

Operation Manual

ERO•SCAN™ Pro



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Compliance

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Trademark Notice

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1 Introduction

The ERO•SCAN™ Pro Test Instrument is designed to be a screening device for cochlear hearing loss and/or middle ear pathology (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. However, a passing result using this instrument is not an indication that the full auditory system is normal. Thus, a PASS test result should not be allowed to override other indications that hearing is not normal. A full audiologic evaluation should be administered if concerns about hearing sensitivity persist. A REFER test result should not be assumed to be an indicator of a lack of auditory function or the presence of pathology; however, it should be followed with full audiologic diagnostic testing and/or medical evaluation as appropriate.

NOTE: Sensitivity and specificity of this type of device are based on the test characteristics defined by the user, and may vary depending on environmental and operating conditions.

1.1 Intended Use

The ERO•SCAN™ Pro OAE Test Instruments primary use is for testing of cochlear function in infants, children and adults by measuring otoacoustic emissions (OAEs). As an upgrade option to the device, impedance measurements (tympanometry and ipsilateral acoustic reflex) can be conducted in combination or separate from OAE measurements. This instrument is suitable for use in all settings, including hospitals, schools, physician's offices and audiologist practices. Factory defined protocols allow for simple screening measurements and user customizable protocols allow for diagnostic evaluations.

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.

1.2 Instrument Description

What is the ERO•SCAN Pro Instrument?

The ERO•SCAN™ Pro test instrument is a hand-held device designed to provide an objective measure of middle ear and outer hair cell function through the measurement of otoacoustic emissions and tympanometry (using an optional external tympanometry probe). It consists of the handheld unit, external probe(s), printer, single-use eartips and other accessories (Figure 1). 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 the OAE or tympanometry results, and



Figure 1

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. LEDs 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.

1.3 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 (Figure 2).

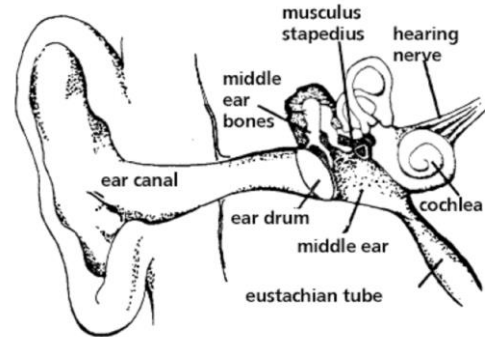


Figure 2

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 will 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.

1.4 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 Hz 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

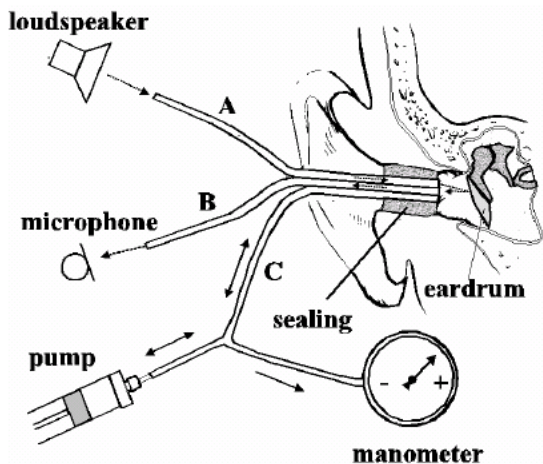


Figure 3

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 (Figure 3) is connected to the microphone inside the probe which receives the sound. Together with a third tube (Figure 3), all three are inserted near to the eardrum 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.

When performing tympanometry during a measurement, 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. In Figure 4, 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.

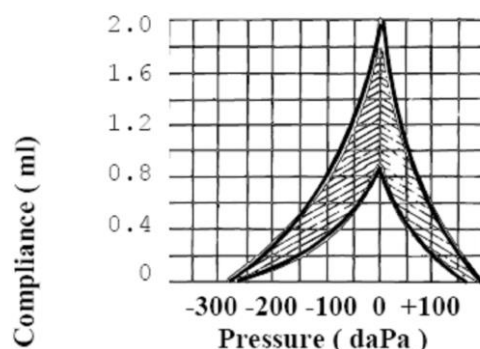


Figure 4

NOTE: 1.02 mm H₂O = 1.0 daPa.

2 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™ Pro Instrument probe tip must not be inserted into an ear at any time without a disposable eartip properly affixed.

IMPORTANT NOTE:



In the event of a critical system failure, the message shown to the left (Figure 5) will be displayed. Discontinue use of the instrument and contact your Special Equipment Distributor or contact MAICO Diagnostic by phone at (888) 941-4201 or by fax at (952) 903-4100.

Figure 5

2.1 Disclaimer



The MAICO ERO•SCAN™ Test Instrument is designed to be a screening device for hearing loss. Sensitivity and specificity of this type of device are based on the test characteristics defined by the user, and may vary depending on environmental and operating conditions. The presence of otoacoustic emissions suggests normal outer hair cell function, which in turn correlates to normal hearing. However, a passing result using this instrument is not an indication that the full auditory system is normal. Thus, a PASS result should not be allowed to override other indications that hearing is not normal. A full audiologic evaluation should be administered if concerns about hearing sensitivity persist. A REFER test result should not be assumed to be an indicator of a lack of auditory function; however, it should be followed with full audiologic diagnostic testing.

NOTE: Under certain circumstances, especially in low-humidity environments, common electrostatic discharge may cause this instrument to turn itself off. This effect causes no permanent damage, and the instrument may be turned on again by the normal procedure of holding the DOWN button.

2.2 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.

Printer AC Power Source Precautions

- The printer AC power source converts main voltage (120 V AC or 230 V AC) to a low voltage (12 V DC) for powering the printer. Use only the power source supplied for this purpose.
- This product is for indoor use only. Do not expose to water or excessive dust.
- This product is not suitable for operation in the presence of flammable anesthetic mixture with air or with nitrous oxide.





- Do not cover the power source body as it may result in excessive heating. The power source operates when the plug is inserted into an outlet. To turn it off, remove the plug from the outlet. The outlet must be easily accessible and located near the printer. Should a faulty condition occur, remove the plug from the outlet immediately.
- High Voltage Inside! Do not remove the power supply cover! All service or maintenance must be done by trained personnel. Return the power supply to the manufacturer for service.

Optional Printer Rechargeable Battery Precautions



- Do not attempt to open the battery pack. The printer battery pack contains Ni Mh cells. Cadmium is a potentially toxic heavy metal, and exposing the cells increases the risk of leakage or short-circuiting.
- Do not short circuit the battery contacts. This could cause burns or a fire.
- Disconnect the printer power supply before removing or replacing the battery pack.



- Observe local regulations for handling, transport, and disposal of Ni-Mh cells. Regulations in many areas prohibit the disposal of Nickel-Cadmium cells. Complete battery packs may be returned to the manufacturer for recycling.



- The battery pack must be charged for a minimum of five hours before using the printer for the first time. Failure to fully charge the battery pack before use may reduce the life of the battery pack.

2.3 Cleaning and Disinfecting the Unit

Wipe the surface with a cloth slightly dampened with mild detergent or normal hospital bactericides. Do not immerse the unit. Do not clean the unit with isopropyl alcohol or other solvents.

3 Getting Started

3.1 Unpacking the system

Standard System Parts (OAE) (Figure 6)

- (1) ERO•SCAN™ Pro Hand-held unit w/ internal probe
- (1) Cradle
- (1) USB cable
- (4) AA/UM-3/R6 Alkaline batteries
- (4) Internal probe tips (4/pkg)
- (1) Box of disposable eartips in assorted sizes
- (1) Thermal Paper Printer with Lithium Ion battery installed with:
- (1) Thermal printer paper roll
- (1) Printer charger
- (1) Power supply cord
- (1) Printer cable
- (1) ERO•SCAN™ Pro PC software CD
- (1) Operating Manual

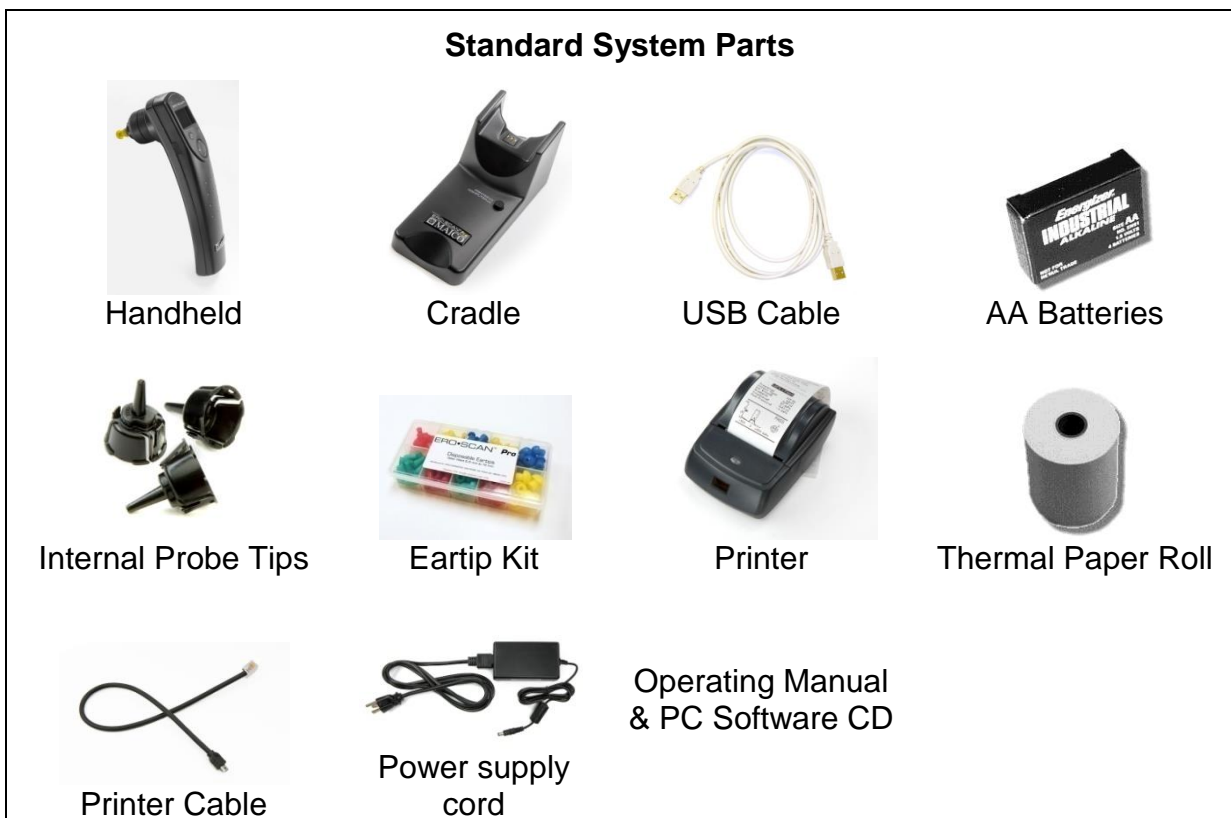


Figure 6 Additional Standard Parts for ERO•SCAN™ Pro with Tympt

- (1) External Tymp•OAE Probe with:
- (1) Calibration cavity
- (4) External probe tips (4/pkg)



Figure 7

Optional System Parts (Figure 8)

- (1) External OAE•Probe
- (4) External probe tips (4/pkg)
- (1) External Tymp•OAE Probe

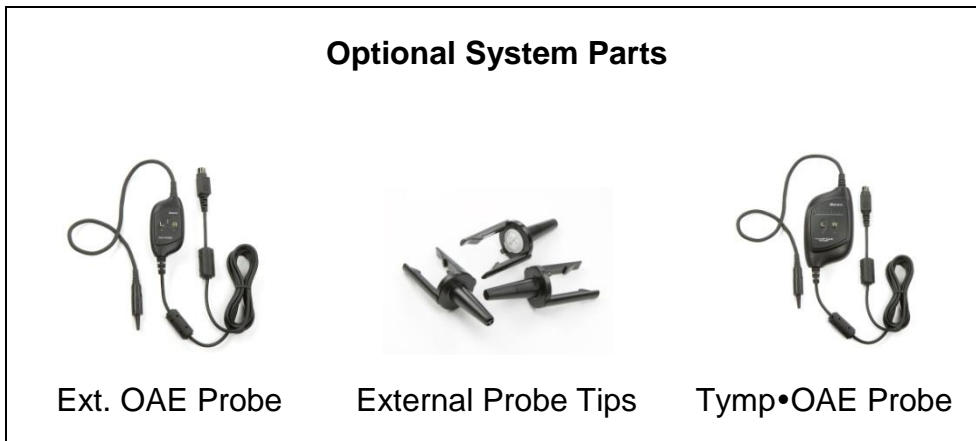


Figure 8

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

1.1 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 (Figure 9)



Figure 9

1.2 Environmental conditions

The MAICO ERO•SCAN™ Pro should be operated in a quiet room, so that the examinations are not influenced by outside noises.

Electro-medical instruments, which emit strong electromagnetic fields (e.g. microwaves-radiotherapy devices), can influence the function of the MAICO ERO•SCAN™ Pro. Therefore the use of these instruments is not allowed in close proximity to the MAICO ERO•SCAN™ Pro.

The test room must be at normal temperature, usually 15°C / 59°F to 35°C / 95°F, to guarantee precise measuring results. If the device has been cooled down (e.g. during transport), please wait until it has warmed up.

4 Getting familiar with the ERO•SCAN™ Pro

1.3 Controls and display

See Figure 10.

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 10

4.1 Internal Probe

The internal probe is located on the underside of the ERO•SCAN™ Pro instrument (Figure 11). 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).



Figure 11

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.

4.2 External Probes (optional)

There are two types of external probe available for use with the ERO•SCAN™ Pro instrument (Figure 12). Each consists of the following basic parts (Figure 13):

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



Figure 12



Figure 13

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.



Figure 14

Tympanometry with a 226 Hz or 1000 Hz probe tone

Acoustic reflexes with 226 Hz probe tone (stimulus options: 0.5, 1, 2 and 4 kHz), broadband noise, low pass noise and 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 (Figure 14).

Each probe provides a status indicator in the form of LED(s) located on the keypad (Figure 10, page 13). 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

1. Turn off the ERO•SCAN™ Pro and insert the external probe plug into the socket on the top of the ERO•SCAN™ Pro (Figure 15). The plug will fit only in one direction. The arrows on the plug should face the display on the ERO•SCAN™ Pro.
2. 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.



Figure 15



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.

5 Conducting a Measurement

5.1 Quick Start

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.

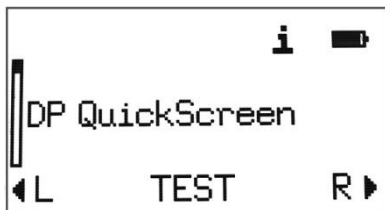


Figure 16

1. Turn on the instrument.
2. From the main menu, select the desired protocol or series using the up or down arrows on the navigator (Figure 16).
3. Select an eartip and place it 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 10, page 13) or press the L or R button on the external probe (Figure 14).

NOTE: The exact sequence for these steps can be adjusted based on user preferences, the probe being used (internal or external), and the patient being tested (adult or pediatric).

Additional information on each step is provided below.

IMPORTANT NOTE: When Tympanometry Probe is connected, the pump will perform an initialization. Do NOT insert the Tympanometry 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.

5.2 Powering on the Instrument

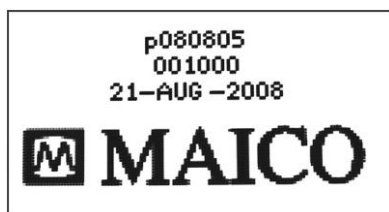


Figure 17

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 (Figure 17) 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 (Figure 16).

IMPORTANT NOTE: 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.

5.3 Selecting a Protocol or Protocol Series

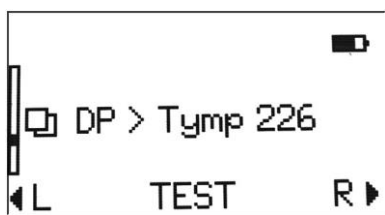


Figure 18

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 (Figure 18).

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 0.

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.

5.4 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 0 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.

