Operating Instructions ERO•SCAN® *Pro*

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1 Introduction

The ERO•SCAN® Pro test Instrument is indicated for testing cochlear and middle ear function in infants, children, and adults by measuring otoacoustic emissions (OAEs), tympanometry, and acoustic reflex (with optional external Tymp•OAE Probe™). The presence of otoacoustic emissions suggests normal outer hair cell function, which in turn correlates to normal hearing. The presence of a normal tympanogram suggests normal middle ear function and the presence of acoustic reflex responses at or below 95 dB HL indicates normal inner hair cell function.

The ERO•SCAN Pro is intended to be used by hearing healthcare professionals (i.e. ENT doctors, audiologists) and/or technicians, neonatal nurses and school nurses who have been trained by a hearing healthcare professional.

1.1 Instrument Description

What is the ERO•SCAN Pro Instrument?

The ERO•SCAN Pro test instrument consists of the handheld unit, external probe(s), printer, single-use eartips and other accessories. The ERO•SCAN Pro instrument may be used as a screening tool, or in conjunction with conventional tests as part of a full diagnostic evaluation.

The ERO•SCAN Pro instrument contains the hardware and software for generating the test stimuli, measuring and displaying test results, and storing the results until they are printed or downloaded to the PC software. The plastic housing contains circuit boards that provide the signal processing and display the test results. The instrument also contains 4 AA/UM-3/R6 alkaline batteries to power the device. The instrument uses an organic LED display (OLED) and light-emitting diodes (LEDs) to provide a visual display of test data and test conditions to the operator. Two membrane-type push buttons and a 4-way navigation control located on the control panel of the device allow the user to power the instrument on and off, control testing, and initiate printing.

The probe sections of the instrument and external probes house a microphone, two transducers, and two speaker tubes which produce test stimuli and measure the sound pressure level (SPL) present in the sealed ear canal. Additionally, the combined Tymp•OAE Probe™ contains a mechanical pump system and pressure sensor to control and monitor air pressure variation in the ear canal. Each probe houses a keypad with two buttons (right and left) which can be used to start a test with the probe. LED's on the probe keypad indicate ear being tested and test status.

Interface of the instrument to the ear canal is accomplished through disposable eartips made of industrial elastomer, which fit onto the probe tip. The disposable eartips are color coded to facilitate easy selection by size.

How are the Results Stored and Reported?

When the ERO•SCAN Pro is set in its default settings, the instrument will store the results from one patient (most recent left and right ear test for each available protocol) in its non-volatile memory for

subsequent printing. The results are displayed via the display on the front of the device and are stored in the device's internal memory. After testing is completed, results can be printed using the optional thermal paper printer or the default PC printer via software interface. Tests can also be exported to a computer database via optional software. Test results are stored in the non-volatile memory so the operator can delay printing until a later time if desired.

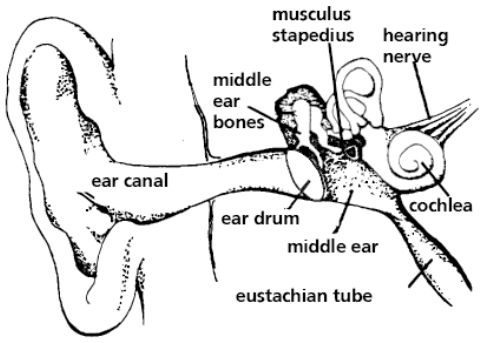
1.2 Otoacoustic Emissions

What Are DPOAEs?

Distortion Product Otoacoustic Emissions (DPOAEs) are acoustic signals that can be detected in the ear canal of a person with normal outer hair cell function, subsequent to stimulation of the auditory system with a pair of pure tones at frequencies f_1 and f_2. The resulting emission of interest is the distortion product tone at the frequency $2f_1$-f_2.

What Are TEOAEs?

Transient Evoked Otoacoustic Emissions (TEOAEs) are acoustic signals that can be detected in the ear canal of a person with normal outer hair cell function, subsequent to stimulation of the auditory system with a series of wideband clicks.



What Do Otoacoustic Emissions Results Tell Us?

Available evidence suggests that otoacoustic emissions (OAEs) are generated by the cochlea's outer hair cells, and that the presence of OAEs is an indication that the outer hair cells are normal. Although OAE test data provide no indication of inner hair cell function, or of hearing ability, current research indicates that the majority of hearing-impaired individuals can be identified by a simple OAE test. Patients who fail to generate OAEs should be rescreened and/or referred for additional audiological testing.

How Does the ERO•SCAN Pro Device Measure DPOAEs?

The ERO•SCAN Pro instrument generates a series of test tones, directs them into the ear canal, and then measures the level of the DPOAE tone generated by the cochlea. By using different test frequencies, the ERO•SCAN Pro device provides an estimate of outer hair cell function over a wide range of frequencies.

How Does the ERO•SCAN Pro Device Measure TEOAEs?

The ERO•SCAN Pro instrument generates a series of clicks, directs them into the ear canal, and then analyzes the spectrum of the returning signal, separating the noise and emission. By using bandpass filters, the ERO•SCAN Pro device provides an estimate of outer hair cell function over a wide range of frequencies.

How Does the ERO•SCAN Pro Device Work?

The digital signal processor in the instrument generates two pure tones (f_1 and f_2) for DPOAEs or a series of wideband clicks for TEOAEs through a digital-to-analog converter. These tones or clicks are presented to the ear via speaker tubes located in the probe. A microphone in the probe measures the sound in the ear canal and transmits the signal to the analog-to-digital converter. The digital signal processor then uses Fast-Fourier Transforms (FFTs) to filter the signal into narrow frequency bands, and detects any emissions present. The level of these emissions can be compared with the level of the noise.

The SPL and frequencies of the test tones and the averaging time used to process the signals can be determined by the tester through adjustable settings maintained in static memory within the ERO•SCAN Pro instrument.

What Frequency Range of Hearing is Estimated?

DPOAEs: Approximately 1.5 kHz to 12 kHz (depending on the frequency range selected). Since the health of the hair cells in the region of the f_2 test frequency are estimated, and a) the $2f_1$-f_2 emission frequency is at about six-tenths of the f_2 frequency, b) emissions tend to be weak below 600 Hz or so, and c) the ambient noise tends to be highest at low frequencies, the lowest f_2 test frequency that can be routinely measured is about 1 kHz. TEOAEs: Roughly 500 Hz to 4 kHz. TEOAEs can be reliably recorded at lower frequencies than DPOAEs, but cannot be measured reliably above 4 kHz.

1.3 Tympanometry

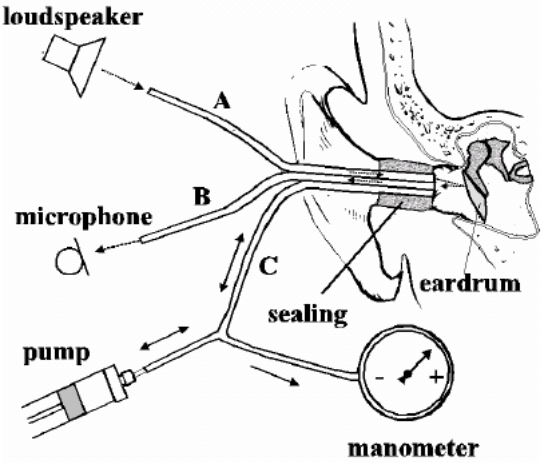
What is tympanometry?

Tympanometry is the objective measurement of middle ear mobility (compliance) and pressure within the middle ear system. During the test, a probe tone (226 or 1,000 Hz) is presented to the ear canal by means of the Tymp•OAE Probe. This tone is used to measure the change in compliance in the middle ear system while the air pressure is varied automatically from a positive value (+200 daPa) to a negative value (-400 daPa max.).

How is compliance measured?

Maximum compliance of the middle ear system occurs when the pressure in the middle ear cavity is equal to the pressure in the external auditory canal. This is the highest peak of the curve as it is recorded on the chart. The position of the peak on the horizontal axis and on the vertical axis of the chart will provide diagnostic information regarding the function of the middle ear system. Examples of normal and abnormal tympanograms can be found in a later section of this manual.

What other measurements are calculated?



Gradient calculations are reported as the tympanogram width at half of peak compliance expressed in daPa. A "limits" box is available on both the display and printout to aid in diagnosis. Compliance is measured with respect to an equivalent volume of air, with the scientific quantity milliliter (ml). Air pressure is measured in deca-Pascals (daPa).

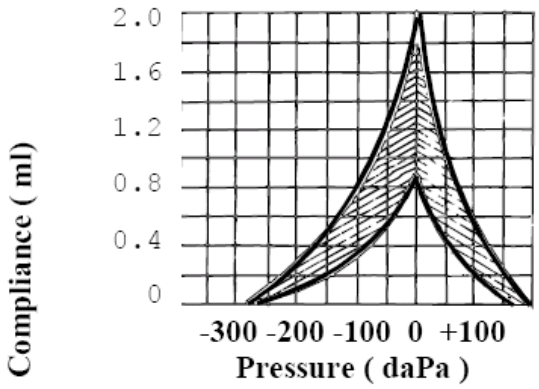
What does tympanometry tell us?

The impedance measurement assists in diagnosing of the condition of the middle ear and can therefore not be compared directly with other audiometric tests such as sound or speech audiometry which assists in the measurement of hearing. Furthermore, the impedance measurement is an objective measuring method which does not depend on the cooperation of the test person and can therefore not be falsified by the patient.

The impedance measurement examines the acoustic resistance of the middle ear. If the eardrum is hit by a sound, part of the sound is absorbed and sent via middle ear to the inner ear while the other part of the sound is reflected. The stiffer the eardrum is the more sound is reflected and the less sound reaches the inner ear. Inside the probe of the impedance measuring instrument a small loudspeaker is installed which emits a low frequency sound through a tube (Figure 3) into the auditory canal before the

eardrum. Another tube is connected to the microphone inside the probe which receives the sound. Together with a third tube, all three are inserted deeply into the ear canal and are made airtight against outside pressure by the ear tip. A manometer and a pump, which can produce both positive and negative pressure, are connected with tube C. Less sound is reflected to the microphone when the eardrum is stiff and the eardrum transmits the majority of the sound via the middle ear to the inner ear. The highest compliance is normally reached with an air pressure corresponding to the outside pressure.

While performing tympanometry measurements, a continuous change of positive and negative pressure is produced by the pump of the instrument in the outer auditory canal. The compliance is measured simultaneously and shown in a diagram (the tympanogram) which illustrates the compliance in ml or mmho over the pressure in daPa. The area for normal tympanogram curves is hatched. Here you can see that the highest compliance is reached with normal pressure. When you create positive and negative pressure the eardrum stiffens - the compliance decreases. So you can draw conclusions on the condition of the middle ear from the form and the values of the tympanogram.



NOTE: 1.02 mm H2O = 1.0 daPa.

1.4 Acoustic Reflex

Acoustic reflex refers to the reflexive contraction of the stapedius muscle in response to sound stimulation (typically 70-100dB). This contraction causes reduced mobility of the ossicular chain and reduces the compliance of the tympanic membrane which is measured by the probe as a change in admittance. The Stapedial (acoustic) reflex is always bilateral in response to loud sound presented to either ear, and the lowest level that causes a change in admittance is called the reflex threshold. Typically the average threshold is around 85dB HL with normal limits falling between 70 and 95dB HL.

2 Getting Started

2.1 Unpacking the system

Standard System Parts:
(1) ERO•SCAN Pro Hand-held unit w/ internal probe
(1) External OAE•Probe™ or
(1) External Tymp•OAE Probe™
(1) Cradle
(1) USB cable
(1) Box of disposable eartips in assorted sizes
(4) AA/UM-3/R6 Alkaline batteries
(4) Internal probe tips (4/pkg)
(4) External probe tips (4/pkg)
(1) ERO•SCAN Pro PC software CD
(1) Operating Manual

Optional System Parts:
(1) Calibration cavity
(1) Thermal Paper Printer with Lithium Ion battery installed with:
(1) Thermal printer paper roll
(1) Printer charger
(1) Printer data cable

Note: It is recommend that you save the box and packing materials in case you need to store or ship the system.

Standard System Parts


Handheld
589


Eartip Kit
589-7


Cradle
589-2


USB Cable
1025-2088


Operating Manual
1162-0802

AA Batteries
1145-2002


Internal Probe Tips
589-4


External Probe Tips
589-5

PC Software CD
589-8

Optional Parts


Thermal Paper Roll
586-8


Calibration Cavity
589-9


Printer Kit
589-10

Probes

Standard w/ OAE Units


OAE•Probe
589-1

Standard w/ Tymp Units


Tymp•OAE Probe
589-3

2.2 Battery Installation

The ERO•SCAN Pro instrument uses 4 AA/UM-3/R6 Alkaline batteries. Open the battery compartment by sliding the battery panel down and install the batteries as indicated on label inside the compartment. Once the batteries are correctly in place, slide the panel back onto its tracks to close the battery compartment.

3 Getting familiar with the ERO•SCAN Pro Instrument

3.1 Controls and display (Figure 1)

Power Button:

Press to power on
Press and hold to power off

Info Button:

View detailed information about the selection

Navigator:

Up/down arrows change the selection shown on the middle line
Left/right arrows initiate the action shown in the bottom line of the display.

Test Status Indicators:

Green – indicates the instrument is ready to test
Yellow – indicates test is in progress
Amber – indicates an error condition

Figure 1

3.2 Internal Probe

The internal probe is located on the underside of the ERO•SCAN Pro instrument. It allows for the measurement of DPOAEs in the range of 1.5 kHz to 6 kHz and TEOAEs in the range of 0.7 kHz to 4 kHz.

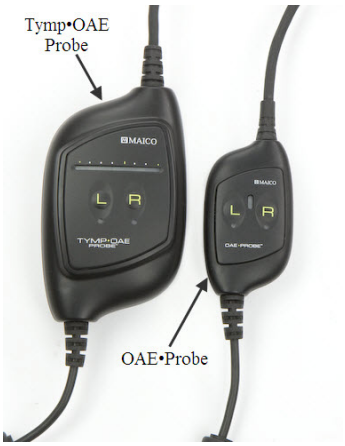
Note: Tympanometry, acoustic reflex, and high frequency DPOAE measurements are not supported by the internal probe of the ERO•SCAN Pro.

The internal probe consists of a patented dual isolated spring design which prevents hand movement from being transferred to the ear canal where it would be measured as noise (a common problem with any truly handheld OAE probes). The internal probe assembly houses the microphone which measures the acoustic information present in the ear canal and the tubing which carries the stimulus from the receiver(s) to the ear canal. Interface of the instrument to the ear canal is accomplished through disposable eartips made of industrial elastomer, which fit onto the probe tip. A disposable internal probe tip snaps to the shaft of the spring assembly and serves as an attachment point for the disposable eartips.

3.3 External Probes

There are two types of external probe available for use with the ERO•SCAN Pro instrument. Each consists of the following basic parts:

Connection cable – connects probe to ERO•SCAN Pro instrument by way of the connector
Probe enclosure – contains the circuitry, one receiver, and, in the case of the Tymp•OAE Probe, the pump and pressure sensor
Keypad – consists of LED status indicators and Right/Left test start buttons
Probe cable – connects the probe enclosure to the probe head
Probe head – contains the microphone and one receiver
Probe tip – disposable tip onto which the eartip is affixed for sealing to the ear



OAE•Probe™

The OAE•Probe allows for the measurement of:

DPOAEs in the range of 1.5 kHz to 12 kHz
TEOAEs in the range of 0.7 kHz to 4 kHz.

Tymp•OAE Probe™

The Tymp•OAE Probe allows for measurements of:

DPOAEs in the range of 1.5 kHz to 12 kHz
TEOAEs in the range of 0.7 kHz to 4 kHz
Tympanometry with a 226 Hz or 1000 Hz probe tone
Acoustic reflexes with 226 Hz probe tone (stimulus options: 0.5, 1, 2, & 4 kHz; broadband noise, low pass noise & high pass noise) or 1000 Hz probe tone (stimulus options: broadband noise)

The external probe keypads consist of a left (indicated by *L*) and right (indicated by *R*) button to initiate the selected test protocol or series. Below the left and right buttons are blue (for left) and amber (for right) LEDs which illuminate during testing to indicate the ear under test.

Each probe provides a status indictor in the form of LED(s) located on the keypad. In the case of the OAE•Probe the indicator is between the left and right buttons. On the Tymp•OAE Probe the indicator is a row of LED's above the left and right buttons.

The LED located between the left and right buttons indicates status of the probe:

Green:	Probe has been detected and instrument is ready to test
Flashing Yellow:	AutoStart in process
Solid Yellow:	Testing in progress

The status indicator bar on the Tymp•OAE Probe will indicate the pressure sweep of the pump by showing a sweeping sequence of lights.

Note: When idle (not testing) the probe status LED should be solid green. If the LED is yellow when idle then the probe has not been detected by the instrument. Power off the instrument, check the probe connection, and turn the instrument on again to detect the probe. The status LED should now be solid green.

The external probes are preferred by most users when conducting OAE measurements for infants, young children, and other difficult to test populations such as individuals with multiple handicaps. The external probe allows the user to insert the probe tip into the ear and then wait until the patient is quiet before starting the test. The internal probe may be preferred by some users for fast OAE testing of cooperative patients.

Installing the External Probe

Turn off the ERO•SCAN Pro and insert the external probe plug into the socket on the top of the ERO•SCAN Pro. The plug will fit only in one direction. The arrows on the plug should face the display on the ERO•SCAN Pro.

Turn on the ERO•SCAN Pro. The status indicator on the external probe keypad will be solid green indicating the ERO•SCAN Pro has detected the presence of the remote probe. Disconnect and reinsert the connector if the status indicator on the probe is not illuminated or is yellow rather than green. To return to using the internal probe of the handheld, turn the instrument off, disconnect the external probe and power up the instrument again.

Note: Misalignment of the plug and socket when installing the remote probe can cause damage to the pins in the plug and the pin receptacles in the socket. The plug and socket should be visually inspected prior to each installation of the remote probe. If damage is observed, contact your Special Equipment Distributor or Maico Diagnostics.

4 Conducting a Measurement

4.1 Quick Start

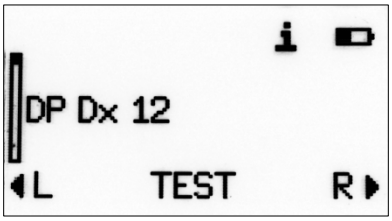


Figure 2

The ERO•SCAN Pro instrument arrives preloaded with default protocols and ready to test. Testing with the external probe can be started with just five easy steps.

1. Turn on the instrument.
2. From the main menu (Figure 2), select the desired protocol or series using the up or down arrows on the navigator.
3. Select an eartip and place if fully on the probe tip.
4. Secure the probe to the patient and insert the eartip deeply into the patient's ear.
5. To begin a test Press the right or left arrow button on the control panel (Figure 1) or press the L or R button on the external probe.

Additional information for each step is provided below.

When Tymp•OAE Probe is connected, the pump will perform an initialization. Do NOT insert the Tymp•OAE Probe into the ear canal while the pump is performing this initialization. The probe should be placed in the ear canal either BEFORE or AFTER the pump initialization.

4.2 Powering on the instrument

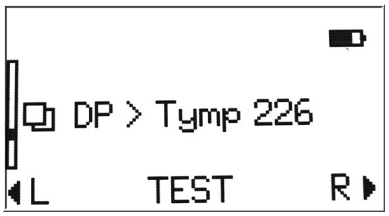
To turn on the ERO•SCAN Pro instrument, press the power button located on the handheld control panel just below the left corner of the display window.

A flash screen showing the firmware version (first line), serial number (second line), and date set in the instrument (third line) will illuminate briefly before showing the main display.

If testing with the external probe, be sure to connect the external probe prior to powering on the instrument. When the probe is detected the status indicator on the external probe keypad will be green.

If testing with the internal probe, be sure the external probe is disconnected prior to powering on the instrument.

4.3 Selecting a Protocol or Protocol Series



Protocols are individual DPOAE, TEOAE, tympanometry or acoustic reflex measurements. Protocol series are a sequence of individual protocols linked together. A series can be composed of any combination of DPOAE, TEOAE, tympanometry or acoustic reflex protocols that are loaded into the instrument. The series will run with just one button press (left/right arrow on control panel or R/L button on probe) to begin testing. Series are indicated by multiplicity symbol to the left of the Series name.

Each instrument comes preloaded with protocols and protocol series. For a description of the protocols and series included see Appendix B. For information on creating and customizing protocol series see section 9.

The protocol selected will default to the last protocol or series used to conduct a measurement. This makes it easy to switch to the other for testing. To select a different protocol or series use the up and down arrows on the navigator located on the instrument control panel.

4.4 Selecting an Eartip

The ERO•SCAN Pro instrument comes with a box of disposable eartips that fit a variety of ear canal sizes. The probe tip must have an eartip attached before inserting it into an ear canal. The eartip kit has 12 different size eartips that are color-coded for easy selection. The determination of the appropriate eartip size should be made by persons with proper training and experience. The eartip must seal the ear canal. The best test results are obtained when the eartip is inserted deeply into the ear canal instead of flush with the ear canal opening. The fit should be secure so that the probe will remain in the ear canal even with a light tug on the probe.

Caution must be taken, however, to ensure that the eartip does not extend too deeply into the ear canal. Use only the eartips approved for use with the instrument. Contact your local special equipment distributor or Maico Diagnostics for ordering information. The eartips are disposable and should be replaced after each patient. Do not attempt to clean or reuse these eartips.

