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This manual applies to firmware version 7.65.01 and higher.



1 Introduction

Thank you very much for purchasing a quality product from the MAICO family. This automatic OAE-test system MAICO ERO•SCAN™ is manufactured to meet all quality and safety requirements, and has been certified with the CE-symbol according to Medical Directive 93/42/EEC.

In designing the MAICO ERO•SCAN™ we placed particular importance in making it a user-friendly device, meaning its operation is simple and easy to understand. And because all functions are software controlled, upgrading later to new, extended measurement functions will be simple and inexpensive. That means that you have invested in a device that will adjust to your future needs.

This user manual should make it as easy as possible for you to become familiar with the functions of the MAICO ERO•SCAN™. Please open out the flap of illustrations on the last page. The description of the position (e.g.) of controls, displays and connections, found again in the text, will make it easier for you to learn how to operate the MAICO ERO•SCAN™.

If you have problems or have ideas for further improvements, please get in touch with us. Simply call.

Your MAICO-Team



2 Important Safety Instructions

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



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

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 Cleaning 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.

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.

NOTICE: 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.

READ THIS SECTION CAREFULLY BEFORE USE

Printer AC Power Source Precautions



- The printer AC power source converts main voltage (120V AC or 230V AC) to a low voltage (12V 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.

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.

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.



3 Purpose

The purpose of the ERO•SCAN test system is to provide a rapid measurement and documentation of Distortion Product Otoacoustic Emissions (DPOAEs) or Transient Evoked Otoacoustic Emissions (TEOAEs) at several frequencies.

What Are DPOAEs?

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

What Are TEOAEs?

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

What Do Otoacoustic Emissions Results Tell Us?

Available evidence suggests that otoacoustic emissions (OAEs) are generated by the cochlea's outer hair cells, and that the presence of OAEs is an indication that the outer hair cells are normal. Although OAE test data provide no indication of inner hair cell function, or of hearing ability, current research indicates that the majority of hearing-impaired individuals 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 Device Measure DPOAEs?

The ERO•SCAN 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 device provides an estimate of outer hair cell function over a wide range of frequencies.

How Does the ERO•SCAN Device Measure TEOAEs?

The ERO•SCAN 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 device provides an estimate of outer hair cell function over a wide range of frequencies.

How Does the ERO•SCAN 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 instrument.

What Frequency Range of Hearing is Estimated?

DPOAEs: Approximately 1 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.



4 Description

What is the ERO•SCAN Instrument?

The MAICO ERO•SCAN™ Otoacoustic Emission test instrument is a hand-held device designed to provide an objective test of outer hair cell function through the measurement of Distortion Product Otoacoustic Emissions (DPOAEs) or Transient Evoked Otoacoustic Emissions (TEOAEs). Versions with either DPOAEs or TEOAEs or a combined instrument with both methods are available. The MAICO ERO•SCAN™ consists of the hand-held unit, printer, single-use eartips and other accessories. The MAICO ERO•SCAN™ instrument may be used as a screening tool, or in conjunction with conventional tests as part of a full audiological evaluation.

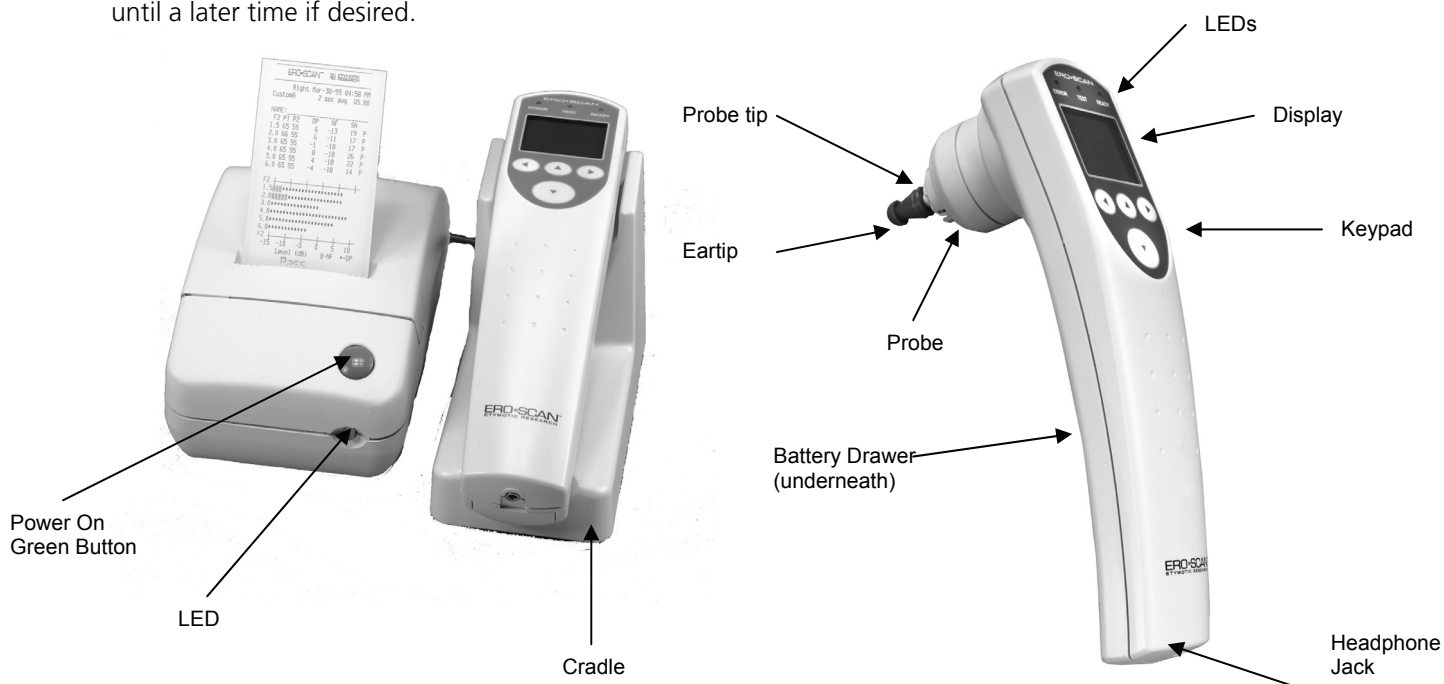
The MAICO ERO•SCAN™ instrument contains the hardware and software for generating the test tones, measuring and displaying the DPOAEs or TEOAEs, and storing the results until they are printed. The plastic housing contains circuit boards that provide the signal processing and display the test results. The instrument also contains four A/UM-3/R6 alkaline batteries to power the device. The instrument uses a liquid-crystal display (LCD) and three light-emitting diodes (LEDs) to provide a visual display of test data and test conditions to the operator. The probe section of the instrument houses a microphone and two speaker tubes which produce test stimuli and measure the sound pressure level (SPL) present in the sealed 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. The disposable eartips are colour coded to facilitate easy selection by size. Four membrane-type push buttons located on the keypad of the device allow the user to control testing and printing, and to reset test protocols. Printing will commence upon placement of the instrument into the cradle.

In the default test mode, the MAICO ERO•SCAN™ instrument will store the results from one patient (left and right ear) in its non-volatile memory for subsequent printing. However, the MAICO ERO•SCAN™ instrument can store up to 50 test results. The results are displayed via the LCD 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 printer and/or exported to a computer. Test results are stored in the non-volatile memory so the operator can delay printing until a later time if desired.

PC-Interface: A serial RS 232C interface for data transfer to a connected computer is built in. A program for Windows is available as accessory.

How are the Results Stored and Reported?

When the ERO•SCAN is set in its default settings, the instrument will store the results from one patient (left and right ear) in its non-volatile memory for subsequent printing. However, the ERO•SCAN instrument can store up to 50 test results. The results are displayed via the LCD 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 printer and/or exported to a computer. Test results are stored in the non-volatile memory so the operator can delay printing until a later time if desired.



5 Setup

5.1. Unpacking the System

Your MAICO ERO•SCAN™ is carefully inspected and packed for shipping. However, it is a good practice to thoroughly inspect the outside of the shipping box for signs of damage. If any damage is noted, please notify the carrier immediately.

Carefully remove the instrument from the shipping box. Remove the plastic bags and inspect the parts for any damage.

Notify the carrier immediately if any mechanical damage is noted. This will assure that a proper claim is made. Save all packing material so the claim adjuster can inspect it as well. Notify your dealer or MAICO when the adjuster has completed the inspection.

SAVE ALL THE ORIGINAL PACKING MATERIAL AND THE SHIPPING CONTAINER SO THE INSTRUMENT CAN BE PROPERLY PACKED IF IT NEEDS TO BE RETURNED FOR SERVICE OR CALIBRATION.

Please check that all accessories listed below are received in good condition. If any accessories are missing or damaged, immediately notify your dealer or MAICO.

Standard accessories:

- | | |
|---|---|
| (1) ERO•SCAN Hand-held Unit | (1) Box of 156 Eartips (12 sizes) |
| (1) Cradle | (4) Probe Tips |
| (1) Printer | (4) AA/UM-3/R6 Alkaline Batteries (already installed) |
| (1) Printer AC Power Supply + Power Cable | (1) Thermal Printer Paper Roll (already installed) |
| (1) Printer Cable | (1) Operating instruction manual |



5.2. Connection to the Printer

Connect one end of the printer cable ① into the port ② located on the underside of the cradle as shown in Figure 1 to the right.

After firmly pushing the broad connector end into place, turn the screws on either side to tighten it.

Insert the cable (battery option two cables into the slot ③ provided on the bottom of the cradle.

Return the cradle to right side up.

The other end of the cable ① should be plugged firmly into the inlet at the rear of the printer ④. The flat side on the small connector (look for the arrow) goes to the bottom of the printer. The cover of the connector will slide back to ease installation of the connector.

Plug the power supply cord into the power supply and into an electrical wall outlet.

The printer indicator light ⑤ (located on the front of the printer) will shine steady green.

If you have the optional printer with rechargeable batteries plug the additional short end ⑥ of the cable ① into the external printer power supply.

Plug the power supply cord into an electrical outlet.

If you use the printer only with batteries (option) the printer indicator light ⑤ (located on the front of the printer) will blink green.

The recharging time for the batteries is at least 5 hours.

See the precautions for the batteries and printer power supply at chapter 2.

NOTE for the optional printer with Ni-Mh rechargeable battery pack:

The printer will not run from the power supply, the power supply only charges the battery pack. The battery pack must be charged for a minimum of five hours before using the printer for the first time.

The printer will not function without a charged battery pack attached. Failure to fully charge the battery pack before use may reduce the life of the battery pack.

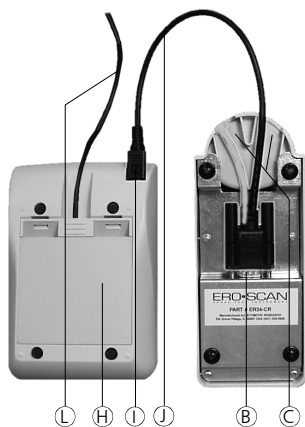


Figure 1

Installation Printer cable



Figure 2

Installation printer cable
(Option)

5.3. Environmental conditions

The MAICO ERO•SCAN™ 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™.

Therefore the use of these instruments is not allowed in close proximity to the MAICO ERO•SCAN™.

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.

6 Quick Start

These steps will allow you to quickly start using the ERO•SCAN OAE Test System. If you have a DPOAE or combined instrument it will be in the DPOAE test mode. If you have a TEOAE instrument it will be in the TEOAE test mode. Be sure to perform the necessary otoscopic examination prior to testing. Read the entire manual before testing patients.

NOTE: In order to print the test results, the printer must be charged for 5 hours.

Step 1 Place an eartip as far down as possible on the probe tip.

Step 2 Turn on the ERO•SCAN instrument by pressing the large DOWN arrow button ⑩.

Step 3 Select the test ear by pressing the ◀ left ⑨ or ▶ right ⑫ arrow key. Insert the eartip deeply into the patient's ear canal to obtain a seal.

When a seal is obtained, the MAICO ERO•SCAN™ instrument will automatically begin the test by first calibrating and then testing emissions.

The red ERROR LED ⑤ will illuminate if there is noise in the environment. This flashing is normal and will often occur. Once the testing is finished, the unit will display PASS or REFER on the LCD display.

Step 4 When testing is completed on both ears, turn the printer on by pressing the green button on top and place the hand-held unit on the cradle. The most recent test results for both ears will automatically print out.



Figure 3



Figure 4



Figure 5

6.1 Battery Installation

The ERO•SCAN 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 the battery label. Once the batteries are correctly in place, slide the panel back onto its tracks to close the battery compartment.

6.2 Loading Paper into the Printer

Open the cover of the printer by pulling up and back. Orient the paper roll so that the paper will feed from the bottom of the roll (see Figures 4 and 5). Place the roll of paper into the printer by holding the white paper-holder lever back against the case. Allow the lever to slide back so that it fits onto the hub on the paper roll. The paper roll should move freely on the hub. Pull the green paper-roller release lever forward until it snaps in place to disengage the roller. Slide the end of the paper under the roller; it will come out from the front of the roller. Pull the paper end through the roller until it extends about 3 inches above the roller. Push the paper-release lever back. Push the green button on the top of the printer to advance the paper. The printer indicator light on the front of the printer will now flash green if the paper was properly installed. Pressing the green button twice rapidly will print a test run.