5.5 Preparing the Patient

If 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.

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 (Figure 19). 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.

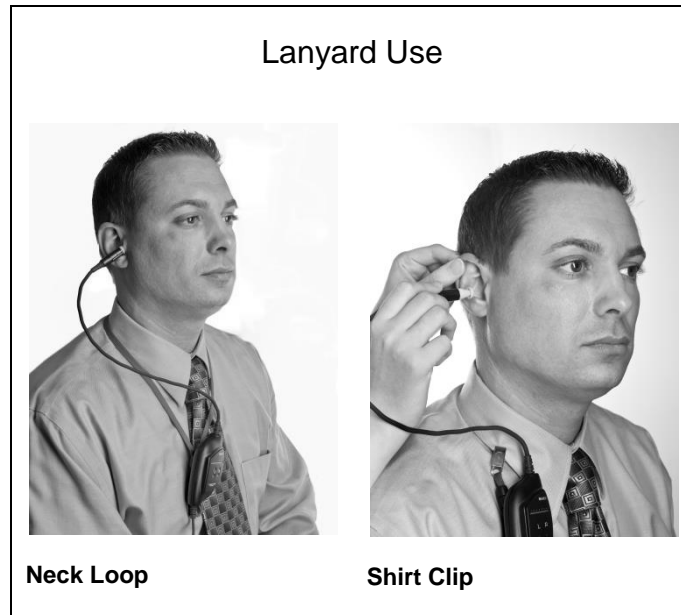


Figure 19

IMPORTANT NOTE: 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

5.6 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:



Figure 20

Probe not in ear or leak (Figure 20):

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.

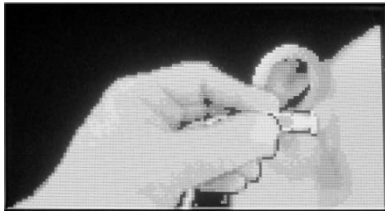


Figure 21

Probe in ear and seal detected (Figure 21):

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.



Figure 22

Probe blocked (Figure 22):

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 wall of the ear canal.

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 section 0 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 an hourglass symbol will appear to the right of the display (Figure 23). Test results are shown 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. The display on the ERO•SCAN™ Pro test instrument will indicate the results of the test with a graphic display. The display will be generated and shown during the test and can be reviewed after the test is complete. The display you see might differ depending on the settings used for the test.

The results of the test are automatically displayed on screen (Figure 24) and saved in memory as soon as the test is complete. The results will be saved even if the unit turns off or the batteries are temporarily removed. This screen indicates the test ear and further gives the results of the test. “PASS” on the screen indicates the patient passed the screening, “REFER” indicates that the patient did not pass the screening.

For additional information on test results, please see section 5 of this manual.

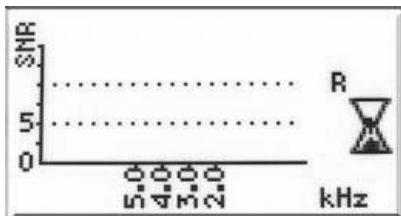


Figure 23

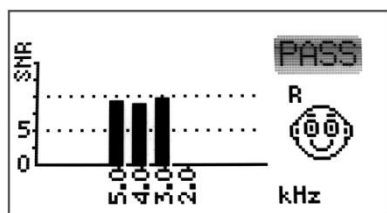


Figure 24

5.7 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 (Figure 25). The selection menu will offer the following options:

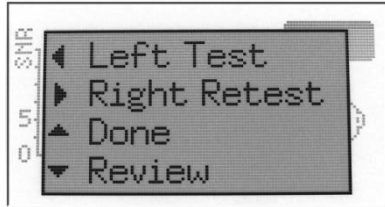


Figure 25

1. Left – starts a left ear test of the selected protocol
2. Right – starts a right ear test of the selected protocol
3. Done – return to the main menu to select another protocol or action
4. Review – return the result screen

NOTE: From the review display press any arrow key to bring up the selection menu

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 (Figure 26):

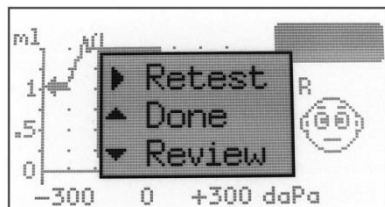


Figure 26

1. Retest – starts the previous test in the series
2. Done – return to the main menu to perform the following actions:
 - a. Repeat the entire series on the same ear
 - b. Test the other ear
 - c. Select a new protocol or series
3. Review – return the result screen

NOTE: From the review display press any arrow key to bring up the selection menu.

6 Interpreting Results

6.1 Understanding the OAE Results Display

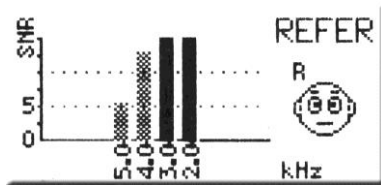


Figure 27

During OAE testing the results will appear on the screen as the test progresses. The display shows a graph with up to 10 columns. Each frequency (DPOAEs) or frequency band (TEOAEs) is indicated by one column (Figure 27). The number of columns shown will vary depending on the number of frequencies being tested with the selected protocol. The signal-to-noise ratio (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 solid yellow columns meet the SNR pass criteria for that frequency. The darker 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.

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 (Figure 27) press any arrow key to bring up the selection box (Figure 25).** See Figure 28 and Figure 29 for examples of the test details view.

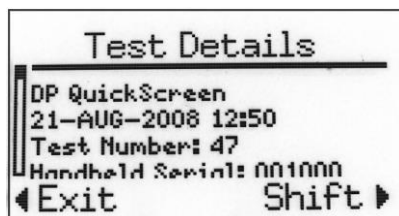


Figure 28

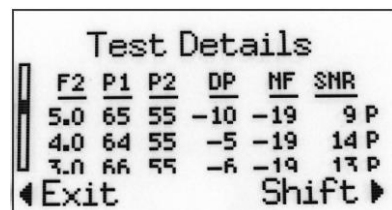


Figure 29

6.2 Understanding the Tympanometry Results Display

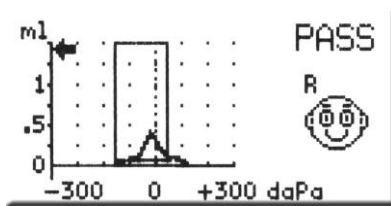


Figure 30

After having completed a tympanometry measurement you can see the results on the display (Figure 30). 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.

To view test details such as the protocol name, date/time of test, test number, serial number, 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. 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 (Figure 28) press any arrow key to bring up the selection box (Figure 26). See Figure 32 and Figure 31 for examples of the test details view.

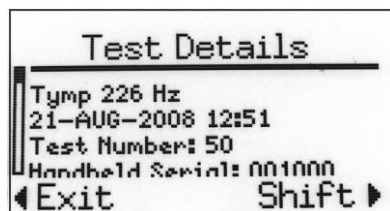


Figure 32

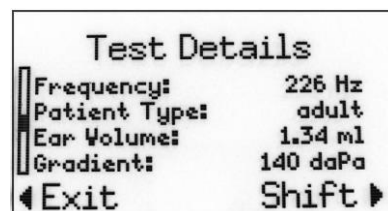


Figure 31

6.3 Interpreting the Tympanometric test result

As a general rule, values for ear canal volume should be between 0.2 ml 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.

6.4 Abnormal 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. 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. 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.

6.5 Understanding the Acoustic Reflex Display Result

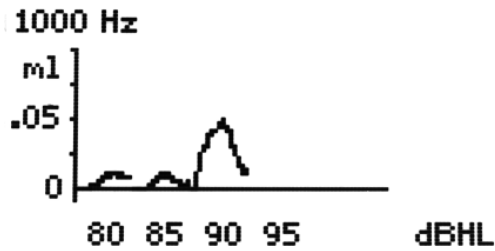


Figure 33

During the measurement of the acoustic reflex the change of the compliance is represented on the instrument display as shown to the left (Figure 33). 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.

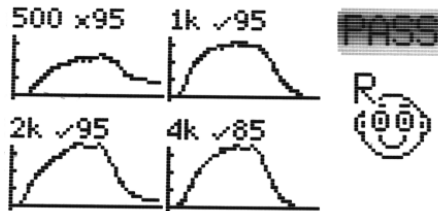


Figure 34

When the test is finished a summary display will show the final compliance change curve for each stimulus presented in the protocol (Figure 34). Above each curve the test stimulus type is indicated by the following:

- 500 = 500 Hz pure-tone BBN = 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).

7 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 9.7 Save Mode (Patients) page 47.

7.1 Reviewing Test Results

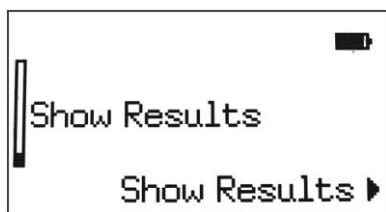


Figure 35

To review test results stored in the instrument scroll down the main menu until *Show Results* is selected and press the right ► arrow button (Figure 35).

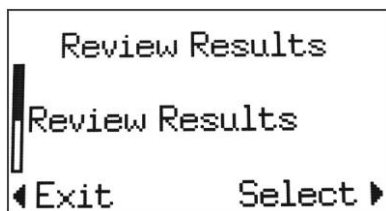


Figure 36

From the *Review Results* screen select *Review Results* using the right ► arrow button (Figure 36).

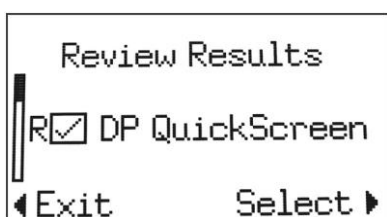


Figure 37

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 (Figure 37).

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.

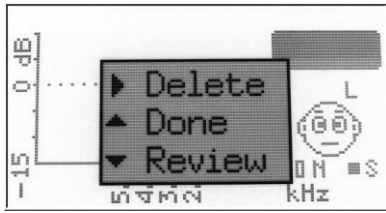


Figure 38

To view a specific test, scroll up or down to select the test and press the right ► arrow button to *Select*. The result display (Figure 28 and Figure 30) will be shown.

From the test result display, press any arrow button to bring up the selection box with the following options (Figure 38):

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.

7.2 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 (Figure 38).

Deleting all tests

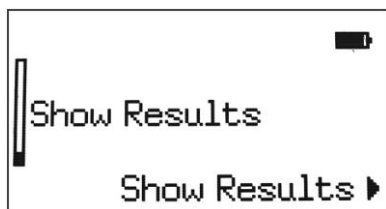


Figure 39

To delete all saved tests select *Show Results* from the main menu (Figure 39).

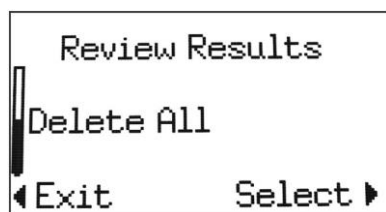


Figure 40

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 (Figure 40). 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*.

8 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.

8.1 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.

NOTE: 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 (Figure 41) 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 (Figure 42).



Figure 41



Figure 42

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

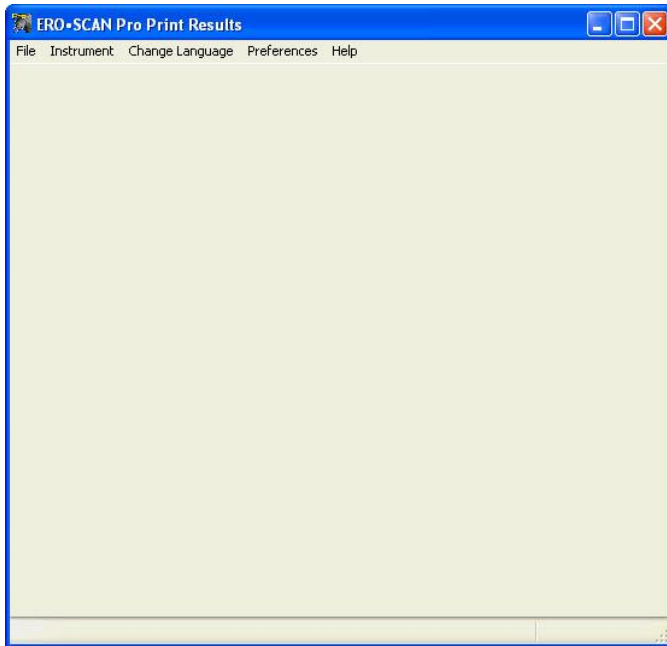


Figure 43

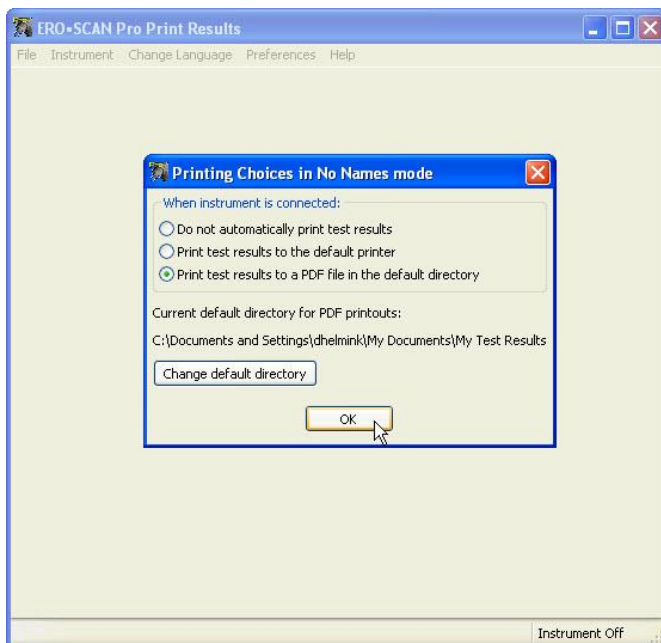


Figure 44

Open the *Print Results* application by double clicking on the application icon. Figure 43 shows the open application.

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 (Figure 44). 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 the instrument is 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.

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.

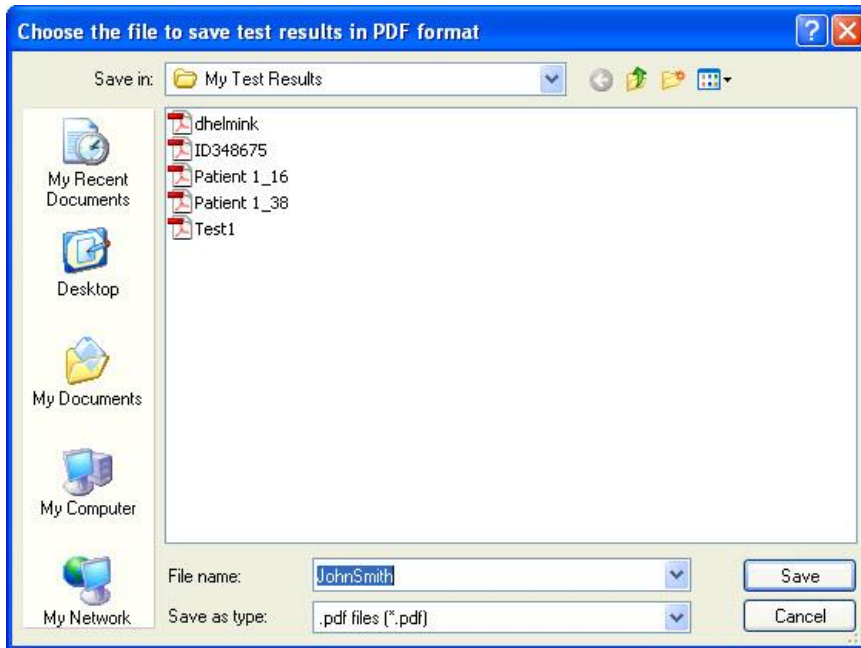


Figure 45

If the print to PDF option has been selected you will be prompted to save the file (Figure 45). You can use the default name or a custom file name of your choice.

To view the test results, navigate to the directory where the file is saved.

Figure 46 shows a sample print out produced by the Quick Print to PDF and to the default PC printer.