After selecting an eartip, push it onto the probe tip until it is flush against the base of the probe tip. The sound outlet tubes on the probe tip are recessed to minimize the likelihood of clogging. If the probe tip does become plugged or clogged, it must be replaced. See section 11 on care and maintenance for further information. To remove the eartip, grasp the eartip at the base and twist it while pulling it straight off the end of the probe tip.

4.5 Preparing the Patient

When possible, otoscopic or visual examination of the patient's ear canals should be performed prior to testing. Excessive cerumen or vernix in the ear canals may interfere with the test and give invalid or incomplete results. Patients with excessive cerumen, debris, or foreign bodies in the ear canals should be referred to an audiologist or physician for removal of the blockage prior to testing.

Place the patient in a position that will allow easy access to the patient's ears. The patient should remain still and quiet while the test is being performed.

Explain to the patient that the measurement is painless. The patient does not have to respond when there are loud test sounds or when the pressure in the auditory canal changes. The patient should be instructed not to swallow, chew or move during the measurement.

In addition, when performing acoustic reflex measurements explain to the patient that loud test sounds will occur during the reflex measurement. It is very important that the patient does not move because movements can be perceived as a false compliance change.

Ambient Noise Levels in the Testing Environment

The ERO•SCAN Pro uses a novel noise-rejection algorithm that permits accurate DPOAE and TEOAE measurements in background noise as high as 65 DB SPL A-weighted (typical office environment). If the ambient noise level rises too high (and/or the eartip seal is poor), then all samples will be noisy and accurate measurements will be impossible, in which case the test result will indicate "noisy."

Securing the External Probe to the Patient

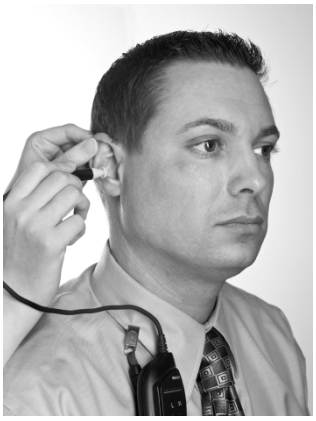
The external probe is positioned on the patient using the lanyard affixed to the back of the probe enclosure. The lanyard is designed to be used as either a neck loop or a shirt clip. Selecting the style for use will depend on patient factors and the preferences of the user.

Adjusting Lanyard

The lanyard is affixed to the probe enclosure with an auto-locking mechanism. To adjust the lanyard position, slide the locking mechanism down (toward to the connection cable) and hold the mechanism in the downward position while pulling the lanyard in the desired direction. Pull the lanyard down (toward the connection cable) to use the shirt clip or up (toward the probe cable) to use it as a neck loop. Once in position, release the locking mechanism and pull up gently on the lanyard.

Lanyard Use

Neck Loop



Shirt Clip

Secure the probe enclosure using the neck loop or shirt clip such that there is no weight on the probe cable and eartip. The probe enclosure should be positioned as close to the ear as possible.

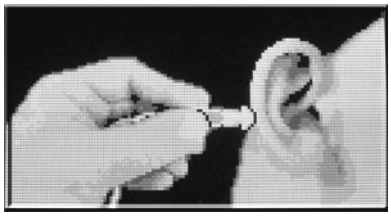
4.6 Conducting a measurement

After selecting the desired protocol or series, press the right or left arrow button on the navigator or *L* or *R* button on the external probe keypad to begin a measurement. Select the left arrow or *L* button to start a left ear test. Press the right arrow or *R* button to start a right ear test.

AutoStart

The first phase in the test sequence is AutoStart which checks the fit of the probe in the ear canal. The actual calibration and measurement will commence once an adequate probe fit has been achieved. The sequence can be started with the probe placed in the ear or prior to positioning the probe in the ear. This is a matter of user preference. Users of the internal probe tend to prefer to start the test before positioning the probe in the ear.

AutoStart consists of low-frequency, alternating tones which are used to check for the following conditions: Seal of the eartip to the ear canal, leak, blocked probe, clogged probe tip, stability of the probe, and noise. During AutoStart the condition of the probe in the ear is represented by the following images:



AutoStart 1

Probe not in ear or leak (AutoStart 1):
This image indicates the probe is outside the ear canal or there is no seal. Continue to insert the probe into the ear canal. If this condition persists, a different eartip may be required. Be sure the eartip is securely seated deep in the ear canal.

AutoStart 2

Probe in ear and seal detected (AutoStart 2):
This image indicates the probe is in the ear canal. The test will start soon as long as all conditions of AutoStart are met. If the test does not begin, that may be the result of instability (probe is moving because fit is not secure or the patient is too active) or there is excessive noise present. If this image persists and testing does not begin, refit the probe and try again. A different eartip may be required.

AutoStart 3

Probe blocked (AutoStart 3):
This image indicates the probe is blocked. The eartip or probe tip might be blocked by ear wax (cerumen) or vernix (birth fluid) or the probe has been pushed against the ear canal wall.
Remove the probe from the ear and check for wax/debris then reinsert changing angle or position of the probe until AutoStart image 2 appears. If the blocked probe condition persists, see section10 on Troubleshooting.

Note: Do not hold the probe in the ear during OAE testing. This will introduce noise into the measurement. Common sources of noise are environmental (room noise), biological (patient breathing, moving, talking, chewing, etc.), or physical (probe movement).

Testing ears with PE tubes

To test OAE's of individuals with PE tubes or middle ear perforations, the AutoStart may need to be disabled. This is accomplished by first inserting the probe with eartip attached into the ear canal. Be sure the fit is deep and secure to obtain a proper seal, To disable AutoStart at the main menu select the ear to be tested by holding down the right or left arrow key for 3 seconds until the green light turns off. Once the key is released, the ERO•SCAN Pro will calibrate and test as usual.

Calibration

The ERO•SCAN Pro will automatically perform a calibration prior to each frequency tested (DPOAE) or at the start of each test (TEOAE).

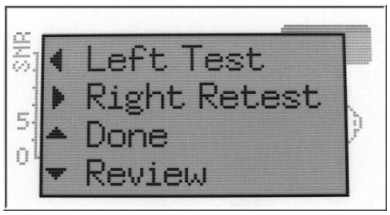
Test Phase

During the test phase a flashing indicator will appear to the right of the display. Test results are displayed as they are collected. For more information regarding test results see section 5.

Testing is complete when the green "READY" light is illuminated. Both the tester and patient should remain as still and quiet as possible until the green light turns on.

4.7 Proceeding to the next test

Proceeding after a single protocol measurement

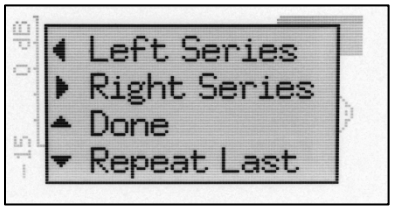


After testing has been completed the selection menu will automatically appear in about 5 seconds. The selection menu will offer the following options:

- Left – starts a left ear test of the selected protocol
- Right – starts a right ear test of the selected protocol
- Done – return to the main menu
- Review – return to the result screen*

*Bring the selection menu up by pressing any arrow key

Proceeding after a Series measurement



Proceeding following a Series is slightly different than what was described above. The selection menu will offer a different set of options:

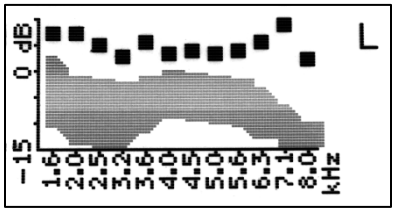
- Left Series – starts the complete series for the left ear
- Right Series – starts the complete series for the right ear
- Done – Returns to the main menu
- Repeat Last – starts the series from the last test performed

5 Understanding the Test Results

5.1 Understanding the OAE Results Display

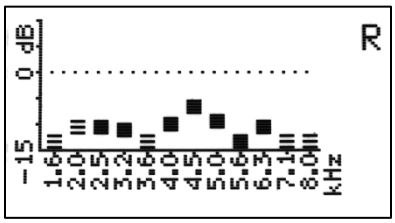
During OAE testing the results will appear on the screen as the test progresses. The display shows a graph with up to 12 columns. Each f2 frequency (DPOAEs) or frequency band (TEOAEs) is indicated by one column. The number of columns shown will vary depending on the number of frequencies being tested with the selected protocol. The test frequency is shown along the horizontal axis at the bottom of the display. Three different OAE viewing options are described below:

DP/TE-Gram



The *DP/TE-Gram graph* displays the absolute values of the signal (emission) as a block plotted at the intersection point of the test frequency (Hz) along the horizontal axis and the amplitude (dB SPL) along the vertical axis.

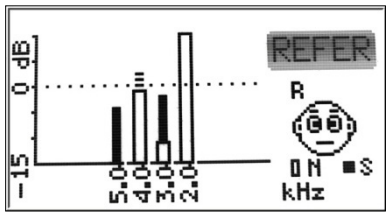
Note: Boys Town normative data may optionally be shown on the display for qualifying DPOAE measurements when the DP/TE-Gram graph is used as shown in the display to the left. See Setup section 8.10 for more information regarding Boys Town norms.



A bright solid block indicates that the SNR is at least 6 dB for DPOAE and 4 dB for TEOAE. A hashed block indicates that the SNR is less than these specified values. Examples are shown in the display to the left.

This allows the user to judge the quality of the measurement and the possible influence of noise while still viewing the absolute emission values on a simple to read display.

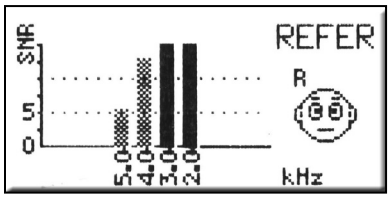
Value Graph



The *Value graph* displays the absolute values of the signal (emission) and noise floor. The noise is represented by an open bar. The signal is a represented by a solid bar when it meets the pass criteria and as a dashed bar when it fails to meet the pass criteria for the protocol. When viewing the value graph the user can immediately see if noise was a contributing factor in obtaining a Refer.

For example on the test result shown to the left we can see that the measurement at 2 kHz (the bar farthest to the right) is completely obscured by noise (no measurable signal). At 3 kHz there is some noise in the measurement, but the measured signal at that frequency meets or exceeds the pass criteria. At 4 kHz the signal emerging above the noise does not meet the pass criteria. At 5 kHz there is no noise in the measurement. This is an example of a test that should be repeated after an attempt is made to reduce noise (environmental or patient) and obtain a better probe fit.

SNR Graph



The *SNR graph* shows signal-to-noise ratio (SNR) for each test frequency. SNR is the difference between the measured emission and measured noise floor. The SNR is shown on the vertical axis so the height of each column represents the SNR for that test frequency. For example, if the column goes to the top of the display then the SNR is 15 dB or greater.

The bright solid yellow columns meet the SNR pass criteria for that frequency. The hashed columns do not meet the pass criteria set for that frequency.

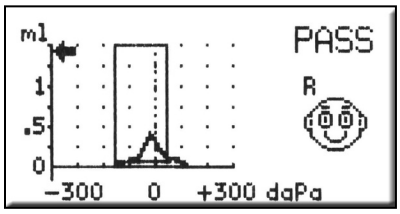
Note: if the protocol does not have a pass criteria then all the columns will appear hashed.

Test Details

To view test details such as the protocol name, date/time of test, test number, serial number, OAE signal, noise floor value and signal-to-noise ratio (numerical data) press the info button located on the instrument control under the bottom right corner of the display. Use the up and down arrow buttons to scroll through the details screen. If any details are out of the viewable area select SHIFT to extend the viewable area of the display. When finished viewing the details, select EXIT to return to the results screen. From the results screen press any arrow key to bring up the selection box.

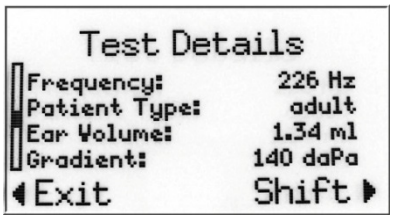
5.2 Understanding the Tympanometry Results Display

Tympanogram



After having completed a tympanometry measurement you can see the results on the display. On the left side of the display you see a graph of the tympanogram. The area surrounded by the box is valid for "normal" tympanograms. The curve that appears on the graph represents the movement of the ear drum. When the peak of the curve appears inside the box, the screening is generally considered a PASS. The ear canal volume is represented on the display by the arrow on the graph directed toward the vertical axis of the graph.

Test Details



To view test details such as the ear canal volume, gradient, compliance, and peak pressure (numerical data) press the info button located on the instrument control under the bottom right corner of the display.

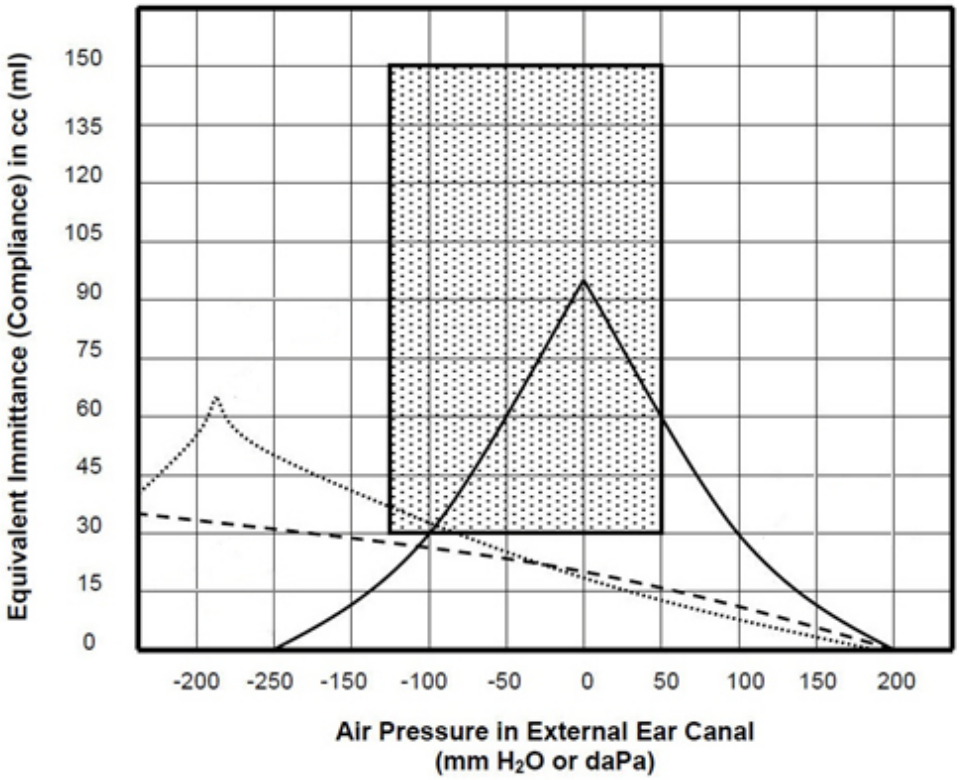
5.3 Interpreting the Tympanometric test result

As a general rule, values for ear canal volume should be between 0.2 and 2.0 ml (children and adults). A variance will be seen within this range depending on the age and ear structure of the person. For example, a 2.0 ml or larger reading in a small child could indicate a perforation in the tympanic membrane, while it may be a normal reading in an adult. You will become more familiar with the normal ranges when you use the instrument.

The normal range for compliance is 0.2 ml to approximately 1.8 ml. A compliance peak within the range indicates normal mobility of the middle ear system. A peak found outside of these limits may indicate one of several pathologies.

Middle ear pressure should be equivalent to ambient air pressure (0 daPa on an air pressure scale). Minor shifts of the peak compliance to the negative may occur with congestion and are rarely to the positive side. Establish criteria for abnormal negative pressure when you become more familiar with using the equipment. It is generally accepted that negative pressure of greater than -150 daPa indicates a referral for medical evaluation.

5.4 Abnormal Tympanometric Values



It is the purpose of this section to provide samples of tympanograms which reflect abnormal states of the middle ear mechanism. It is not the intention of this section to provide you with a complete guide to interpreting results. Complete information regarding pathologies and abnormal impedance testing can be found in published audiology literature.

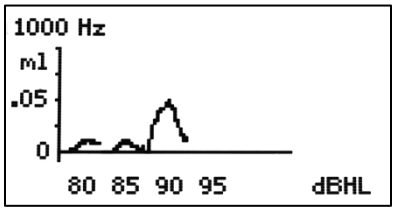
A perforation in the tympanic membrane will cause a high ear canal volume measurement because the instrument will measure the volume of the entire middle ear space. The ERO•SCAN Pro may refuse to run the test, with the instrument indicating a seal problem, or a flat tympanogram will be recorded since no movement will occur with a change in air pressure.

An extremely flaccid tympanic membrane or an ossicular chain discontinuity will yield a very high peak compliance in the presence of normal middle ear pressure and ear canal volume will be normal.
A fixation of the ossicular chain, as in otosclerosis, will produce a tympanogram with very low compliance in the presence of normal middle ear air pressure while ear canal volume is normal.

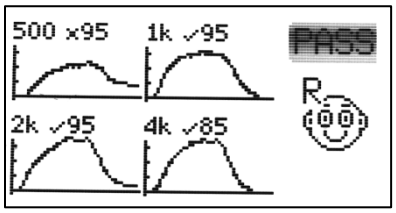
Middle ear fluid such as in serious otitis media will yield a very flat tympanogram with no definite peak and negative air pressure. A resolving case or beginning case may produce a reduced peak in the presence of severe negative middle ear pressure. The ear canal volume is normal and the reflex is either absent or at an elevated level.

Eustachian tube dysfunction in the absence of fluid will show a normal compliance curve, but it will be displayed to the negative side of the tympanogram. Ear canal volume will be normal.

5.5 Understanding the Acoustic Reflex Display & Result



During the measurement of the acoustic reflex the change of the compliance is represented on the instrument display as shown to the left. The zero-line at the bottom of the graph indicates the measured compliance without a test sound. Changes in compliance are shown as deviations from the zero-line. If a Stapedial reflex occurs, the compliance increases and the curve rises. The change in compliance is shown for each intensity level for the stimulus being presented.



When the test is finished a summary display will show the final compliance change curve for each stimulus presented in the protocol. Above each curve the test stimulus type is indicated by the following:

500 = 500 Hz pure-tone	BN = Broadband noise
1k = 1,000 Hz pure-tone	LP = Low pass noise
2k = 2,000 Hz pure-tone	HP = High pass noise
4k = 4,000 Hz pure-tone	

The stimulus type is followed by a yes/no indication that the compliance change reached the selected criteria to consider the reflex present. A compliance change meeting or exceeding the selected criteria is indicated by a ☑ symbol (default criteria is 0.05 ml) followed by the stimulus intensity (in dB HL) where the Stapedial reflex was measured. A compliance change failing to meet the criteria is indicated by a ☒ symbol followed by the maximum intensity level.

The overall test outcome is indicated by PASS or REFER in the upper right corner of the display. This is determined by the pass criteria established for the protocol. See Appendix B for additional information on default protocols.

A correct interpretation of the measuring results can only follow in connection with the tympanogram, the graphic reflex display (to rule out artifact) and other actual data. But in principle a Stapedial reflex indicates that the patient hears on the "stimulus ear" and that the sound lead functions.

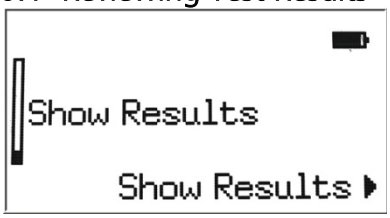
Note: the acoustic reflex measurement is automatically conducted with pressure held at peak compliance (compensated).

6 Managing Test Results

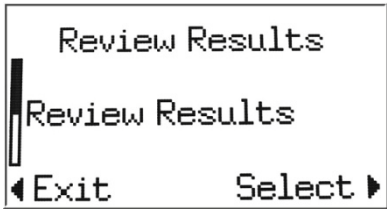
The ERO•SCAN Pro saves one right and one left ear test for each protocol. Once a new test for that ear and protocol is started, the previous results are overwritten. **When testing is completed, the results should be printed before a new patient is tested.** When the test results are printed (to PDF, PC printer or thermal printer) they are marked for deletion and will be erased when a new test is started.

Note: the ERO•SCAN Pro can be configured to save up to 350 tests organized by patient numbers. For more information on this option see section 8.7.

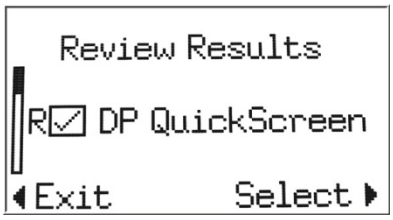
6.1 Reviewing Test Results



To review test results stored in the instrument scroll down the main menu until *Show Results* is selected and press the right ▸ arrow button.



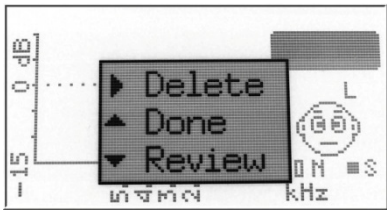
From the *Review Results* screen select *Review Results* using the right ▸ arrow button.



Review Results will display all tests saved in the instrument. For each saved test the ear under test, the test outcome, and the protocol name are shown.

L or *R* indicates the ear tested (right or left)
☑ indicates a PASS result
☒ indicates a REFER result
A dash (-) in the result box indicates no pass criteria was established for the protocol or the test outcome was No Seal, Noisy, or Fit Error

To view a specific test, scroll up or down to select the test and press the right ▸ arrow button to *Select* to view the results.