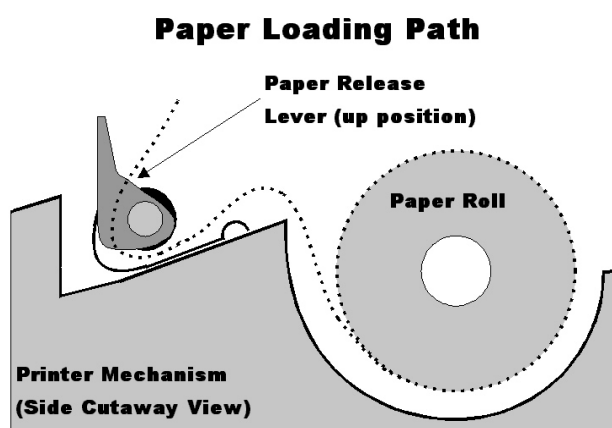


Figure 4

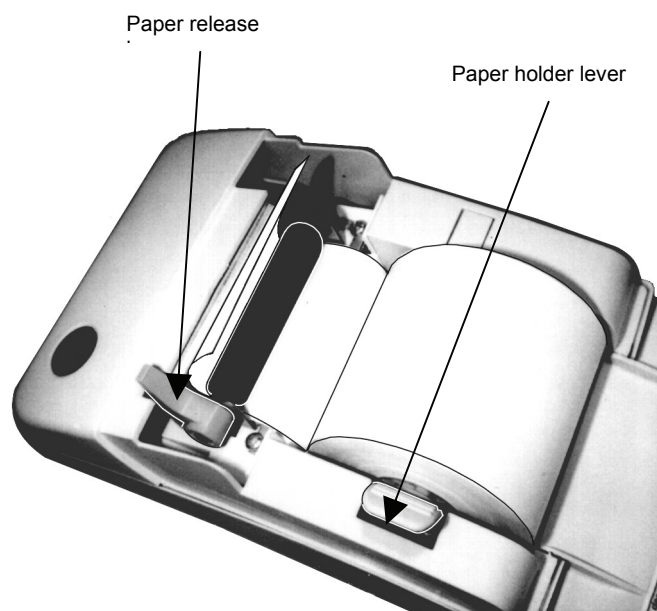


Figure 5

6.3 Attaching Eartips

The ERO•SCAN 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. 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. Ordering information can be found on page 29 or inside the eartip box. 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 the section *Probe Tip Replacement* on 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.

7 Operating Instructions

7.1. Preparing the Patient for Testing

Otoscopic 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 the ERO•SCAN instrument to be held steady while testing is in progress. The patient should remain still and quiet while the test is being performed.

7.2. Control Buttons

The ERO•SCAN instrument uses 4 buttons to control all functions of the instrument. These buttons are arranged in a directional cursor format. The arrows on the keys (← LEFT, → RIGHT, ↑ UP, ↓ DOWN) correspond to the arrows that are used on the screen. The screen will indicate which button to push by showing the appropriate arrow.

NOTE: The UP key will always bring the instrument back to either the previous menu or the main menu. The UP key will also turn the unit off when the instrument is at the Main Menu.

7.3. Turning On the Instrument

To turn on the ERO•SCAN instrument, press the large DOWN key located below the instrument's display screen. Three small lights (red, yellow and green) will appear briefly just above the display screen. The green ready light will remain on. Figure 6 shown below will quickly appear. This display will indicate the type of instrument, software version, serial number, and operating mode (DP, TE, DP custom or TE custom).

If the batteries have sufficient power, the ERO•SCAN instrument will automatically check the date and time settings. If there are no date/time errors detected, the Main Menu (Figure 7) will appear on the display.

NOTE: If this is the first time the ERO SCAN instrument is being used, or if you wish to change the date or time, see *Setting the Clock* for instructions on setting the correct date and time.



Figure 6



Figure 7
Main Menu

Automatic Shutdown

The ERO•SCAN instrument has an automatic "shutdown" feature, designed to prolong battery life. The unit will automatically shut down after 1 minute (default) of inactivity. To turn it back on, simply press the large DOWN key. This feature can be re-programmed for various periods of inactivity before "shut-down." (See the *Changing Instrument Settings – Auto-Shutdown Time* section for further information on this feature.)

7.4. Testing in the Default Modes for Both DPOAE and TEOAE

For either DPOAEs or TEOAEs there are a default test protocol and a user definable protocol called a "custom" setting. The default protocols will be used unless a custom protocol is selected by the user. See *Changing Instrument Settings - Test Mode*. Appendix E contains information on custom protocols, and the Advanced Options for DPOAE Testing or TEOAEs allow the user to change test protocols.

The settings for testing in the default **DP** protocol are as follows:

Number of Frequencies Tested = 4	Averaging Time = 4 Seconds
Frequency Range = 2 kHz to 5 kHz	Pass SNR (Signal-to-Noise Ratio) = 6 dB
P1 (Intensity of F1 in dB SPL) = 65	Number of Passing Frequencies for Overall Test Pass = 3
P2 (Intensity of F2 in dB SPL) = 55	

The settings for testing in the default **TE** protocol are as follows:

Number of Bands Reported = 6	Averaging Time = 64 Seconds
Frequency Range = 1.5 kHz to 4 kHz	Pass SNR (Signal-to-Noise Ratio) = 4 dB
Click Presentation Level = 83 dB	Number of Passing Frequencies for Overall Test Pass = 3
SPL Peak Equivalent	

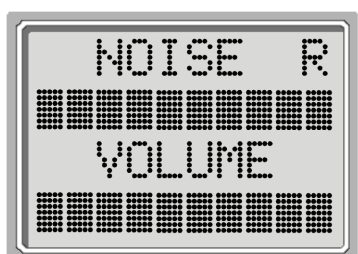


Figure 8

7.4.1 To Begin Testing

To begin testing, place an eartip as far down as possible on the probe tip, turn on the ERO•SCAN instrument by pressing the down button and select either the LEFT or RIGHT arrow key to indicate which ear will be tested. After the test ear is selected, Figure 8 will be shown. This display shows two horizontal bar graphs representing the environmental noise (NOISE) and the ear canal volume (VOLUME).

When both bars fill the screen from left to right, the environmental noise is high and the ear canal volume is large. As the unit is inserted into the ear canal, both horizontal bars should decrease from right to left indicating a decrease in environmental noise and ear canal volume. To obtain a seal and measure emissions, gently insert the eartip into the patient's ear canal. It should fit snugly and comfortably.

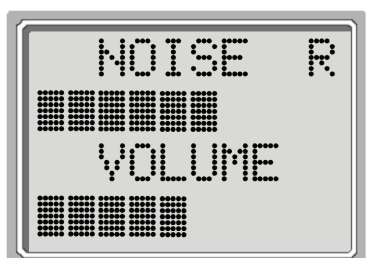


Figure 9

The best test results are obtained when an eartip is inserted deeply into the ear canal instead of flush with the ear canal opening (See Appendix F). The NOISE and VOLUME bar readings should be used as an indication that the unit is sealing the ear canal. If the VOLUME and NOISE bars continue to fill the screen, the unit is not sealing the ear canal, and appropriate adjustments should be made until a decrease in these bars is seen.

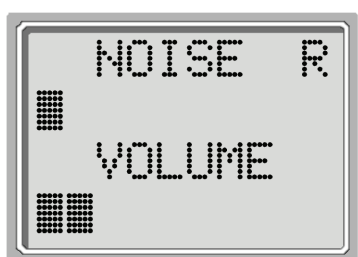


Figure 10

Note that for an adult, the VOLUME bar will decrease to about half (Figure 9), while for a newborn or child, the VOLUME bar will decrease further to the left (Figure 10). The NOISE bar will show a decrease from the original reading. When a seal is obtained, the unit will automatically begin testing (autostart) and the yellow test LED will illuminate throughout the test.

When testing DPOAEs, the default test time is 16 seconds. When testing TEOAEs, the default test time is 64 seconds, however, the test will automatically stop when the pass criteria has been met or exceeded. The arrow key can be used to abort a TEOAE test in progress.

To test children with PE tubes, the autostart needs to be disabled. This is accomplished by first inserting the ERO•SCAN with appropriate ear tip into the ear canal and obtaining a proper seal. To disable autostart at the main menu select the ear to be tested by holding down the RIGHT or LEFT arrow keys for 3 seconds until the green "test" light turns off. Once the key is released, the ERO•SCAN will calibrate and test as before.



Figure 11

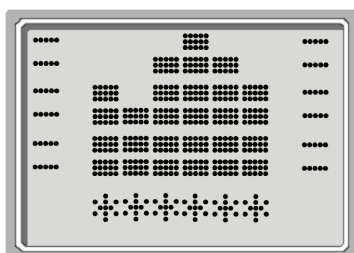


Figure 12

7.4.2 Auto Calibration

The ERO•SCAN instrument will automatically perform a calibration at the start of each test and figure 11 will briefly be shown on the LCD. During calibration a series of tones will be presented to the ear canal to calibrate the levels of the frequencies to be tested. It is very important that the ERO•SCAN unit be held steady in the patient's ear canal while the yellow test LED is illuminated.

Following the automatic calibration of the test tones, a set of bars should appear on the display (figure 12). These are the test results which are displayed as the emissions are measured. Two bars are used to represent the signal-to-noise ratio measured at each of the test frequencies (DPOAEs) or in each of the frequency bands (TEOAEs).

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 graphic display is explained in the *Interpreting Test Results* section on page 25 and 26.

complete. The results will be saved even if the unit turns off or the batteries are temporarily removed. This

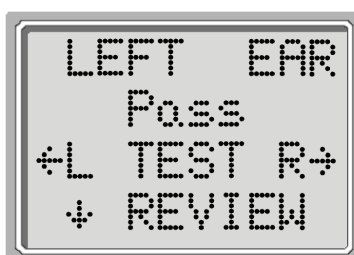


Figure 13

7.4.3 Reviewing Results

When testing is complete, a display similar to figure 13 will appear. The results of the test are automatically saved in memory as soon as the test is complete. This screen again 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. "NOISY" indicates that excessive noise was present during the test. "NO SEAL" indicates that a seal was not maintained throughout the test. "FIT ERR" indicates inadequate probe placement in the ear canal to produce target stimulus intensities. When the test result is "Noisy", "No Seal", or "FIT ERR" the tester should reposition the probe, selecting a different size eartip if necessary, and retest. If the test result is "REFER" the tester can determine from the printout whether the test should be repeated. To review the results, push the DOWN arrow key to return to the bar graphs.

After reviewing the results, again push the DOWN arrow key to return to the Main Menu. Once a new test for that ear is started, the previous results are erased. **By default, the ERO•SCAN instrument will save only the last test for each ear. When testing is completed, the results should be printed before a new patient is tested.** Note, however, that the ERO•SCAN instrument can be configured to store up to 50 tests in the unit for printing at a later time. It is important to keep a record of the test number for each patient if this feature is used. See *Save Mode/Storing Test Results* on page 18 to set up the device to save 50 tests in memory.



7.4.4 Test Technique

As with other otoacoustic emission test instruments, there is a technique to learn when using the ERO•SCAN instrument, especially for newborns and infants. Experience with existing OAE systems suggests that it may take up to 3 months to become completely proficient at screening newborns. When testing a newborn or infant with the ERO•SCAN instrument, 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. Prepare the ERO•SCAN unit by turning on the device, selecting the test ear and eartip. **It is very important to select the eartip and push the arrow key which selects the test ear before placing the ERO•SCAN instrument into the newborn's ear canal. Pushing the button after the eartip is in the ear canal may startle the baby and will cause a noisy test result.** Gently place the probe tip into the infant's ear canal using a cone-shaped or small (green or yellow) mushroom-shaped eartip.

The cone-shaped eartips tend to insert deeper down into the ear canal than the mushroom-shaped eartips. This deeper insertion into the ear canal allows for the measurement of larger emissions due to the reduced ear canal volume. Deeper insertion of the probe tip is desirable, however, it may also waken the newborn and cause them to startle. If this happens, the use of the mushroom-shaped eartips is more desirable. The use of a mushroom-shaped eartip is more effective in testing if the eartip enters the ear canal, rather than sitting flush with the ear canal opening. Warming the eartips prior to insertion also helps to keep the baby calm during testing.



Figure 14

7.4.5 Remote Probe (Optional)

As an alternative to testing with the internal probe of the ERO•SCAN instrument, a remote probe can be purchased as an option. This probe may be preferred by some users for the testing of infants and other difficult to test populations such as individuals with multiple handicaps. The probe allows the user to insert the probe tip into the ear and then wait until the patient is quiet before starting the test.

Installing the Remote Probe

1. Remove the protective cover from the top of the ERO•SCAN using a fingernail or small screwdriver (Figure 14).
2. Turn off the ERO•SCAN and insert the remote probe plug into the socket on the top of the ERO•SCAN (Figure 15). The plug will fit only in one direction. The arrows on the plug should face the display on the ERO•SCAN.



Figure 15

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

3. Turn on the ERO•SCAN. The yellow TEST light on the display will light briefly, indicating the ERO•SCAN has detected the presence of the remote probe. Disconnect and reinsert the connector if the yellow light is not seen.

Note: All testing is done through this probe until it is unplugged. ERO•SCAN settings do not need to be changed in order to use this probe.

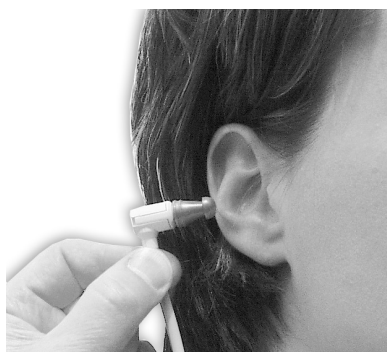


Figure 16

Testing with the Remote Probe

1. The remote probe uses the same disposable eartips as the ERO•SCAN probe. Place the eartip fully onto the probe tip (Figure 16).
2. Never use the probe without an eartip installed. Use the shirt clip on the remote probe box to secure the probe to clothing or bedding.
3. Check the ear canal for cerumen or vernix before inserting the probe.
4. Turn on the ERO•SCAN and select the ear to be tested.*
5. Insert the probe into the ear canal (Figure 17). Lift gently on the outer ear during insertion to straighten the ear canal and ensure proper placement.
6. The AUTO-START function automatically begins the test when the probe is inserted correctly. If the ERO•SCAN does not start the test, reposition the probe.