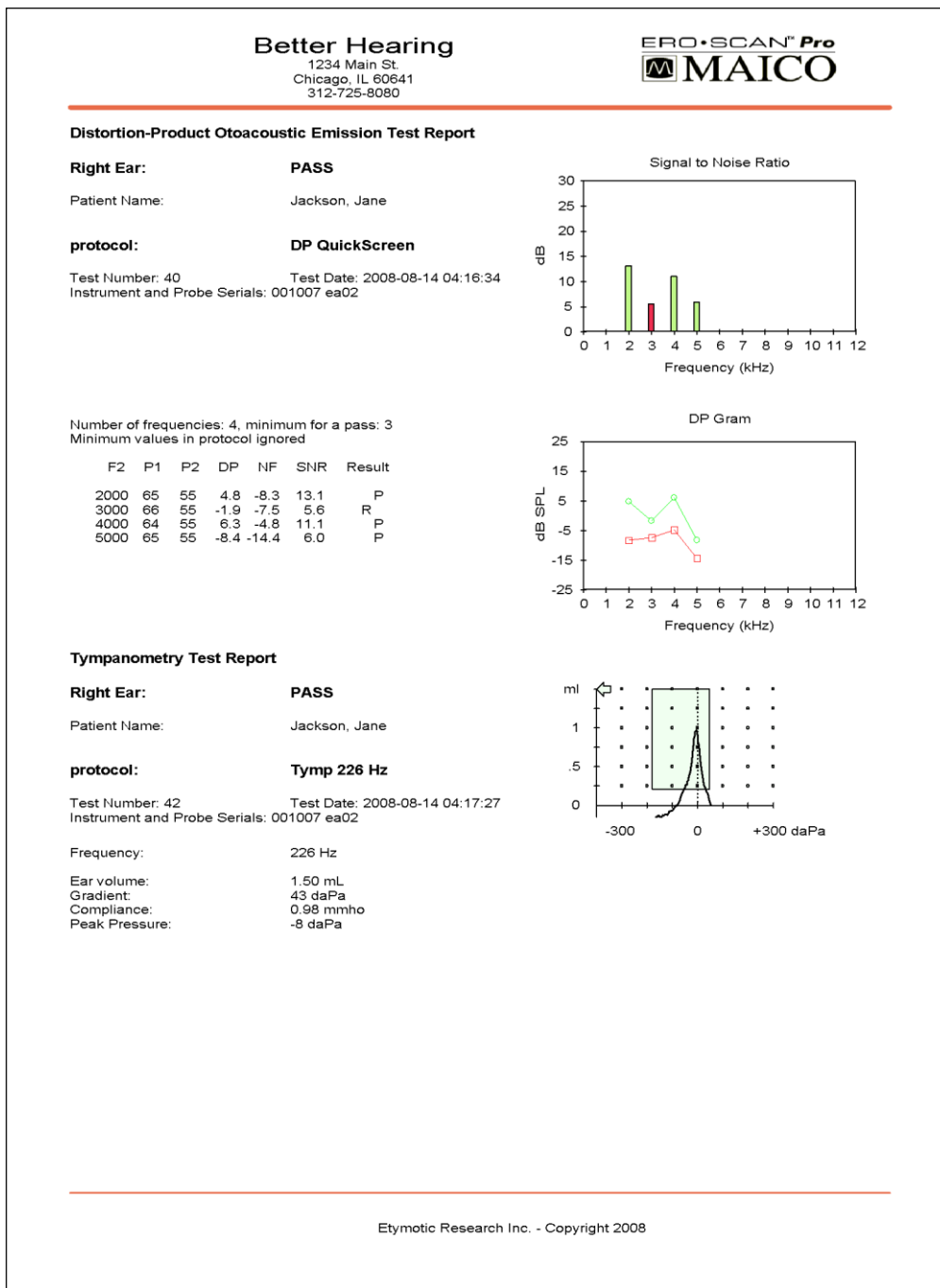


Figure 46

Figure 47 shows a sample print out produced by the Quick Print to PDF and to the default PC printer.

Acoustic Reflex Test Report

Right Ear: PASS

Patient Name: Joe Smith

Protocol: Ipsi 4F Auto

Test Number: 170 Test Date: 2012-05-09 13:59:37
 Tester: GATES, CYNTHIA
 Instrument and Probe Serials: 1003 T0941015
 Probe tone: 226 Hz
 Pressure: 0 daPa (uncompensated)
 Number of stimuli: 4
 Minimum for a pass: 3

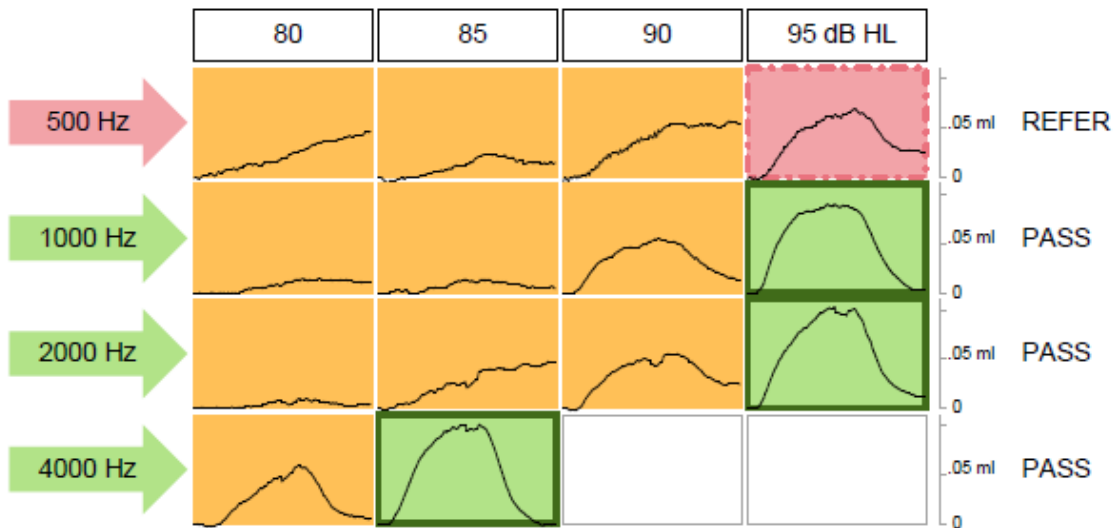


Figure 47

This example shows a DPOAE test result on the top half and a Tympanometry test result on the bottom half.

The header for each test shows the ear tested, test result, protocol name, date/time of the test, test number, instrument & probe serial numbers.

Patient number is indicated or a blank space is provided to write in the name. (See section 9.7 for information on using numbered patients).

OAE PDF or PC 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

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

Data table:

Frequency = probe tone frequency (226 Hz 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.

8.3 Thermal printer set up

The optional printer is supplied with a data cable, thermal paper roll. The printer arrives with the rechargeable lithium ion battery installed. See Figure 48 for overview of the printer.

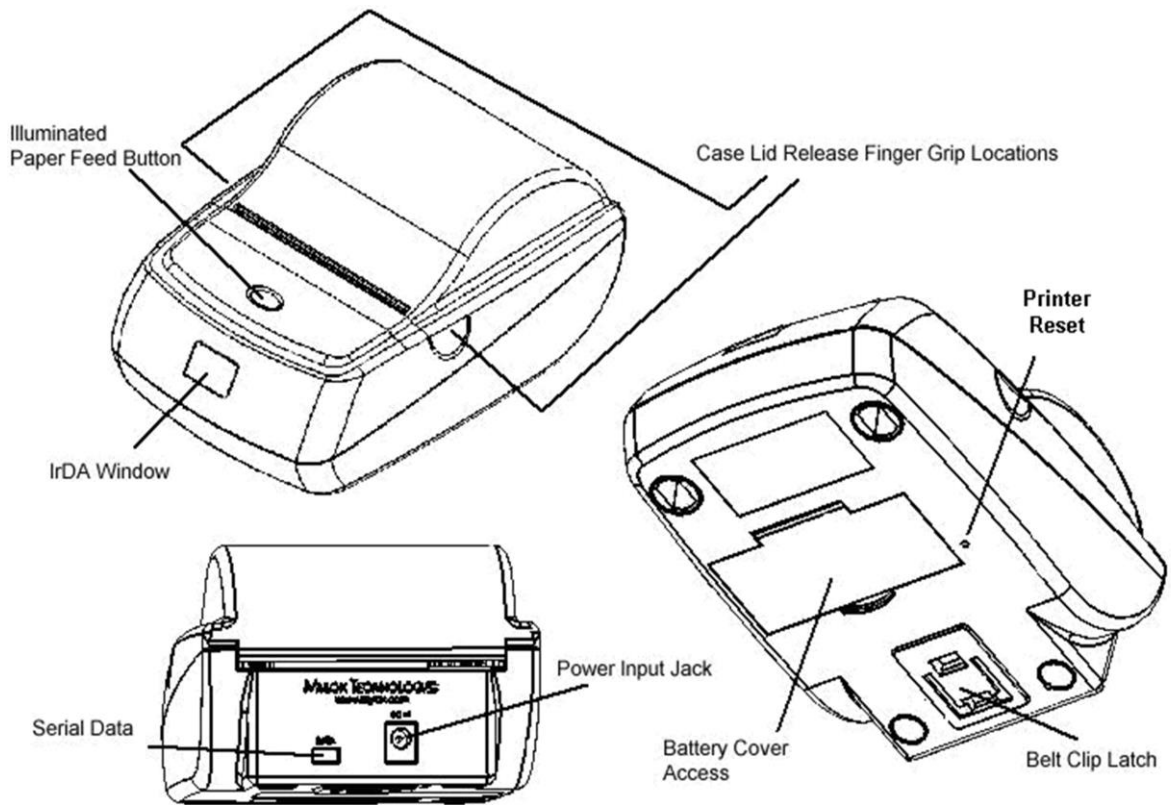


Figure 48

Installing the paper roll

1. Open the printer by applying your fingers to both sides of the lid and pull upwards (Figure 49). Note that the status LED turns amber when the lid is opened.
2. Insert the new paper roll. Be sure to note the correct direction that the paper comes off the roll as shown (Figure 50).

Pull out a small amount of paper and then close the lid (Figure 51). The printer should auto feed approx. 2 inches (50 mm) of paper, this should ensure correct alignment and confirms that paper is feeding smoothly. The front panel LED should turn green and the printer is now ready to receive print data.

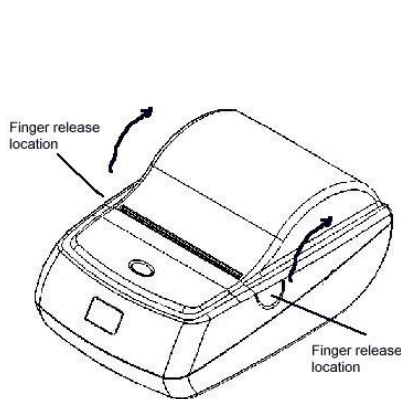


Figure 49

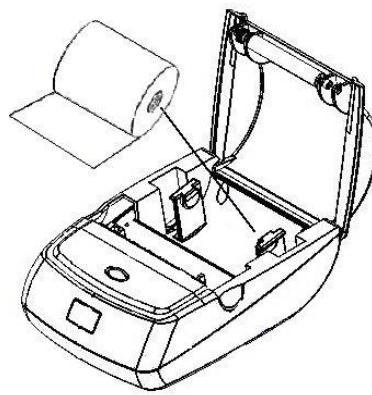


Figure 50

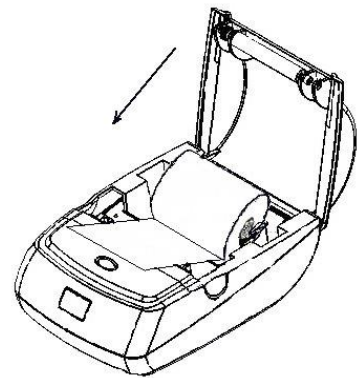


Figure 51

NOTE: To order more paper, contact your local special instrument distributor or MAICO Diagnostics .

Printer Button and Indicator Lights

A single 'tap' of the paper feed button wakes the printer during battery save mode (Figure 52).

When the Paper feed button is pressed it will advance the paper until released. The paper feed button is disabled during a print cycle. If the button is 'double clicked' with the printer in an 'awake' status the printer will enter the self-test mode.

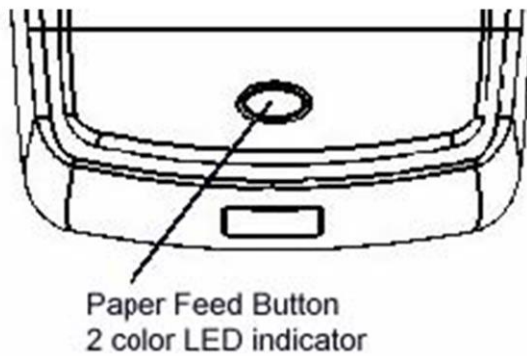


Figure 52

Printer LED Codes

The 2 color LED indicator provides information regarding the status of the printer

- Green: Power on
- Amber: Error – Paper out, door open
- Off: Printer Off (in sleep mode)

8.4 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 (Figure 53).

Place the two-position button located on the upper right of the top side of the cradle in the raised position for printer use (Figure 54).



Figure 53



Figure 54

8.5 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.

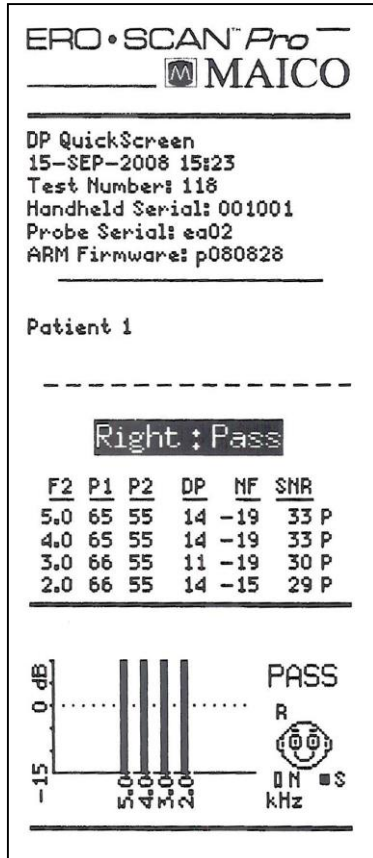


Figure 55

DPOAE Printout:

Figure 55 shows 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 9.7 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.

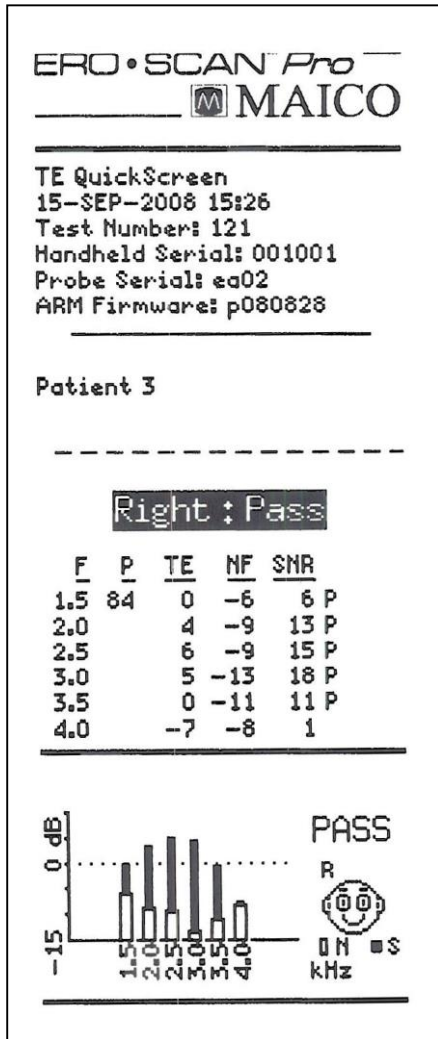


Figure 56

TEOAE Printout:

Figure 56 shows 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 9.7 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.