From the test result display, press any arrow button to bring up the selection box with the following options:

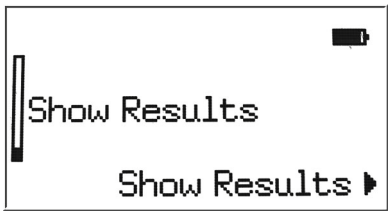
Press the right ▸ arrow button to delete the test result
Press the up ▴ arrow button to return to the list of saved tests
Press the down ▾ arrow button to return to the test result
Press the info button to view the test details

6.2 Deleting Test Results

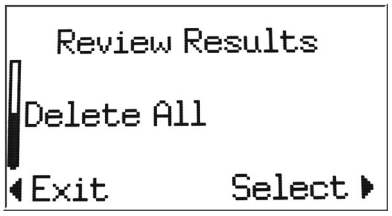
Deleting a single test

To delete a single test(s) follow the steps outlined in the previous section (above) and choose *delete* from the options provided on the selection menu.

Deleting all tests:



To delete all saved tests select *Show Results* from the main menu.



From the *Review Results* screen, use the up ▲ and down ▼ arrow buttons on the control panel to select *Delete All* and select the action by pressing the right ▶ arrow button. When prompted, confirm selection by pressing the down ▼ arrow button for *Yes*. To return to the *Review Results* screen without deleting saved tests, press the up ▲ arrow for *No*.

7 Printing Test Results

There are three options for printing tests results from the ERO•SCAN Pro:

1. Quick Print to PDF
2. Quick Print to the default PC printer
3. Fast and portable printing is an option with the thermal paper printer

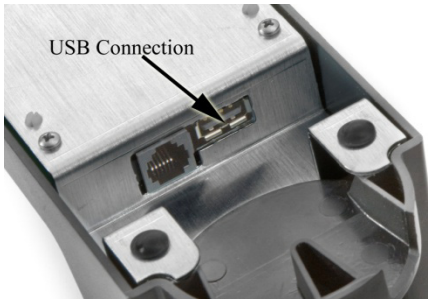
These printing options are explained in this section.

7.1 Connecting the cradle to a computer

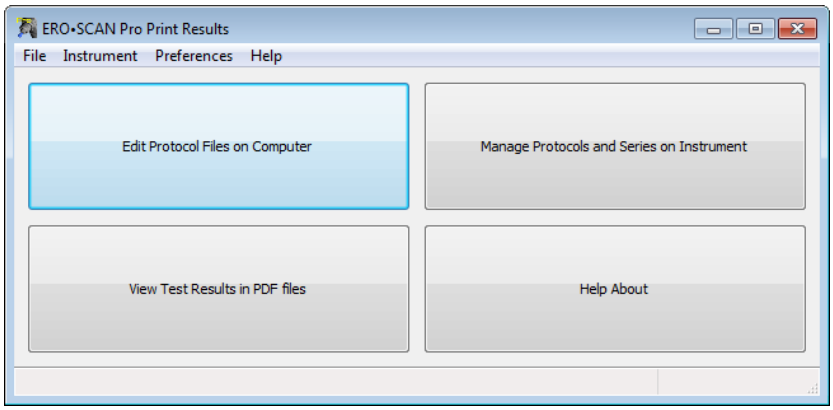
Connecting to the computer will allow access to additional features such as Quick-print to PDF or the default 8.5 x 11 PC printer and customization of protocols and series. See section 9 for more information on customizing protocols and series. See Appendix A for software installation instructions.

> The ERO•SCAN Pro PC software must be installed prior to connecting the cradle to the computer. See appendix A for software installation instructions.

Use the included USB cable to connect the cradle to the computer by connecting one end of the cable to the USB port on the underside of the cradle and the other end to the desired USB port on the computer. Place the two-position button located on the upper right of the top side of the cradle in the down position for computer use.



7.2 Quick-Print to PDF or to the default PC printer

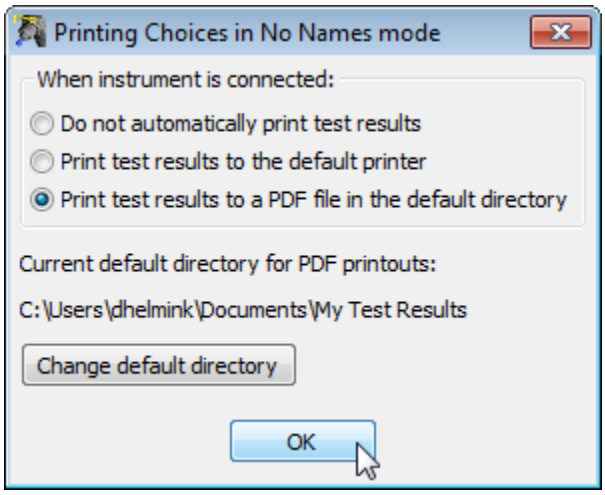


Open the *Print Results* application by double clicking on the application icon.

Place the ERO•SCAN Pro gently in the cradle.

Transfer of test data will occur automatically when the instrument is placed in the cradle.

This application will print to a PDF file or print to the default PC printer.



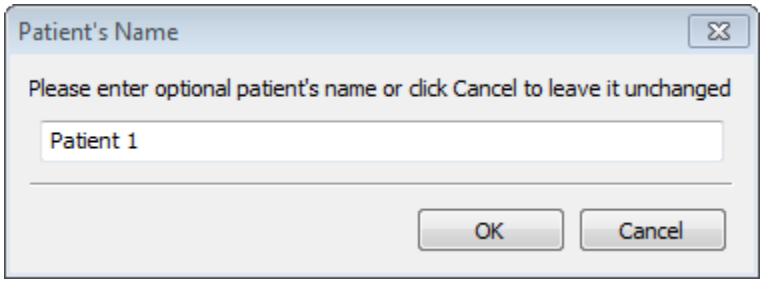
The first time test data is transferred to the application you will be prompted to establish your printing preferences. You can also set your preferences by selecting *Preferences* and then *Printing Test Results* from the menu.

Do not automatically print test results: no action will be taken when he instrument in placed in the cradle

Print test results to the default printer: the test results will be sent to the default PC printer and and an 8.5 x 11 page will be printed. There will be no electronic copy saved.

Print test results to a PDF file in the default directory: the test results will be sent to a PDF file that can be named and saved for import into electronic medical records systems or for printing in the future.

Note: During installation of the application a folder will be created at C:_\My Documents\My Test Results. The default directory can be changed in the printing preferences.



The application will give the user the option to add the patient's name to the print out. Enter the patient's name and click [OK]. Click [Cancel] to skip this step if no patient name is desired.

You will be prompted to save the file. The software will suggest a file name or you may use a file name of your choice. Click [Cancel] to abort the file save.

To view a saved PDF file, click the *View Test Results in PDF files* button in the main window or navigate to the directory where the file is saved using Windows Explorer.

OAE PDF or PC Printout

Distortion-Product Otoacoustic Emission Test Report

Right Ear:

Patient Name: Joe Smith

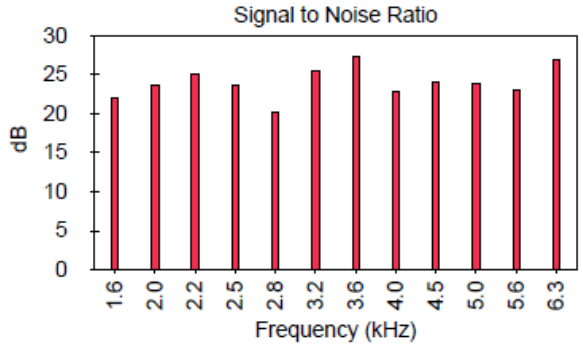
Protocol: **DP Dx 12**

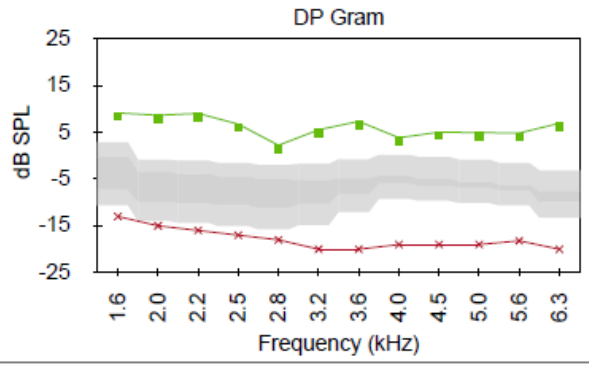
Test Number: 171 Test Date: 2012-05-09 14:00:16
Tester: GATES, CYNTHIA
Instrument and Probe Serials: 1003 T0941015

Number of frequencies: 12, minimum for a pass: 0

Minimum values in protocol ignored

F2	P1	P2	DP	NF	SNR	Result
1600	66	55	9	-13	22	
2000	66	55	9	-15	24	
2200	66	56	9	-16	25	
2500	66	55	7	-17	24	
2800	66	55	2	-18	20	
3200	66	55	6	-20	26	
3600	65	55	7	-20	27	
4000	65	55	4	-19	23	
4500	65	55	5	-19	24	
5000	65	55	5	-19	24	
5600	65	55	5	-18	23	
6300	70	60	7	-20	27	





Data table:

F2 = the f2 frequency
P1 = the sound pressure level of f1
P2 = the sound pressure level of f2
DP = the level of the emission in dB SPL
NF = the noise floor in dB SPL
SNR = the signal-to-noise ratio (DP level minus the noise floor)
P = indicates that the pass criteria has been met for the indicated frequency

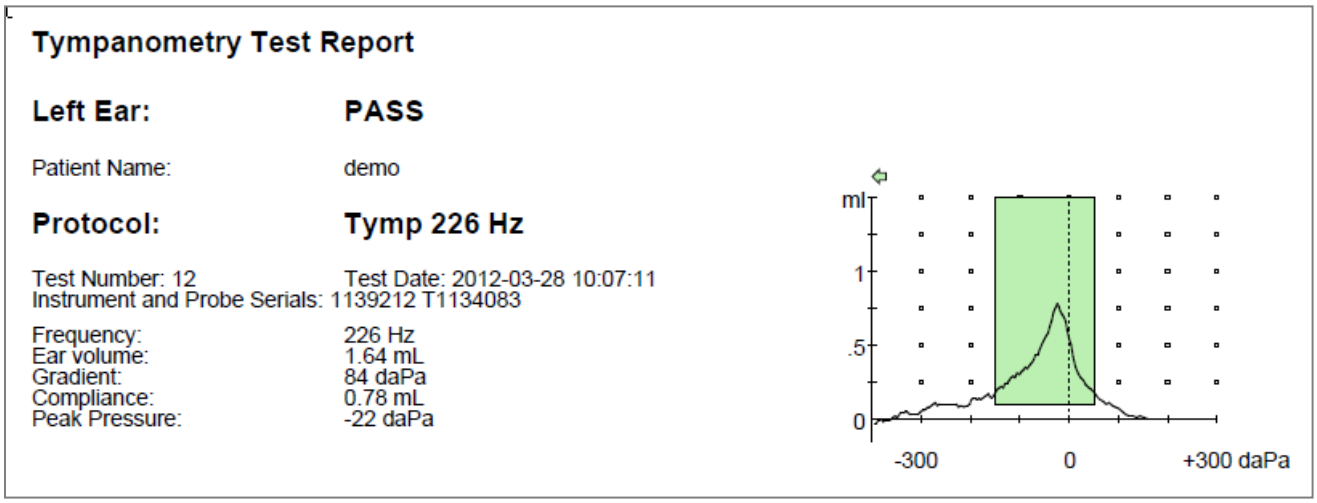
Signal to Noise Graph:

Vertical axis = SNR (dB)
Horizontal axis = f2 frequency tested (Hz)
Green bars indicate that the pass criteria have been met. Red bars indicate that SNR and/or DP amplitude have not been met.

DP-Gram Graph

Vertical axis = indicates the absolute value of the signal or noise in dB
Horizontal axis = f2 frequency tested (Hz)
The green line is the signal. The red line is the noise. The difference between the two lines is the signal-to-noise ratio.

Tympanometry PDF or PC Printout



Tympanometry Test Report

Left Ear: **PASS**

Patient Name: demo

Protocol: **Tymp 226 Hz**

Test Number: 12 Test Date: 2012-03-28 10:07:11
Instrument and Probe Serials: 1139212 T1134083

Frequency: 226 Hz
Ear volume: 1.64 mL
Gradient: 84 daPa
Compliance: 0.78 mL
Peak Pressure: -22 daPa

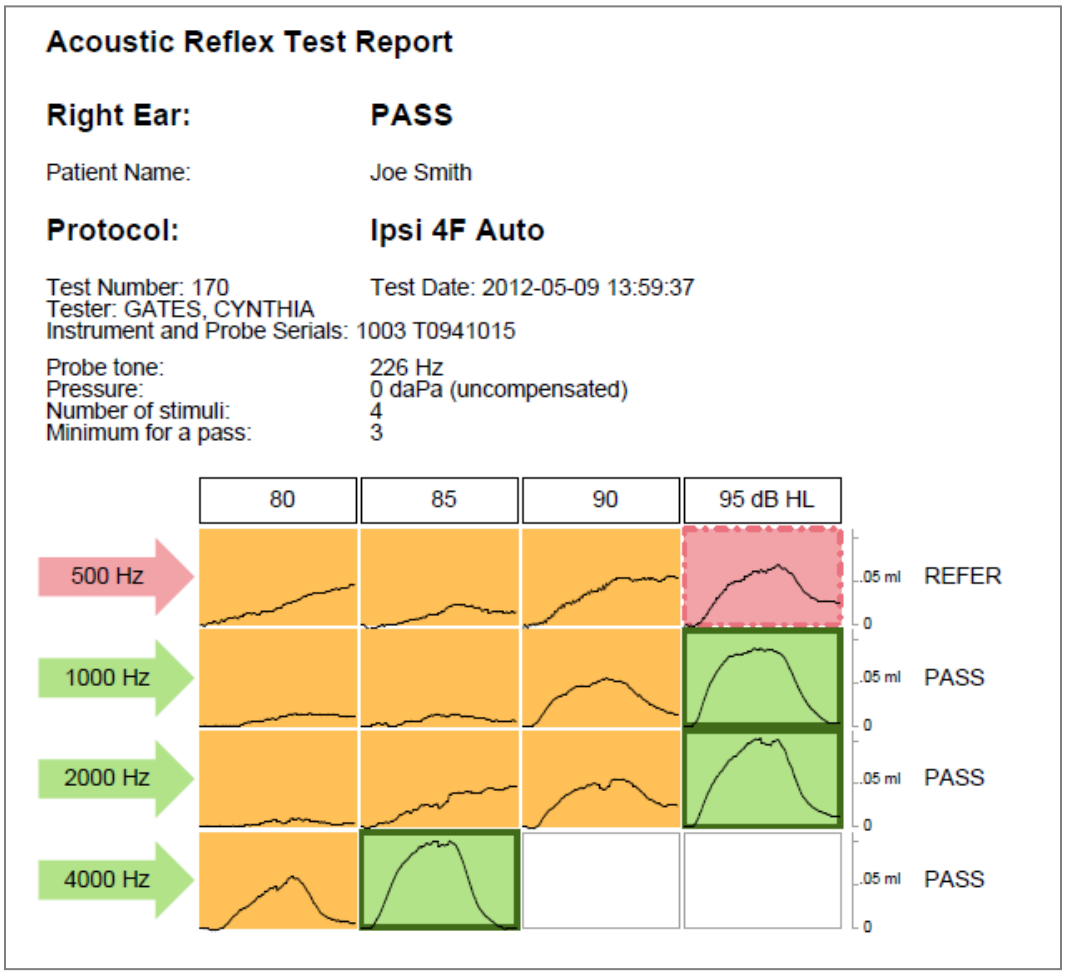
Data table:

Frequency = probe tone frequency (226 or 1,000 Hz)
Ear volume = indicates the volume of the external ear canal
Gradient = indicates graph width in daPa value (tympanometric width at 50% of the peak)
Compliance = displays the peak compliance
Peak Pressure = displays the pressure corresponding to peak compliance

Graph:

Vertical = relative canal volume (ml) indicated by the arrow and dynamic compliance indicated by the peak of the curve (ml)
Horizontal = pressure corresponding to peak compliance (daPa)
If the tympanogram is within the preset limits, the peak will be within the box displayed on the screen and the test result will be *Pass*.

Acoustic Reflex PDF or PC Printout



Data table:

Pressure = pressure compensation to match point of peak compliance from preceding tympanometry measurement

Number of stimuli = number of test stimuli included in the protocol (up to four allowed)

Minimum for a pass = number of passing stimuli required to meet the compliance change criteria

Graphical table:

Each horizontal row shows the compliance changes for one stimulus type plotted as a function of stimulus intensity which is indicated in the header for each vertical column.

The solid line shows the measured compliance change for a particular combination of stimulus and intensity

Green = compliance change criteria has been met

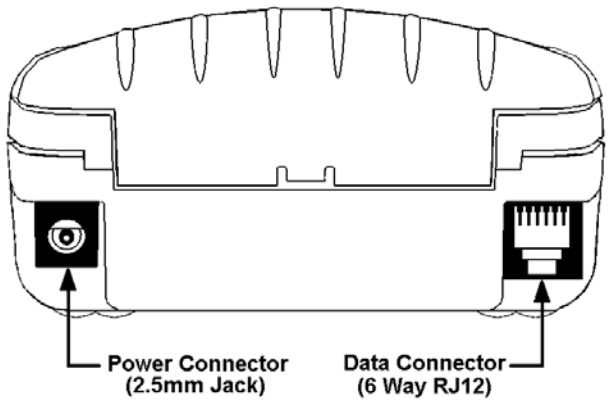
Yellow = compliance change criteria has not been met

Red = the maximum intensity has been reached without meeting the compliance change criteria

Pass/refer is indicated at the end of each horizontal row

7.3 Thermal printer set up

Use the included data cable to connect the cradle to the printer. First, insert the appropriate end of the data cable into the port located on the underside of the cradle. Connect the cradle and printer by inserting the appropriate end of the data cable into the data port on the back of the printer. Next, connect the 2.5mm jack on the power supply to the power connector located on the back of the printer. Finally, connect the appropriate ends of the power cord into the power adapter and an outlet.

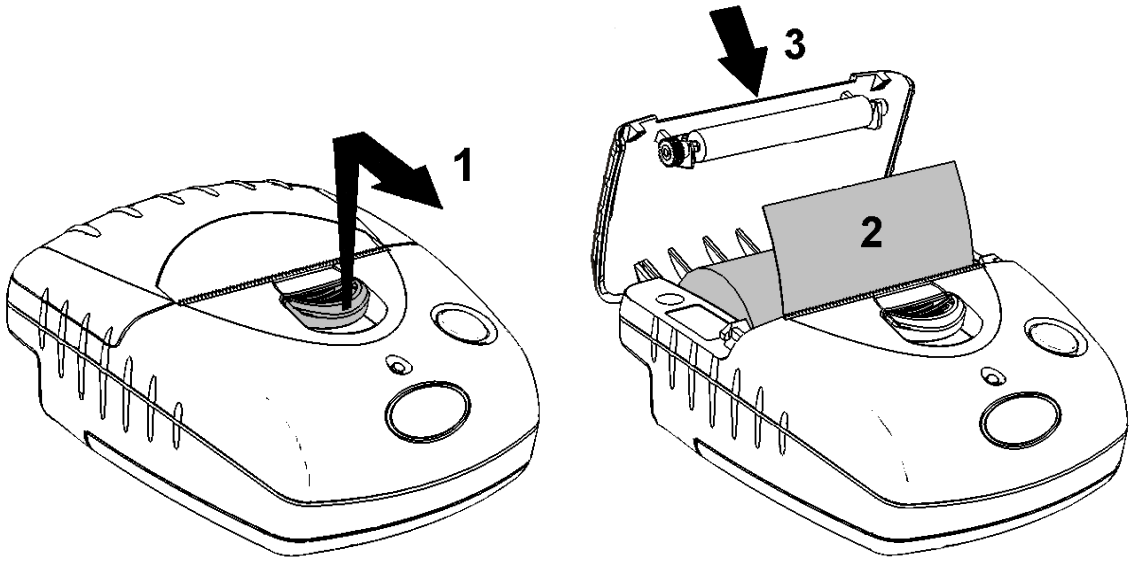


The printer is permanently powered up and ready to print once the power supply is connected to the printer and an outlet. The light on the face of the printer will illuminate solid green when the printer is powered up and ready to print. A flashing green light indicates the printer is not ready (paper low, no paper loaded, lid open, etc…). No light indicates the printer is off.

Paper:
Paper rolls must be 57.5 (±0.5) mm wide, 55 mm maximum diameter, and have thermally sensitive coating on the outside. The printer will accept rolls which are coreless or wound on a core.

Note: To order more paper, contact your local special instrument distributor or Maico Diagnostics.

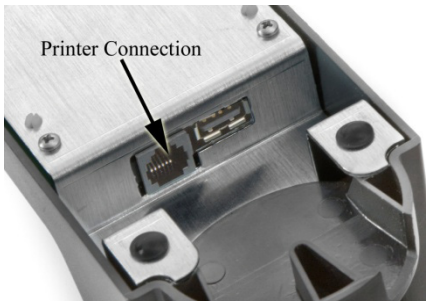
Procedure for loading paper:
Slide the lid release button forward until the lid springs open.
Unwind a small amount of paper from the roll and insert paper roll into the printer with the paper coming up from under the roll.
Close the lid.