Figure 17

***NOTE:** When testing infants or young children it is recommended that the probe be placed in the ear before selecting the test ear on the ERO•SCAN. When the child is quiet, select the ear to be tested.



Noise Sources

When the noise level exceeds the noise rejection limit of the instrument, the red ERROR light will appear. The ERROR light will usually appear while testing. The light will appear infrequently if the noise level in the ear canal is low, and it will appear more often if the noise level in the ear canal is high. Otoacoustic emissions are very low-level sounds. Any noise in the ear canal at the time of testing can mask this emission. This noise can come from a variety of sources.

The largest source of noise can come from the patient. This is biological noise, such as movement, coughing, sucking, talking, etc. The patient must be calm and not move or talk. Ambient noise in the testing environment can also be a large source of noise during the test. A properly sealed eartip can block a large amount of this noise, but performing the testing in a relatively quiet environment is recommended. Another source of noise is the tester. The ERO•SCAN instrument has an isolation mechanism that will isolate most of the tester's hand movement and associated noise from the probe, but the tester should hold the instrument as steady as possible.

Printing the Results

It is recommended that the results be printed after each patient. The ERO•SCAN instrument will save the most recent test results for each ear and print only these results in the "Default" mode. This allows the user to retest a patient after a "REFER" result and to print out only the most recent test result for each ear. Turn the printer on by pressing the green button before placing the instrument in the cradle. The test results that are stored will print out automatically. The results of the most recent test from each ear will continue to be stored in memory until another test is completed.

NOTE: The ERO•SCAN instrument automatically prints test results stored in memory each time the instrument is placed in the cradle. If the instrument is set to the "L/R" save mode, only the most recent test result for each ear will be printed. If it is set to the "50" save mode the printer will print all tests stored in the ERO•SCAN memory. For ease of recordkeeping, it is recommended that you print test results after each patient.

The ERO•SCAN instrument can be configured to store up to 50 tests in memory before printing. See the section *Changing Instrument Settings - Save Mode/Storing Test Results* on page 17 for instructions to save more than two tests in memory.



Figure 18

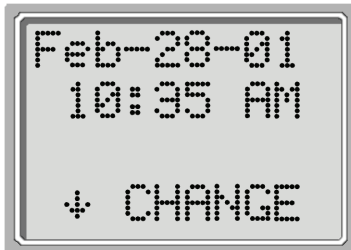


Figure 19



Figure 20

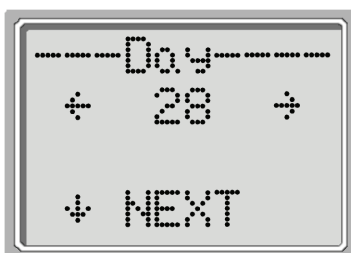


Figure 21



Figure 24



Figure 23



Figure 22

Setting the Clock

When the ERO•SCAN test instrument is first used, the correct date and time will need to be set on its internal clock. The date and time are listed on the test printout as month-day-year (e.g., Feb-28-01). The clock should be set prior to testing, as changing it after tests are saved will not change the date on the printout (i.e., whatever date was previously in memory will be the date on the printout).

Seasonal time changes such as Daylight Savings Time will also require resetting the clock. If the instrument's batteries go dead and are not replaced within approximately one hour, figure 18 as shown on the left may appear. If this message appears, reset the time and date.

To change the time and date press ↓SETUP at the main menu. Figure 19 will show the current date and time presently set in the unit. If the time and date are correct, press the UP key to escape back to the main menu. If either the date or time is incorrect, press the ↓CHANGE key to access the menu to change the month (figure 20). Press the LEFT or RIGHT keys to scroll forward or backward through the months.

You will see the abbreviated name for each month. When the desired month appears on the display, press the DOWN key to enter the day selection screen (figure 21). Pressing the LEFT or RIGHT keys will scroll through the days of the month.

After the correct day is selected, press the DOWN key to enter the year selection (figure 24). Pressing the LEFT or RIGHT keys will scroll through the years. When the correct year is selected, press the DOWN arrow key to enter the hour menu (figure 23). Again use the LEFT or RIGHT arrow keys to set the correct hour. Press the DOWN arrow key to enter the minute menu (figure 22) and use the LEFT or RIGHT arrows to select the correct minute. When the correct minute is selected, pressing the DOWN arrow key will return to the Main Menu.

The time and date changes are automatically saved.

8 Changing Instrument Settings

To Access Menus

The ERO•SCAN instrument allows the user to change many of the instrument's settings or functions. These settings include the Test Mode, Clearing Test Results, Auto-Shutdown Time, Headphone Level, Minimum Amplitude Value, Save Mode, Clock Mode, Language, and Reset to Default Settings. To access the menus to change these functions, press the ↓SETUP key from the Main Menu (figure 7, page 10) to enter the CHANGE menu (figure 19, page 16). At this menu, hold down the ↓CHANGE key for 3 seconds until the Ready light (green LED) turns off. Releasing the ↓key will then access the menus to change the instrument settings.

Test Mode

The Test Mode menu (figure 25) allows the user to change the test protocol. The Test Modes that can be selected include either DP (DPOAE) and DP Custom or TE (TEOAE) and TE Custom. All protocols in the unit come with preset test values (Appendix E) which can also be customized using the Advanced Option menus. Programming these custom protocols is described in the Advanced Options section for DPOAEs on page 20 and for TEOAEs on page 23.

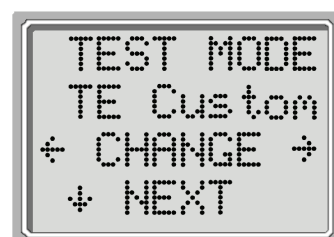


Figure 25

NOTE: Units with both DPOAE and TEOAE capability will allow the user to choose among 4 modes, DP, DP Custom, TE, or TE Custom.

Clearing Test Results

The Test Results Clear menu (figure 26) allows the user to clear the test results stored in the unit without printing them. Select the LEFT or RIGHT arrow key to clear the results and select Yes or No to verify clearing (or not clearing) the results (figure 27).

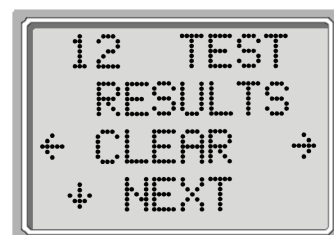


Figure 26

Auto Shutdown Time

The Power Off menu (figure 28) refers to the Auto-Shutdown time which controls how long the ERO•SCAN instrument waits before shutting itself off after a period of inactivity. It is not necessary to manually turn off the ERO•SCAN unit. The Automatic Shutdown feature is designed to prolong the battery life of the instrument when it is not in use. By default, the instrument automatically shuts off after 1 minute has elapsed.

The Auto-Shutdown time may be increased or decreased by pressing the ←CHANGE→ keys. The times available are 30 seconds (0.5 minute), 1, 2, or 4 minutes. Once you have made your selection, press ↓NEXT.

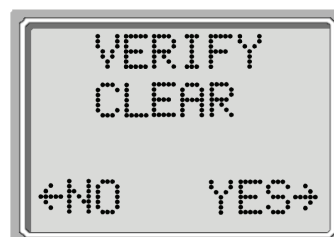


Figure 27

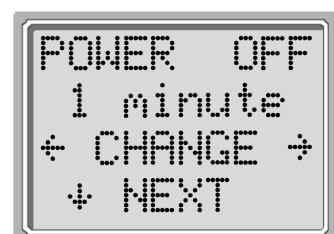


Figure 28



Figure 29

Headphone Level

The Headphone Level menu (figure 29) is next. Using the headphones provided with the ERO•SCAN instrument enables the examiner to listen to the calibration and test tones (DP Instruments only). The headphone plug should be inserted into the jack at the bottom of the ERO•SCAN instrument. The headphones may be used both as a learning tool and for real-time monitoring of the ear canal during the test.

Press the ←CHANGE→ keys to change the volume level for the headphones. The volume level may be set from 1 - 9 with 1 being the lowest volume level and 9 as the highest volume level. The default value is 5 and should be suitable for most situations.

NOTE: Changing the headphone volume will not change the intensity of the test tones that are presented to the patient.

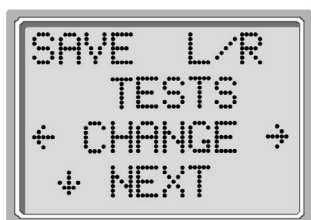


Figure 30

Save Mode/Storing Test Results

The Save Mode menu is shown in figure 30. The ERO•SCAN unit automatically stores only the most recent test result for each ear (L/R). The unit has the capacity to store 50 individual tests. To change the mode to save up to 50 tests, press the LEFT or RIGHT arrow keys to change the menu to 50. It is recommended that you go to the Test Results Clear screen (described on page 17) to clear any previous memory locations after you first select this option. When the ERO•SCAN unit has a full memory (50 saved tests), it will not allow any further testing. At this point either the results must be printed or they must

be cleared from memory. It is important to keep a record of the test number for each patient if this feature is used.

Upon saving test number 45, the red "ERROR" light will come on. At this point, five more tests can be stored. Press ↓CONTINUE to proceed with testing. When 50 tests are saved, select ↓TEST from the Main Menu, the display will ask if you want to clear all 50 results. (NOTE: You may print or download the saved results at this time.) If you choose ↓CLEAR, all 50 tests will be deleted and the test numbers will start again at 1. The ERO•SCAN unit will ask to verify your decision to erase all stored tests. To print, select ↓MAIN MENU, turn on the printer, and set the instrument on its cradle. All stored tests will be printed.

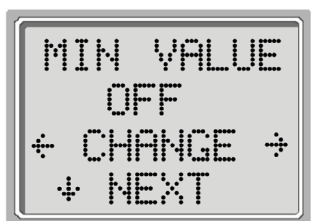


Figure 31

Minimum Amplitude

Select the ↓NEXT key to exit this menu. The Minimum Amplitude screen is displayed. This setting allows the user to set the unit to include minimum amplitude values in the pass/refer criterion. If the MIN VALUE is set to "ON", a result is not considered a pass unless the amplitude at each frequency is equal to or greater than the minimum value programmed into the unit. 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 ERO•SCAN is set

with this feature turned off when it is shipped from the factory.

The minimum DP amplitude is -5 dB SPL.

The minimum TE amplitude is -12 dB SPL.

Clock Mode

Select the ↓NEXT key to enter the Clock Mode (figure 32). This menu allows the user to change the clock from a 12 hour mode to a 24 hour mode. To change the clock mode, press the ←CHANGE→ keys. Press the ↓NEXT to exit this menu.

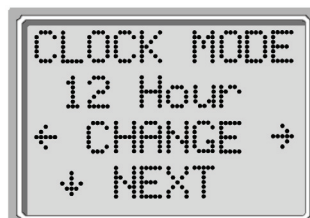


Figure 32

Language

The Language setting allows the user to select among several languages. Language options include English, German, Spanish, and French. To change the language, press the ←CHANGE→ keys until the desired language is shown. Press the ↓NEXT to exit this menu.



Figure 33

Reset to Default

Selecting the LEFT or RIGHT arrow key in the Reset to Default menu (Figure 34) will return the instrument settings to their original factory settings. (NOTE: This does not affect the custom settings.)

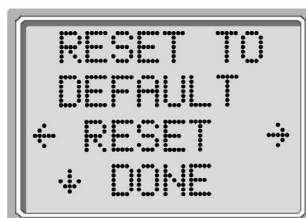


Figure 34

9 Advanced Options for DPOAE Testing

The Advanced Options menus permit modification of the test stimuli and measurement values for the **DP Custom** Protocol. Changes to the protocol should be made only by qualified personnel, usually the administrator. If you are not familiar with the use of these variables, do not attempt to change the protocols. Changes to any of these characteristics may yield test results that differ from those obtained in other test modes.

The ERO•SCAN instrument comes with pre-programmed settings for the **DP** and **DP Custom** protocols. See Appendix E for the manufacturer settings of these protocols. Test protocol changes are saved in the non-volatile memory so the settings will be retained even when changing the batteries.

Instructions for Customizing a Test Protocol

1. Go to the Main Menu. Press the DOWN arrow key once. ↓CHANGE is displayed.
2. **Now hold the DOWN arrow key for 3 seconds** (until the green Ready LED turns off). If you push the DOWN arrow key without holding it for 3 seconds, you will scroll through date and time, etc., rather than accessing the displays that allow you to make changes to the custom protocols.
3. The next display you see is TEST MODE (figure 35). Use the LEFT or RIGHT arrow keys to select **DP Custom**.
4. **Hold the DOWN arrow key again for 3 seconds** (until the green Ready LED turns off). If you do not hold it for 3 seconds, you will see the Test Results Clear screen. Now you will be able to scroll through the other characteristics (Number of Frequencies, Frequency Range, P1 and P2 Levels, Averaging Time, PASS SNR Level and Number of Frequencies for PASS) and make changes desired by using the LEFT or RIGHT arrow keys.