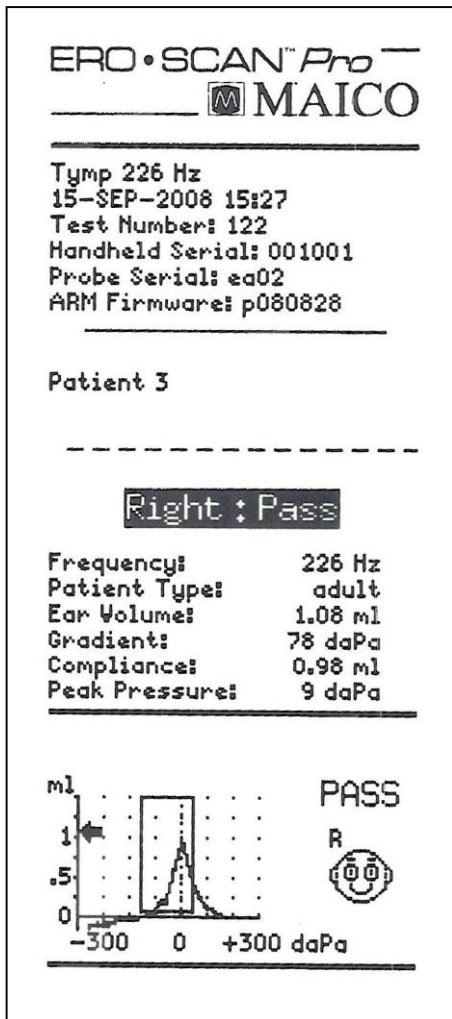


Figure 57

Tympanometry Printout:

Figure 57 shows 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 9.7 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*.

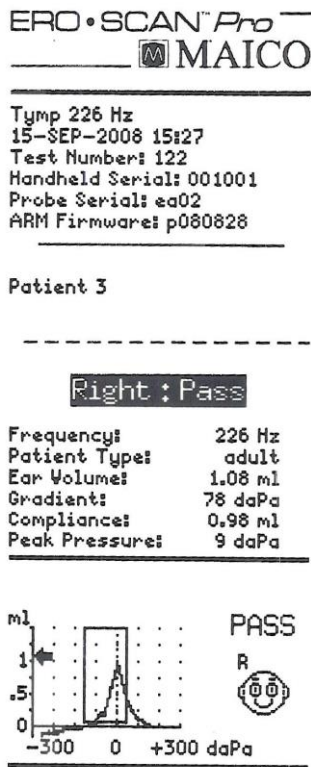


Figure 58

Tympanometry Printout:

Figure 58 shows 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 9.7 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 6.5 (Understanding the Acoustic Reflex Display Result) for explanation.

9 Set Up

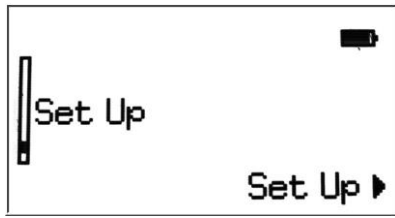


Figure 59

To enter the *Set Up* menu, scroll down the main menu to *Set Up* and select by pressing the right ▶ arrow button (Figure 59).

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.

9.1 Language

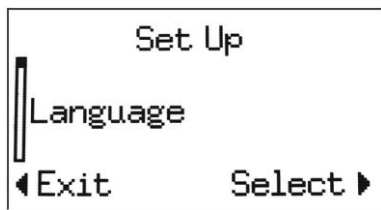


Figure 60

To change the language, select *Language* from the *Set Up* menu (Figure 60). 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.

9.2 Time/Date

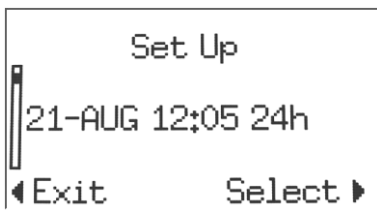


Figure 61

To set the instrument time and date, from the set up menu select the item showing the current date and time settings (Figure 61). 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 (Figure 62) Use the up ▲ and down ▼ arrow buttons to change the selected portion of the Time/Date.



Figure 62

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.



Figure 63

When 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 (Figure 63). Press the right ▶ arrow to save the time/date.

9.3 Display Contrast

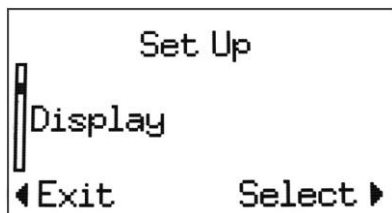


Figure 64

To change the contrast of the display, select *Display* from the set up menu (Figure 64).

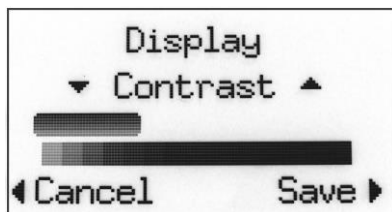


Figure 65

Use the up ▲ and down ▼ arrows to adjust the contrast. When done adjusting the contrast press the right ▶ arrow button to *Save* and exit (Figure 65).

9.4 Instrument Details

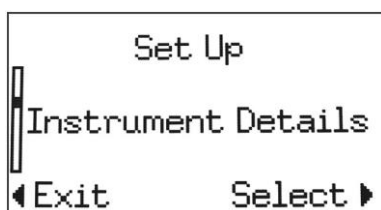


Figure 66

To view the instrument details, select *Instrument Details* from the set up menu (Figure 66). Instrument details will show the serial number of the instrument, connected probe, firmware (embedded operating software) version and a summary of other instrument settings.

9.5 DP Early Stop

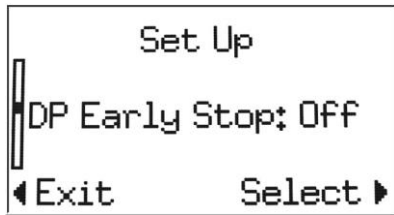


Figure 67

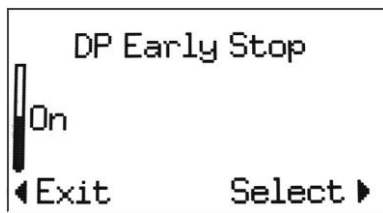


Figure 68

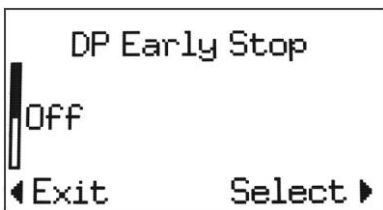


Figure 69

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 (Figure 67). Using the up ▲ and down ▼ arrow buttons on the control panel select *off* (Figure 69) or *on* (Figure 68) and then press the right ► arrow button to *select* and exit.

9.6 OAE Minimums

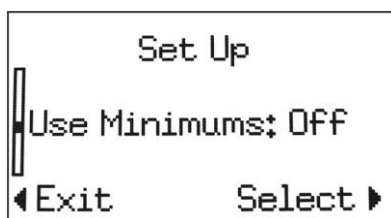


Figure 70

This setting allows the user to select if minimum amplitude values will be used as part of the pass/refer criterion (Figure 70). 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 0.

To change this setting, select *Use Minimums* from the *Set Up* menu (Figure 70). 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 (see Figures 61 and 62 for an example).

9.7 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.

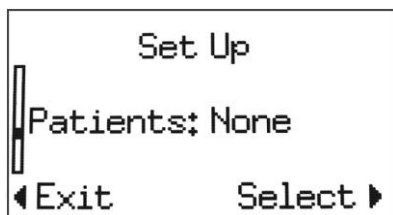


Figure 71

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.

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

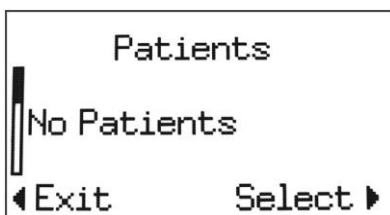


Figure 73

To change this setting, select *Patients* from the *Set Up* menu (Figure 73). Using the up ▲ and down ▼ arrow buttons on the control panel select *No Patients* (Figure 73) or *Numbered Patients* (Figure 72) and then press the right ► arrow button to *select* and exit.

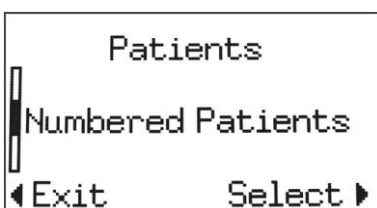


Figure 72

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.

9.8 Sounds

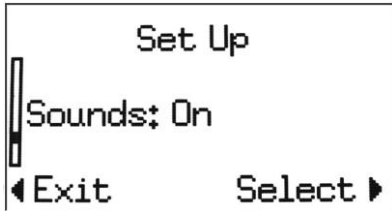


Figure 74

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 (Figure 74). 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 (see Figure 68 and Figure 69 for an example).

9.9 Graph Style

There are two options for viewing the DPOAE test results. The standard SNR graph will display the signal-to-noise ratio (difference between the emission and the noise floor) as a bar for each frequency tested. The SNR graph provides a very simple method to view the test results.

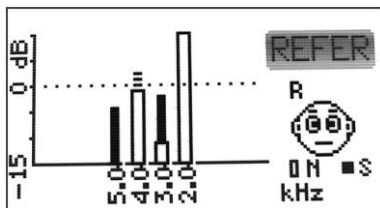


Figure 75

The *Value graph* displays the absolute values of the signal (emission) and noise floor (Figure 75). The noise is represented by an open bar. The signal is 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. The value graph provides a more complete view of the test results. 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 in figure 68 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.

Note: if the *value graph* is select, the thermal paper printout will show the value graph. If the *SNR graph* is selected, the thermal paper printout will show the SNR graph.

9.10 Reset

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

10 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.

10.1 Creating/Editing Protocol Files

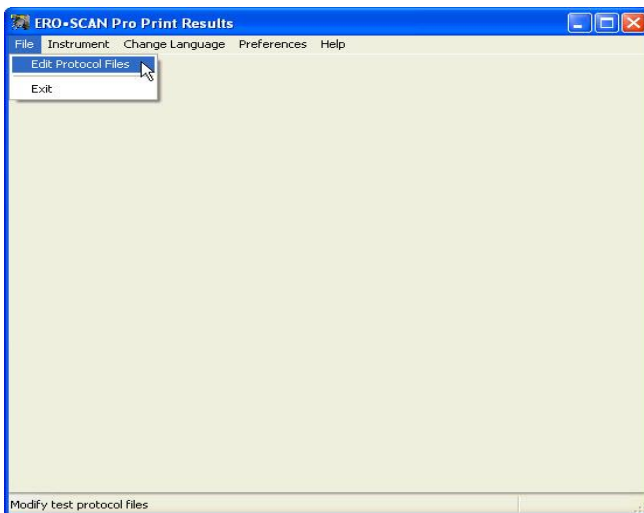


Figure 76

Protocol files originate on the computer and are then loaded to the ERO•SCAN™ Pro instrument. To create or edit a protocol file, open the *Print Results* application, click on the *File* menu, and then select *Edit Protocol Files* (Figure 76).

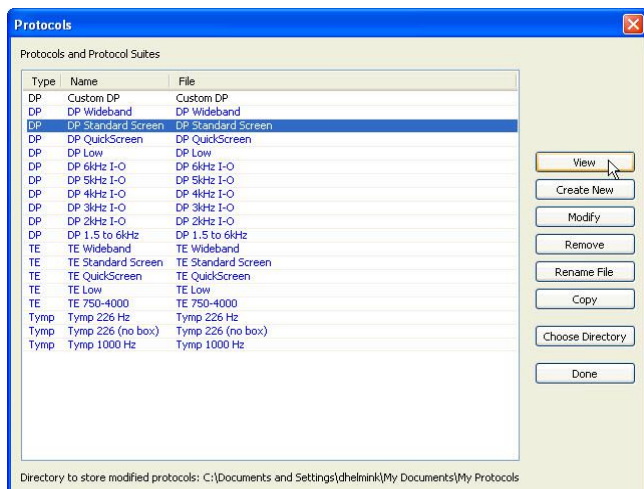


Figure 77

Figure 77 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 in 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 (Figure 77) 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 list

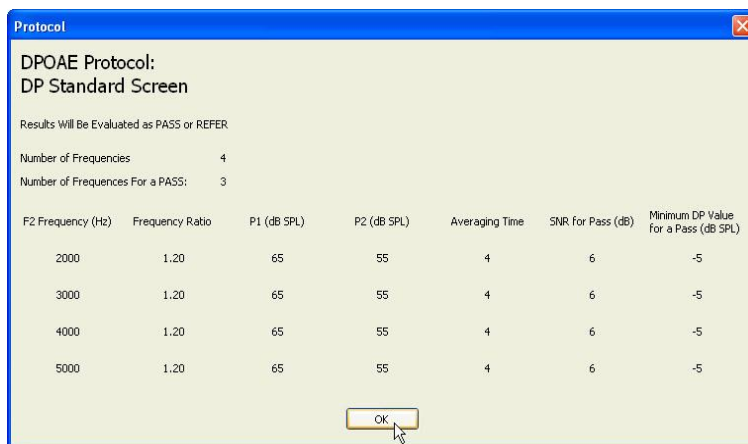
Rename File – this allows the user to change the file name for the protocol

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

View



The screenshot shows a window titled 'Protocol' with a sub-header 'DPOAE Protocol: DP Standard Screen'. Below this, it states 'Results Will Be Evaluated as PASS or REFER'. The parameters are as follows:

F2 Frequency (Hz)	Frequency Ratio	P1 (dB SPL)	P2 (dB SPL)	Averaging Time	SNR for Pass (dB)	Minimum DP Value for a Pass (dB SPL)
2000	1.20	65	55	4	6	-5
3000	1.20	65	55	4	6	-5
4000	1.20	65	55	4	6	-5
5000	1.20	65	55	4	6	-5

Summary statistics shown above the table:

- Number of Frequencies: 4
- Number of Frequencies For a PASS: 3

An 'OK' button is visible at the bottom center of the window.

Figure 78

To view protocol parameters, select the desired protocol and click the View button located on the right panel of the Protocol window (

Figure 77).

All the measurement and pass criteria parameters will be displayed (see Figure 78 for an example).

Creating a DPOAE Protocol

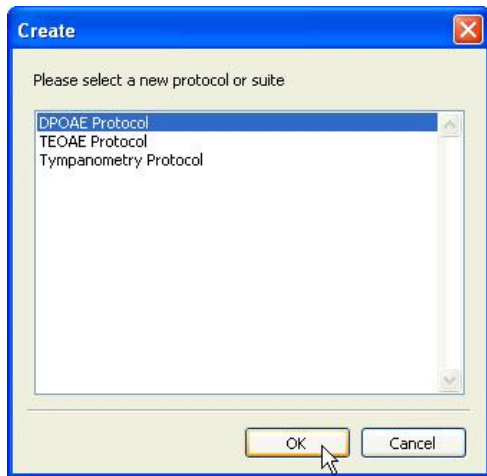


Figure 79

To create a new protocol file, click the Create New button located on the right panel of the protocol window (

Figure 77).

A selection window will appear (Figure 79). Choose the type of protocol being created (DPOAE, TEOAE, or Tympanometry) and click *Ok*.

Figure 80 shows the window for creating or modifying a DPOAE Protocol.

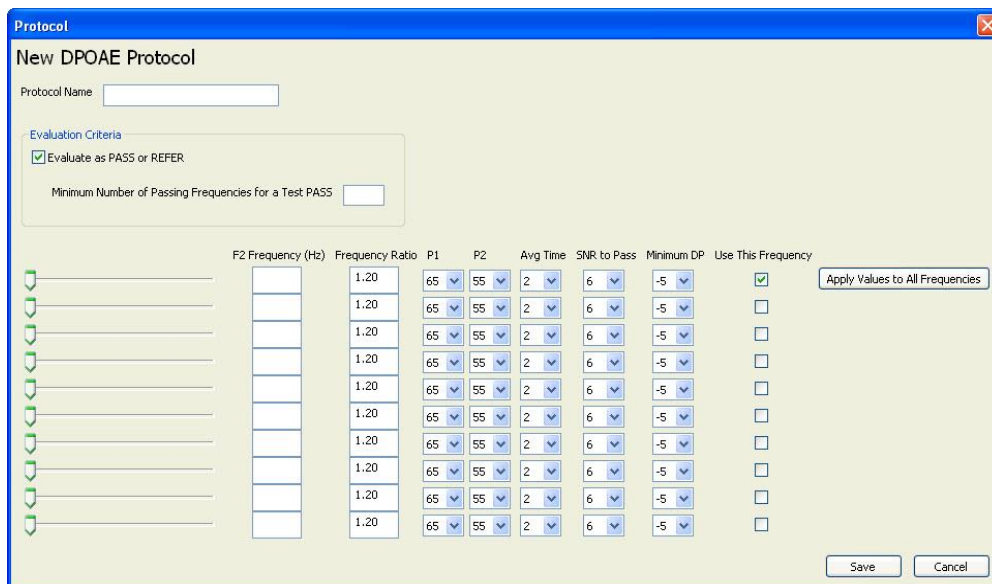


Figure 80

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 (f_2/f_1). The f_2/f_1 ratio is adjustable between 1.1 to 1.4.