After loading, check that the paper is straight and advances properly. Tear off any excess paper by pulling the paper sharply towards you across the serrated tear bar. In the event of a jam or other paper loading problem, release the lit and straighten the paper before closing again.

Pressing the paper feed button when the printer is idle advances the paper. "Double-clicking" the button (pressing and releasing the button twice in quick succession) prints a demo/test message showing the printer firmware version and settings.

7.4 Connecting the cradle to the Printer



Use the included printer connection cable to connect the cradle to the printer. Connect the appropriate end of the connection cable into the serial data port at the rear of the printer. Connect the opposite end of the data cable into the printer connector on the underside of the cradle.

Place the two-position button located on the upper right of the top side of the cradle in the raised position for printer use.

7.5 Printing with the Thermal Paper Printer

Be sure the printer power is on and the button on the cradle is in the printer position. Place the instrument gently in the cradle. A printer icon should appear on the display and the test results should begin printing immediately.

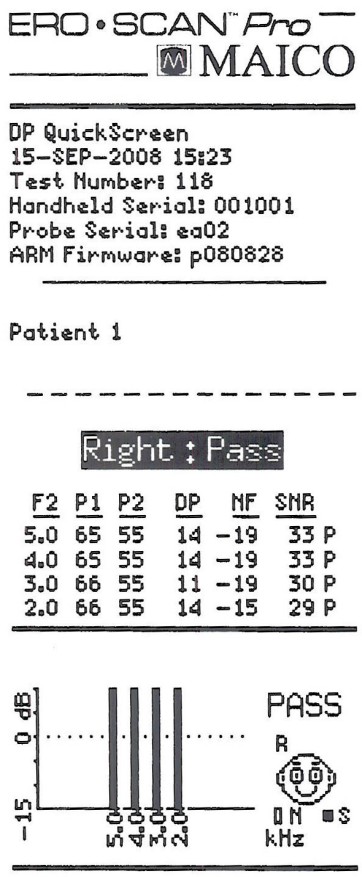


Figure 47

DPOAE Printout:

To the left is a sample DPOAE printout from the thermal paper printer.
The header shows the protocol name in the first line followed by the date/time of the test, test number, instrument serial number, probe serial number, and firmware version.

Patient number is indicated or a blank line is provided to write in the name. (See section 8.7 for information on using numbered patients).

The ear (Right or Left) and the test result (Pass or Refer) will be indicated on the printout.

Data table:
F2 = the f2 frequency
P1 = the sound pressure level of f1
P2 = the sound pressure level of f2
DP = the level of the emission in dB SPL
NF = the noise floor in dB SPL
SNR = the signal-to-noise ratio (DP level minus the noise floor)
P = indicates that the pass criteria has been met for the indicated frequency

Graph:
Vertical axis = SNR (dB)
Horizontal axis = f2 frequency tested (Hz)
Solid bars indicate that the pass criteria have been met. Hashed bars indicate that SNR and/or DP amplitude have not been met.

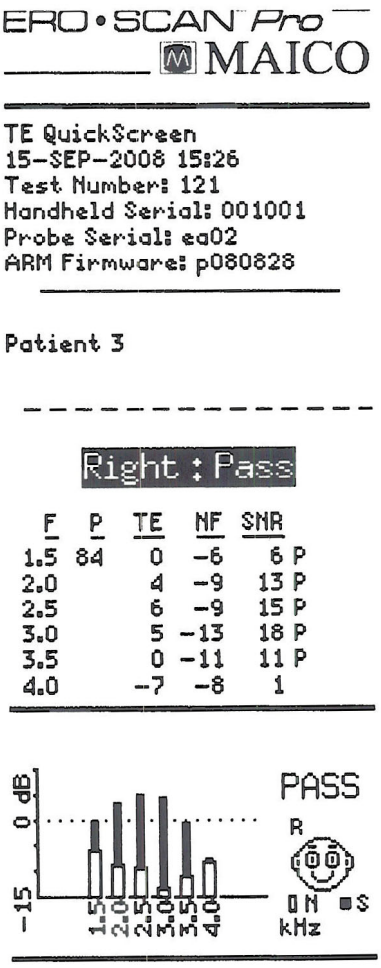


Figure 48

TEOAE Printout

To the left is a sample TEOAE printout from the thermal paper printer.
The header shows the protocol name in the first line followed by the date/time of the test, test number, instrument serial number, probe serial number, and firmware version.

Patient number is indicated or a blank line is provided to write in the name. (See section 8.7 for information on using numbered patients).

The ear (Right or Left) and the test result (Pass or Refer) will be indicated on the printout.

Data Table:
F = the frequency band
P = peak pressure level of the click stimulus
TE = the level of the emission in dB SPL
NF = the noise floor in dB SPL
SNR = the signal-to-noise ratio (TE level minus the noise floor)
P = indicates that the pass criteria has been met for the indicated frequency

Graph:
Vertical axis = SNR (dB)
Horizontal axis = frequency band (Hz)
Solid bars indicate that the pass criteria have been met. Hashed bars indicate that SNR and/or DP amplitude have not been met.

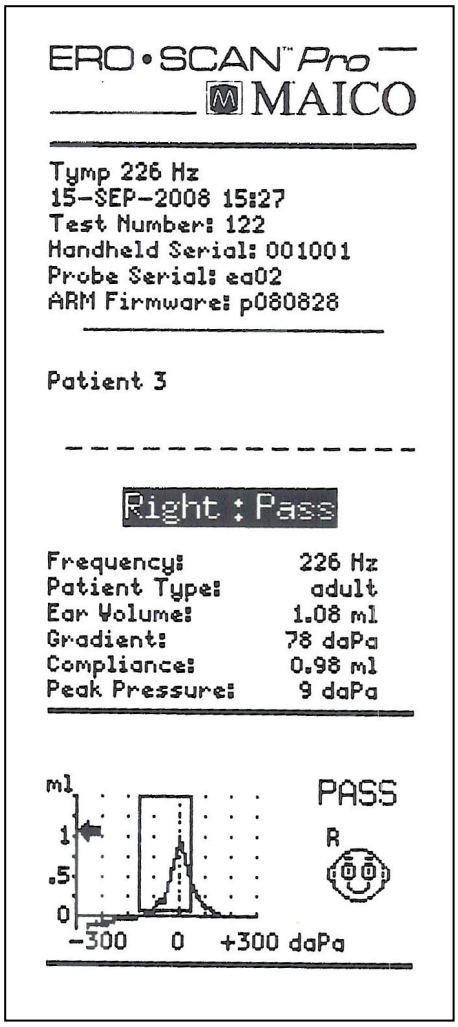


Figure 49

Tympanometry Printout

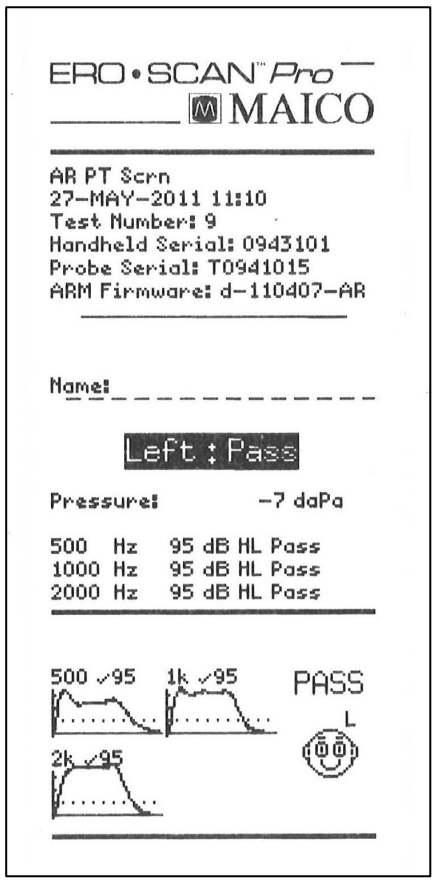
To the left is a sample tympanometry printout from the thermal paper printer.
The header shows the protocol name in the first line followed by the date/time of the test, test number, instrument serial number, probe serial number, and firmware version.

Patient number is indicated or a blank line is provided to write in the name. (See section 8.7 for information on using numbered patients).

The ear (Right or Left) and the test result (Pass or Refer) will be indicated on the printout.

Data table:
Frequency = probe tone frequency (226 or 1,000 Hz)
Ear volume = indicates the volume of the external ear canal
Gradient = indicates graph width in daPa value (tympanometric width at 50% of the peak)
Compliance = displays the peak compliance
Peak Pressure = displays the pressure corresponding to peak compliance

Graph:
Vertical = relative canal volume (ml) indicated by the arrow and dynamic compliance indicated by the peak of the curve (ml)
Horizontal = pressure corresponding to peak compliance (daPa)
If the tympanogram is within the preset limits, the peak will be within the box displayed on the screen and the test result will be *Pass*.



Acoustic Reflex Printout

To the left is a sample acoustic reflex printout from the thermal paper printer.
The header shows the protocol name in the first line followed by the date/time of the test, test number, instrument serial number, probe serial number, and firmware version.

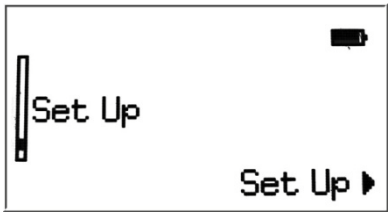
Patient number is indicated or a blank line is provided to write in the name. (See section 8.7 for information on using numbered patients).

The ear (Right or Left) and the test result (Pass or Refer) will be indicated on the printout.

Data table:
Pressure = pressure compensation to match point of peak compliance from preceding tympanometry measurement

Graph:
See section 5.5 for explanation

8 Set Up

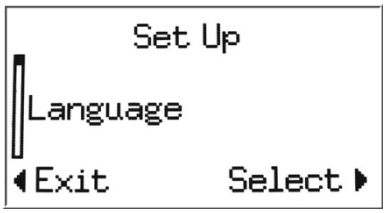


To enter the *Set Up* menu, scroll down the main menu to *Set Up* and select by pressing the right ▸ arrow button.

Scroll through the set up menu options using the up ▲ and down ▼ arrow buttons on the control panel. To change the settings, select item to be changed by pressing the right ▸ arrow button.

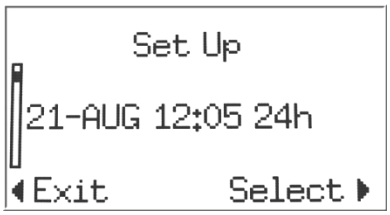
Note: the current setting for each option is displayed after the colon.

8.1 Language



To change the language, select *Language* from the *Set Up* menu. Scroll through the language options using the up ▲ and down ▼ arrow buttons on the control panel. To change the settings, select another language and press the right ▸ arrow. The languages available will vary by instrument.

8.2 Time/Date



To set the instrument time and date, from the set up menu select the item showing the current date and time settings. Use the right ▸ arrow button to enter the *Time/Date* menu.

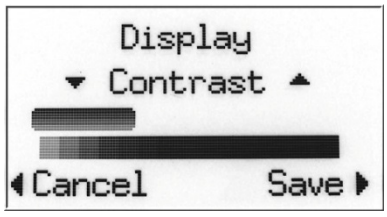
Use the left ◂ and right ▸ arrow buttons to select a portion of the time or date. The selected portion of the date will appear highlighted. Use the up ▲ and down ▼ arrow buttons to change the selected portion of the Time/Date.

The time can be showing using a 12 hour (am & pm) or 24 hour clock. To use the 12 hour clock, select *am* or *pm* in the last portion of the time. For the 24 hour clock, select *24h* in the last portion of the time.

When the time and date are set as desired, press the right ▸ arrow button until *Save*▸ appears in the bottom right corner of the display of the display. Press the right ▸ arrow to *save* the time/date.

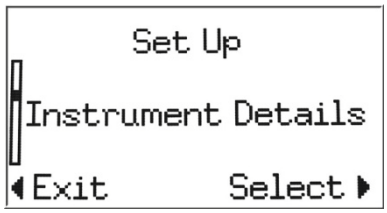
8.3 Display Contrast

To change the contrast of the display, select *Display* from the set up menu.



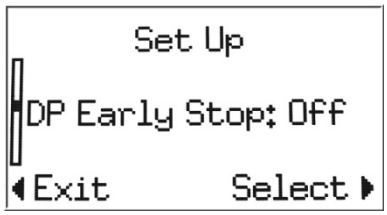
Use the up ▲ and down ▼ arrows to adjust the contrast. When done adjusting the contrast press the right ▶ arrow button to *Save* and exit.

8.4 Instrument Details



To view the instrument details, select *Instrument Details* from the set up menu. Instrument details will show the serial number of the instrument, connected probe, firmware (embedded operating software) version and a summary of other instrument settings.

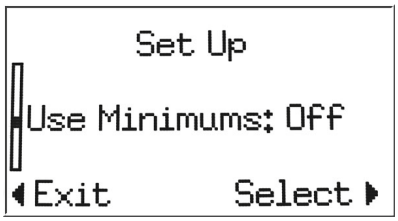
8.5 DP Early Stop



The user can select how the instrument will operate when performing a DPOAE test. With the *DP Early Stop feature off*, testing will be completed at all frequencies included in the selected protocol. The test is complete when all frequencies have been measured. If the *DP Early Stop* feature is *on,* the measurement will stop as soon as the instrument can determine that the criteria for a PASS or REFER result has been met. In this case some frequencies may not be measured, but testing will be completed faster.

To change this setting, select *DP Early Stop* from the *Set Up* menu. Using the up ▲ and down ▼ arrow buttons on the control panel select *off* or *on* and then press the right ▶ arrow button to *select* and exit.

8.6 OAE Minimums



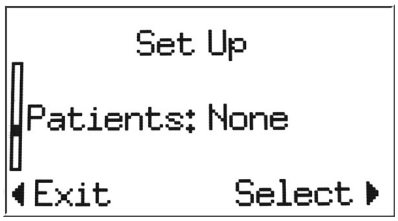
This setting allows the user to select if minimum amplitude values will be used as part of the pass/refer criterion. If *Use Minimums* is *on*, a result is not considered a pass unless the OAE amplitude is equal to or greater than the minimum value set in the protocol. This is in addition to meeting the other pass criteria including the minimum SNR and the number of passing frequencies for overall test "Pass."

The default minimum DP amplitude is -5 dB SPL.
The default minimum TE amplitude is -12 dB SPL.

Users of diagnostic instruments can set the minimum amplitude value when creating custom protocols. Note: if *Use Minimums* is *on* then the minimum amplitude values are applied to all OAE protocols that have a value established within the protocol. For more information regarding minimum amplitudes in custom protocols, see section 9.

To change this setting, select *Use Minimums* from the *Set Up* menu. Using the up ▲ and down ▼ arrow buttons on the control panel select *on* or *off* and then press the right ▶ arrow button to *select* and exit.

8.7 Save Mode (Patients)



In the default operation mode, the ERO•SCAN Pro saves the most recent right and left ear test for each protocol. Once a new test for that ear and protocol is started, the previous results are overwritten. When the test results are printed they are flagged for deletion and will be erased when a new test is completed.

The user can choose to enable the *Numbered Patients* feature. When *Numbered Patients* are enabled the instrument will automatically add a new menu, *Patient Names*, as the first screen that appears when the instrument is powered on. This menu will be automatically populated with two selections, *Patient 1* and *No Name*. To perform and save a test for *Patient 1*, select Patient 1 using the right ▶ arrow button. The main menu with all available protocols will appear. Select the desired protocol and conduct a measurement as described previously in this manual.

Once a test has been completed for *Patient 1*, the instrument will automatically add *Patient 2* to the Patient Names menu. The automatic numbering will continue until the test results are printed, at which point all the numbered patients and test results will be flagged for deletion and then erased when a new test is started. The new test will become the first test for Patient 1 and the automatic numbering sequence will begin again. The instrument can hold up to 350 test results. The number of patients is not limited.

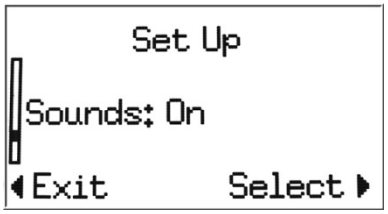
NOTE: Users may also use the "Delete All" option found at the bottom of the Patient menu. Upon confirming the selection, all tests and all patient placeholders will be deleted. An empty placeholder for Patient 1 will appear in the Patient menu.

Use the *No Name* place holder for tests that are not associated with a specific patient.

To change this setting, select *Patients* from the *Set Up* menu. Using the up ▲ and down ▼ arrow buttons on the control panel select *No Patients* or *Numbered Patients* and then press the right ▶ arrow button to *select* and exit.

Note: The ERO•SCAN Pro also supports the upload of patient names by way of the optional Patient Management software. See Patient Management Manual (1162-0806) for more information.

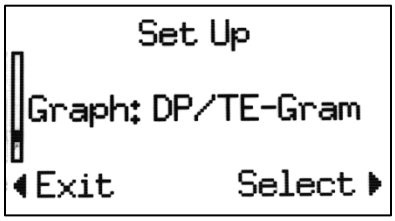
8.8 Sounds



The ERO•SCAN Pro provides audible feedback to the user to indicate when testing is complete.

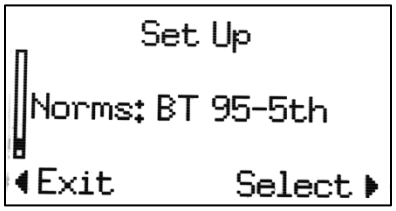
To change this setting, select *Sounds* from the *Set Up* menu. Using the up ▲ and down ▼ arrow buttons on the control panel select *on* or *off* and then press the right ▶ arrow button to *select* and exit.

8.9 Graph Style



There are three options for viewing the DPOAE test results: SNR graph, Value graph, and DP/TE-Gram. These are explained in section 5.1.

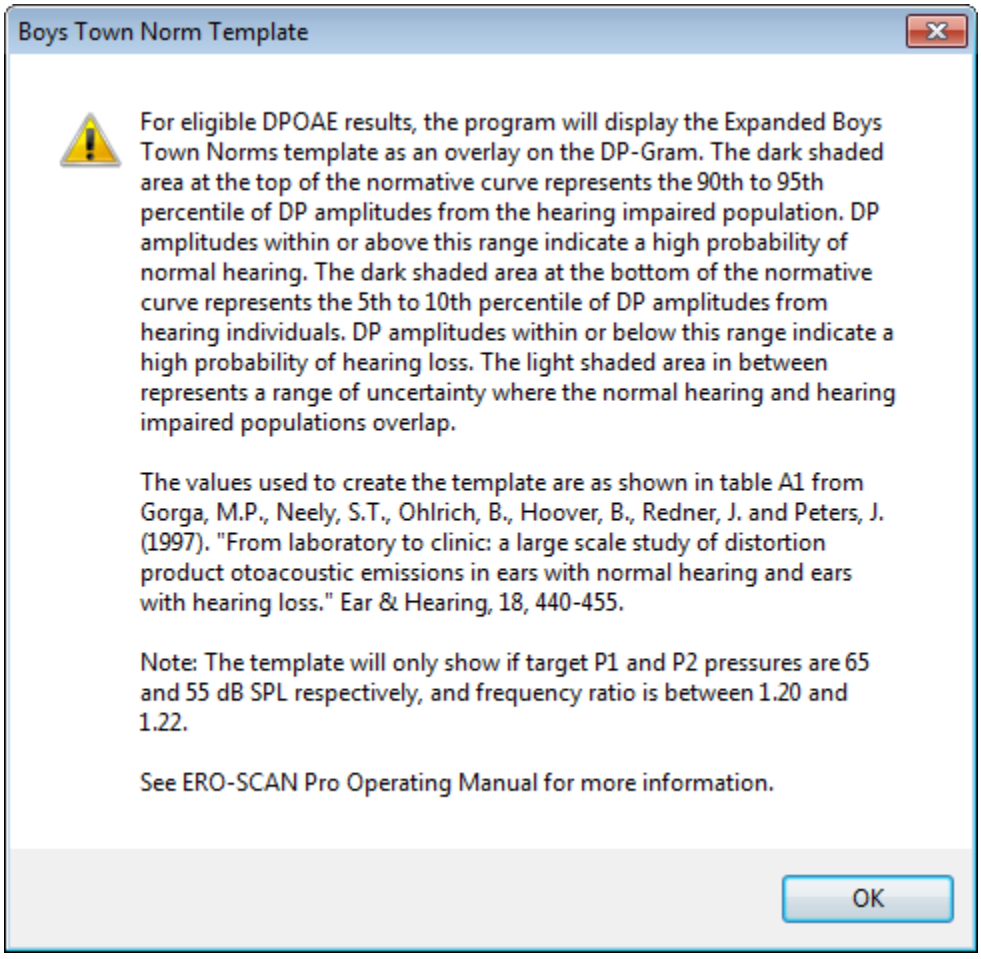
8.10 Norms



When viewing DPOAE results using the DP/TE-Gram option (section 8.9), the user may optionally show the Boys Town normative data on the instrument display.

The user can select to show the 95th to 5th range or the 90th to 10th range. The authors of the referenced normative study (Gorga et al. 1997) suggest the 95th to 5th range as most accurately separating normal hearing and hearing impaired populations.

The Boys Town Norms template is explained in the following window. Users should refer to the reference article for additional information.