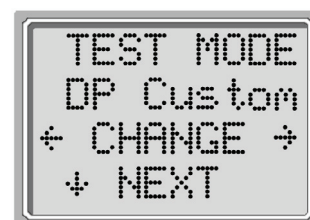


Figure 35

Selecting the Number of Frequencies

The ERO•SCAN can be set to test at either 4 or 6 frequencies. Press the ←CHANGE→ keys to select an option and the ↓NEXT key to exit (figure 36). The ERO•SCAN can also be set to perform a 6 frequency test with an extended high-frequency range by selecting 6-HF while at this menu. When 6-HF has been selected, the test frequencies will be: 2, 4, 6, 8, 10, 12 kHz. See Appendix G for additional information.

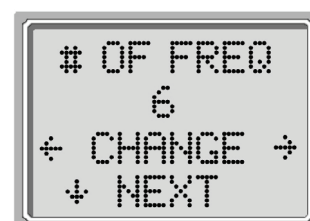


Figure 36

Note: The extended high-frequency range test can only be performed with the remote (external) probe labeled as High-Frequency Compatible. If the remote probe is absent when a high-frequency test is attempted, the following message will appear: HF Remote Probe Only. If this message appears, turn the ERO•SCAN off, install the remote probe, and turn the ERO•SCAN on again.

Selecting the Frequency Range

There are three options for the frequency range to be tested. These options are as follows:

Frequency Range	4-Frequency Test	6-Frequency Test
2.0 to 5.0 kHz	2, 3, 4, 5 kHz	2, 2.5, 3, 3.5, 4, 5 kHz
2.0 to 6.0 kHz	2, 3, 4, 6 kHz	2, 2.5, 3, 4, 5, 6 kHz
1.5 to 6.0 kHz	1.5, 3, 4, 6 kHz	1.5, 2, 3, 4, 5, 6 kHz

Press the ←CHANGE→ keys to select an option and the NEXT key to exit (figure 37).



Figure 37

Note: The extended high-frequency range is selected from figure 36.

Selecting the Level of Primary Tones

The intensity of the primary tones (P1, P2) may be changed to any level between 40 dB SPL and 70 dB SPL. The level P1 will change in 1-dB increments by pushing the LEFT or RIGHT arrow keys (figure 38).

Press the ↓NEXT key to set the level of P2 as with P1 above (figure 38).

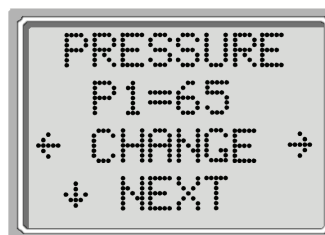


Figure 39

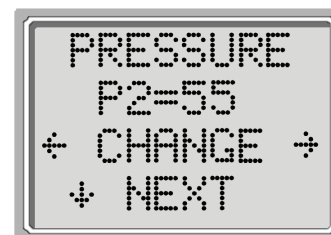


Figure 38

NOTE: When the high-frequency range (6-HF) is selected, P1 and P2 cannot be changed. Figures #38 and #39 will not be accessible.

Setting the Averaging Time

The Averaging Time can be changed to one of four settings. The Averaging Time will have a large impact on the time required to perform the test and on the signal-to-noise ratio (SNR). A 0.5-second average for 6 frequencies would produce a test in about 4 seconds. A 2-second average for 6 frequencies would produce a test in about 14 seconds. The possible settings for the Averaging Time are as follows:

0.5 sec., 1.0 sec., 2.0 sec., 4.0 sec.

Press the ←CHANGE→ keys to select an option and the ↓NEXT key to exit (figure 40).

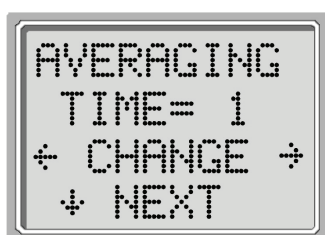


Figure 40

Setting the PASS SNR Level

In order to provide a PASS / REFER determination for each test, the PASS SNR must be set. This number refers to the number of decibels that the DPOAE signal must be above the noise to be considered a PASS at that frequency. The limits for the PASS SNR are 3 dB to 10 dB. Pressing the LEFT or RIGHT arrow keys will increase or decrease the requirement. This requirement is used in combination with the number of frequencies (discussed below) to determine an overall PASS / REFER for each test.

Press the ←CHANGE→ keys to select an option and the ↓NEXT key to exit (figure 41).

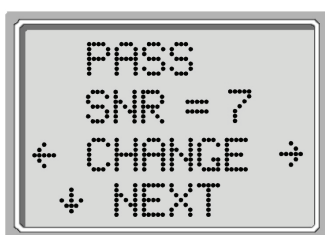


Figure 41

NOTE: A PASS/REFER determination is not provided when the high frequency range is selected. Display #32 will not be accessible.

Setting the Number of Frequencies for PASS

The number of frequencies required for determining a PASS can be set from 0 to 6. If the setting is on 0, then no indication of PASS / REFER will be made. This setting is used in conjunction with the PASS SNR to set the criteria for the overall test PASS / REFER indication. For example, if the PASS SNR is set to 5 dB and the number of frequencies for PASS is set to 3, then the test must contain at least 3 frequencies where the emission is at least 5 dB above the noise to indicate a PASS.

The number of frequencies for PASS should also be based on the number of frequencies being tested. Setting the number of frequencies for PASS to 5 when only 4 frequencies are being tested would result in every test being labeled as a REFER. To disable the PASS / REFER indication set the number of frequencies for pass to 0.

Press the ←CHANGE→ keys to select an option and the ↓NEXT key to exit (figure 42).

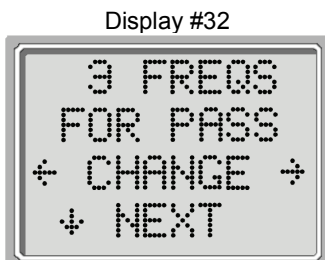


Figure 42

NOTE: When the high-frequency range is selected, figure 42 will not be accessible.

Reset Protocol

Selecting the LEFT or RIGHT arrow key in the Reset Protocol menu (figure 43) will return the selected protocol settings to their original factory settings. (Note: This does not affect the instrument settings or the settings of any other protocol.)

Save Protocol

Once all of the settings have been determined for the custom program, these settings can be saved by selecting the ←SAVE→ keys. This will save the selected settings as the Custom program selected and will be stored in this custom program until new settings are selected and saved (figure 44).

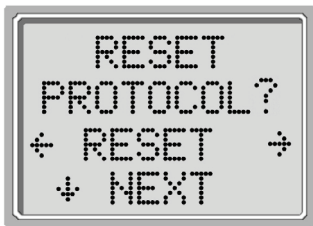


Figure 44



Figure 43

10 Advanced Options for TEOAE Testing

The Advanced Options menus permit modification of the test stimuli and measurement values for the **TE Custom** Protocol. Changes to the protocol should be made only by qualified personnel, usually the administrator. If you are not familiar with the use of these variables, do not attempt to change the protocols. Changes to any of these characteristics may yield test results that differ from those obtained in other test modes.

The ERO•SCAN instrument comes with pre-programmed settings for the **TE** and **TE Custom** protocols. See Appendix E for the manufacturer settings of these protocols. Test protocol changes are saved in the non-volatile memory so the settings will be retained even when changing the batteries.

Instructions for Customizing a Test Protocol

1. Go to the Main Menu. Press the DOWN arrow key once. CHANGE is displayed.
2. **Now hold the DOWN arrow key for 3 seconds** (until the green Ready LED turns off). If you push the DOWN arrow key without holding it for 3 seconds, you will scroll through date and time, etc., rather than accessing the displays that allow you to make changes to the custom protocols.
3. The next display you see is TEST MODE (figure 45). Use the LEFT or RIGHT arrow keys to select TE Custom.
4. **Hold the DOWN arrow key again for 3 seconds** (until the green Ready LED turns off). If you do not hold it for 3 seconds, you will see the Test Results Clear screen. Now you will be able to scroll through the other characteristics (Frequency Range, Averaging Time, PASS SNR Level and Number of Frequencies for PASS) and make changes desired by using the LEFT or RIGHT arrow keys.

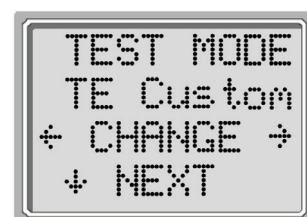


Figure 45

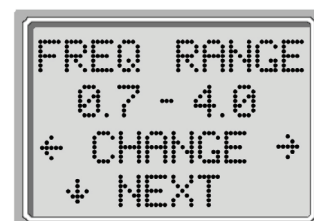


Figure 46

Selecting the Frequency Range

There are two options for the frequency range to be tested. These options are as follows:

Frequency Range	6-Frequency Test
0.7 to 4.0 kHz	0.7, 1.0, 1.4, 2.0, 2.8, 4.0 kHz
1.5 to 4.0 kHz	1.5, 2.0, 2.5, 3.0, 3.5, 4.0 kHz

Press the ←CHANGE→ keys to select an option and the ↓NEXT key to exit (figure 46).

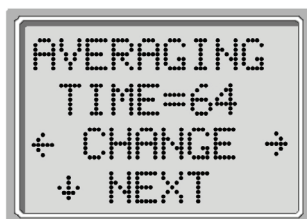


Figure 47

Selecting the Averaging Time

The Averaging Time can be changed to one of four settings. The Averaging Time will have a significant impact on the time required to perform the test and on the signal-to-noise ratio (SNR). A 4-second average would produce a test in about 7 seconds. A 16-second average would produce a test in about 18 seconds. The possible settings for the Averaging Time are as follows:

4, 8, 16, 32 or 64 seconds

The instrument will automatically stop the test when the pass criterion is met prior to the averaging time. Press the ←CHANGE→ keys to select an option and the NEXT key to exit (figure 47).

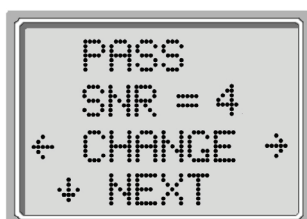


Figure 48

Setting the PASS SNR Level

In order to provide a PASS / REFER determination for each test, the PASS SNR must be set. This number refers to the number of decibels that the TEOAE signal must be above the noise to be considered a PASS at that frequency. The limits for the PASS SNR are 3 dB to 10 dB. Pressing the LEFT or RIGHT arrow keys will increase or decrease the requirement. This requirement is used in combination with the number of frequencies (discussed below) to determine an overall PASS / REFER for each test.

Press the ←CHANGE→ keys to select an option and the NEXT key to exit (figure 48).

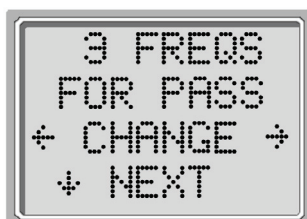


Figure 49

Setting the Number of Frequencies for PASS

The number of frequencies for determining a PASS can be set from 0 to 6. If the setting is on 0, then no indication of PASS / REFER will be made. This setting is used in conjunction with the PASS SNR to set the criteria for the overall test PASS / REFER indication. For example, if the PASS SNR is set to 4 dB and the number of frequencies for PASS is set to 3 then the test must contain at least 3 frequencies where the emission is at least 4 dB above the noise to indicate a PASS.

Press the ←CHANGE→ keys to select an option and the NEXT key to exit (figure 49).

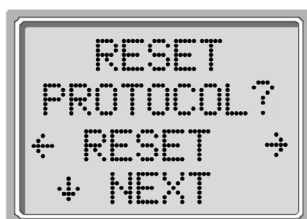


Figure 50

Reset Protocol

Selecting the LEFT or RIGHT arrow key in the Reset Protocol menu (figure 50) will return the selected protocol settings to their original factory settings. (Note: This does not affect the instrument settings or the settings of any other protocol.)

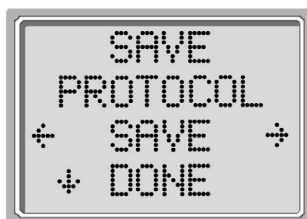


Figure 51

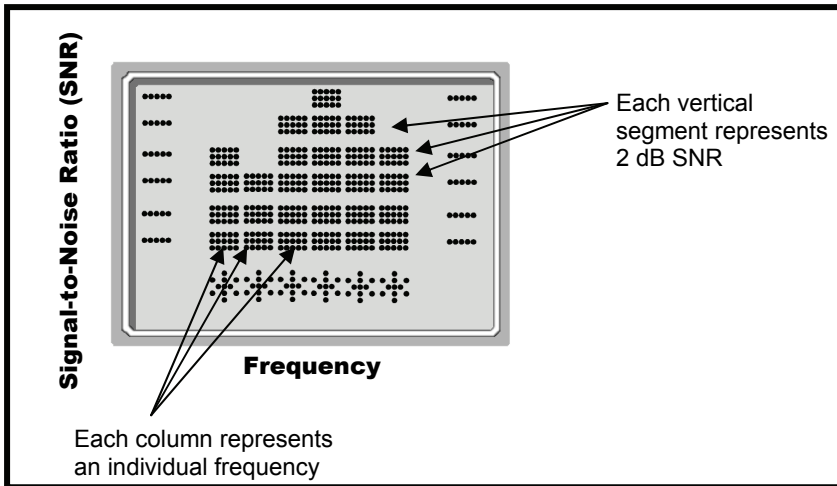
Save Protocol

Once all of the settings have been determined for the custom program, these settings can be saved by selecting the ←SAVE→ keys. This will save the selected settings as the custom program selected and will be stored in this custom program until new settings are selected and saved (figure 51).

11 Interpreting Results

Understanding the Display

The display on the ERO•SCAN 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 might differ depending on the settings used for the test.