P1/P2: these settings control the intensity of the two primary tones (f_1 and f_2). P1 and P2 are adjustable between 40 dB SPL 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 dB 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 dB SPL 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

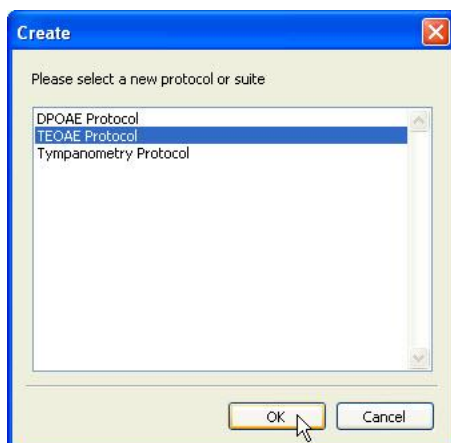
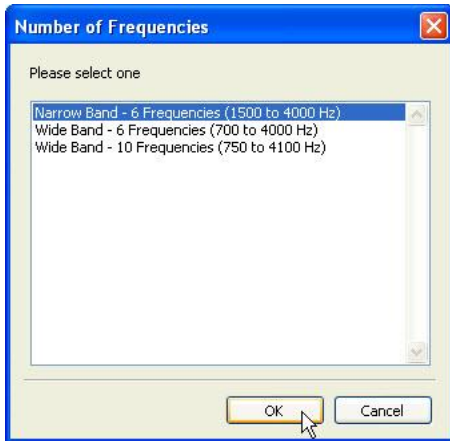


Figure 81

To create a new protocol file, click the Create New button located on the right panel of the protocol window (Figure 77).

A selection window will appear (Figure 81). Choose TEOAE and click *Ok*.



There are three frequency range options when creating a new TEOAE protocol. (Figure 75)

Narrow Band – 6 frequencies (1,500 to 4,000 Hz) which includes: 1,500, 2,000, 2,500, 3,000, 3,500, and 4000 Hz

Wide Band – 6 Frequencies (700-4,000 Hz) which includes: 700, 1,000, 1,400, 2,000, 2,800, and 4,000 Hz

Wide Band – 10 Frequencies (750-4100 Hz) which includes: 750, 1,100, 1,500, 1,900, 2,250, 2,600, 3,000, 3,400, 3,750, and 4,100 Hz

Figure 82

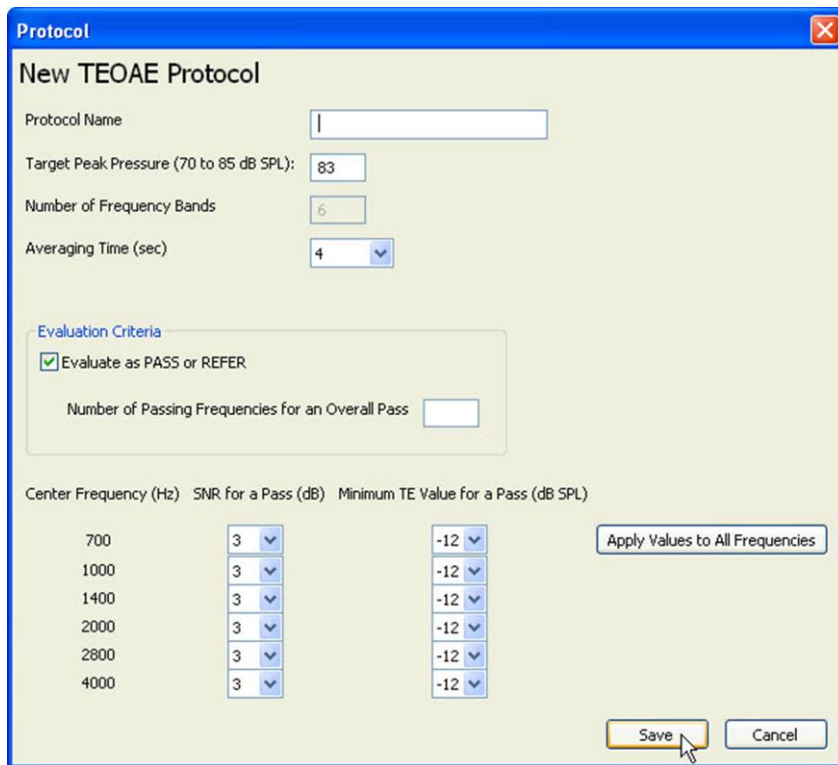


Figure 83

Figure 83 shows 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 dB SPL 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*.

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

Creating a Tympanometry Protocol

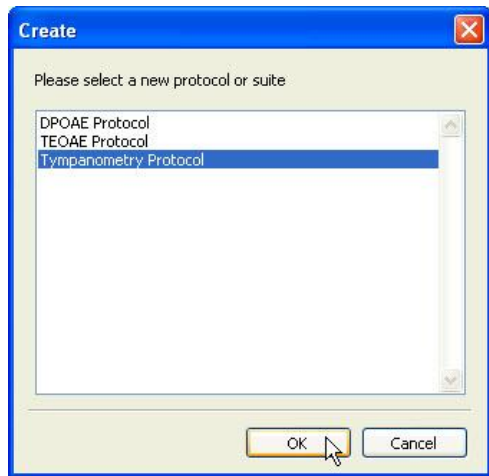


Figure 84

To create a new protocol file, click the Create New button located on the right panel of the protocol window (

Figure 77).

A selection window will appear (Figure 84). Choose TEOAE and click *Ok*.

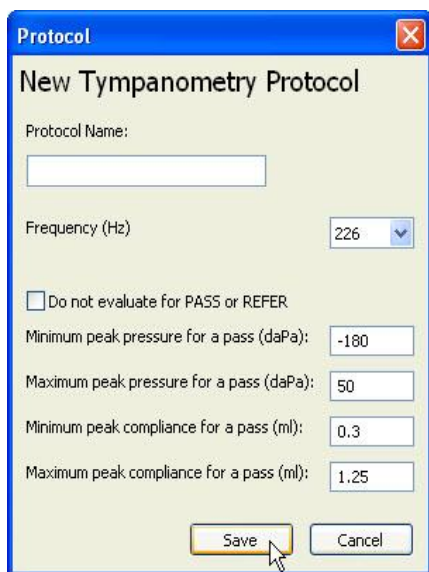


Figure 85

Figure 85 shows 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 1,000 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 be 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 daPa to 400 daPa)

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

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

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

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 77 on page 49). 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 77 on page 49). 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 10.2.

Creating an Acoustic Reflex Protocol

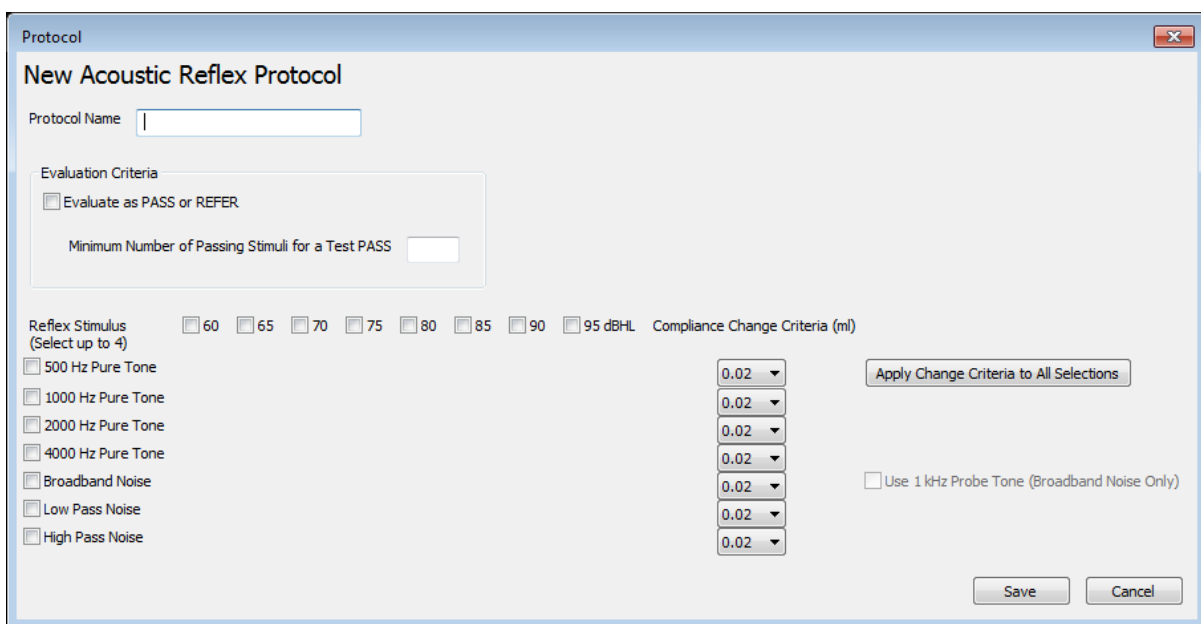


Figure 86

In Figure 86 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 to 95 dB_{HL}, 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 1 kHz 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 (Figure 87).

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 87). 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*" (Figure 87).

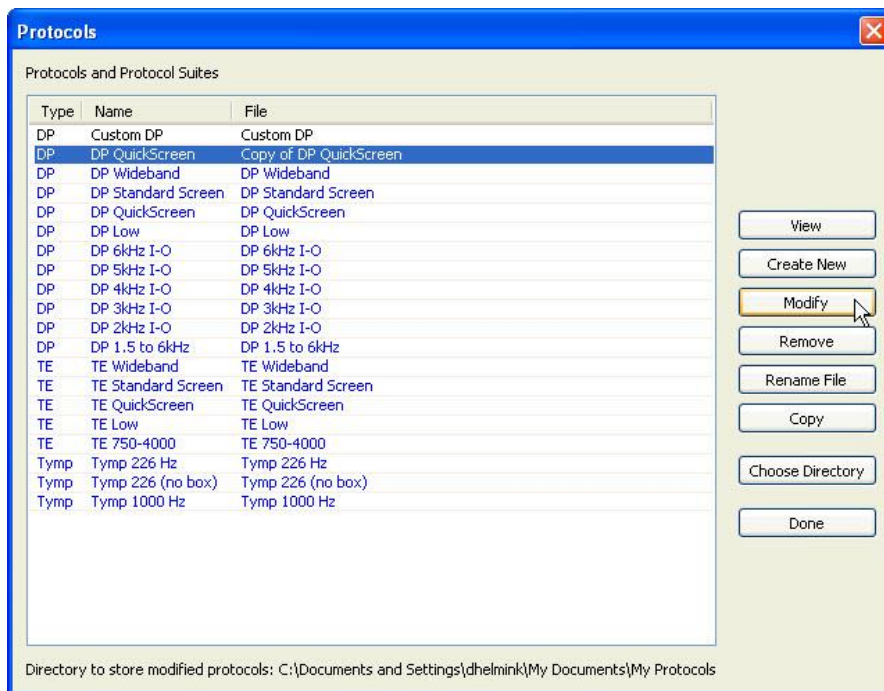


Figure 87

Select the new copy of the existing protocol and click the *Modify* button located on the right panel of the protocol window (Figure 87). To modify the protocol follow the instructions provided above and save changes.

10.2 Managing Protocols in the Instrument

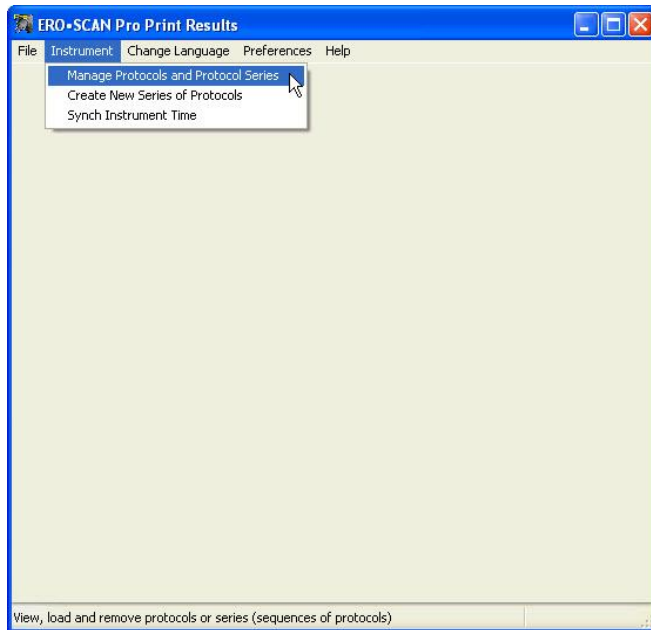


Figure 88

To load new or modified protocols into the instrument or to remove unused protocols from the instrument, click on the *Instrument* menu, and then select *Manage Protocols and Protocol Series* (Figure 88).

Figure 89 shows 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

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

Done: exit

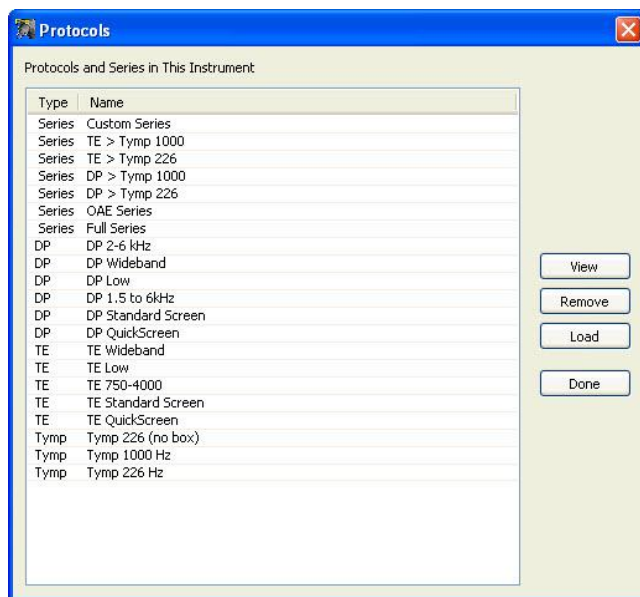


Figure 89

Remove Protocol or Series

To remove a protocol or series from the instrument, select the protocol or series to be removed and click the *Remove* button located in the right panel of the Protocols in Instrument window (Figure 89). When prompted confirm the action by clicking Yes.

Removing a protocol from the instrument does not delete the file from the protocol directory on your computer. You can reload that protocol if you change your mind in the future.

When series are removed from the instrument they are DELETED. There is no file saved on the instrument. It is important to understand that series are created within the instrument using protocol files that were previously loaded into the instrument. For that reason, when a series is removed from the instrument it no longer exists in any location. A series can easily be recreated (see instructions in the next section) if you wish to restore it in the future.