8.11 Reset

To restore the instrument back to the manufacturer default settings, select *Reset* from the *Set up* menu and confirm the selection when prompted.

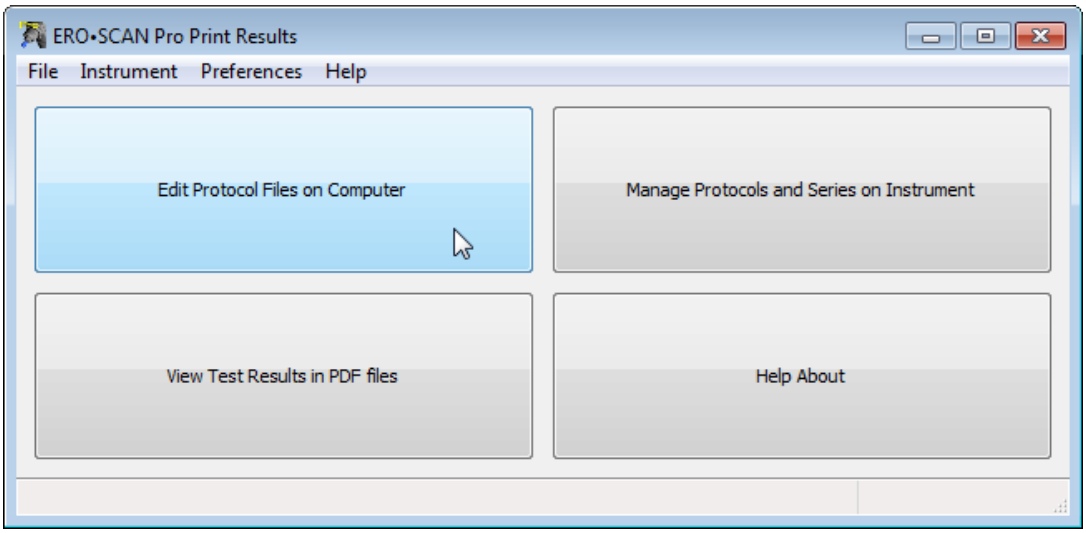
9 Customizing Protocols and Series

Users of any instrument type can create series of protocols. Users of diagnostic instruments can also customize individual protocols. The *Print Results* software application is used to create and manage custom protocols and series. This section will explain how to customize protocols and series. For software installation instructions see Appendix A.

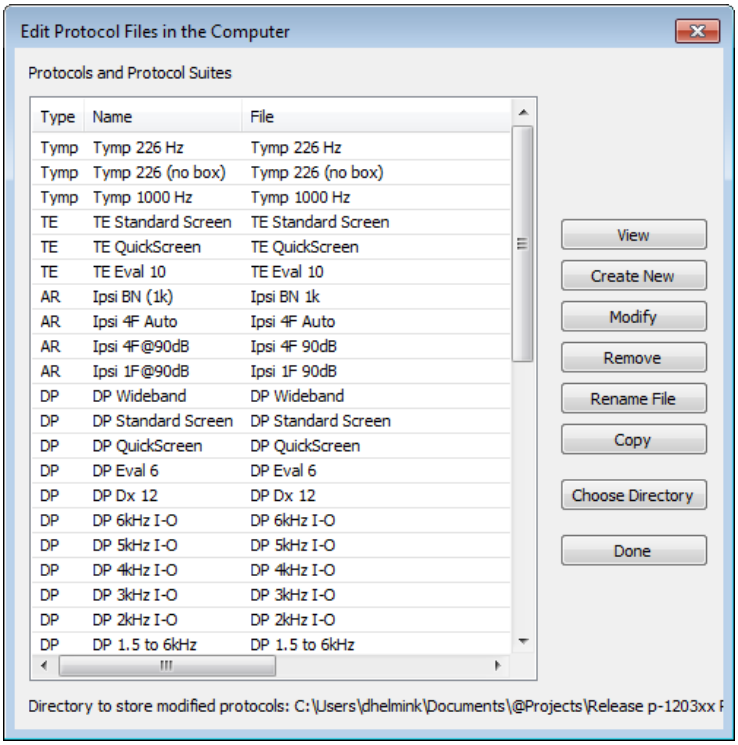
Protocols are files which contain the specific test parameters to conduct a DPOAE, TEOAE, or tympanometry test and assign a Pass or Refer to the test result. A series is a set of linked protocols that run in sequence by pressing one button to begin the series. Each ERO•SCAN Pro comes preloaded with protocols and series.

CAUTION: Protocols should only be created or modified by hearing healthcare professionals, such as audiologists and ENT physicians, with adequate education and experience in the areas of otacoustics emissions, tympanometry and acoustic reflexes. Individuals without adequate education and experience should use the provided default protocols or seek supervision from a qualified hearing healthcare professional.

9.1 Creating/Editing Protocol Files



Protocol files originate on the computer and are then loaded to the ERO•SCAN Pro instrument. To create or edit a protocol file, click on the button, Edit Protocol Files on the Computer, located in the upper left corner of the main window.



The Protocols dialog to the left shows the protocol files stored on the computer. This list can consist of protocols loaded into the instrument and protocol files which are currently located only on the computer.

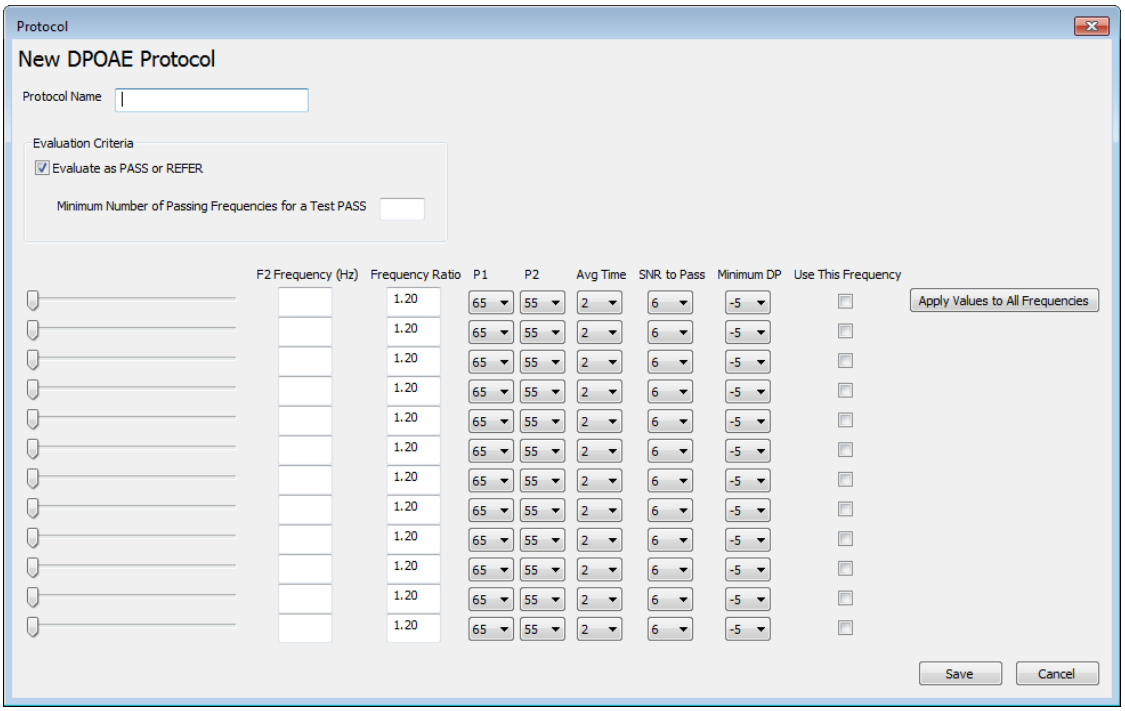
Manufacturer default protocols appear in blue font. User created or modified protocols appear in black font.

The right panel of the Protocols window contains a number of buttons to perform various functions related to creating, editing, and managing protocol files saved on the computer. These functions are:

View – displays the settings and parameters for the selected protocol.
Create New – begins the process to create a new DPOAE, TEOAE or Tympanometry protocol file
Modify – opens the protocol file for editing
Remove – deletes the protocol file from the
Rename File – this allows the user to change the file name for the protocol
Copy – creates a duplicate of the selected protocol which can then be used as the starting point for a user defined custom protocol
Choose Directory – allows the user to select change the location where custom protocol files are saved
Done – exits the protocol window

Creating a DPOAE Protocol

To create a new protocol file, click the *Create New* button located on the right panel of the protocol window. A new dialog will appear, select *DPOAE Protocol*.



The New DPOAE Protocol dialog above shows the window for creating or modifying a DPOAE Protocol.

Protocol Name: the text entered into the Protocol Name field is what will appear in the instrument when the protocol is loaded. This should be kept to approximately 14-16 characters in length so that the full protocol name can be viewed on the instrument display.

Evaluation Criteria: check the box if a Pass or Refer outcome should be determined for this protocol. Indicate the number of passing frequencies required for the overall test result to be *Pass.* Number of passing frequencies for a test pass can be set to any value between 1 and 10, but cannot exceed the total number of frequencies tested.

F2: use the slider bars or type the numerical value into the text box to set the f2 frequency. The f2 frequency is customizable in 100 Hz increments between 1.5 and 12 kHz.

Frequency Ratio: the frequency separation between the two primary tones (f2/f1). The f2/f1 ratio is adjustable between 1.1 to 1.4.

P1/P2: these settings control the intensity of the two primary tones (f1 and f2). P1 and P2 are adjustable between 40 and 70 dB SPL. The maximum paired setting is 70/60. The minimum paired setting is 40/40.

Averaging Time: established the length of time the OAE will be measured and averaged at each test frequency. This is adjustable between 1 and 4 seconds. Note: Longer averaging time generally results

in better test outcomes particularly when measuring in noisy environments, but shorter averaging times may be desirable for pediatric populations.

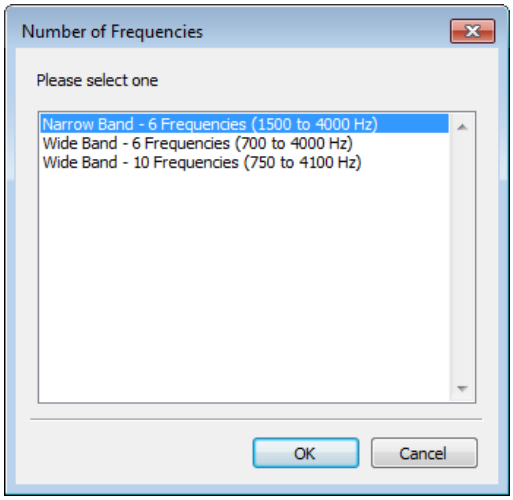
SNR to Pass: defines the minimum SNR required for that frequency to be considered a passing frequency. SNR to Pass is adjustable between 3 and 10 dB

Minimum DP: defines the minimum DPOAE (signal) amplitude required for that frequency to be considered a passing frequency. Minimum DP is adjustable between -20 and 0 dB SPL. If the user does not wish to use minimum amplitude as part of the Pass criterion, n/a can be selected for this parameter and/or the instrument setting for *DP Minimums* can be set to *off*.

Note: when creating or modifying a protocol, the desired setting can be established for the first test frequency (top row) and then applied to all frequencies by clicking the *Apply Values to All Frequencies* button.

Creating or Modifying TEOAE Protocols

To create a new protocol file, click the *Create New* button located on the right panel of the protocol window. A new dialog will appear, select *TEOAE Protocol*.



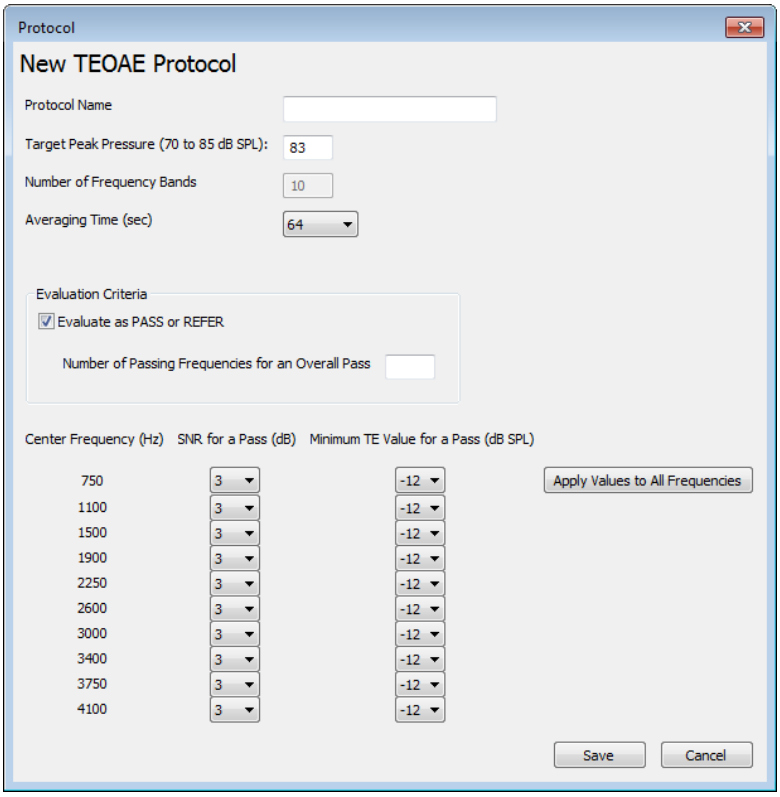
The selection window shown below will appear.
There are three frequency range options when creating a new TEOAE protocol.

Narrow Band – 6 frequencies (1500 to 4000 Hz) which includes: 1500, 2000, 2500, 3000, 3500, and 4000 Hz

Wide Band – 6 Frequencies (700-4000 Hz) which includes: 700, 1000, 1400, 2000, 2800, and 4000 Hz

Wide Band – 10 Frequencies (750-4100 Hz) which includes: 750, 1100, 1500, 1900, 2250, 2600, 3000, 3400, 3750, and 4100 Hz

Note: all TEOAE test frequencies refer to the center of the frequency band or filter.



Above is the TEOAE protocol editing window.

Protocol Name: the text entered into the Protocol Name field is what will appear in the instrument when the protocol is loaded. This should be kept to approximately 14-16 characters in length so that the full protocol name can be viewed on the instrument display.

Target Peak Pressure: sets the target intensity for the click stimulus. Target peak pressure is adjustable between 70 and 85 dB SPL.

Averaging Time: the maximum length of time the TEOAE measurement will run before displaying a Pass or Refer result. The test will stop automatically once a Pass result is obtained. The averaging time can be adjusted between 8 and 64 seconds.

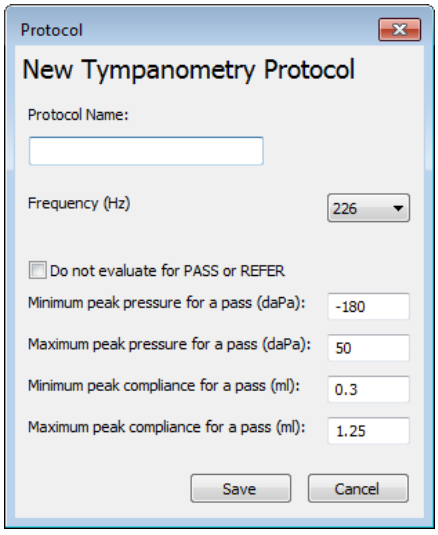
Evaluation Criteria: check the box if a Pass or Refer outcome should be determined for this protocol. Indicate the number of passing frequencies required for the overall test result to be *Pass.* Number of passing frequency bands for a test pass can be set to any value between 1 and 10, but cannot exceed the total number of frequency bands tested.

SNR to Pass: defines the minimum SNR required for that frequency to be considered a passing frequency band. SNR to Pass is adjustable between 3 and 10 dB

Minimum TE: defines the minimum TEOAE (signal) amplitude required for that frequency band to be considered a passing frequency. Minimum DP is adjustable between -20 and 0 dB SPL. If the user does not wish to use minimum amplitude as part of the Pass criterion, n/a can be selected for this parameter and/or the instrument setting for *Use Minimums* can be set to *off.*

Creating a Tympanometry Protocol

To create a new protocol file, click the *Create New* button located on the right panel of the protocol window. A new dialog will appear, select *Tympanometry Protocol*.



To the left is the Tympanometry protocol editing window.

Protocol Name: the text entered into the Protocol Name field is what will appear in the instrument when the protocol is loaded. This should be kept to approximately 14-16 characters in length so that the full protocol name can be viewed on the instrument display.

Frequency: sets the probe tone frequency for the tympanometry measurement. The selections for probe tone frequency are 226 and 1000 Hz.

Evaluate Pass or Refer: A within limits box will be shown on the tympanometry display and print out by default for the 226 Hz probe tone measurement. The Pass or Refer outcome will is based on the presence or absence of the tympanometric peak within the limits box. If no limits box or Pass/Refer outcome is desired, check the box *Do not evaluate Pass or Refer*.

Setting the within limits box:

Minimum peak pressure for a pass: selects the low pressure limit for the box (-300 to 400)

Maximum peak pressure for a pass: selects the high pressure limit for the box (-300 to 400)

Minimum peak compliance for a pass: selects the low peak compliance limit for the box (0.0 to 2.0)

Maximum peak compliance for a pass: selects the high peak compliance limit for the box (0.0 to 2.0)

Modifying a Protocol

To change the settings of an existing protocol, click the *Modify* button located on the right panel of the protocol window (Figure 68). The protocol editing window for that protocol will open. Make the desired changes and click *Save*.

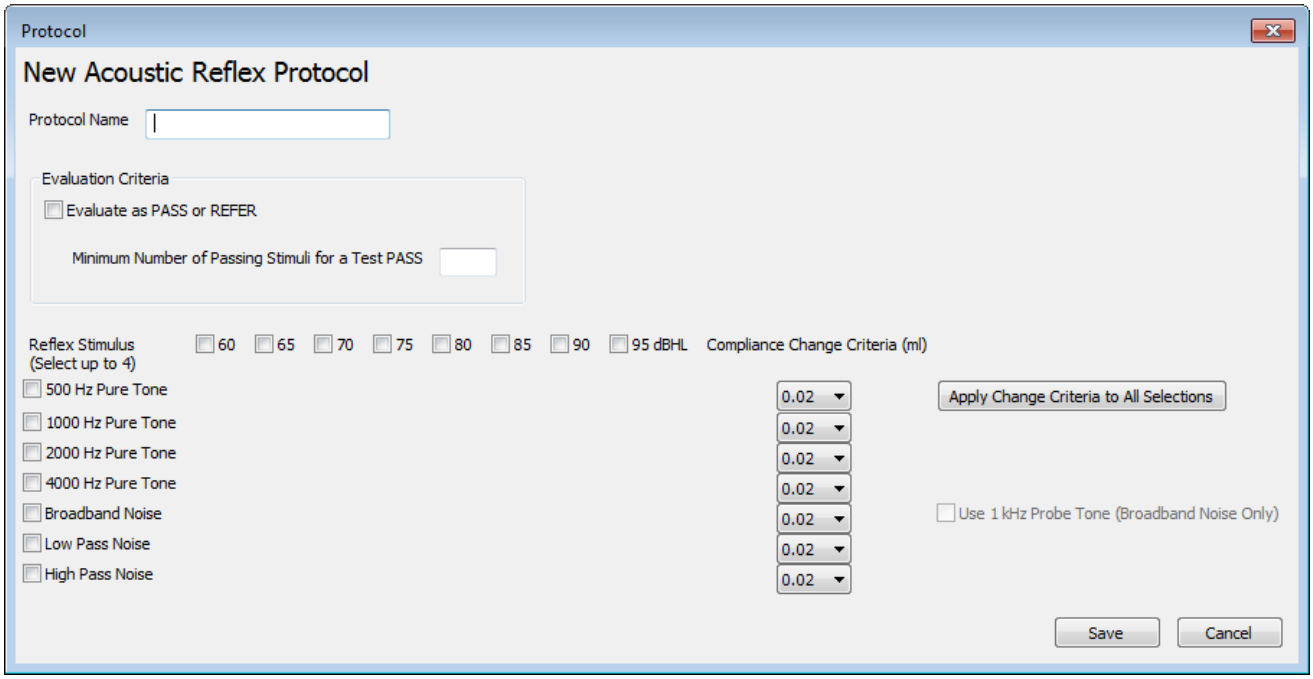
Manufacturer default protocols cannot be modified by the user. They can, however, be copied and used as the starting point for user defined custom protocols. See instructions below for copying a protocol.

Removing a Protocol

To permanently delete a protocol from the directory, click the *Remove* button located on the right panel of the protocol window (Figure 68).

Removing a protocol file from the directory does NOT remove it from the instrument. To remove a protocol from the instrument, follow the instructions provided below in section 9.2.

Creating an Acoustic Reflex Protocol



Above is the Acoustic Reflex protocol editing window.

Protocol Name: the text entered into the Protocol Name field is what will appear in the instrument when the protocol is loaded. This should be kept to approximately 14-16 characters in length so that the full protocol name can be viewed on the instrument display.

Evaluation Criteria: check the box if a Pass or Refer outcome should be determined for this protocol. Indicate the number of passing frequencies required for the overall test result to be *Pass.* Number of passing frequency bands for a test pass can be set to any value between 1 and 4, but cannot exceed the total number of frequency bands tested.