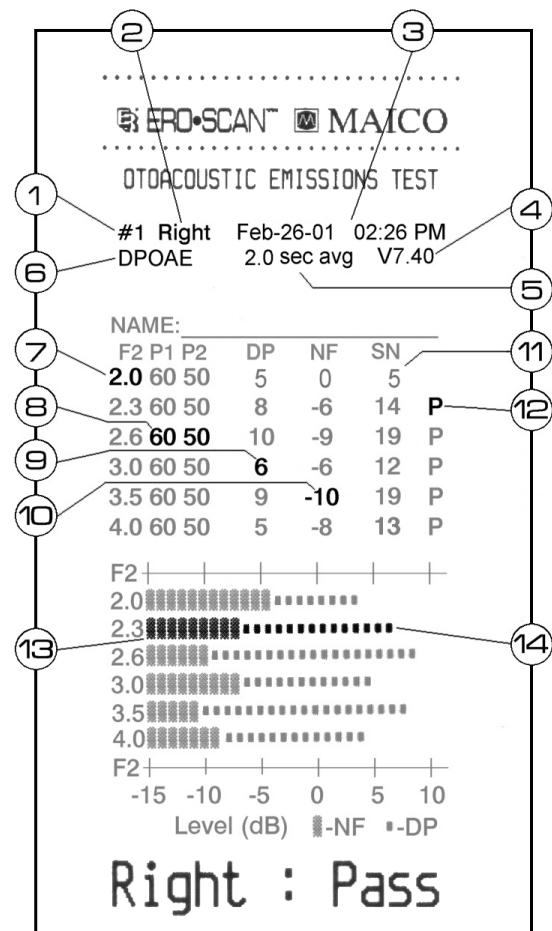
The display shows a 6-column graph. Each frequency (DPOAEs) or frequency band (TEOAEs) is indicated by one column. Either 4 or 6 columns appear depending on how many frequencies are tested. Each row represents 2 dB of signal-to-noise ratio (SNR). For example, if the column goes to the top of the display then the SNR is 12 dB or greater (6 rows of 2 dB each).

The display is shown while the test is being performed. To review the display after the test is finished, press the ↓REVIEW key to look at the display.

Understanding the DPOAE Test Results

Each test will generate its own printout.

1. The test number.
2. The ear selected.
3. The time and date of the test, based on the setting of the internal clock. If the clock is set correctly, this time and date will be correct.
4. The software version number.
5. The averaging time used for this test.
6. The mode selected for this test.
7. The f2 frequency.
8. The pressure levels of f1 and f2 respectively.
9. The level of the emission in dB SPL.
10. The noise floor in dB SPL.
11. The signal-to-noise ratio (DP level minus the noise floor).
12. A "P" indicates that the signal-to-noise ratio for the test was equal to or above the SNR criterion.
13. The thick bars indicate the noise floor in dB SPL.
14. The small bars indicate the emission level in dB SPL.

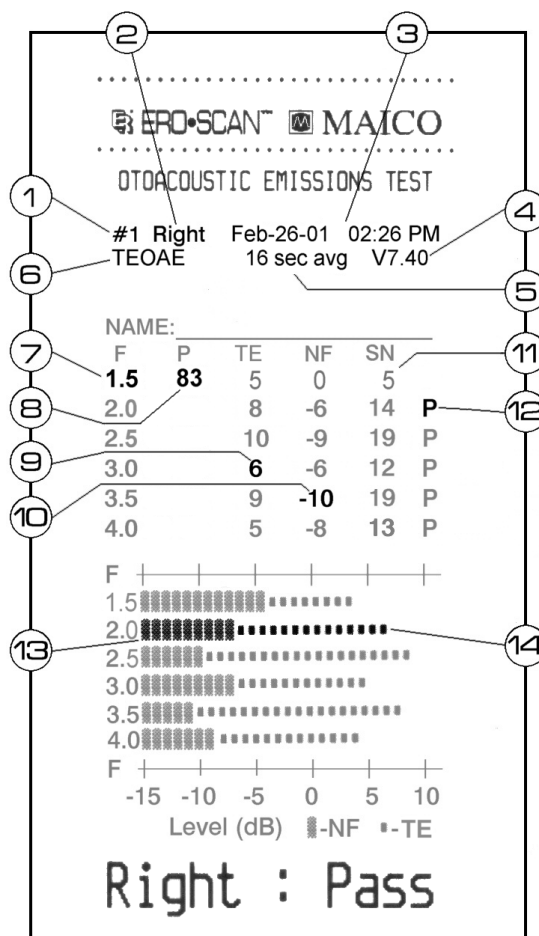




Understanding the TEOAE Test Results

Each test will generate its own printout.

1. The test number.
2. The ear selected.
3. The time and date of the test, based on the setting of the internal clock. If the clock is set correctly, this time and date will be correct.
4. The software version number.
5. The averaging time used for this test.
6. The mode selected for this test.
7. The frequency band.
8. The peak pressure level.
9. The level of the emission in dB SPL.
10. The noise floor in dB SPL.
11. The signal-to-noise ratio (TE level minus the noise floor).
12. A "P" indicates that the signal-to-noise ratio for the test was equal to or above the SNR criterion.
13. The thick bars indicate the noise floor in dB SPL.
14. The small bars indicate the emission level in dB SPL.



A Note about Rounding Results

The user needs to be aware that the SNR and single PASS criterion are calculated from the full internal precision of the instrument, and not from the values shown in the printout for the emission (TE) and noise floor (NF) estimates.

This approach is used to preserve the full precision of the test results, but can result in some apparent errors in the printout due to the effects of rounding. In the printout example above, assume the actual values at 1.5 kHz were TE = 4.5 dB, NF = -0.4 dB, which results in SN = 4.9 dB. The printout values are rounded up to the nearest integer and are shown as TE = 5, NF = 0, and SN = 5. This can result in what appears to be an error with regard to the pass criterion. If the pass criterion is 5 dB while the actual SN = 4.9, the printed value will be 5 but a "P" will NOT be printed (as shown for #11 above).

Again, the pass/refer criterion is based on the full precision of the results, and not the rounded values that are printed. The full precision value for the SN must be equal to or greater than the pass criterion (5 dB in this example) for the "P" to be printed. A similar apparent problem can occur in which the printed SN value appears to be incorrect. If the actual values were TE = 4.5 dB, NF = 0.4 dB, resulting in SN = 4.1 dB, the printed values would be TE = 5 dB, NF = 0, SN = 4. The printed SN value of 4 dB appears to be an error, but is in fact correct.

12 Cleaning and Maintenance

Cleaning 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 keypad. **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.

Maintenance

This instrument requires no regular maintenance beyond routine cleaning and battery replacement. The probe tip requires replacement only when it becomes clogged.

12.1 Probe Tip Replacement

Probe tips are disposable and should be replaced when they become clogged. Four replacement probe tips are included with this instrument. Do not attempt to clean the probe tip. (See the *Replacement Parts* section on page 29 for ordering information.)

To replace the probe tip, squeeze the tabs as shown in the picture Figure 1. The tabs should audibly snap off the probe assembly. Pull the probe tip directly off the probe and discard it.



Figure 1

Obtain a replacement probe tip and orient the tip as shown in the picture Figure 2. The probe tip will only fit on one way; be careful not to force the tip in place. Push the tip directly down onto the probe. Once the probe tip is in place on the probe, push firmly downward on the top of the tabs one at a time until a click is heard. Tug lightly on the probe tip to verify that the tip is securely attached.



Figure 2

Probe Tip Replacement: Remote Probe

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 remote probe until each tab is released (Figure 3a).
2. Slide the probe tip off the front of the probe and discard (Figure 3b).

To replace:

1. Align a replacement tip with the front of the probe (Figure 3c). **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 lightly on the tabs to snap them into place (Figure 3d).

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

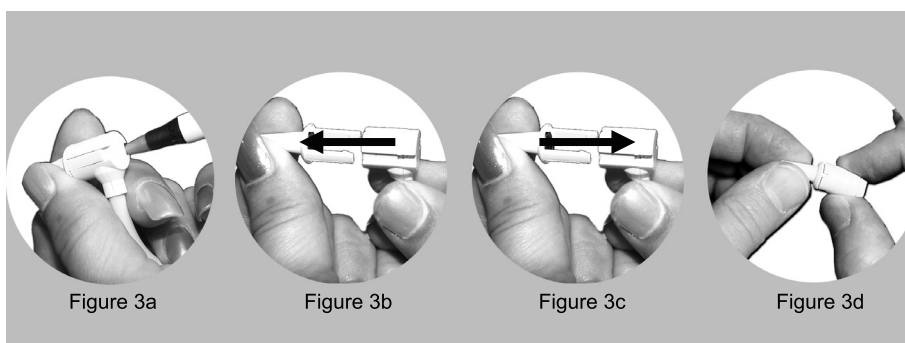


Figure 3a

Figure 3b

Figure 3c

Figure 3d

13 Troubleshooting

1. Problem: Instrument does not turn on.

Solutions:

- The DOWN arrow key must be pressed for a full second.
- Check that the batteries are installed correctly.
- Install new batteries.

2. Problem: The test will not start even though the instrument is in an ear canal.

Solutions:

- Try a different size eartip.
- Verify that the eartip is sealed in the ear canal via feedback from the NOISE and VOLUME bars during AUTO-START.
- Check that the instrument will start when inserted in the calibration cavity.
- Reseat or replace the probe tip.

3. Problem: The printer doesn't print.

Solutions:

- Press the green button on the printer and try again.
- If the printer light doesn't turn on, plug in the printer power supply to charge the battery.
Note: You will have to wait a period of time before printing will occur even when AC power is provided.
- Verify that the printer battery pack is installed correctly.
- If paper comes out of the printer but there is no text on the paper then the paper is in backwards.
Remove the paper and reinstall the paper so that it feeds from the bottom of the roll.
- Check that the printer cable is correctly attached to the cradle and the printer.
- Are there any tests in memory to be printed?

4. Problem: "Printer paper low" message appears on LCD.

Solutions:

- Open printer cover and reposition or replace the paper roll.

14 Replacement Parts

1 Printer paper roll	Part. No. 70 50 77
1 Set (4 Pcs.) Probe tips	Part. No. 70 50 81
1 Set Eartips 3 mm (yellow)	Part. No. 70 50 63
1 Set Eartip 4 mm (red)	Part. No. 70 50 64
1 Set Eartips 5 mm (blue)	Part. No. 70 50 65
1 Set Eartips 6 mm (green)	Part. No. 70 50 66
1 Set Eartips 7 mm (yellow)	Part. No. 70 50 67
1 Set Eartips 8 mm (red)	Part. No. 70 50 68
1 Set Eartips 9 mm (blue)	Part. No. 70 50 89
1 Set Eartips 10 mm (green)	Part. No. 70 50 90
1 Set Eartips 11 mm (yellow)	Part. No. 70 50 91
1 Set Eartips 12 mm (red)	Part. No. 70 50 92
1 Set Eartips 13 mm (blue)	Part. No. 70 50 93
1 Set Eartips 14 mm (green)	Part. No. 70 50 94
1 Set Eartips 15 mm (yellow)	Part. No. 70 50 95
(1 Set Eartips contains 10 pieces)	



11 mm
yellow



12 mm
red



13 mm
blue



14 mm
green



15 mm
yellow



6 mm
green



7 mm
yellow



8 mm
red



9 mm
blue



10 mm
green



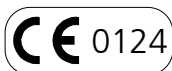
3 mm
yellow



5 mm
blue



15 Technical Data



The MAICO ERO•SCAN is an active, diagnostic medical product according to the class IIa of the EU medical directive 93/42/EEC.

Standards: IEC 601-1

Approvals: US F.D.A 510 (k) #980533 (DPOAE); (k) #010165 (TEOAE)
Environment conditions: + 15 ... +35° C / + 59 ... + 95° F (operation)
+ 5 ... + 50 ° C / + 41 ... + 122° F (storage)
Maximum humidity 90 % (storage and operation)

PROBE SPECIFICATIONS

Measurement Type: Distortion Product Otoacoustic Emissions (DPOAE) and/or Transient Evoked Otoacoustic Emissions (TEOAE)
Frequency Range: 1.5 to 12 kHz (DPOAE) .7 to 4 kHz (TEOAE)
DPOAE Stimulus Intensity Range: 40 to 70 dB SPL - Note: Measurements conducted at 10 and 12 kHz can lead to results with high standard deviation.
TEOAE Stimulus Intensity Range: 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

INSTRUMENT SPECIFICATIONS

Power Supply: (4) AA/UM-3/R6 cells - Alkaline (6 V total)
Battery Life: Approximately 300 tests
Instrument Weight: 10.6 oz. (300 g) including batteries
Dimensions: W x D x H: 21 x 9 x 5 cm

PRINTER SPECIFICATIONS

Type: Thermal dot matrix line printer
Speed: >10 lines per second
Operating Noise: <50 dB SPL
Weight: 1.4 lbs. (630 g) including battery pack
Power Supply: EN60601-1
Input: 100-240 V~, 50-60 Hz, 1.2A
Output: +12 V, 5.0 A
Paper: Calculator-type thermal roll - 2.25" wide

PRINTER with optional rechargeable battery

Power Supply: Ni-Mh rechargeable battery pack
Recharger: Plug-in transformer 12V 400mA/ 230V~50Hz double insulated
Battery Life: Approximately 300 tests

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

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

16 Warranty, Maintenance and Service

The OAE-test system MAICO ERO•SCAN™ is guaranteed for 1 year. 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.



17 Safety Regulations

Electrical Safety



The OAE-Test system MAICO ERO•SCAN™ 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).



