising a hand or dropping a block. Teaching a child to respond is often time consuming and difficult
- Testing can be performed on special-needs children
- School personnel can easily be trained to do OAE testing
- Easy to screen children who speak English as a second language
- Screening can be done in less than half the time when compared to using traditional methods

### WHAT OAEs CAN TELL US

- A **PASS** indicates normal OAEs and this correlates with normal hearing and normal cochlear function
- A **REFER** means OAEs were not present and is suggestive of a possible hearing loss greater than 30 dB HL or an outer or middle ear disorder (e.g., otitis media)



## INSTRUMENT

- Calibrates before each test
- AutoStart
- Automatically saves data to non-volatile memory
- Automatic power-down
- Time and date clock





# Pediatrics

*Hearing loss is not always identified by newborn screening. This is why pediatricians are usually the first professionals parents approach with concerns about their child's hearing.*

*Hospital based and private practice pediatricians routinely screen infants and young children for hearing loss and middle ear disorders using otoacoustic emissions.*

*A pediatrician's office can benefit dramatically from having OAE testing capability. A normal, cochlea will be associated with normal OAEs and normal hearing levels. Therefore, if the OAE is absent, cochlear hearing loss and/or middle ear pathology is likely.*



## REIMBURSEMENT

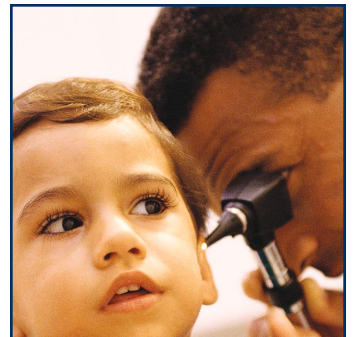
OAE tests can be billed under two CPT codes. The ERO•SCAN test protocol determines which code to use.

- **92587**  
Evoked otoacoustic emissions; limited (single stimulus level, either transient or distortion products)
- **92588**  
Comprehensive or diagnostic evaluation (comparison of transient and/or distortion product otoacoustic emissions at multiple levels and frequencies)

Based on current reimbursement rates, most professionals will find the cost of equipment recouped in 6-12 months.

## PEDIATRIC USES

- Follow-up infants from nursery screening and well baby checks
- Identify and monitor middle ear pathology (e.g., otitis media)
- Detect late-onset hearing loss
- Monitor ototoxic medication
- Identify educationally significant hearing loss
- Obtain objective cochlear function results from both ears of toddlers
- Together with an otoscopic exam or tympanometry, OAEs will rule out middle ear pathology.
- Repeat OAEs can be used to monitor middle ear problem resolution and ensure normal cochlear function



## PROBE

- Completely self-contained; no external cables
- Low-noise, high-accuracy probe
- Mechanically-isolated probe permits hand-held operation with no degradation in noise specification



# Otolaryngology & Audiology

*Otoacoustic Emissions have emerged as an essential part of the hearing assessment process in Otolaryngology and Audiology Offices.*

*OAEs are an integral part of hearing assessment.*

*OAEs are fast, noninvasive, cost-effective and have valuable diagnostic implications for patient treatment.*

## ADVANTAGES OF OAEs

- OAEs give information about hearing and middle ear status with only one test
- OAEs are objective
- No need to instruct or condition the patient
- Effective with difficult-to-test patients
- OAEs can be performed by office personnel

## HIGH-FREQUENCY DPOAEs

Measurements may prove useful for:

- Ototoxic drug monitoring in young patients
- Prospective studies of noise-induced hearing loss
- Obtaining scientific data on the effect of aging on DPOAEs