Using the check boxes under the *Reflex Stimulus* column, select up to 4 stimuli to be presented.
Using the check boxes 60-95 dBHL, select up to 6 intensities to be presented

Green check marks and/or red anti symbols will be shown in the area corresponding to each stimulus-intensity combination. The green check mark indicates an allowed combination, whereas the red anti symbol indicates a conflict between the stimulus type and the intensity.

The compliance change criterion determines the amount of compliance change required to consider the acoustic reflex present. This is selectable between 0.03 ml and 0.09 ml.

Note: when using the 1kHz probe tone, broadband noise is the only allowable stimulus type. Use the check box to the left of the broadband noise stimulus row to select this option.

Renaming a Protocol File

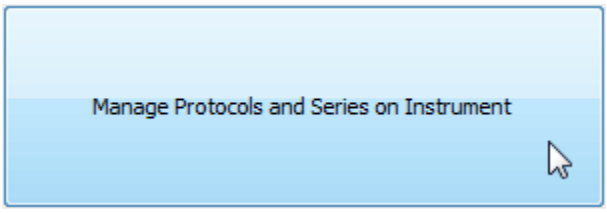
The protocol name that appears in the instrument is a parameter established within the protocol file. The Windows file name for the protocol can and may be different than the protocol name. For ease of managing protocols you may want to rename protocol files so that the protocol name and file name match. To rename a protocol file, click the *Rename* button located on the right panel of the protocol window.

Copying a Protocol File

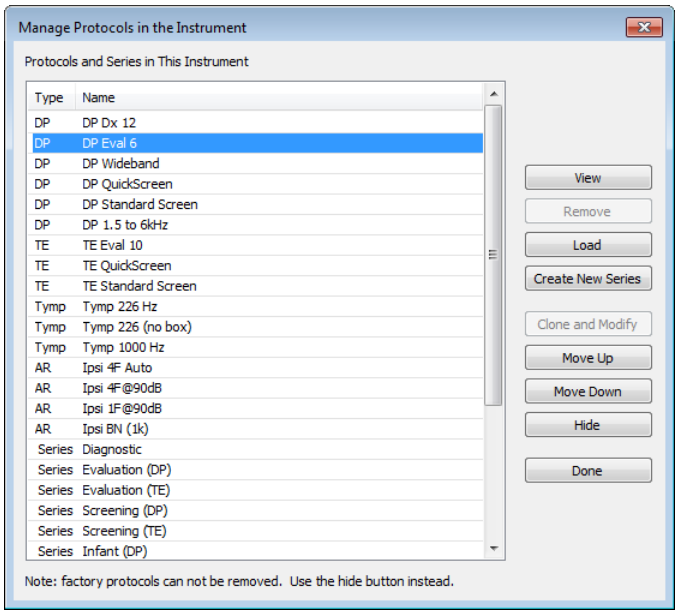
To copy a protocol, select the protocol to be copied and click the *Copy* button located on the right panel of the protocol window (Figure 68). The copied protocol file will appear in the list of protocols with the same protocol name, but the file name will be "Copy of *selected protocol*" .

Select the new copy of the existing protocol and click the *Modify* button located on the right panel of the protocol window (Figure 68). To modify the protocol follow the instructions provided above and save changes.

9.2 Managing Protocols in the Instrument



To load new or modified protocols into the instrument or to remove unused protocols from the instrument, click on the button located in the upper right corner of the main window *Manage Protocols and Protocol Series* .



This dialog allows the user to manage the protocols and series in the instrument. On the right panel of the window are the following buttons:

View: displays the selected protocol or series settings

Remove: removes the selected protocol or series from the instrument

Create New Series: opens the "Create New Series" dialog shown in figure 85. Instructions for creating a new series of protocols can be found in section 9.3 of this manual.

Load: opens the directory from which the user can select a protocol file to load in the instrument

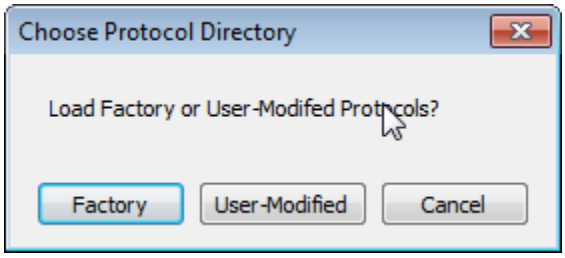
Done: exit

Remove Protocol or Series

To remove protocols or series from the instrument, select the protocols or series to be removed and click the *Remove* button located in the right panel of the Protocols in Instrument window. Use ctrl+click or shift+click to select multiple protocols to remove or load.

Manufacturer default protocols cannot be removed – use the hide button instead.
When series are removed from the instrument they are DELETED permanently.

Load Protocols



To load a protocol into the instrument, click the *Load* button located in the right panel of the Protocols in Instrument window.

When prompted (Figure 80) select the appropriate directory for the protocol being loaded.

Factory = manufacturer created protocols
User = user modified or created protocols

Select the protocol or protocols you wish to load and click *Open*.

Note: Custom protocols will display an unlock symbol in front of the protocol name on the instrument display.

Each protocol must have a unique name. When attempting to reload a protocol file from the computer directory that has been modified from the version currently loaded in the instrument, you must first remove the old protocol by that name and then load the modified protocol. If the protocol being removed and reloaded was used in any series then the series will need to be removed and recreated using the new protocol file.

9.3 Creating Series

Protocol series are a sequence of individual protocols which are linked together. A series can be composed of any combination of DPOAE, TEOAE, or Tympanometry protocols that are present in the instrument. Series are indicated on the instrument main menu by the multiplicity symbol to the left of the series name. Series help to streamline the testing process by minimizing the number of button presses required to run multiple protocols on a single patient. When using series, the probe can be placed in the ear canal and a group of sequenced protocols for that ear can be started and completed by pressing only one button to begin the right or left series.

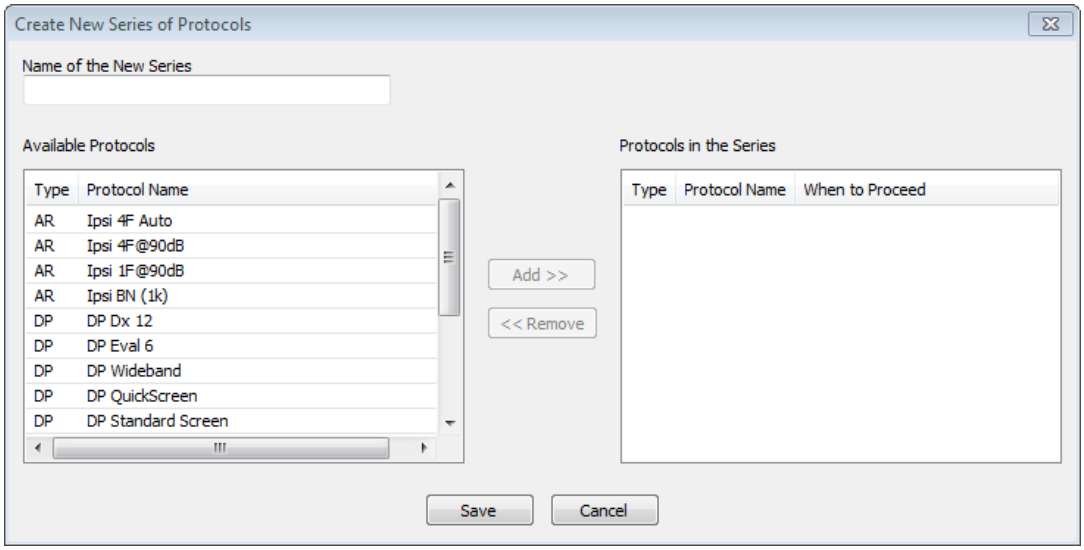
Each instrument comes preloaded with protocols and protocol series. For a description of the protocols and series included see Appendix B.

The users of all instruments can create custom series.

To create a new series, click on the *Manage Protocols and Protocol Series* button located in the upper right corner of the main window.

Then click on 

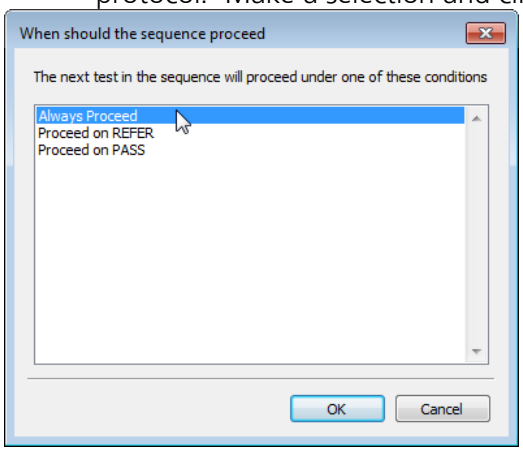
the button located in the right column of the Manage Protocols dialog.



Step 1: Type the series name into the text box provided. Series names should be kept to approximately 12 characters in length to ensure the full protocol name will display on the instrument.

Step 2: From the list of *Available Protocols* on the left of the window, select the first protocol for the series and then click *Add*.

Step 3: You will be prompted to determine when the testing sequence should proceed to the next protocol. Make a selection and click *Ok*.



Always proceed = testing will proceed to the protocol in the series regardless of test outcome

Proceed on Refer = testing will proceed to the next protocol in the series only when the outcome of selected test is *Refer*.

Proceed on Pass = testing will proceed to the next protocol in the series only when the outcome of selected test is *Pass*.

These rules can help improve the efficiency of testing by applying the logic you may use typically in your practice setting. For example, you may want to start with an OAE test and only proceed with the tympanometry test when there is a Refer outcome on the OAE test. Another option might be to start with a tympanometry test and only proceed with the OAE test when the tympanometry result is within normal limits (Pass). Finally, you may choose to establish a complete test battery series that runs a several protocols in sequence regardless of the outcome of any single protocol.

Continue repeating step 2 (selecting from available protocols) and step 3 (determining how to proceed) as described above until the series contains the desired protocols. When finished, click *Save* on the *Create New Series of Protocols* window. Confirmation that the series was successfully loaded into the instrument is provided. When the instrument is removed from the cradle the new series will appear in the list of protocols.

Note: if the series contains any OAE frequencies above 6 kHz or a tympanometry protocol then the appropriate external probe must be connect in order for the series to be shown in the instrument.

10 Troubleshooting

Problem	Possible Causes	Resolution
Test will not progress past AutoStart	Probe fit is poor and/or noise level is too high.	Reposition or refit eartip (trying a different size if necessary) and reduce environmental or patient noise if possible. If problem persists, check that the test will start in a cavity or in your own ear.
	Clogged probe tip.	Replace probe tip.
	Probe tip is not fully attached.	Press firmly on the probe tip tabs until secure.
	External probe has not been detected.	Check connector, power off the instrument and then power on again.
	Equipment malfunction.	Contact your special instrument distributor or Maico Diagnostics.
Protocols or series are missing from the menu	The external probe which supports the test function (high frequency DPOAE or tympanometry) is not connected.	Turn off the instrument, connect the probe and turn the instrument on again to detect the probe.
	The protocols were removed from the instrument using the PC software (possible only for diagnostic instruments).	Reload protocols using PC software.
Instrument does not turn on	Power button was not depressed long enough.	The power button must be pressed for one full second. Try again
	Batteries are dead or installed improperly.	Install new batteries according to the label in the battery compartment.
No communication between instrument and computer	Button on cradle is the printer position.	Check that the button on the cradle is the computer position (down).
	Cradle is not connected to the computer.	Check USB connector on the underside of the cradle and on the computer. Be sure the cable is fully seated in both connectors.
	Communication settings within PC software are incorrect.	Check and correct communication settings. See Appendix A for instructions.
Thermal printer does not print.	Button on cradle is in the computer position	Check that the button on the cradle is in the printer position (up).
	Cradle is not connected to the printer.	Check the printer connection cable on the underside of the cradle and the back of the printer. Be sure the cable is fully seated in both connectors.
	The printer is in sleep mode.	When the printer is ready to print the button will be green. Press the button to wake the printer from sleep mode.
	Printer battery is not charged.	Plug the printer in to the charger. When the printer is ready to print the button will be green. Press the button to wake the printer from sleep mode.
	Paper is not installed correctly.	An amber light will appear when the paper is low or incorrectly installed. Follow the instructions in section 7.3 to replace or reposition the paper roll.
	There are no tests in the memory.	Confirm there are tests saved in the instrument. Follow the instructions in section 6.1 for reviewing test results.
	Printer is stuck in error mode	Reset the printer following instructions provided in section7.3

11 Care and Maintenance

11.1 Cleaning and Disinfecting the Instrument

This instrument and its accessories may be wiped clean with a damp cloth using a mild antiseptic solution (e.g., cetylcide). Take care not to put excessive pressure on the clear display window or allow any utensil to puncture the display window or control panel. **Do not allow any fluid to enter the device.** Do not immerse the instrument in fluids or attempt to sterilize the instrument or any of its accessories.

11.2 Maintenance & Calibration

This instrument should be calibrated annually by your special equipment distributor or by Maico Diagnostics. Beyond that, it requires no regular maintenance other than routine cleaning and battery replacement. The probe tip requires replacement only when it becomes clogged.

11.3 Probe Tip Replacement

Probe tips are disposable and should be replaced when they become clogged. Four replacement probe tips of each type (internal and external) are included with this instrument. Do not attempt to clean the probe tip.

Internal Probe Tip Replacement

To replace the probe tip, squeeze the tabs as shown in the picture to the right. The tabs should audibly snap off the probe assembly. Pull the probe tip directly off the probe and discard it.

Obtain a replacement probe tip and orient the tip with the arrows on the face of the probe tip directed toward the top of the instrument. The probe tip will only fit on one way; be careful not to force the tip in place. Push the tip directly down onto the probe. Once the probe tip is in place on the probe, push firmly downward on the top of the tabs one at a time until a click is heard. Tug lightly on the probe tip to verify that the tip is securely attached.

External Probe Tip Replacement

To remove:
Using a small pointed object, such as a pen or small screwdriver, push in the notches on the left and right sides of the rear of the external probe until each tab is released (Figure 11A).
Slide the probe tip off the front of the probe and discard (Figure 11B).

To replace:
Align a replacement tip with the front of the probe (Figure 11C). Align the tab on the external probe tip with the notch on the probe body. **The tip will only fit in one direction.** If the tip does not fit securely on the probe, remove the probe tip and reorient it.
Press firmly on the tabs to snap them into place (Figure 11D).

NOTE: If the probe tip is not inserted completely, the ERO•SCAN Pro will not perform a test.


Figure 11A

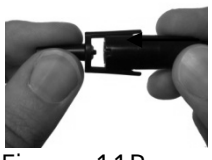


Figure 11B

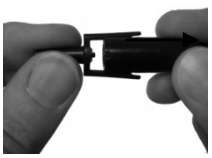


Figure 11C

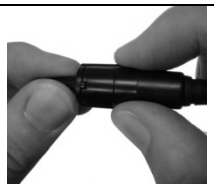


Figure 11D

12 Important Safety Precautions

The ERO•SCAN Pro Test System should be used only by those individuals trained to perform the testing for which it has been designed. No person should attempt to use this instrument without the necessary knowledge and training to understand how this equipment is to be properly utilized and interpreted.

The ERO•SCAN Instrument probe tip must not be inserted into an ear at any time without a disposable eartip properly affixed.

IMPORTANT

In the event of a critical system failure, the message shown to the left will be displayed. Discontinue use of the instrument and contact your Special Equipment Distributor or contact Maico Diagnostics by phone at (888) 941-4201 or by fax at (952) 903-4100.

12.1 Precautions

READ THIS ENTIRE MANUAL BEFORE ATTEMPTING TO USE THIS SYSTEM.

- Use this device only as described in this manual.
- Use only the disposable eartips designed for use with this instrument.
- Never insert the probe tip into the ear canal without affixing an eartip.
- The eartips are disposable and for single patient use only. Do not clean or reuse eartips.
- Use only disposable 1.5v AA/UM-3/R6 Alkaline batteries for the test instrument. Do not use rechargeable cells in this device; do not mix battery types and do not mix old and new batteries.
- Remove the batteries from the instrument if it will not be used for 4 weeks or more.
- Do not immerse the unit in any fluids. See the Care and Maintenance section of this manual for proper cleaning procedures.
- Do not drop or otherwise cause undue impact to this device. If the instrument is dropped or otherwise damaged, return it to the manufacturer for repair and/or calibration. Do not use the instrument if any damage is suspected.
- Use and store the instrument indoors only. Do not use this instrument or its accessories in temperatures below 40°F (4°C) or above 100°F (38°C), or in relative humidity of more than 90%.
- Do not attempt to open or service the instrument. Return the instrument to the manufacturer for all service. Opening the instrument case will void the warranty.
- Do not operate the printer if the power supply has a damaged cord or plug. See the instructions on the following page.
- Do not expose the printed results to sunlight or heat. Printing on thermal paper fades with exposure to light or heat.
- Photocopies of test results should be made if the records are to be kept indefinitely.

13 System Specifications

DPOAE SYSTEM

PRIMARY TONES:	Frequency: F2 from 1.5 kHz to 12 kHz Intensity: Up to 6 kHz: 40/40 to 70/60 dB SPL Over 6 kHz: 40/40 to 65/55 dB SPL
MIC SYSTEM NOISE:	<=-20 dB SPL @ 2 kHz (1 Hz Bandwidth)
ARTIFACT:	<-20 dB SPL @ 2F1-F2 Frequency
F1/F2 RATIO:	1.2 (default) adjustable 1.1 to 1.4
F1/F2 DIFFERENTIAL:	0 to 30 dB SPL

TEOAE SYSTEM

STIMULUS:	Adjustable up to 83 dB SPL Broadband Click
CLICK BANDWIDTH:	500 Hz to 4000 Hz
ANALYSIS BANDS:	6 or 10 Bands
ARTIFACT:	<-10 dB SPL

TYMPANOMETRY SYSTEM

PROBE TONE:	Frequencies: 226 Hz, 1000 Hz Level: 85 dB SPL with in-ear calibration
AIR PRESSURE:	Range: 0.05cc to 3.0cc: +300 to -400 daPa 3.0cc or greater: at least +200 to -200 daPa Capacity: 0.05cc to > 5.0 cc Speed: 60 daPa/Sec. nominal 500 to 700 daPa/sec (depending on ear volume).
TEST TIME:	2.5 seconds nominal (depending on ear volume).

OVERPRESSURE LIMIT: 1.0cc ear canal volume < 3 psi (2000 daPa)

ACOUSTIC REFLEX SYSTEM

STIMULUS:	500, 1000, 2000, 4000 Hz Pure tone Broadband noise, low pass noise, high pass noise
PROBE TONE:	226 or 1000 Hz
STIMULUS INTENSITY:	500-4,000 Hz 70-95 dB HL, in 5 dB steps Noise stimulus 60-90 dB HL, in 5 dB steps
STANDARDS:	IEC60645-5 ANSI S3.39-1987

14 Warranty

Maico Diagnostics warrants that this product is free from defects in material and workmanship and, when properly used, will perform in accordance with applicable specifications. If this instrument does not meet these criteria within one year of original shipment, it will be repaired, or at our option, replaced at no charge when returned to our service facility. Changes in the product not approved by Maico Diagnostics shall void this warranty. Maico Diagnostics shall not be liable for any indirect, special or consequential damages, even if notice has been given of the possibility of such damages.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

For assistance with this ERO•SCAN Pro® Test System contact your Special Equipment Distributor or contact Maico Diagnostics by phone at (888) 941-4201 or by fax at (952) 903-4100.

The serial number of your instrument can be found inside the battery compartment and the printer serial number is under the rechargeable battery. Please write the instrument and printer serial numbers below for future reference.