Specifications are subject to change



MAICO Diagnostic GmbH

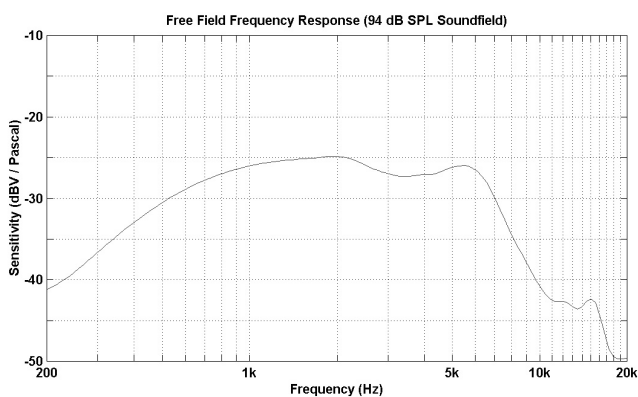
Salzuffer 13/14
D-10587 Berlin
Germany
Tel.: ++49 30 70 71 46 - 20
Fax: ++49 30 70 71 46 - 99

Email: export@maico.biz
Internet: www.maico.biz

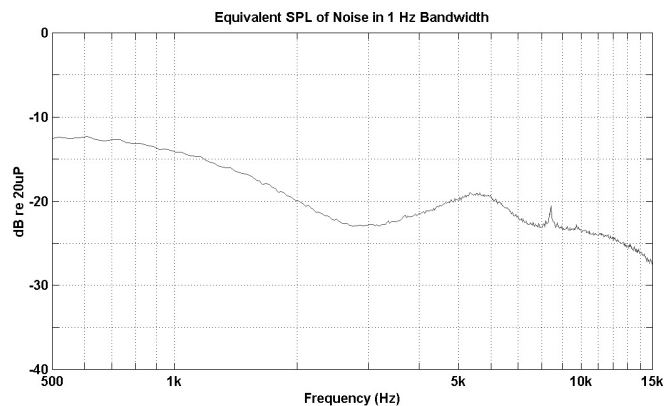


Appendix A

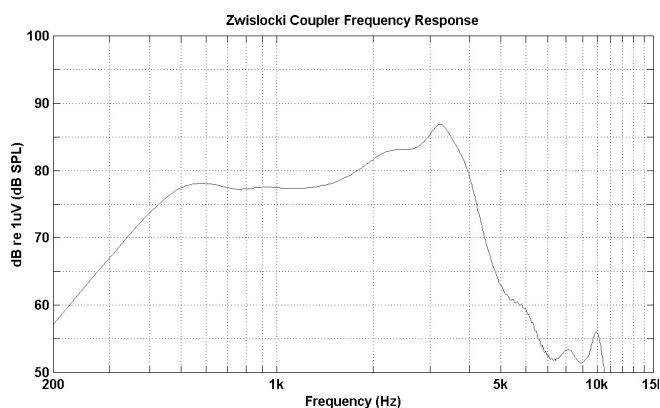
Internal Probe Specifications



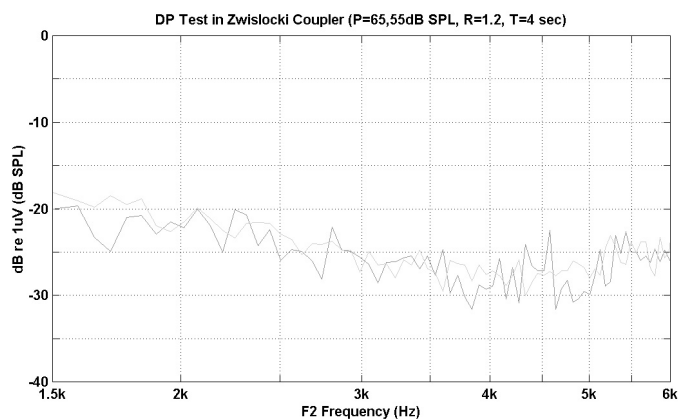
Microphone Frequency Response (Nominal)



System Noise Floor (Nominal)



Sound Source Frequency Response (Nominal)

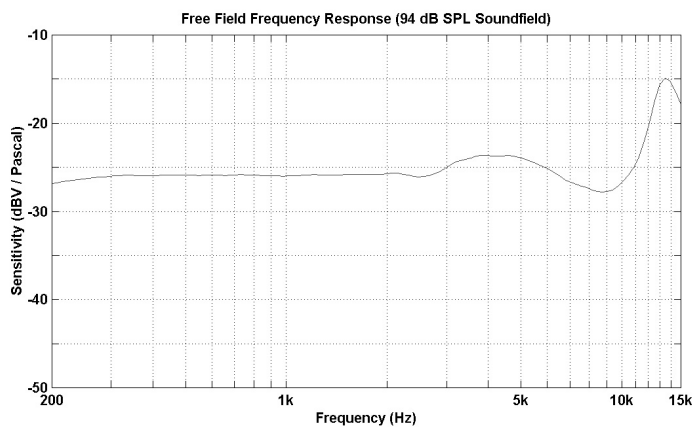


System Distortion + Noise (Nominal)

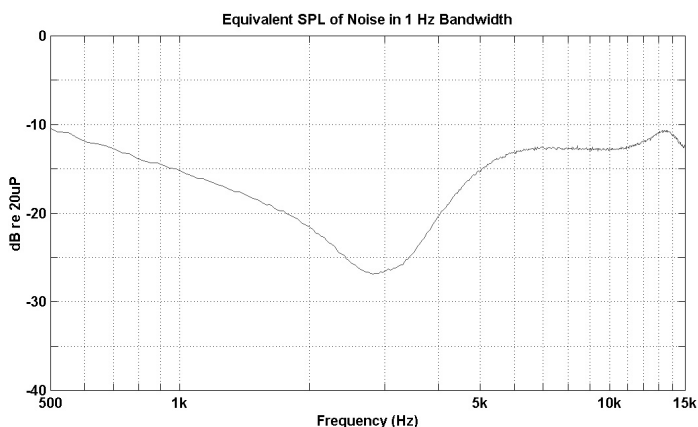


Appendix A

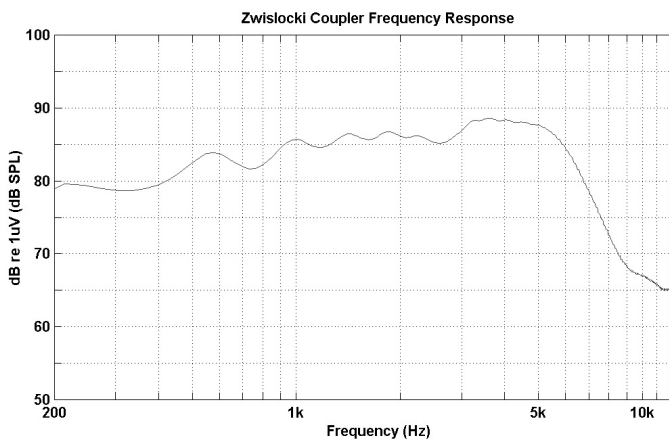
Remote Probe Specifications



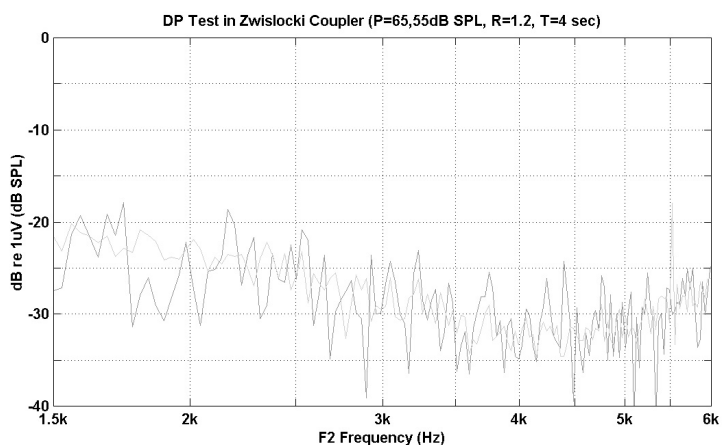
Microphone Frequency Response (Nominal)



System Noise Floor (Nominal)



Sound Source Frequency Response (Nominal)

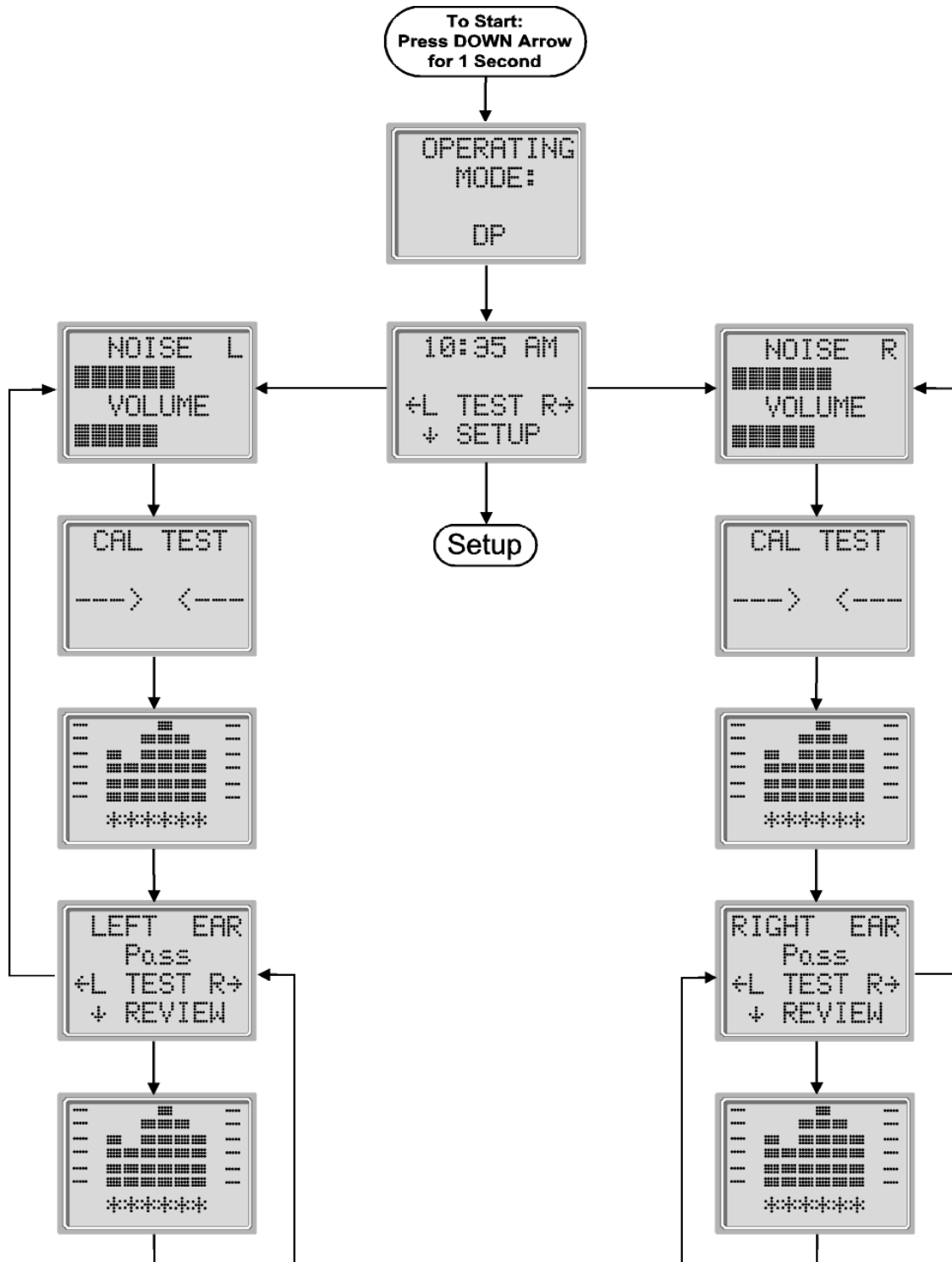


System Distortion + Noise (Nominal)