Load Protocols

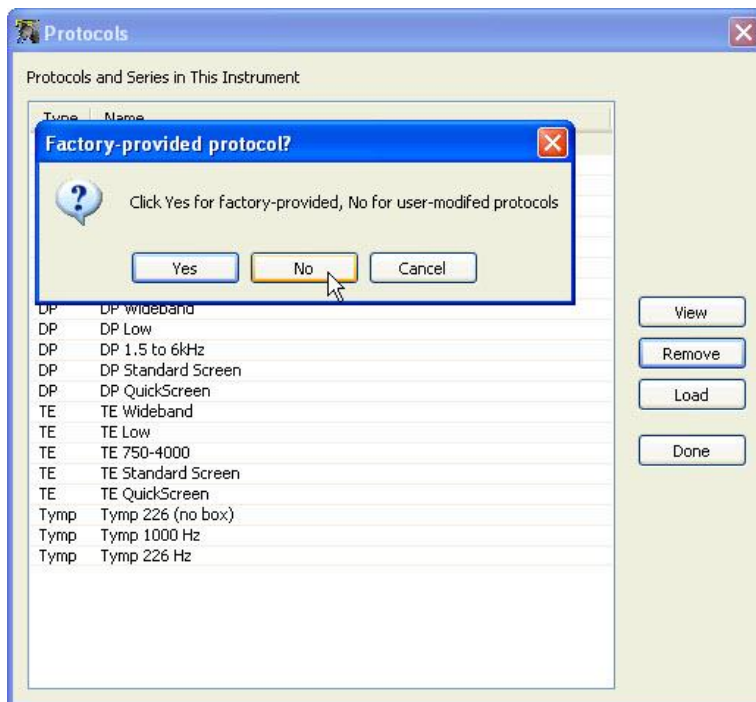


Figure 90

To load a protocol into the instrument, click the *Load* button located in the right panel of the Protocols in Instrument window (Figure 89).

When prompted (Figure 90) select the appropriate directory for the protocol being loaded.

Yes = directory for manufacturer default protocols

No = user modified or created protocols

Select the protocol you wish to load and click *Open* (Figure 91).

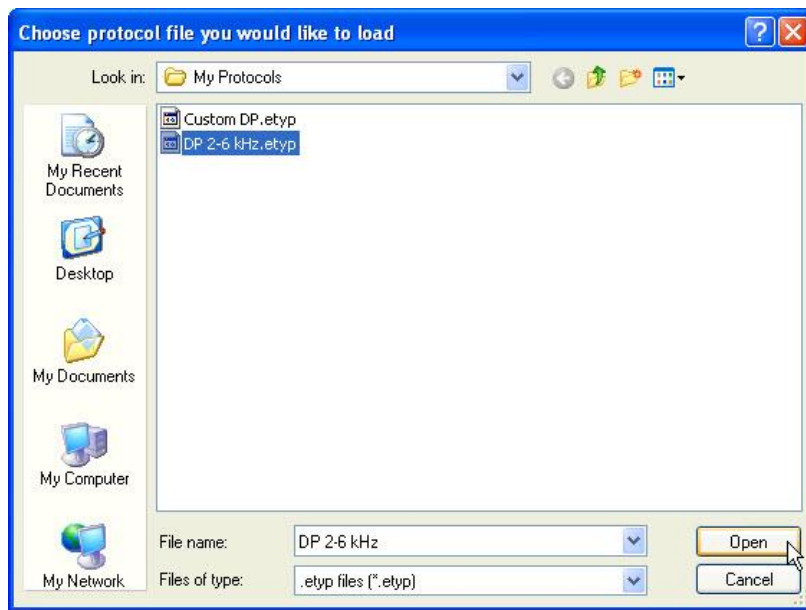


Figure 91

A status bar will indicate that the protocol is being loaded. When complete the refreshed list of protocols in the instrument will show the newly added protocol.

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.

10.3 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 by multiplicity symbol to the left of the series name (Figure 18). 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.

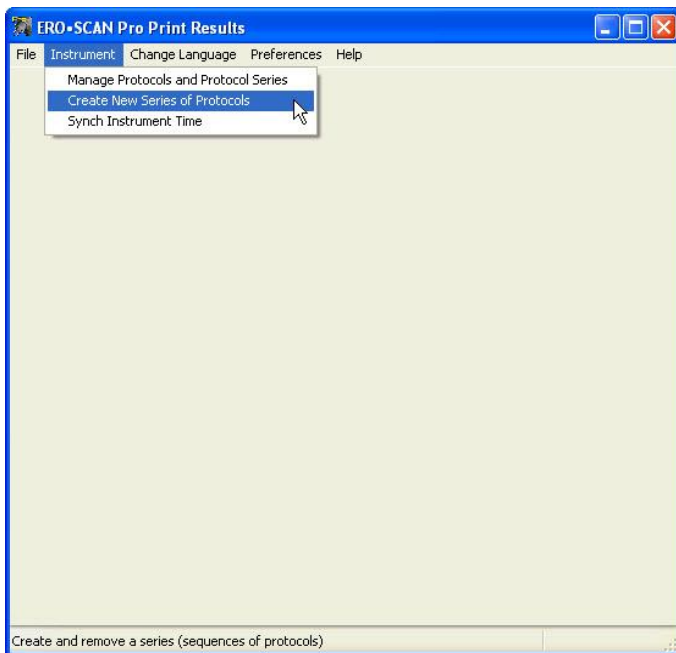


Figure 92

To create a new series, click on the *Instrument* menu, and then select *Create New Series of Protocols* (Figure 92).

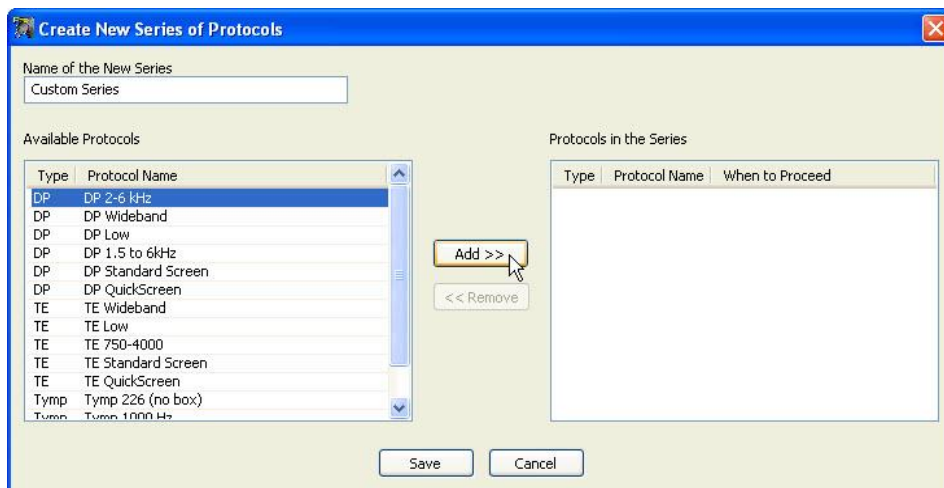


Figure 93

- 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* (Figure 93).
- Step 3:** You will be prompted to determine when the testing sequence should proceed to the next protocol (Figure 94). Make a selection and click *Ok*.

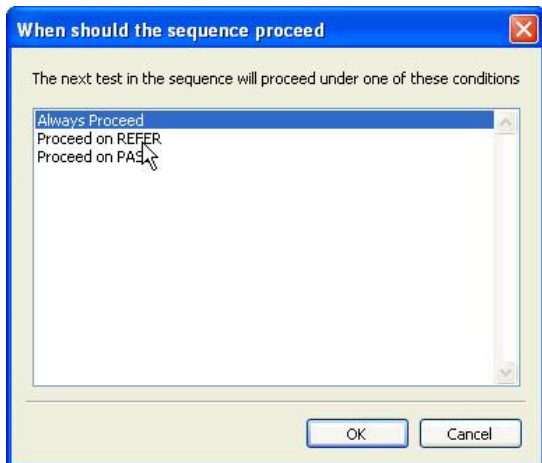


Figure 94

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*.

NOTE: 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 (Figure 93).



Figure 95

Confirmation that the series was successfully loaded into the instrument is provided (Figure 95). 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.

11 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.
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.

PROBLEM	POSSIBLE CAUSES	RESOLUTION
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 8.3 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 7.1 for reviewing test results.

12 Care and Maintenance

12.1 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., cetylalcohol). 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.

12.2 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.

12.3 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 Figure 96. 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 (Figure 97). 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.



Figure 96



Figure 97

External Probe Tip Replacement

To remove:

1. 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 98).
2. Slide the probe tip off the front of the probe and discard (Figure 99).

To replace:

1. Align a replacement tip with the front of the probe (Figure 100). 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.
2. Press firmly on the tabs to snap them into place (Figure 101).

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

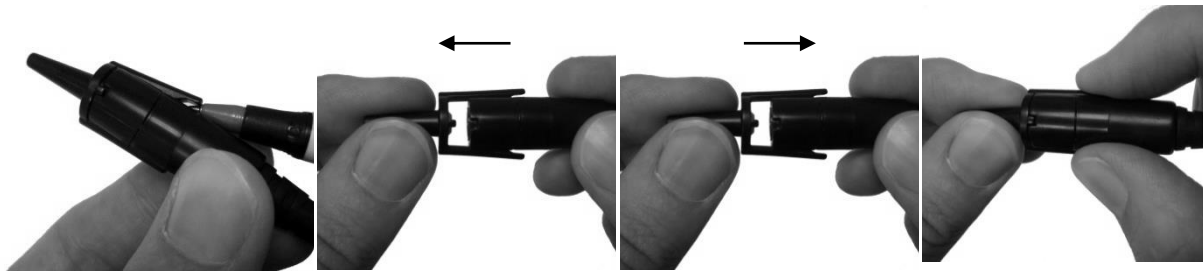


Figure 98

Figure 99

Figure 100

Figure 101

13 System Specifications

INSTRUMENT SPECIFICATIONS

Power Supply:	(4) AA/UM-3/R6 cells - Alkaline (6 V total)
Battery Life:	App. 300 tests
Instrument Dimensions:	210 mm x 55 mm x 47 mm
Instrument Weight:	300 g incl. batteries
User Interface:	The instrument uses a organic LED display (OLED) and three light-emitting diodes (LEDs) to provide a visual display of test data and test conditions to the operator.
Connectors / Communications:	USB
Storage of measurements:	Internal memory for 50 test results

PROBE SPECIFICATIONS

Measurement Type:	Distortion Product Otoacoustic Emissions (DPOAE) Transient Evoked Otoacoustic Emissions (TEOAE)
Frequency Range:	1.5 to 12 kHz (DPOAE) .7 to 4 kHz (TEOAE)
Stimulus Intensity Range:	DPOAE: 40 to 70 dB SPL TEOAE: 83 dB SPL peak equivalent (± 3 dB)
Maximum Output (protection):	90 dB SPL
Microphone System Noise:	-20 dB SPL @ 2 kHz (1 Hz bandwidth) / -13 dB SPL @ 1 kHz (1 Hz bandwidth)
Stimulus Sampling Rate:	31,250 Hz

ENVIRONMENTAL REQUIREMENTS

Operating Temperature:	15 °C to 35 °C (59 °F to 95 °F)
Operating Relative Humidity:	30 % to 90 % (non-condensing)
Maximum Operating Altitude:	2000 meters (6000 feet)
Transport and Storage Temperature:	5 °C to 40 °C (41 °F to 104 °F)



PRINTER SPECIFICATIONS

Printer Type:	Thermal dot matrix line printer
Printer Speed:	> 10 lines per second
Operating Noise:	< 50 dB SPL
Printer Weight:	630 g including battery pack
Power Supply:	Acc. IEC 60601-1
Input:	100-240 V~, 50-60 Hz, 1.2 A
Output:	'+7 V, 5.0 A
Paper:	Calculator-type thermal roll - 5,75 cm (2.25") wide

PROCESSOR SPECIFICATIONS

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

REMOTE PROBE SPECIFICATIONS

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

MAXIMUM SPL

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

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
Note: Measurements conducted at 10 and 12 kHz can lead to results with high standard deviation		
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:	text	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:



IEC 60601-1
IEC 60601-1-1
IEC 60601-1-2
IEC 60601-1-4
IEC 60645-1
IEC 60645-3
IEC 60645-5
IEC 60645-6

ANSI S3.39-2007

14 Warranty, Maintenance and Service

The OAE-test system MAICO ERO•SCAN™ Pro is guaranteed for 2 years. This warranty is extended to the original purchaser of the instrument by MAICO through the Distributor from whom it was purchased and covers defects in material and workmanship for a period of one year from date of delivery of the instrument to the original purchaser.

The instrument may be repaired only by your dealer or by a service centre recommended by your dealer. We urgently advise you against attempting to rectify any faults yourself or commissioning non-experts to do so.

In the event of repair during the guarantee period, please enclose evidence of purchase with the instrument.

In order to ensure that your instrument works properly it should be checked at least once a year. This check has to be carried out by your dealer.

Send the device to your dealer or to a service centre authorized by your dealer.

Please also include a detailed description of the faults.

In order to prevent damage in transit, please use the original packing if possible when returning the instrument.

Notice

Within the European Union it is illegal to dispose electric and electronic waste as unsorted municipal waste. Electric and electronic waste may contain hazardous substances and therefore has to be collected separately. According to this all MAICO products sold after August 13, 2005, are marked with a crossed-out wheeled bin.



Article (9) of DIRECTIVE 2002/96/EC on waste electrical and electronic equipment (WEEE) allows producers and users other than private households to conclude special agreements concerning the collection of WEEE. To avoid additional distribution costs, MAICO is using this opportunity and has changed their sales contracts. With the conclusion of the sales contract the customer takes over the responsibility for the proper collection and treatment according legal regulations.

15 Safety Regulations

Electrical Safety



The OAE-Test system MAICO ERO•SCAN™ Pro is a battery driven low voltage instrument.

The instruments are not intended for operation in areas with an explosion hazard.

Measuring security

To guarantee that the instrument works properly, it has to be checked at least once a year.

The service and calibration must be performed by an authorized service centre. In accordance with the regulations of the EU medical directive we will drop our liability if these checks are not done.

Device control

The user of the instrument should perform a subjective instrument check once a week. For your own security, you should copy the printout of the test and store it in your files.

Operation

The instrument should only be handled and operated by trained personnel (audiologists, ENT doctors or personnel with similar qualifications)

Appendix A ERO•SCAN™ Pro Software Installation Instructions

A.1 Application Installation

Insert the included software CD into your computer's CD drive. Your computer may automatically open a folder displaying the files on the CD. If not, navigate to the CD drive using Windows Explorer or your preferred method.

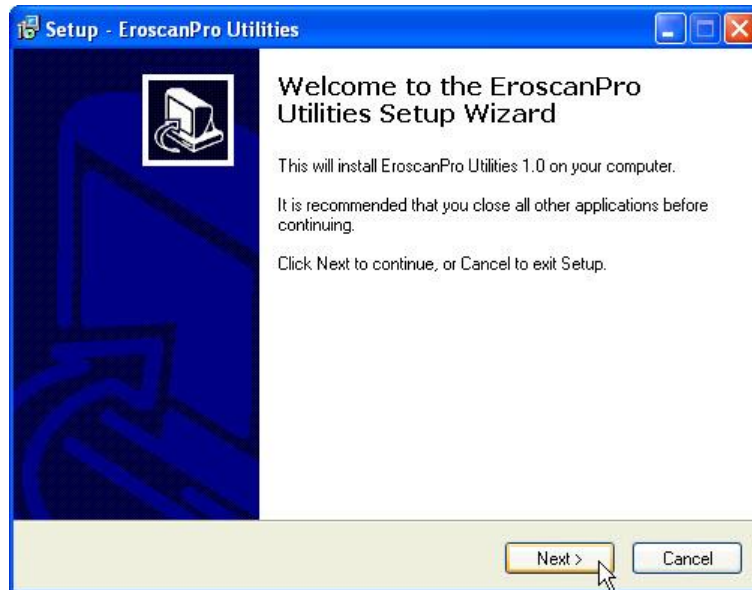
To begin installation double click on the installer file: **EroscanPro_installer_user_p1-081020.exe**

NOTE: Do not connect the ERO•SCAN™ Pro cradle at this time.