ERO•SCAN Pro Instrument Serial Number: _____

Printer Serial Number: _____

Date Purchased: _____

Purchased From: _____

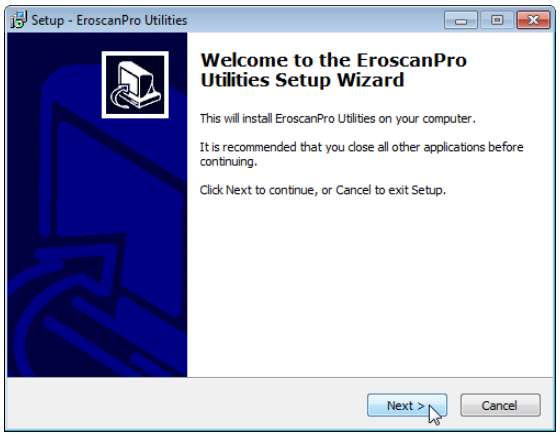
SAVE THIS MANUAL FOR FUTURE REFERENCE

Appendix A: ERO-SCAN Pro Software Installation Instructions

1 Application Installation

To begin installation double click on the installer file: **EroscanPro_installer_user_p-120508.exe**
Then follow the steps as shown below (from left to right by row):

1



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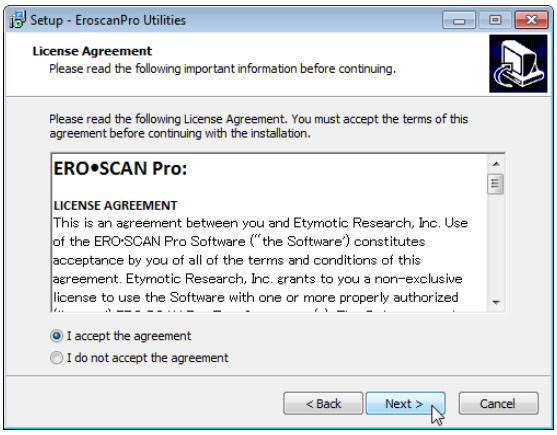

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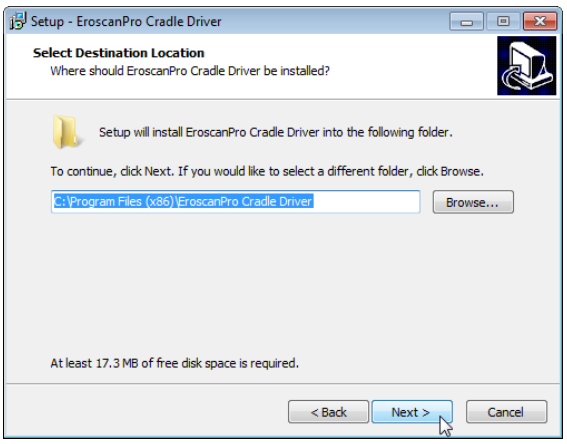

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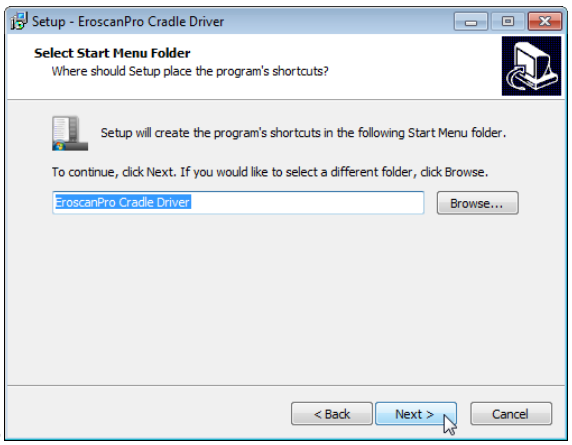

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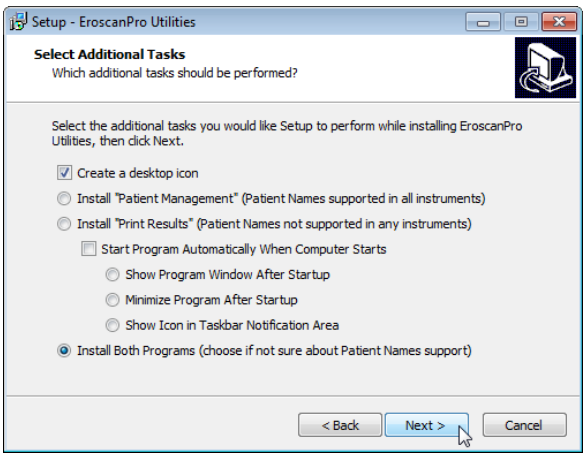

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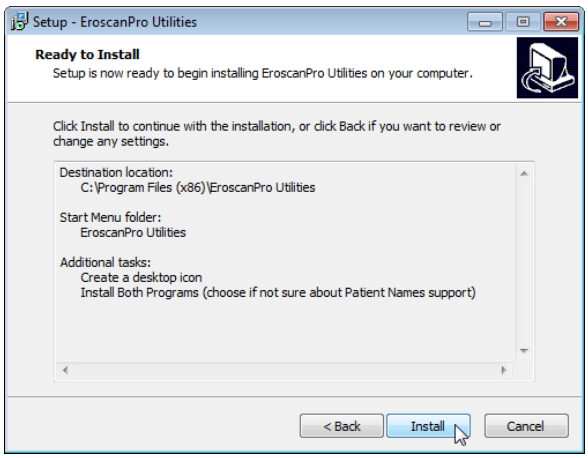
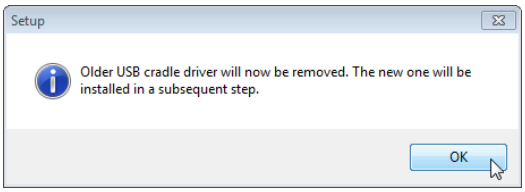


If the installed cradle driver is an older version, it will be uninstalled and the new driver will be installed.

7



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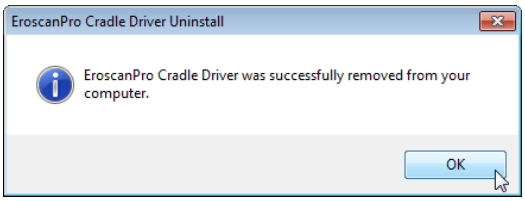

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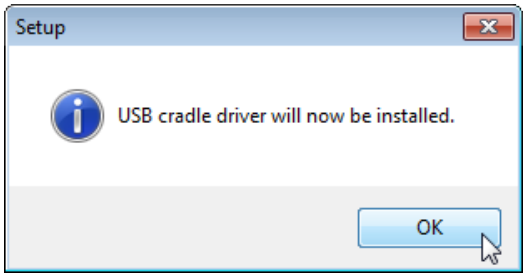

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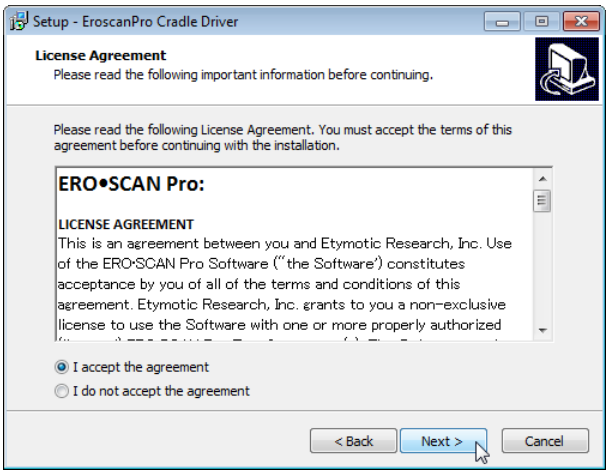

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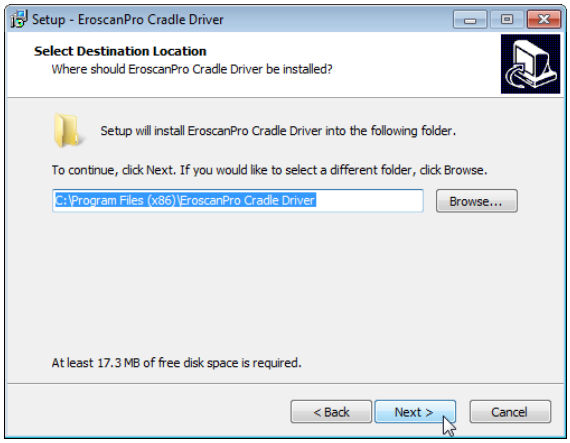

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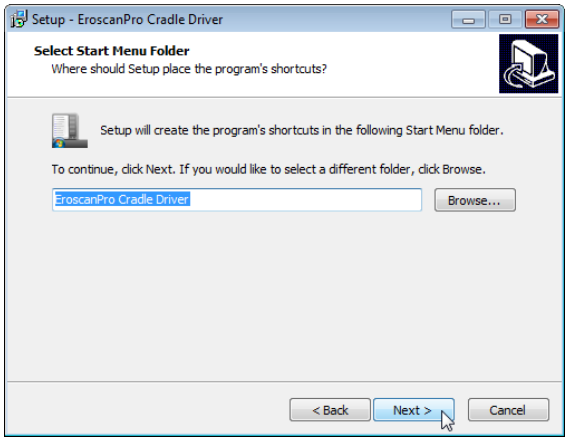

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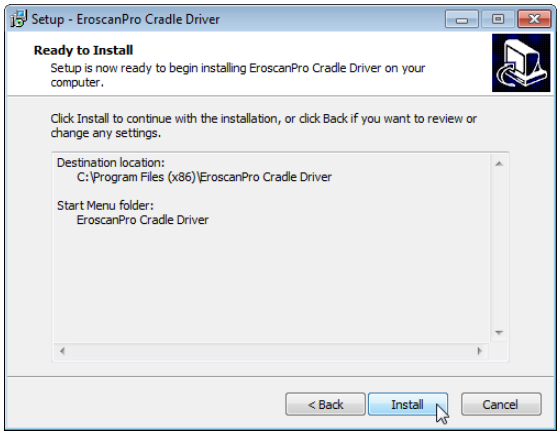
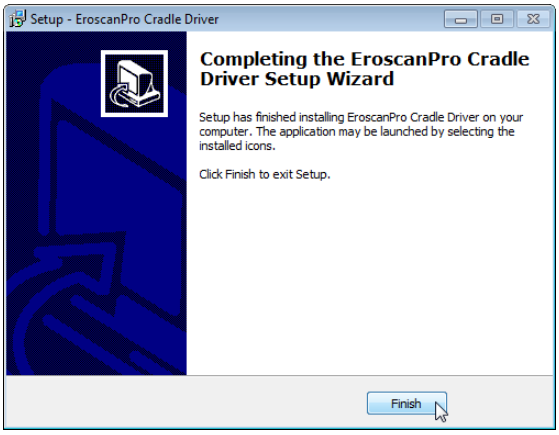
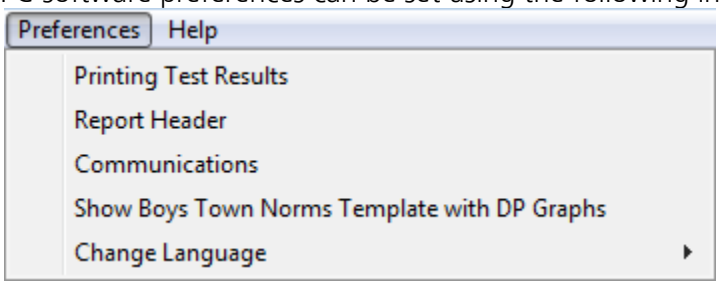


14

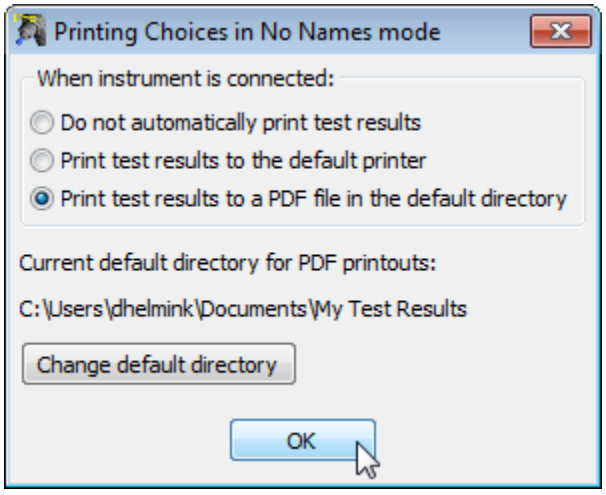


2 Setting PC Software Preferences

PC software preferences can be set using the following in the Preferences menu



Printing Test Results



The first time test data is transferred to the application you will be prompted to establish your printing preferences. You can also set your preferences by selecting *Preferences* and then *Printing Test Results* from the menu.

Do not automatically print test results: no action will be taken when he instrument in placed in the cradle

Print test results to the default printer: the test results will be sent to the default PC 8.5 x 11 printer. There will be no electronic copy saved.

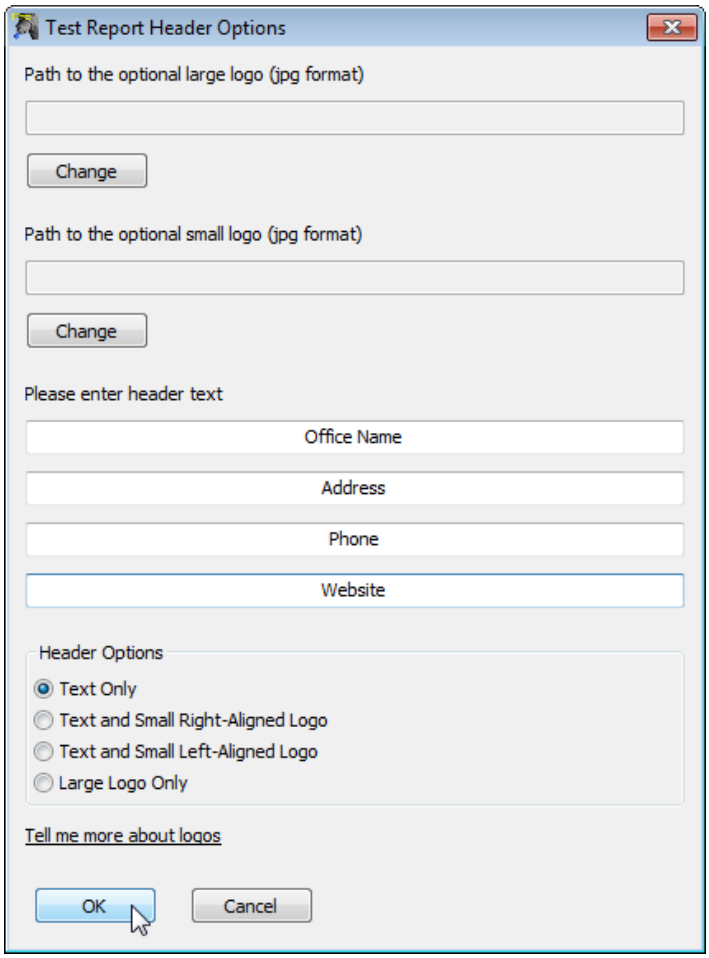
Print test results to a PDF file in the default directory: the test results will be sent to a PDF file that can be named and saved for import into electronic medical records systems or for printing in the future.

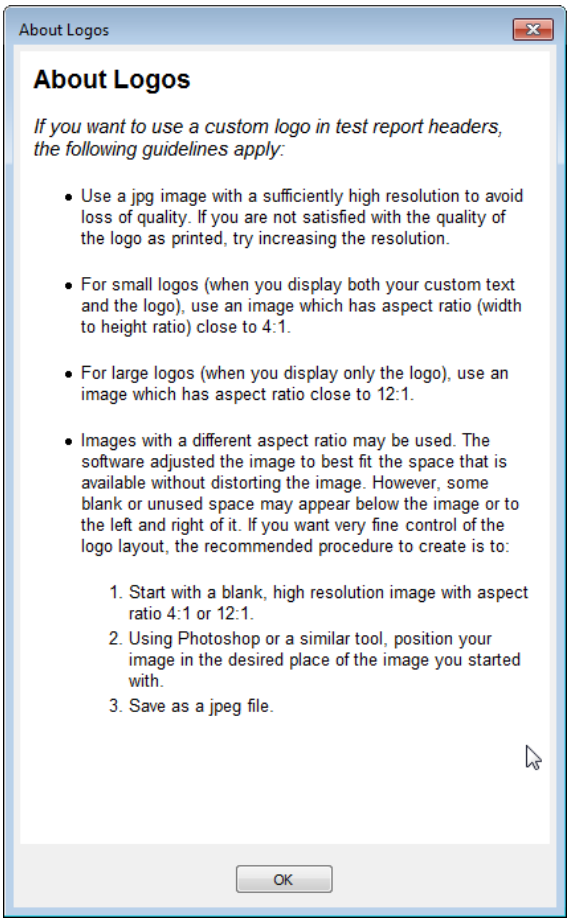
Report Header

Users can optionally choose to customize the printed report header to include practice information and/or logo as desired. Select *Preferences > Report Header*.

For Text only in the report header, enter the desired information into the four text lines available in the Report Header dialog.

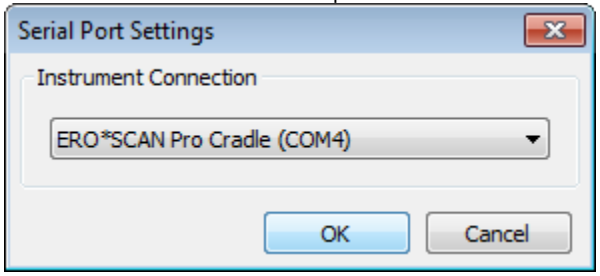
To add a custom logo to the report header, use the *Change* button to set the path to a large or small logo file. Finish by selecting the position of the logo using the *Header Options* at the bottom of this dialog.





Communications

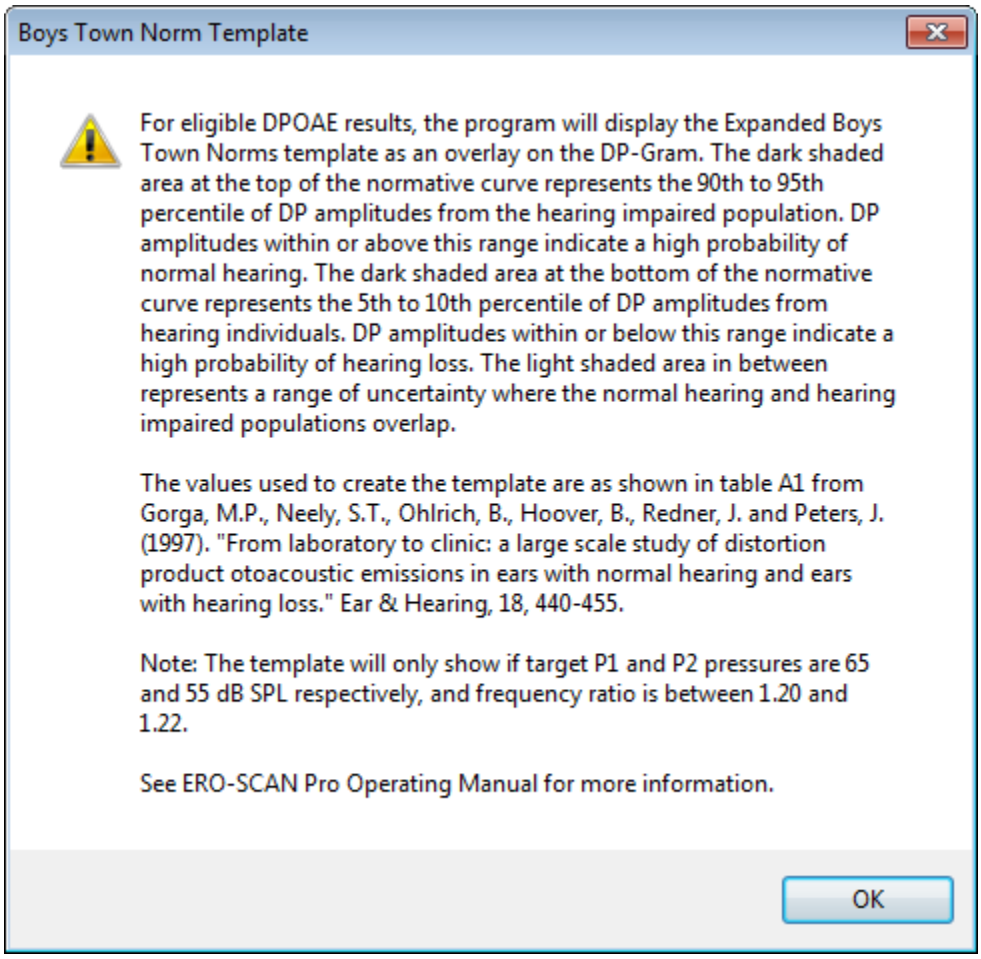
Select the communication port for the cradle with *Preferences > Communications*



Boys Town Norms Template

Users may optionally show the Boys Town Norms template on the DP-Gram of the PDF or printed test report by selecting that option with *Preferences > Show Boys Town Norms Template with DP Graphs.*

The Boys Town Norms template is explained in the following window. Users should refer to the reference article for additional information.



Appendix B: Default Test Protocols and Protocol Series

Screener

DP	TE	Combo	Protocol Name	Protocols Included
X		X	Screening (DP)	Tymp 226 Hz > DP QuickScreen
	X	X	Screening (TE)	Tymp 226 Hz > TE QuickScreen
X		X	Infant (DP)	DP QuickScreen > Tymp 1000 Hz
	X	X	Infant (TE)	TE QuickScreen > Tymp 1000 Hz

Diagnostic

DP	TE	Combo	Protocol Name	Protocols Included
X		X	Diagnostic	Tymp 226 Hz > DP Dx 12
X		X	Evaluation (DP)	Tymp 226 Hz > DP Eval 6
	X	X	Evaluation (TE)	Tymp 226 Hz > TE Eval 10
X		X	Screening (DP)	Tymp 226 Hz > DP QuickScreen
	X	X	Screening (TE)	Tymp 226 Hz > TE QuickScreen
X		X	Infant (DP)	DP QuickScreen > Tymp 1000 Hz
	X	X	Infant (TE)	TE QuickScreen > Tymp 1000 Hz

Screener w/ Ipsi Reflex

DP	TE	Combo	Protocol Name	Protocols Included
X		X	Screening (DP)	Tymp 226 Hz > DP QuickScreen
	X	X	Screening (TE)	Tymp 226 Hz > TE QuickScreen
X		X	Infant (DP)	DP QuickScreen > Tymp 1000 Hz
	X	X	Infant (TE)	TE QuickScreen > Tymp 1000 Hz
X		X	Screening+ (DP)	Tymp 226 Hz > Ipsi 1F 90 dB > DP QuickScreen
	X	X	Screening+ (TE)	Tymp 226 Hz > Ipsi 1F 90 dB > TE QuickScreen
X		X	Infant+(DP)	DP QuickScreen > Tymp 1000 Hz > Ipsi BN (1k)
	X	X	Infant+(TE)	TE QuickScreen > Tymp 1000 Hz > Ipsi BN (1k)

Diagnostic w/ Ipsi Reflex

DP	TE	Combo	Protocol Name	Protocols Included
X		X	Diagnostic	Tymp 226 Hz > DP Dx 12
X		X	Evaluation (DP)	Tymp 226 Hz > DP Eval 6
	X	X	Evaluation (TE)	Tymp 226 Hz > TE Eval 10
X		X	Screening (DP)	Tymp 226 Hz > DP QuickScreen
	X	X	Screening (TE)	Tymp 226 Hz > TE QuickScreen
X		X	Infant (DP)	DP QuickScreen > Tymp 1000 Hz
	X	X	Infant (TE)	TE QuickScreen > Tymp 1000 Hz
X		X	Diagnostic+	Tymp 226 Hz > Ipsi 4F Auto > DP Dx 12
X		X	Evaluation+ (DP)	Tymp 226 Hz > Ipsi 4F@90dB > DP Eval 6
	X	X	Evaluation+ (TE)	Tymp 226 Hz > Ipsi 4F 90 dB > TE Eval 10
X		X	Screening+ (DP)	Tymp 226 Hz > Ipsi 1F 90 dB > DP QuickScreen
	X	X	Screening+ (TE)	Tymp 226 Hz > Ipsi 1F 90 dB > TE QuickScreen
X		X	Infant+(DP)	DP QuickScreen > Tymp 1000 Hz > Ipsi BN (1k)
	X	X	Infant+(TE)	TE QuickScreen > Tymp 1000 Hz > Ipsi BN (1k)

Appendix C: Test Technique and Sequence

Test Technique

As with any other OAE or Tympanometry instrument, there is a technique to learn when using the ERO•SCAN Pro instrument, especially for infants and young children. Experience with existing systems suggests that it may take up to 3 months to become completely proficient at selecting the proper eartip and positioning the probe.