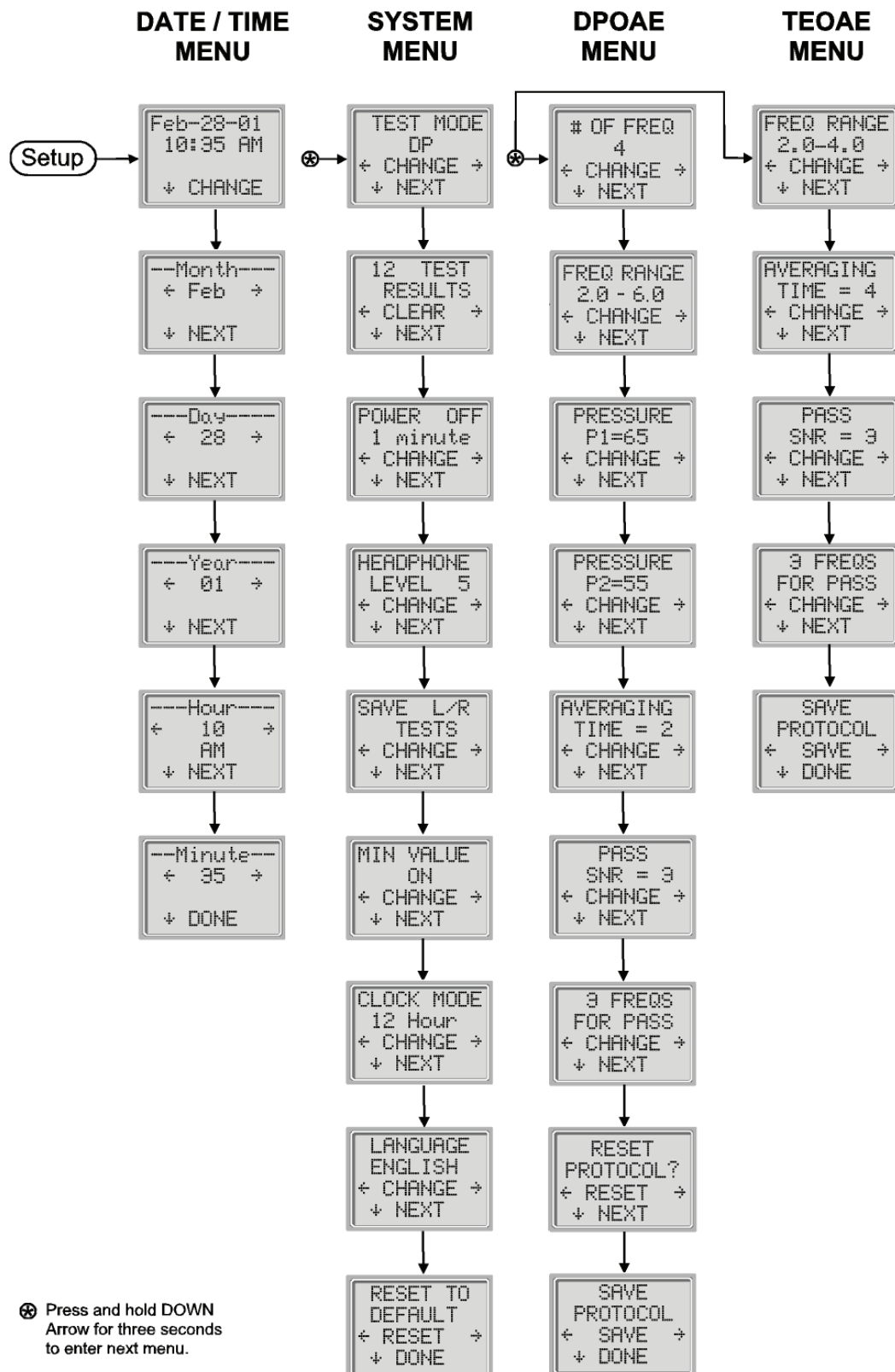
Appendix B

Program Flowchart



Appendix B

Program Flowchart





Appendix C

Test Sequence

A complete test sequence consists of an **autostart**, **calibration** and **test phase**. The **autostart phase** determines when the **calibration 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 phase**.

FOR DPOAE

The **calibration phase** automatically measures the response obtained from a sequence of calibration tones and calculates the voltage needed to obtain the desired pressures. If one or more of the desired pressures cannot be obtained, the instrument terminates operation and displays an error message. A successful calibration leads to the actual test phase.

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.

FOR 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.

Comment About Variations in the SNR Estimate

The user needs to be aware that the SNR estimate has an inherent statistical variation due to the effects of random noise, especially when no emission is actually present. If a test is performed with the instrument's probe placed in a test cavity, it can be shown theoretically that the SNR will be greater than 6 dB approximately 7 times out of 100. This is not a limitation of the instrument, but a fundamental property of the method used to estimate the SNR in all emission testing. In order to reduce the occurrence of this "false" emission, the instrument limits the minimum value of NF, which has the effect of reducing the SNR for tests that have a low noise floor. As the noise level of the test increases, the user will notice that more "false" emissions will appear, which is to be expected.



Appendix D

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.

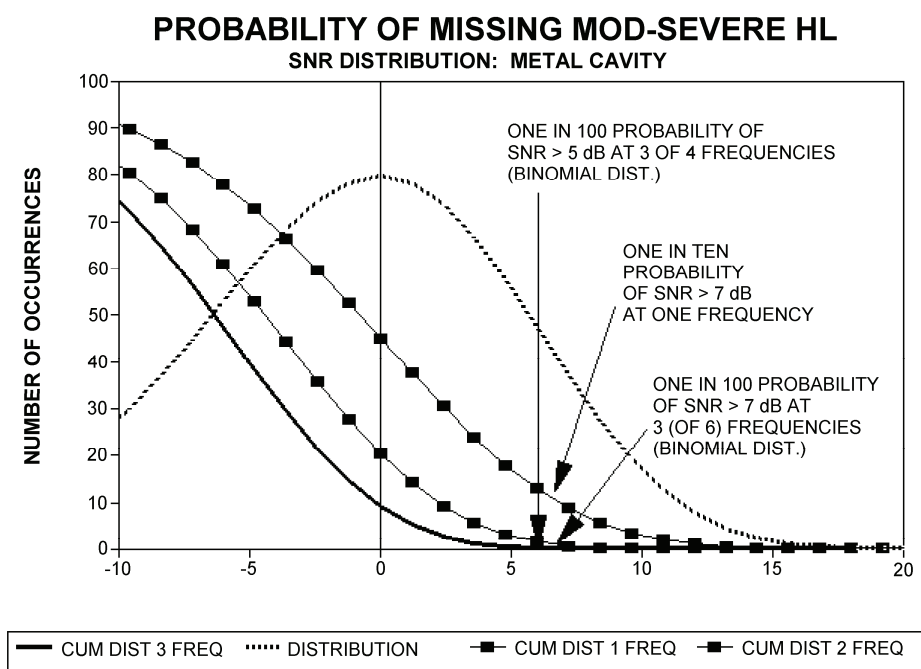
Extended measurements of the noise distributions in both the DPOAE filter channel “DP level” and the rms average of the 4 adjacent channels “N level” indicate that the signal-to-noise ratio (the difference between DP and N) has a standard deviation of 5.5 dB. As shown in the figure below, this implies 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 significant hearing loss to 1% or less. Note: By the binomial distribution, two of three frequencies at >8.4 dB or three of six frequencies at >7 dB should also ensure less than 1% probability of passing a moderately-severe hearing-impaired infant.

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.

Note: The easiest way to obtain a PASS is to a) make sure the eartip is fully seated on the probe tip and b) make sure the eartip is as deeply seated in the ear canal as possible. (See Appendix F.)

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.





Appendix D

Pass/Refer Criteria for TEOAE

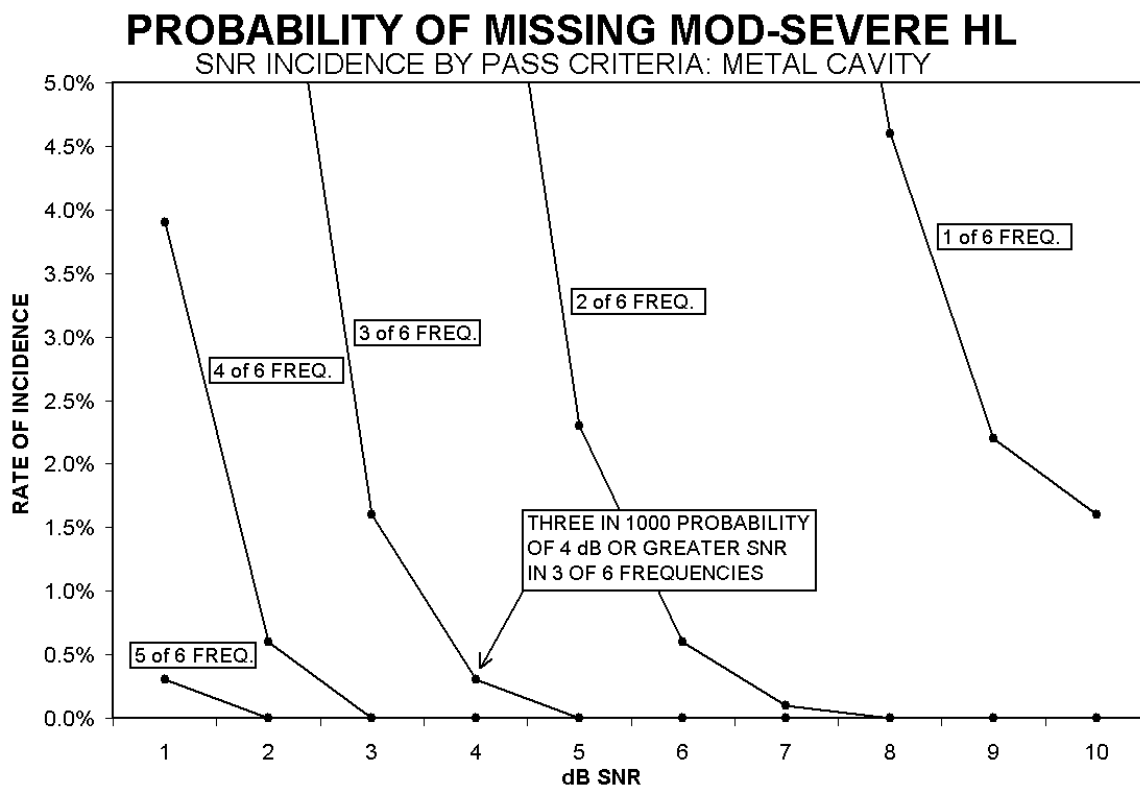
The same basic principles that underlie DPOAE Pass/Fail criteria underlie TEOAE Pass/Fail criteria. In the case of transients, requiring SNR of 4 dB at any three out of the six test frequencies drops the probability of passing an ear with a significant hearing loss to less than 1%.

Note: 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.

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."





Appendix E

Preset Test Protocols

DP

Number of Frequencies Tested = 4
Frequency Range = 2 kHz to 5 kHz
P1 (Intensity of F1 in dB SPL) = 65
P2 (Intensity of F2 in dB SPL) = 55
Averaging Time = 4 seconds per frequency
Pass SNR (Signal-to-Noise Ratio) = 6 dB
Number of Passing Frequencies for Overall Test Pass = 3

DP CUSTOM

Number of Frequencies Tested = 4
Frequency Range = 2 kHz to 5 kHz
P1 (Intensity of F1 in dB SPL) = 65
P2 (Intensity of F2 in dB SPL) = 55
Averaging Time = 2 seconds
Pass SNR (Signal-to-Noise Ratio) = 6 dB
Number of Passing Frequencies for Overall Test Pass = 3

TE

Number of Frequencies Tested = 6
Frequency Range = 1.5 kHz to 4 kHz
Averaging Time = 64 seconds
Pass SNR (Signal-to-Noise Ratio) = 4 dB
Number of Passing Frequencies for Overall Test Pass = 3

TEOAE CUSTOM

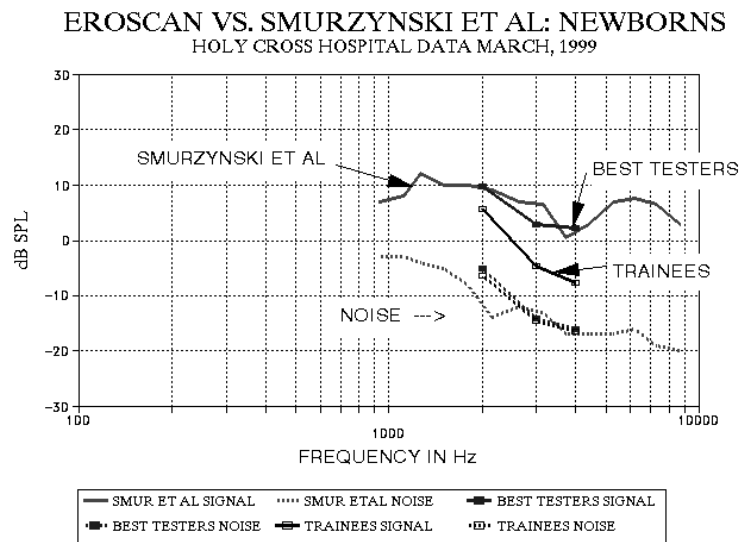
Number of Frequencies Tested = 6
Frequency Range = 700 Hz to 4 kHz
Averaging Time = 64 Seconds
Pass SNR (Signal-to-Noise Ratio) = 4 dB
Number of Passing Frequencies for Overall Test Pass = 3

Appendix F

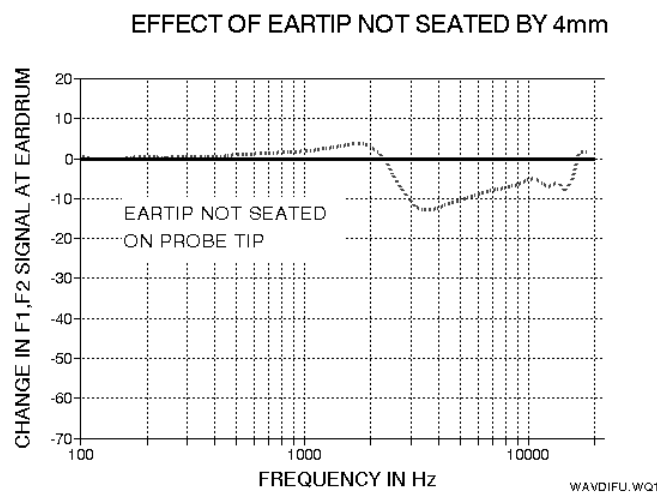
Testing at 4 kHz

Emission levels at 4 kHz are usually stronger than those at 2 and 3 kHz, so 4 kHz should be the easiest frequency at which to obtain a PASS result. Two things can reverse the score: a) a shallow eartip placement in the ear, and b) an eartip that is not fully seated on the probe tip.

Figure 1 illustrates measurements made on newborns at Childrens National Medical Center, Washington, D.C. several years ago (courtesy of Gil Herer). The signal-to-noise ratio at 4 kHz is better than at lower frequencies for the best testers, but the new trainees had trouble obtaining a pass.



Probe microphone data show that an eartip improperly seated on the probe tip can reduce the f1 and f2 signal SPLs at the eardrum by 10-12 dB, producing perhaps a 5-dB reduction in the DP level (Figure 2). Similarly, a shallow placement of the eartip in the ear canal reduces both the f1 and f2 level, and directly reduces the measured SPL of the distortion product.