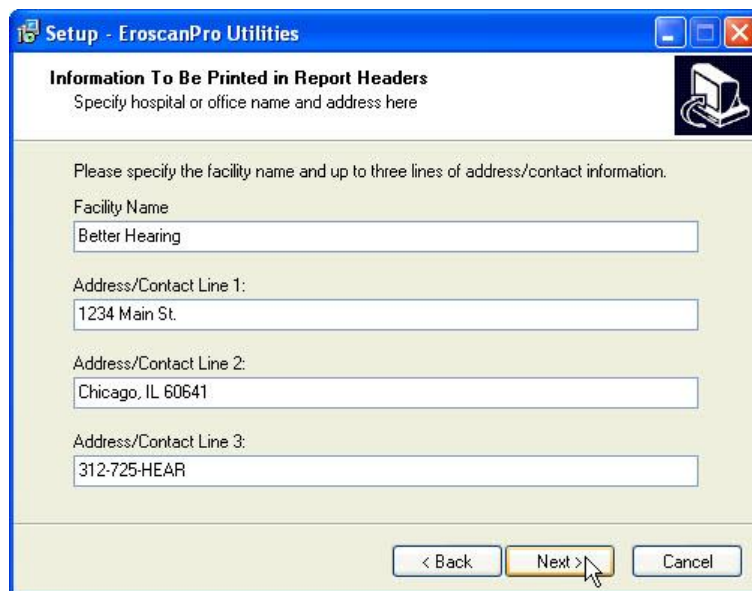


Figure 102

Click 

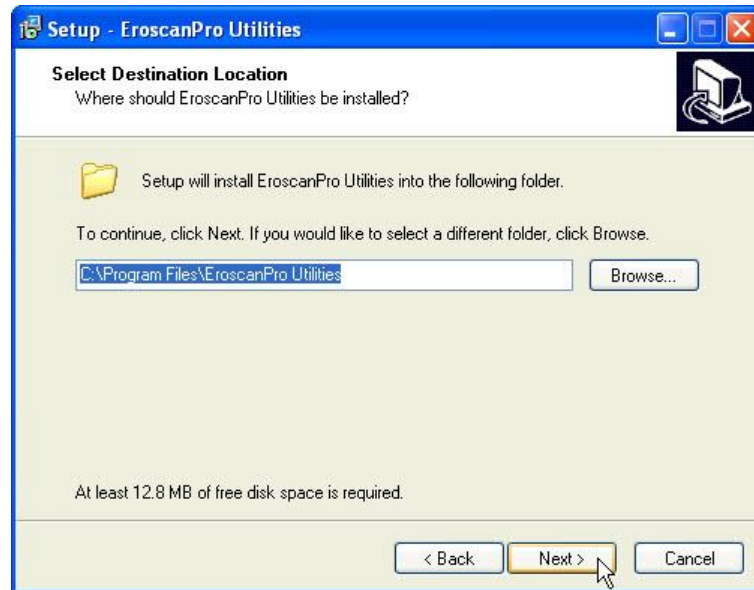


Click  to continue



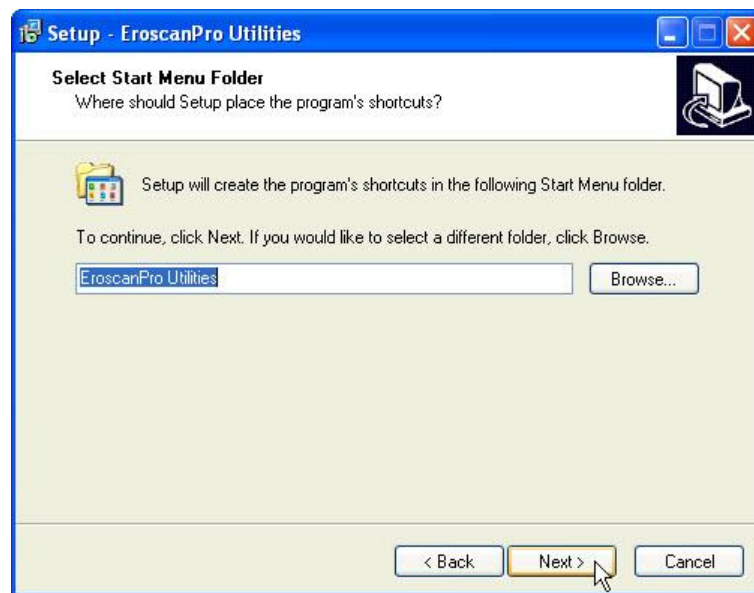
If desired fill in the report header lines. This the information that will appear on the printed test results and/or saved PDF files.

Click  to continue.



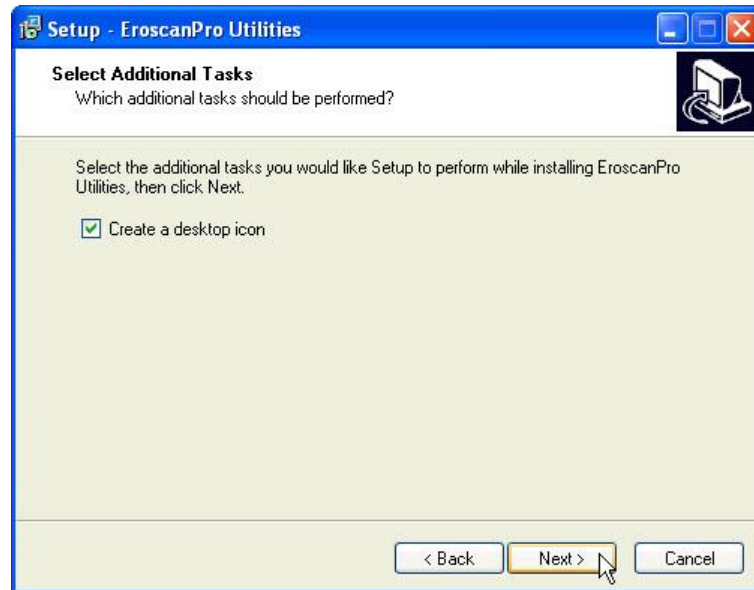
The default file location is recommend for most installations. If you wish to designate an alternate location for the ERO•SCAN™ Pro Utilities program folder you may do so at this point.

Click  to continue.



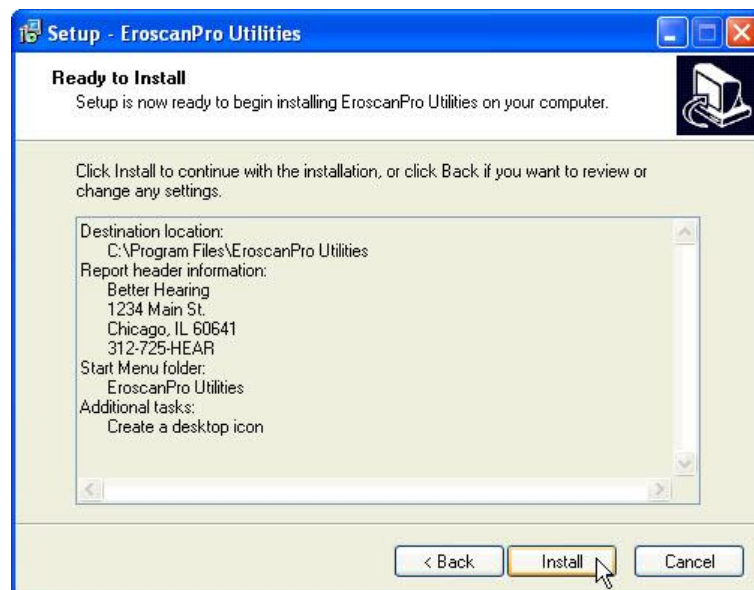
Once again the default settings are recommended for the program's shortcuts. If you wish to specify a different location for the shortcuts you may do so here.

Click  to continue.



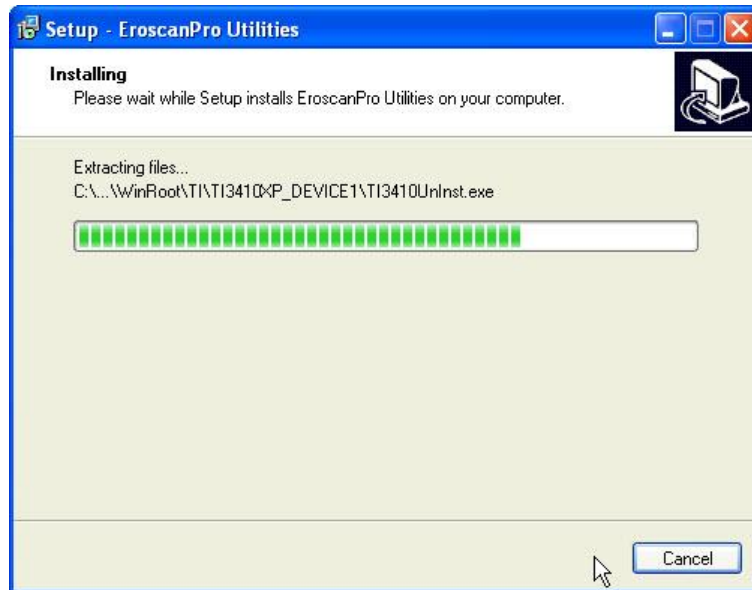
If you would prefer not to have a desktop icon created you can uncheck the box. To create an icon leave the box checked.

Click  to continue.



Review your installation selections. Click *Back* to return to previous screens to make changes.

Click  to continue.



This status window will show during installation. Installation may take a few minutes.



Installation is complete. The cradle driver installation will start automatically.

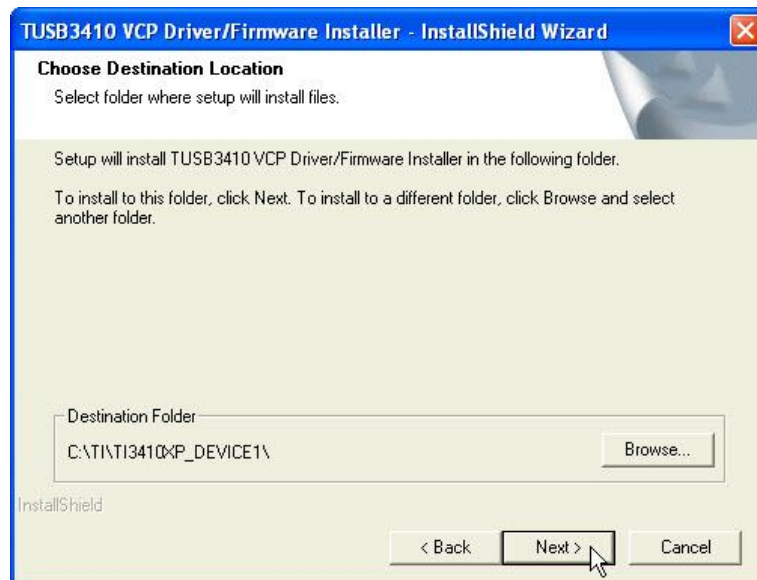
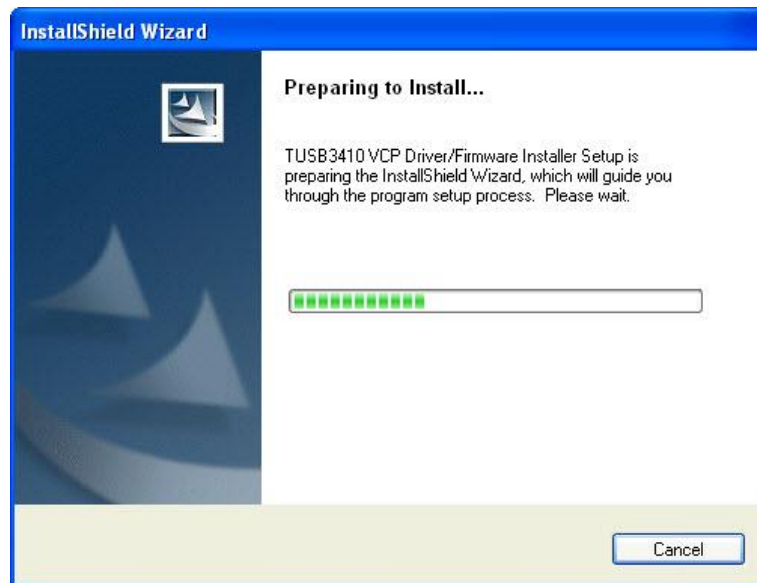
Click  to continue

A.2 Cradle Driver Installation

The cradle driver installation and set up is a multipart process. Please be sure to follow all the steps in the process as outlined below.

Part 1

Cradle driver installation will begin automatically once the PC application installation is complete. **Please be sure the cradle is NOT connected to the computer at this time.**




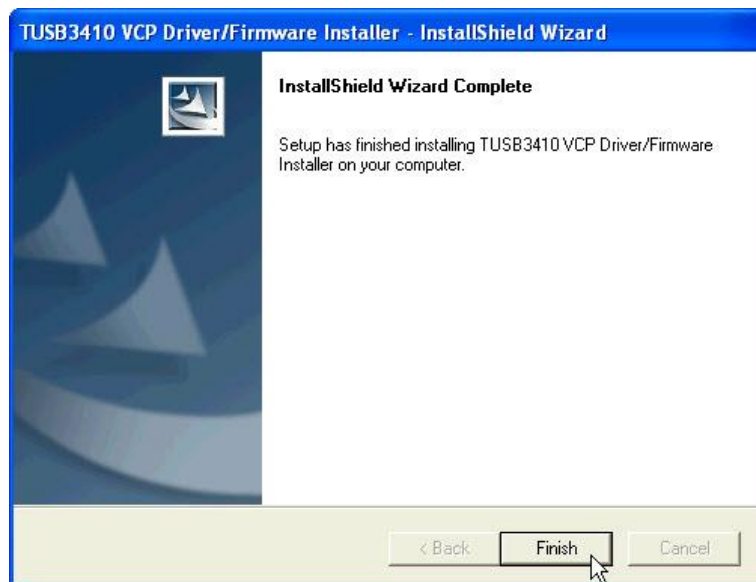
The default location is recommended for most installations. If you wish to specify an alternate location for the driver files you may do so at this time.

Click  to continue.



Please click 

Note: This window will appear two times. Click  on both occurrences to continue with installation.



The first part of the cradle driver installation is complete.

Click  to continue.

Part 2:

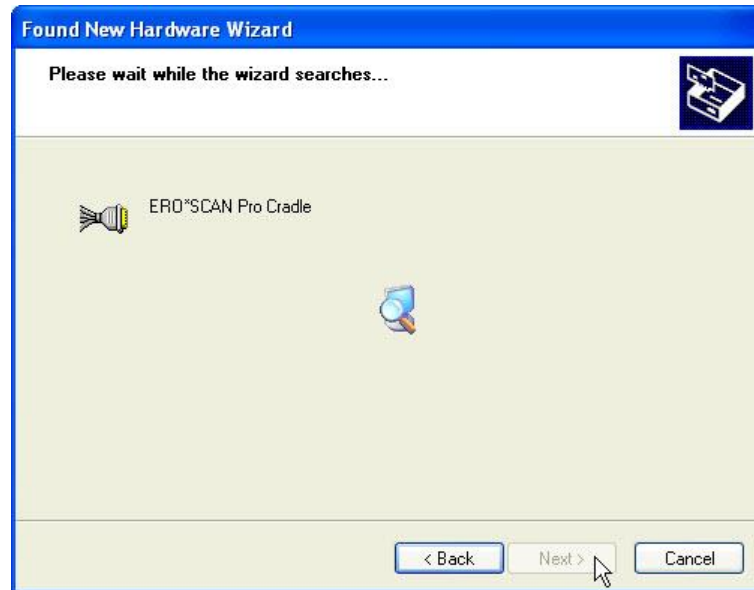
Connect your ERO•SCAN™ Pro cradle to your PC. Your computer will detect the cradle and prompt you to complete the installation process.