When testing an infant, the following suggestions might be helpful: The infant has to be relatively quiet and calm; it is usually preferred for the infant to be asleep. A pacifier may be used to calm the infant; however, sucking will add noise to the test and decrease the likelihood of a passing result. When testing an infant, gently pull down and back on the pinna to straighten out the ear canal. Generally the external probe is preferred for testing newborns. Position the probe pre-amp enclosure so that there is no weight on the probe cable and it is directed away from the infant's hands. Place the probe in the ear canal and, if necessary, wait for the infant to calm before beginning the test. Swaddling the infant in a blanket can help prevent him/her from moving and pulling the probe out of the ear during testing.

When testing a young child, the following suggestions might be helpful: The child has to be relatively quiet and calm. Quiet distracting toys should be used to distract the child during testing. Ideally these toys are something the child can hold during testing. This will keep his/her hands occupied preventing the child from pulling the probe out of the ear. Generally, the external probe is preferred for testing young children. Secure the probe to the patient using the lanyard neckloop or the clip being sure to keep any weight off the probe cable. Although it is a matter of preference, many users prefer to start the test prior to inserting the probe in the ear. This allows the tester to focus on the patient.

Test Sequence

A complete test sequence consists of an **AutoStart, calibration** and **test phase**. The **AutoStart phase** determines when the **calibration and test phase** should proceed, while the calibration phase calibrates the level of the tones that will be applied during the actual **test phase**. Artifact rejection is employed during the **test phase** to reduce the effect of transient noise bursts.

Immediately after the test button is pressed, the **AutoStart phase** of the test begins. **Autostart** checks both the quality and stability of the seal by measuring the response obtained from a sequence of test tones. The stability of the seal is determined by comparing the responses obtained over time. When the level of the response is within an acceptable range and is stable over time, the unit proceeds to the **calibration and test phase**.

<u>DPOAE</u>

The **calibration phase** automatically measures the response obtained from a calibration tone that is present prior to each set of test tones and calculates the voltage needed to obtain the desired pressures. If one or more of the desired pressures cannot be obtained, the instrument continues with measurement, but will display an error message at completion of the test if appropriate.

The **test phase** consists of measuring the response obtained from the pairs of test frequencies (f_1, f_2) applied to the receivers. Two receivers are used, with each receiver generating one frequency in order to reduce intermodulation distortion. Frequency domain estimates of the actual P1, P2, distortion (DP) and noise floor (NF) are obtained via the discrete Fourier Transform, with a bin resolution of approximately 31 Hz. The NF estimate is obtained by averaging the power in the 4 closest (+/-2) bins to the DP bin.

TEOAE

The calibration phase automatically measures the peak pressure obtained from a sequence of clicks and calculates the voltage required to obtain the target peak pressure. If the desired peak pressure cannot be obtained, the unit will use the maximum voltage.

The test phase consists of measuring the response obtained from repeated sequences of clicks applied to the receivers. The click sequence is 3-1-1-1 repeated twice. Signal and noise floor estimates are obtained by adding/subtracting the two response sequences respectively. The energy of the signal and noise floor estimates in various frequency bands is obtained in real time and displayed once per second. The average peak pressure of the stimulus is calculated after completion of the test.

Artifact rejection is employed during the test phase to reduce the effect of transient noise bursts by the use of an adaptive rejection threshold. The unit attempts to accept the quieter sections of the test, while rejecting the noisier portions of the test. When the noise level is approximately constant during the test, the instrument will tend to accept most of the data in the test. However, as the level of the noise becomes more variable over time, the instrument will attempt to accept the quieter portions of the recording. Noise estimates are obtained approximately 32 times per second and a suitable threshold is estimated from the data. Data segments with a noise floor above this threshold are rejected, which tends to lower the noise floor of the test. In order to reduce the possibility of obtaining an artificially low noise floor, the minimum threshold level is limited.

Appendix D: Pass/Refer Criteria

Pass/Refer Criteria for DPOAE

The decision that a DPOAE exists is based on detecting a signal whose level is significantly above the background noise level. This requires a statistical decision, since the random noise level in the DPOAE filter channel can be expected to exceed the average of the random noise levels in the four adjacent filter channels — used as the reference for comparison — roughly half the time.

Extended measurements of the noise distributions in both the DPOAE filter channel "DP level" and the rms average of the 4 adjacent channels "N level" indicate that the signal-to-noise ratio (the difference between DP and N) has a standard deviation of 5.5 dB. This implies a 10% probability of seeing a 7 dB SNR simply from the variability of the noise levels in the 2 filter sets.

Requiring an SNR of 6 dB in three out of four frequencies drops the probability of passing an ear with moderate-to-severe hearing loss to less than 1%. Note: three of six frequencies at >7 dB SNR will also ensure less than 1% probability of passing a moderate-to-severe hearing-impaired ear.

Pass/Refer Criteria for TEOAE

The same basic principles that underlie DPOAE Pass/Fail criteria underlie TEOAE Pass/Fail criteria. In the case of transients, requiring SNR of 4 dB at any three out of the six test frequencies drops the probability of passing an ear with a moderate-to-severe hearing loss to less than 1%.

The SNR limits for transients are lower than the corresponding limits for distortion products primarily because the traditional noise calculation used in TEOAE measurements (and in the ERO•SCAN Pro instrument) gives a 3 dB lower SNR than the calculation used for DPOAEs. Without that difference, the numerical SNR value for a PASS with the two methods would be quite similar.

Note: All manufacturer authorized protocols which provide a Pass/Refer outcome have been verified in a metal cavity (the equivalent of an ear with moderate-to-severe hearing loss) to have a less than 1% probability of passing the DPOAE or TEOAE test. Pass/Refer criteria based on probability statistics of a cavity are independent of age related normative data (Christensen & Killion, 1999).

Users with the goal of detecting mild hearing loss should ensure that the minimum amplitude setting is turned on (see section 8.6) and should collect normative data from the target patient population with the ERO-SCAN Pro to verify the protocol being used meets the screening goal.

Users creating custom protocols should collect normative data to validate any custom Pass/Refer criteria.

Preliminary ERO•SCAN Pro trials with infants indicate that the tester's technique is the single most important variable in the pass rate on normal-hearing infants. Some testers pick up the technique (see *Operating Instructions* Appendix C) with only a couple of days' practice, producing pass rates comparable to those for other DPOAE equipment they have used for months; other testers take longer.

The ERO•SCAN Pro uses a novel noise-rejection algorithm (patent pending) that permits accurate DPOAE and TEOAE measurements in background noise as high as 55-65 dB SPL (A-weighted). Briefly explained, use of available memory in the ERO•SCAN Pro processor permits a post-hoc statistical analysis that identifies those samples whose retention would improve the overall accuracy. Those samples are included in the final analysis; the noisier samples are rejected.

The improved operation in noise with the new algorithm was so substantial that we conducted a complete replica of our original validation tests in "fully impaired ear" cavities and were able to verify that no increase in false negatives (false passes) was introduced. Under no test conditions was any such degradation uncovered.

The artifact rejection can only reject the noisiest samples in a measurement period. If the ambient noise level rises too high (and/or the eartip seal is poor), then all samples will be noisy and accurate measurements will be impossible, in which case the test result will indicate "noisy."

Occasional claims of extraordinarily low probabilities of missing an ear with hearing loss appear to be based on poor statistics. As discussed by Gorga (1999), since the incidence of significant hearing loss is roughly 2 per 1000, verifying a 99.7% accuracy would require testing hundreds of thousands of babies with a given system. Thus to demonstrate that only 3 babies out of 1000 with hearing loss were missed would require follow-up testing on 500,000 babies. To our knowledge, no one has performed such tests to date.

Pass/Refer Criteria for Tympanometry:

Tympanometry measures sound reflection from the tympanic membrane, while air pressure is varied in the ear canal. The tympanogram is a quick measurement providing a snapshot of the overall status of the middle ear. The primary features of a tympanogram are the ear canal volume, peak amplitude of the tympanogram (compliance), pressure point of the peak (pressure), width of the tympanogram (gradient), and overall shape of the curve (Hall & Mueller, 1997). Reported normative values for these measurements vary considerably depending on subject population, methodology, and criteria for the study. For example, the reported limits for pressure can vary by 50 dapa and compliance limits can vary by 0.30 ml depending on the study cited (Gelfand, 2001; Hall & Mueller, 1997). Additionally, the range of values found with various pathologies overlaps the range found with normal ears (Gelfand, 2001; Harris et al., 2005).

Note: The box shown on the tympanogram indicates the normative area where the peak of the tympanogram is expected under normal conditions. The Pass/Refer result is based on presence or absence of the peak within the bounding box. The limits selected are intended to separate normal ears from significantly abnormal ears across most populations.
Users with the goal of detecting mild conditions of the middle ear should ensure that appropriate age related norms are used in setting Pass/Refer criteria.

It is for these reasons that tympanograms are not used in isolation to diagnose or screen for pathologies of the middle ear system, but rather are considered with additional audiological measures, such as Otoacoustic Emissions and Acoustic Reflex measurements as part of a diagnostic or screening battery.

Pass/Refer Criteria for Acoustic Reflex:

An acoustic reflex, or contraction of the Stapedius muscle, occurs under normal conditions when a sufficiently intense sound is presented to the auditory pathway. This contraction of the muscle causes a stiffening of the ossicular chain which changes the compliance of the middle ear system. For best results, this reflex measurement is automatically conducted at the air pressure value where the compliance peak occurred during the tympanometric test. Stimulus tones of varying intensities at 500, 1000, 2000 or 4000 Hz are presented as short bursts. If a change in compliance greater than 0.05 ml is detected, a reflex is considered present.

The required compliance change of 0.05 ml is an industry standard default for impendence systems with automated acoustic reflex measurement and has been verified via real-ear testing with the ERO-SCAN Pro to result in comparable pass/refer results to existing clinical standard equipment (Grason-Stadler, 2005; Interacoustics, 2007; Interacoustics, 2011; Maico, 2005; and Maico, 2011).

A correct interpretation of the measuring results can only follow in connection with the tympanogram, the graphic reflex display and other actual data. But in principle a Stapedial reflex indicates that the patient hears on the "stimulus ear" and that the sound lead on the "probe ear" functions.

Note: The limits selected are intended to separate normal ears from significantly abnormal ears across most populations.
Users with the goal of detecting mild conditions should ensure that appropriate age related norms are used in setting Pass/Refer criteria.

It is for these reasons that acoustic reflex measurements are not used in isolation to diagnose or screen for pathologies of the middle ear system, but rather are considered with additional audiological measures, such as Otoacoustic Emissions and Tympanometry measurements as part of a diagnostic or screening battery.

Appendix E: High Frequency Measurements

High Frequency DPOAE Measurements

In healthy young ears, distortion product otoacoustic emissions are normally present in the 6-12 kHz region. Figure 1 shows ERO•SCAN measurements on a 12 year old. Figure 2 shows ERO•SCAN measurements obtained on an adult male in his 60s.

The results in the figures below are consistent with our findings in testing 8 children (age 5-13 years) and 12 adults (age 50-78 years): normal emissions to 12 kHz in children (Figure 1), and no response above 8 or 10 kHz in older adults (Figure 2).

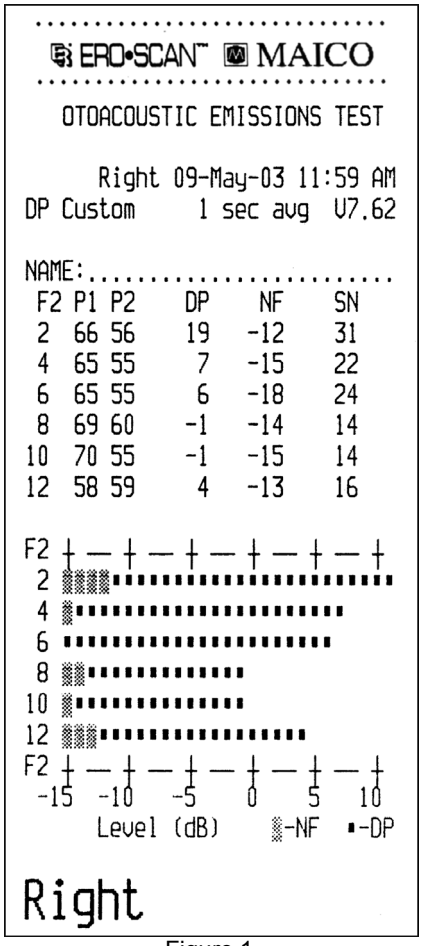


Figure 1

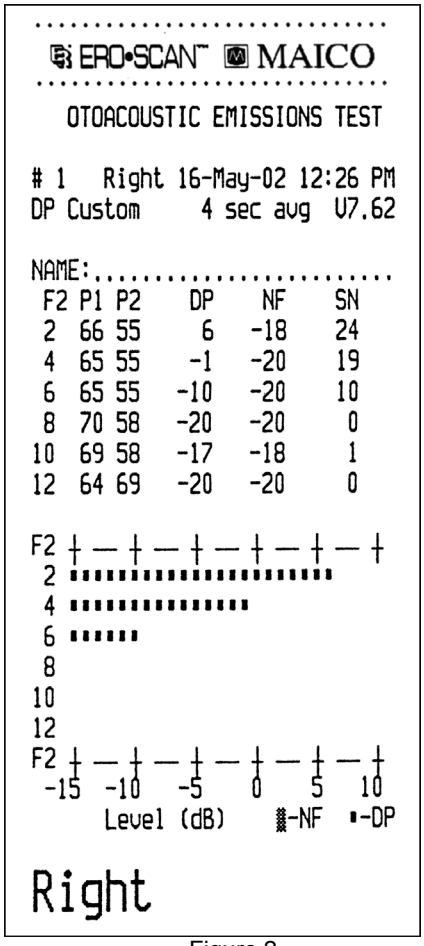


Figure 2

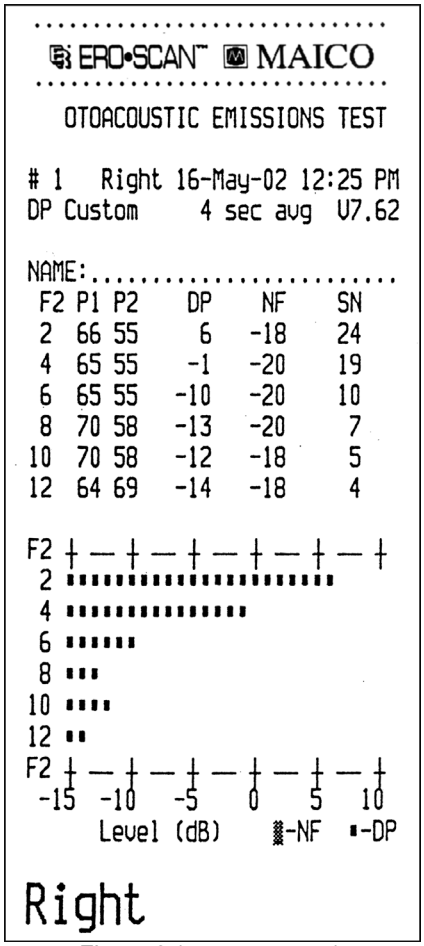


Figure 3 (see next page)

Although sufficient data to establish age-related PASS/REFER norms are not available, high-frequency DPOAE measurements may still prove useful in:

Ototoxic drug monitoring in young patients (and older patients who have measurable OAEs)
Prospective studies of noise-induced hearing loss, especially in young subjects
Obtaining scientific data on the effect of aging on DPOAEs

Important Considerations When Monitoring

Typical of all DPOAE and TEOAE measurements, the lower limit of measurement is determined by noise, most of which has a Gaussian distribution. In the absence of an emission, both the signal and reference channels contain nothing but noise. Just like tossing 10 coins simultaneously where the long-term average will be five heads, it is not unusual to see seven or eight heads in any one toss. Similarly, an apparent SNR of 5 dB or even 10 dB can occasionally appear even though the long-term average SNR in a cavity is 0 dB. In the absence of an emission, a single SNR reading will exceed 5.5 dB one time in six on the average. This is just as true at high frequencies (8, 10, and 12 kHz) as it is at lower frequencies (2, 3, 4, 6 kHz). However, the noise floor is slightly higher at frequencies above 6 khz. To safeguard against mistaking noise for the signal, it is recommended that minimum DPOAE amplitudes be used as part of any protocol measuring frequencies above 6 khz.

To give an actual example: Figure 2 on the previous page indicates the absence of emissions for an adult. Figure 3, a subsequent test on the same subject, shows apparent emissions at 8, 10, and 12 kHz, with displayed SNRs of 7, 5, and 4 dB, respectively. Figure 3 was selected from a large number of tests on that ear to illustrate that such readings can occur by chance.

There appear to be no published norms for the use of high-frequency DPOAEs for ototoxic monitoring, but we can determine the significant difference between the averaged test results from one session to the averaged test results of another session based on known statistical variation. Averaging the results of several DPOAE test improves the reliability compared to a single test. This is particularly important when DPOAE test results are used to monitor changes in hearing sensitivity at specific frequencies over two or more different sessions.

Table 1, below, gives the number of tests required for the comparison between two test sessions.
The critical differences at two different confidence levels (80% and 95%) are shown. An 80% confidence level is normally adequate for clinical testing while a 95% confidence level is common for research reporting, where a reduced risk of error is normally required.

The *critical difference* is the difference between two measurements that probably did not occur by chance. An example: You want to be reasonably (80%) certain that any shift beyond 5 dB will be statistically significant. How many tests must be averaged in each session to obtain this result? The table below indicates that the average of 6 tests in each session will give the desired critical difference of 5.1 dB. Since a 5 dB change is normally considered clinically significant, we suggest the use of at least six tests during each session.

If a more sensitive test is required, more tests must be averaged. For example, averaging 10 tests in each condition gives a 3.9 dB critical difference at the same 80% confidence level. In contrast, a 12.4 dB change would be required at the 80% confidence level when comparing a single test from each session.

Alternately, a 50% increase in testing can be used to improve from an 80% to a 95% confidence level at a given criterion. Example: The average of 4 tests will give a 6.2 dB critical difference at the 80% confidence level; the average of 6 tests will provide the same 6.2 dB at the 95% confidence level.

Table 1

Number of tests averaged	1	2	3	4	6	10	16
95% C.D.	15.2	10.7	8.8	7.6	6.2	4.8	3.8
80% C.D.	12.4	8.8	7.2	6.2	5.1	3.9	3.1

Instructions for Averaging Results

For monitoring purposes, it is the DP level itself that should be averaged. The DP level indicates the health of the outer hair cells and the middle ear, when testing in relatively quiet conditions. The SNR is the measurement of choice in screening, where varying noise levels are present.

Average the DP level at each frequency of interest for the total number of tests performed during one session. Repeat the same procedure for each subsequent session. Compare the frequency-specific average from the prior session to the average from the current session using the critical differences provided in Table 1.

Producing the Desired Eardrum SPL

Siegel (1994) reported that large differences between eardrum SPL and the SPL measured by the microphone in an OAE probe could occur at high frequencies. In our own measurements, we have seen occasional differences as large as 15 dB from the combination of wavelength effects and improper eartip seating.

Following Harris et al (1989), Siegel recommended that at high frequencies the receiver drive required to produce the desired eardrum SPL be predicted from a low-frequency probe measurement of ear canal SPL (to adjust for individual ear canal volume differences) and a previously determined receiver-to-average-eardrum calibration.

The ERO•SCAN follows Siegel's recommendations, additionally imposing an upper limit of 70 dB SPL measured at the microphone of the probe in order to minimize spurious distortion products. The P1 and P2 SPL values printed by the ERO•SCAN unit are those measured by the microphone in the probe in order to minimize spurious distortion products. These provide a check that neither probe is blocked, but as described above may differ from actual eardrum SPLs.

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