## OTOLARYNGOLOGY & AUDIOLOGY USES

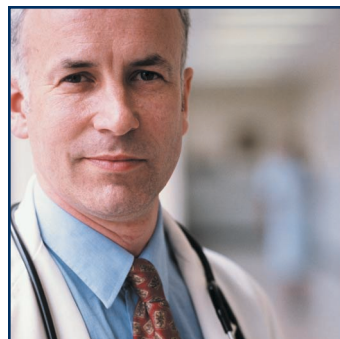
- Monitor middle ear pathology post PE tube insertion
- Rule out retrocochlear pathology
- Differentiate peripheral from central auditory disorders
- Monitor effects of ototoxic medications and occupational noise exposure
- Use in conjunction with high frequency audiometry
- Screen both ears of infants and toddlers
- Evaluate difficult-to-test and developmentally disabled patients
- Identify suspected non-organic hearing loss
- Community hearing screenings

## REIMBURSEMENT

OAE tests can be billed under two CPT codes. The ERO•SCAN test protocol determines which code to use.

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Based on current reimbursement rates, most professionals will find the cost of equipment recouped in 6-12 months.



## PRINTER

- High-speed
- Printed results in 3 seconds
- Test results can be downloaded to a PC with optional database software



# Newborn Screening

*Research confirms that children who are identified and receive intervention before the age of six months have significantly better speech and language development than those identified later.*

The following organizations support universal newborn screening:

- American Academy of Pediatrics
- American Academy of Audiology
- American Speech-Language-Hearing Association

*Otoacoustic Emissions (OAEs) testing is preferred over Auditory Brainstem Response (ABR) testing as a quick, cost-effective measurement tool in the newborn nursery.*



## ADVANTAGES OF OAEs vs. ABR

- Cost, time, and simplicity
- OAEs can easily be measured in 10-30 seconds
- OAE testing can be performed by nurses or trained volunteers
- No interpretation needed: A simple **Pass/Refer** is displayed
- OAE equipment is thousands of dollars less than ABR equipment
- OAEs have very low disposable costs

## REMOTE PROBE ADVANTAGES

The remote probe is recommended when testing newborns.

- Allows head movement
- Provides better comfort and less disturbance
- Reduces noisy recordings
- Reliably tests more infants in less time

**ERO•SCAN'S NOISE REJECTION ALGORITHM IS THE MOST EFFECTIVE ON THE MARKET ALLOWING FOR RELIABLE TESTING IN UP TO 70 dB OF BACKGROUND NOISE**



## REMOTE PROBE

- Recommended for newborns
- Simply plug the remote probe into the top of the ERO•SCAN and it is immediately detected
- No adjustments are needed, and EROSCAN controls are used in the usual way



# ERO•SCAN

OAE TEST SYSTEMS

## Probe Specifications

Measurement Type	Otoacoustic Emissions
Frequency Range	1.5 to 12 kHz (DPOAE) 0.7 to 4 kHz (TEOAE)
Stimulus Intensity	40 to 70 dB SPL (DPOAE) 83 dB SPL (TEOAE)
Maximum Output (protection)	90 dB SPL
Microphone System Noise	-20 dB SPL @ 2 kHz (1 Hz bandwidth) -13 dB SPL @ 1 kHz (1 Hz bandwidth)
Stimulus Sampling Rate	31,250 Hz

## Instrument Specifications

Power Supply	(4) AA/UM-3/R6 cells - Alkaline (6 V total)
Battery Life	Approximately 300 tests
Instrument Weight	10.6 oz. (300 g) including batteries

## Printer Specifications

Type	Thermal dot matrix line printer
Speed	>10 lines per second
Operating Noise	<50 dB SPL
Weight	1 kg (2.2 lbs) including power supply
Power Source	Medical grade power supply (EN 60601-1)
Input	120-240 V
Output	7 V, 5.0 A
Paper	Calculator-type thermal roll – 2.25" wide (57 mm)

## Processor Specifications

Digital Signal Processor	Motorola 56303 24-bit 66 MHz 3.3 V
Storage	2 Mbit EEPROM (non-volatile)
Battery Backup	0.1F 5.0 V (approx. 24 hours)
CODEC	18 bit D/A, 18 bit A/D 96 dB SNR typical
Display	4 line x 10 character STN liquid crystal
Switches	Membrane keypad 1 million + actuation

## Remote Probe Specifications

Length	6 ft. (1.8 m)
Weight	3.6 oz. (102 g)
Connector	8-pin MiniDIN

## Maximum SPL

The maximum sound pressure level output of this instrument remains well below 90 dB SPL throughout the audible frequency range of 20 Hz to 20 kHz. This level is well within OSHA permissible limits of 90 dBA for 8 hours.