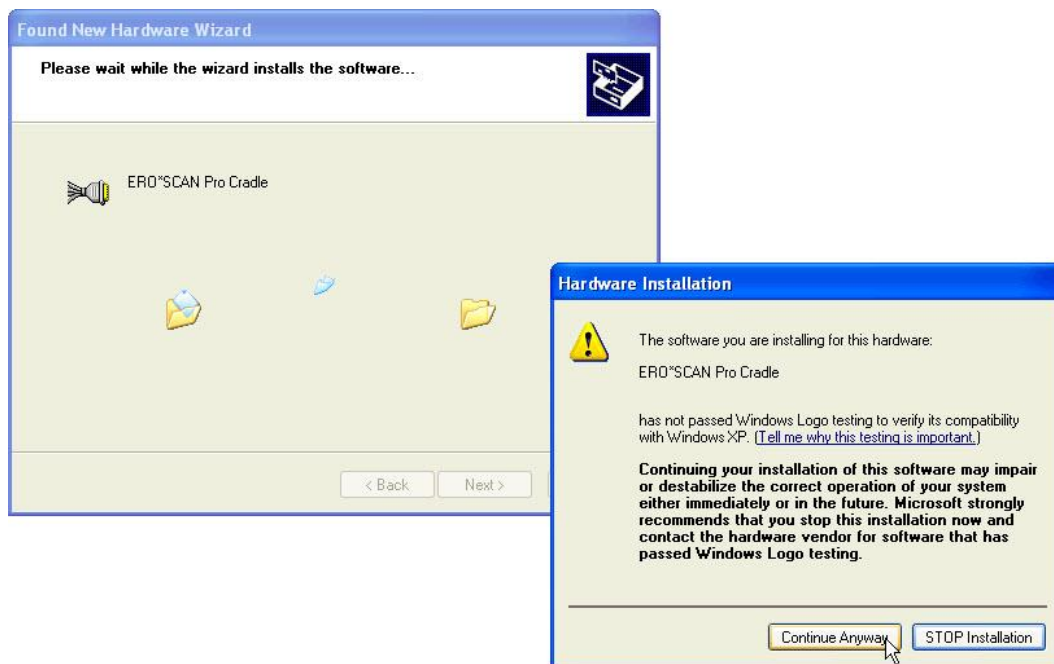
Click  to continue.



Click  to continue.



Click  to continue.



Click  to continue.



This completes Part 2 of the cradle installation. Step 3 will begin automatically.

Click  to continue.

Part 3:

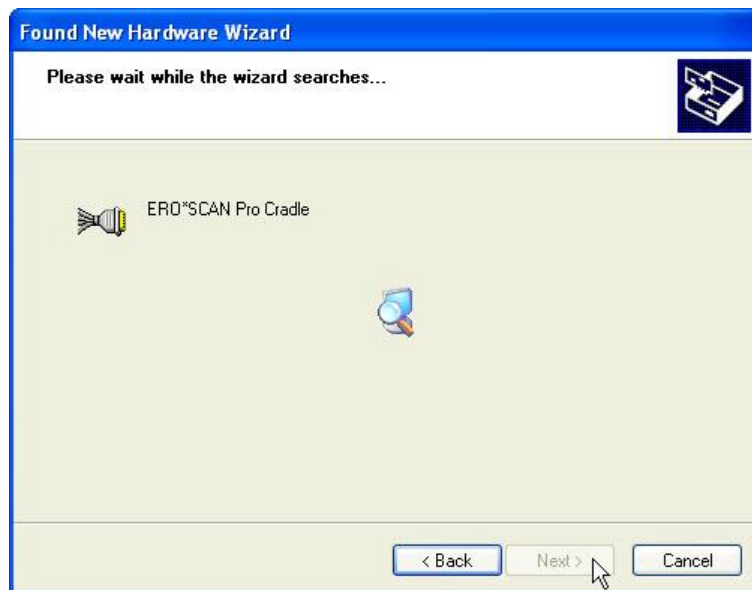
This final step in the installation process will start automatically.



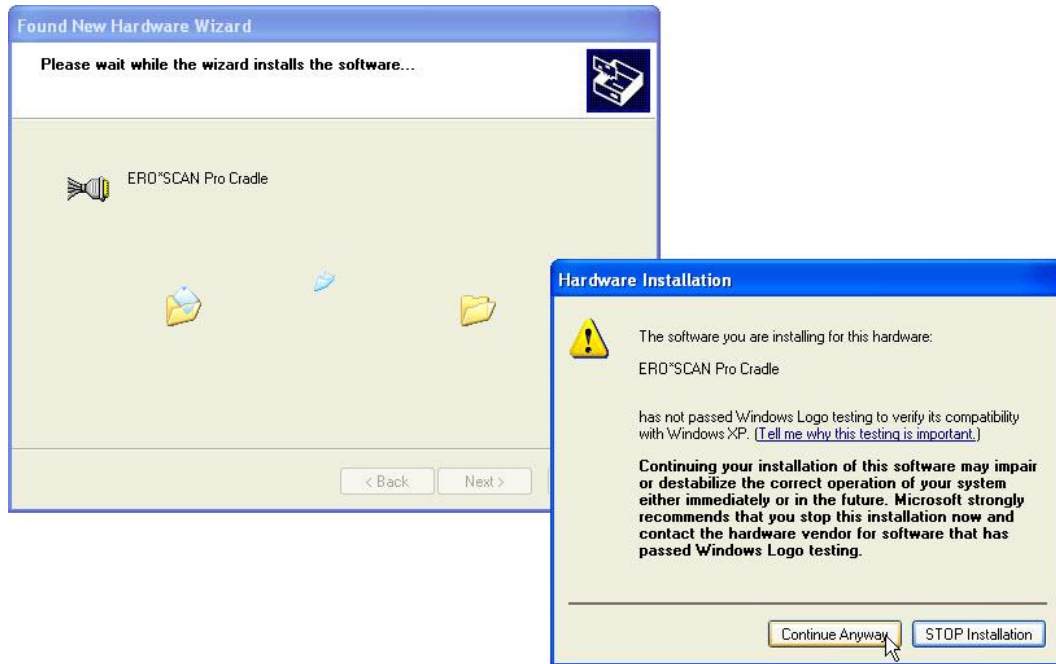
Click  to continue.



Click  to continue.



Click  to continue.



Click  to continue.



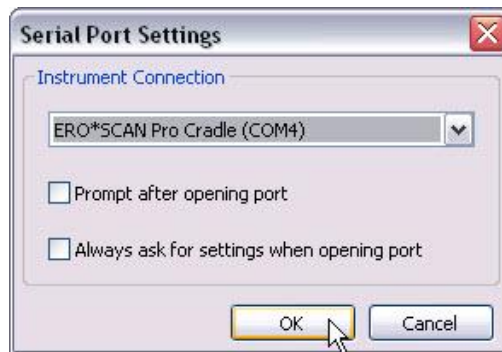
Software installation is complete.


A.3 Cradle Connection Configuration

The first time the ERO•SCAN™ Pro Print Result or Patient Management application is opened you will be prompted to configure your cradle connection.



Click  to continue.



Use the pull down arrow to display a list of communication port options. Select the ERO*SCAN Pro Cradle. Click  to continue.

Cradle installation and configuration is complete.

Appendix B Default Test Protocols and Protocol Series

DPOAE Protocols

DP QuickScreen

Number of frequencies: 4
F2 frequencies (as presented): 5, 4, 3, 2 kHz
P1/P2: 65/55
Averaging time: 2 seconds per frequency
SNR for a passing frequency: 6 dB
of passing frequencies for overall PASS: 3 of 4
Ratio: 1.20
Minimum DP Amplitude (optional): -5 dB

DP Standard Screen

Number of Frequencies: 4
F2 frequencies (as presented): 2, 3, 4, 5, kHz
P1/P2: 65/55
Averaging time: 4 seconds per frequency
SNR for a passing frequency: 6 dB
of passing frequencies for overall PASS: 3 of 4
Ratio: 1.20
Minimum DP Amplitude (optional): -5 dB

DP 1.5 to 6 kHz

Number of Frequencies: 6
F2 frequencies (as presented): 1.5, 2, 3, 4, 5, 6 kHz
P1/P2: 65/55
Averaging time: 2 seconds per frequency
SNR for a passing frequency: 7 dB
of passing frequencies for overall PASS: 3 of 6
Ratio: 1.20
Minimum DP Amplitude (optional): -5 dB

DP Low

Number of Frequencies: 6
F2 frequencies (as presented): 1.5, 2, 3, 4, 5, 6 kHz
P1/P2: 50/40
Averaging time: 4 seconds per frequency
SNR for a passing frequency: 7 dB
of passing frequencies for overall PASS: 3 of 6
Ratio: 1.20
Minimum DP Amplitude (optional): -5 dB

DP Wideband

Number of frequencies: 10
F2 frequencies (as presented): 1.5, 2, 3, 4, 5, 6, 7, 8, 10, 12 kHz
P1/P2: 65/55
Averaging time: 2 seconds per frequency
SNR for a passing frequency: No Pass Criteria
of passing frequencies for overall PASS: No Pass Criteria
Ratio: 1.20
Minimum DP Amplitude (optional): none

TEOAE Protocols

TE QuickScreen

Number of filter bands: 6
Frequencies (center band): 1.5, 2, 2.5, 3, 3.5, 4 kHz
Target Peak Pressure: 83 dB SPL
Averaging time: 32 seconds
SNR for a pass: 4 dB
of passing bands for test PASS: 3
Minimum TE Amplitude (optional): -12 dB

TE Standard Screen

Number of filter bands: 6
Frequencies (center band): 1.5, 2, 2.5, 3, 3.5, 4 kHz
Target Peak Pressure: 83 dB SPL
Averaging time: 64 seconds
SNR for a pass: 4 dB
of passing bands for test PASS: 3
Minimum TE Amplitude (optional): -12 dB

TE 700-4000

Number of filter bands: 6
Frequencies (center band): 0.7, 1.0, 1.4, 2.0, 2.8, 4.0 kHz
Target Peak Pressure: 83 dB SPL
Averaging time: 64 seconds
SNR for a pass: 4 dB
of passing bands for test PASS: 3
Minimum TE Amplitude (optional): -12 dB

TE Low

Number of filter bands: 6
Frequencies (center band): 1.5, 2, 2.5, 3, 3.5, 4 kHz
Target Peak Pressure: 70 dB SPL
Averaging time: 64 seconds
SNR for a pass: no pass criteria
of passing bands for test PASS: no pass criteria
Minimum TE Amplitude (optional): none

TE Wideband

Number of filter bands: 10
Frequencies (center band): 750, 1100, 1500, 1900, 2250, 2600, 3000, 3400, 3750, 4000 Hz
Target Peak Pressure: 83 dB SPL
Averaging time: 64 seconds
SNR for a pass: No pass criteria
of passing bands for test PASS: No pass criteria
Minimum TE Amplitude (optional): none

Tympanometry Protocols

Tymp 226 Hz

Minimum Peak Pressure for a Pass (daPa): -150

Maximum Peak Pressure for a Pass (daPa): 50

Minimum peak compliance for a pass (ml): 0.1

Maximum peak compliance for a pass (ml): 1.5

Tymp 226 Hz (with and without box)

No pass criteria

Tymp 1000 (without box)

No pass criteria

Acoustic Reflex Ipsi

Ipsi 4F Auto

Frequencies: 0.5, 1, 2, 4 kHz

Level: Auto

Ipsi 4F at 90 dB

Frequencies: 0.5, 1, 2, 4 kHz

Level: 90 dB

Ipsi 1F at 90 dB

Frequencies: 1 kHz

Level: 90 dB

Ipsi BN(1k)

Test Signal: Broadband noise

Level: 90 dB

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 newborns 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 a newborn or infant, the following suggestions might be helpful: The newborn 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 newborn, however, sucking will add noise to the test and decrease the likelihood of a passing result. When testing a newborn, 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 newborn's hands. Place the probe in the ear canal and, if necessary, wait for the newborn 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**.

DPOAE

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 moderately-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 moderately-severe hearing-impaired infant.

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 moderately-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™ 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.

Users with the goal of detecting mild hearing loss should ensure that the minimum amplitude setting is turned on (see section XX) 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™ trials with newborns 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* section, page 10) 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™ uses a novel noise-rejection algorithm (patent pending) that permits accurate DPOAE and TEOAE measurements in background noise and babble as high as 55-65 dB SPL (A-weighted). Briefly explained, use of available memory in the ERO•SCAN™ 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 (Mayo Clinic Teleconference, 1998), 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 impedance 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 103 shows ERO•SCAN™ measurements on a 12 year old. Figure 104 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 103), and no response above 8 or 10 kHz in older adults (Figure 104)

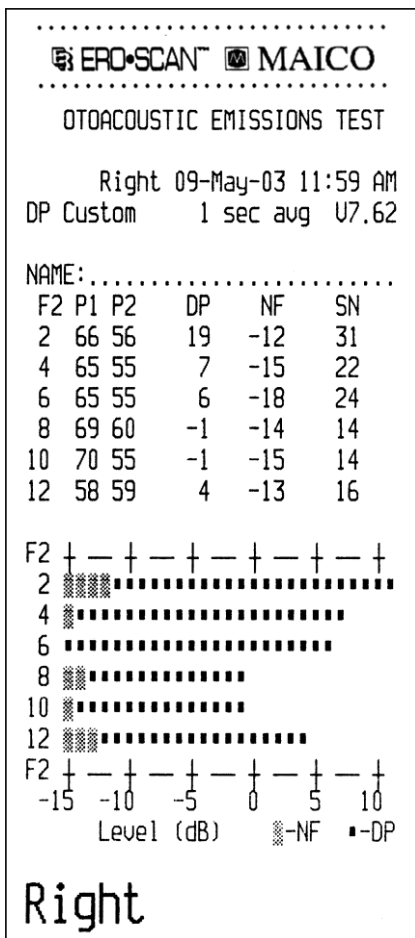


Figure 103

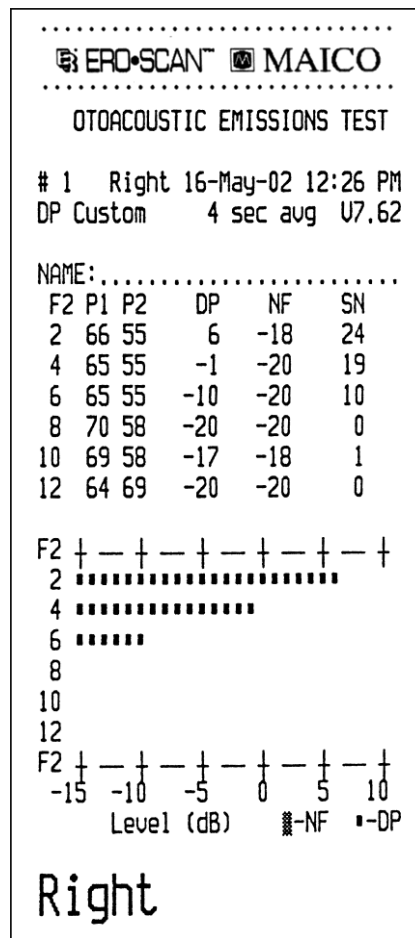


Figure 104

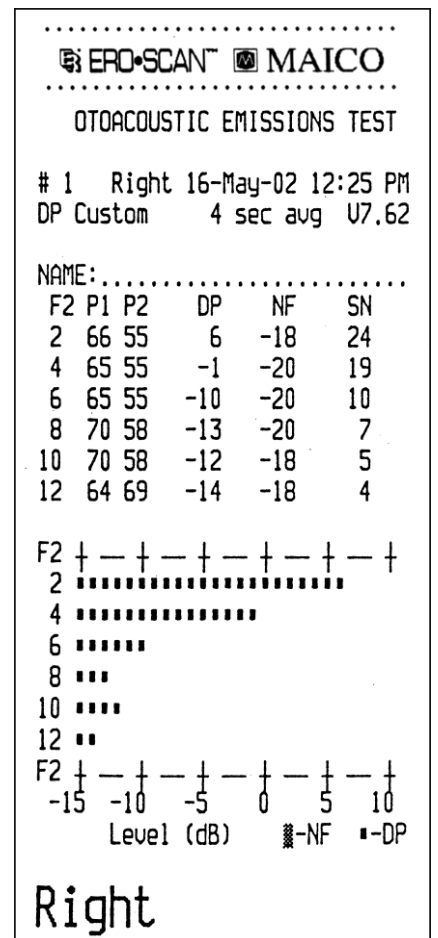


Figure 105 (see next page)

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

1. Ototoxic drug monitoring in young patients (and older patients who have measurable OAEs)
2. Prospective studies of noise-induced hearing loss, especially in young subjects
3. 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 105 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.

1. Average the DP level at each frequency of interest for the total number of tests performed during one session.
2. 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

1. a low-frequency probe measurement of ear canal SPL (to adjust for individual ear canal volume differences) and
2. 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.

16 References

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Specifications are subject to change.



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