Conforms to IEC 601-1.

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U.S. PATENT #5,954,669; 6,056,698; 6,299,584; 6,331,164  
OTHER PATENTS PENDING

Licensed under Otodynamics Ltd. U.S. Patent #4,374,526 and International Patents  
Licensed under Madsen Electronics U.S. Patent #5,738,633 and International Patents  
Printed in USA

The ERO•SCAN OAE System is available in three configurations: Screener, Standard and Combo System

### Product Feature

	ERO•SCAN Screener	ERO•SCAN Standard	ERO•SCAN Combo System
<b>DPOAE/TEOAE</b>	DP or TE	DP or TE	DP and TE
<b>Diagnostic (CPT)<sup>1</sup> 92588</b>	N	Y	Y
<b>Portable</b>	Y	Y	Y
<b>Printer Included</b>	Y	Y	Y
<b>Internal Probe</b>	Y	Y	Y
<b>External Probe</b>	Y	Y	Y
<b>Max.# of Test Frequencies or Bands Reported</b>	4 DP 6 TE	6 DP 6 TE	6 DP 6 TE
<b>Frequency Range</b>	2-5 DP 1.5-4 TE	1.5-12 DP .7-4 TE	1.5-12 DP .7-4 TE
<b>High Frequency DPs to 12 kHz</b>	N	Y	Y
<b>Default Pass/Refer</b>	Y	Y	Y
<b># of Test Protocols</b>	1	2	4
<b>Memory (# tests)/Maximum</b>	50	50	50
<b>Tests All Ages</b>	Y	Y	Y
<b>Tests Patients with PE Tubes</b>	Y	Y	Y
<b>Automatic Self-Calibration in the Ear</b>	Y	Y	Y
<b>Requires Yearly Calibration</b>	N	N	N
<b>Customizable Test Protocols</b>	N	Y	Y
<b>Customizable Pass Criteria</b>	N	Y	Y
<b>Database Software (Cost Option)</b>	Opt	Opt	Opt
<b>Printer Included</b>	Y	Y	Y
<b>Prints Numeric Data</b>	Y	Y	Y
<b>Prints Graphic Data</b>	Y	Y	Y
<b>Customizable Averaging Time</b>	N	Y	Y
<b>Date/Time on Print-Out</b>	Y	Y	Y
<b>Monitoring Headset</b>	Y	Y	Y
<b>OZ Compatible</b>	Y	Y	Y
<b>HI*TRACK Compatible</b>	Y	Y	Y
<b>Completely Isolated Printer "optional" (does not require external line source)</b>	Y	Y	Y
<b>Customizable Parameters (test characteristics)</b>	N	Y	Y
<b>P1 and P2 (DPs)</b>	N	Y	Y
<b>Freq. Range (DPs and TEs)</b>	N	Y	Y
<b>Average Time (DPs and TEs)</b>	N	Y	Y
<b># Freq. Tested (DPs)</b>	N	Y	Y
<b>All test protocol changes can be made through OAE unit alone (Additional software and computer NOT required to change protocols)</b>	Not Customizable	Y	Y
<b>Cost of Disposable Eartips</b>	\$0.15	\$0.15	\$0.15

Opt – Optional Y – Yes N – No <sup>1</sup> can bill for diagnostic DPOAE testing with this unit



**Maico Diagnostics**  
9675 West 76th Street  
Eden Prairie, MN 55344

phone 952-941-4200  
toll free 888-941-4201  
fax 952-903-4200  
www.maico-diagnostics.com

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