With practice, most testers learn to fully seat the eartip on the probe tip and to obtain a deep seal in the ear under test.

Appendix G

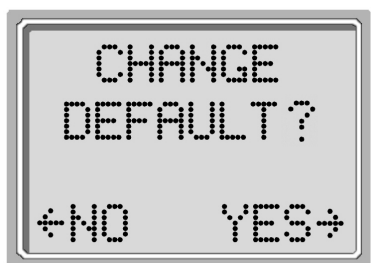
Customizing the Default DP and TE Test Protocols

The DP and TE protocols of the Standard and Combo devices can be customized by the user.

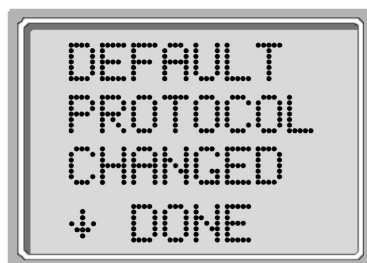
Follow instructions of Customizing a Test Protocol found on page 20 (DPOAE) or page 23 (TEOAE).

At the display showing, "SAVE PROTOCOL" hold the DOWN arrow key for 3 seconds (until the green Ready LED turns off). If you push the DOWN arrow key without holding it for 3 seconds, you will see a display indicating "CANNOT CHANGE DEFAULT" and any changes made to the protocol will be lost.

Following the long DOWN arrow press a display showing, "CHANGE DEFAULT?" will be seen (display #43). Select NO to return to the Main display without making changes to the default protocol. Select YES to save changes (a message will appear to confirm that changes were saved (display #44).



Display #43



Display #44

Once the default protocol has been changed from the factory default, the name of the protocol will appear as "DP*" or "TE*" on the ERO•SCAN display and on the printout.

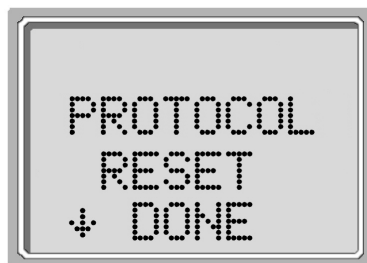
Resetting the Default DP and TE Test Protocols

Selecting the LEFT or RIGHT arrow key in the Reset Protocol menu (display #45) will return the selected protocol settings to their original factory settings.

Note: This does not affect the instrument settings or the settings of any other protocol.



Display #45



Display #46

Once a RESET has been performed the name of the protocols will return to DP and TE.



Appendix H

High Frequency DPOAE Measurements

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

The results in Figures 1 and 2 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, and no response above 8 or 10 kHz in older adults.

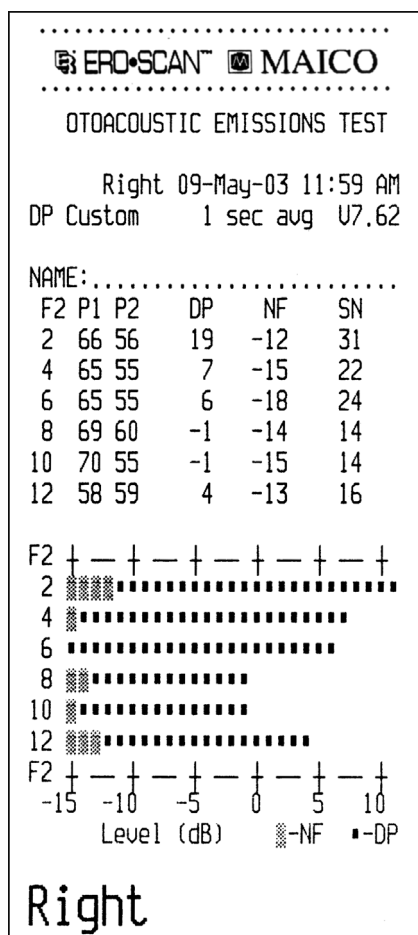


Figure 1

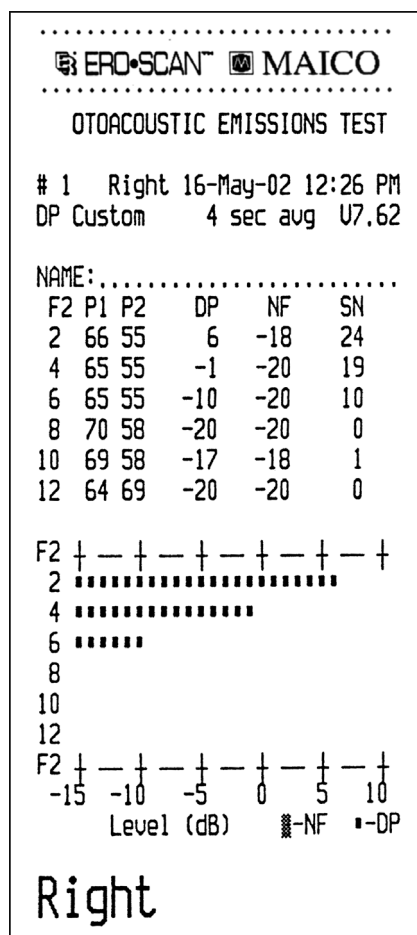


Figure 2

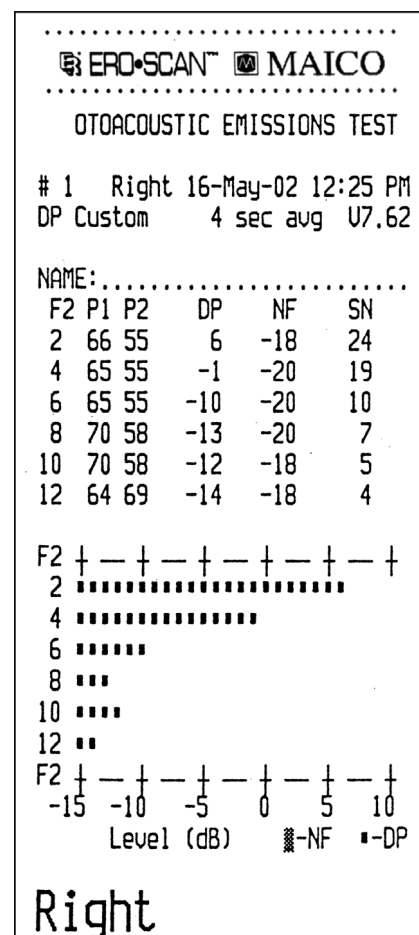


Figure 3

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



Appendix H

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).

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

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

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

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

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

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

Table 1

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



Appendix H

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

- a) a low-frequency probe measurement of ear canal SPL (to adjust for individual ear canal volume differences) and
- b) a previously determined receiver-to-average-eardrum calibration.

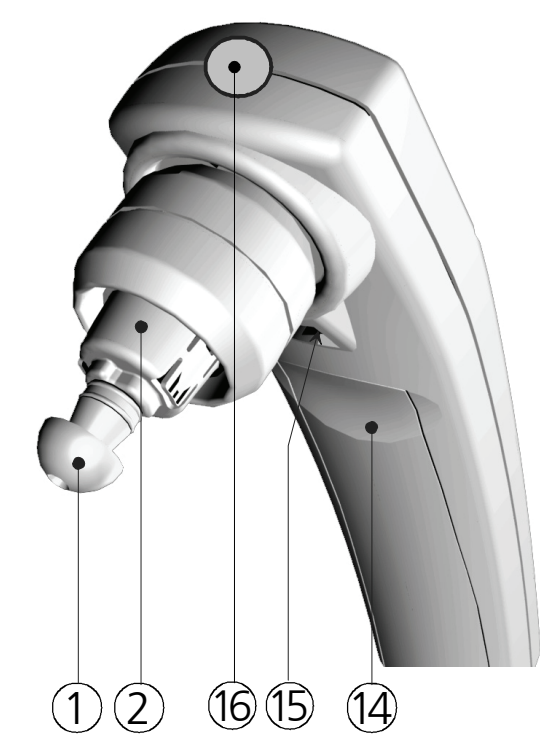
The ERO•SCAN follows Siegel's recommendations, additionally imposing an upper limit of 70 dB SPL measured at the microphone of the probe in order to minimize spurious distortion products. The P1 and P2 SPL values printed by the ERO•SCAN unit are those measured by the microphone in the probe in order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

A Reminder about Technique Instructions for Averaging Results

As discussed in Appendix F, at 4 kHz and above a fully seated eartip and a deeply sealed eartip are crucial to obtaining good emissions. This is especially important at high frequencies.

MAICO ERO•SCAN™ Hand-held unit

- ① Eartip
- ② Probetip
- ③ Control and display area
- ④ Housing
- ⑤ Error-LED (red)
- ⑥ Test-LED (yellow)
- ⑦ Ready-LED (green)
- ⑧ Graphical LCD-display
- ⑨ Left button
- ⑩ Down button
- ⑪ Up button
- ⑫ Right button
- ⑬ Monitor phone connector
- ⑭ Drawer battery compartment
- ⑮ Contacts for data transfer
- ⑯ Plug for external probe

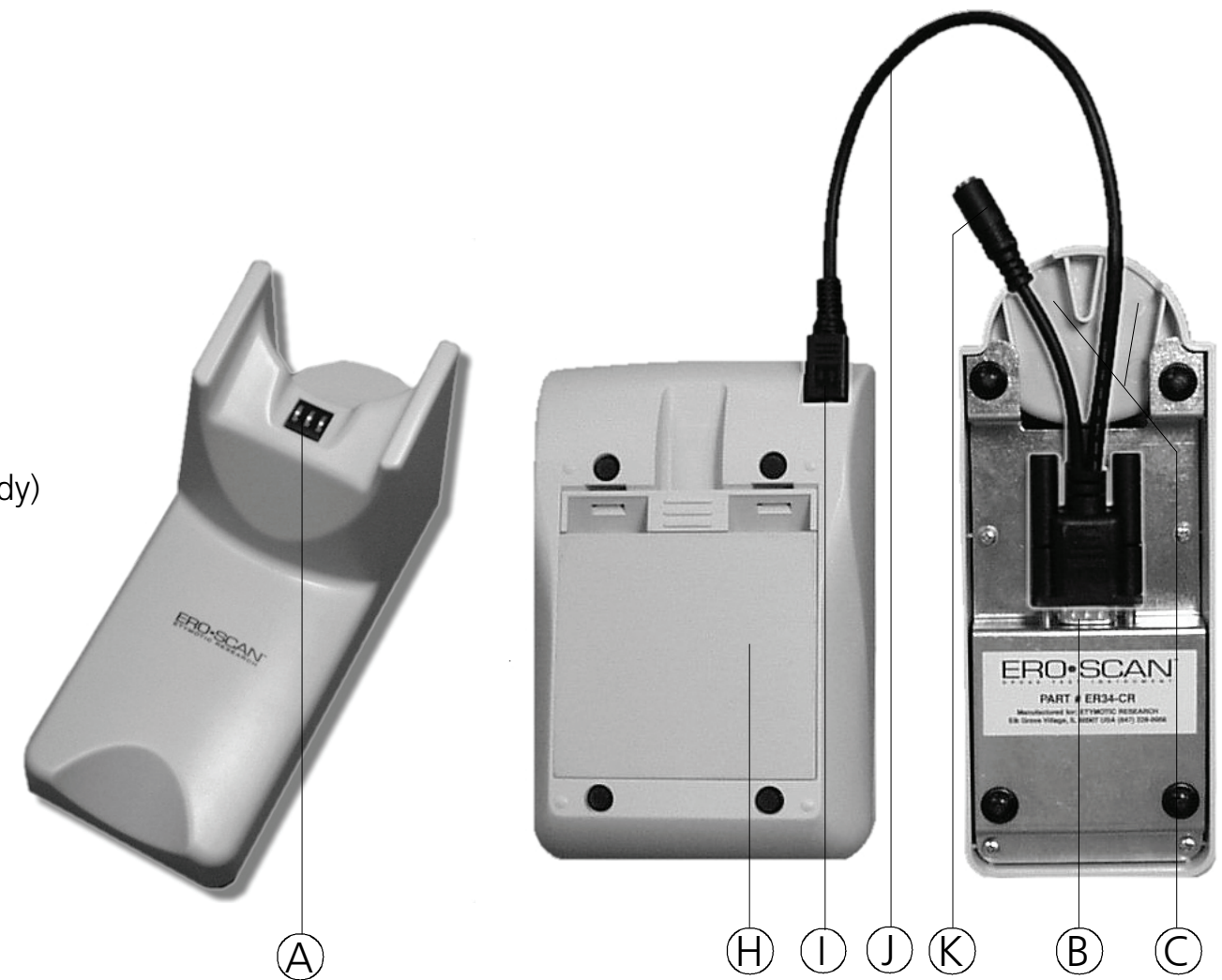


MAICO ERO•SCAN™ External probe

- ⑰ Connector to hand-held unit
- ⑱ Housing
- ⑲ Probe tube
- ⑳ Probetip
- ㉑ Eartip

MAICO ERO•SCAN™ Cradle

- Ⓐ Contacts for data transfer
- Ⓑ Connector for data transfer to printer or PC
- Ⓒ Slots for cables



MAICO ERO•SCAN™ Printer

- Ⓓ Printout paper
- Ⓔ Indicator LED (LED orange = charging; LED green = ready)
- Ⓕ Power on button
- Ⓖ Cover
- Ⓗ Power supply or optional rechargeable battery pack
- Ⓘ Connector



MAICO ERO•SCAN™ Printer cable

- Ⓧ Printer cable
- Ⓨ Cable connector for external power supply (only with battery option)

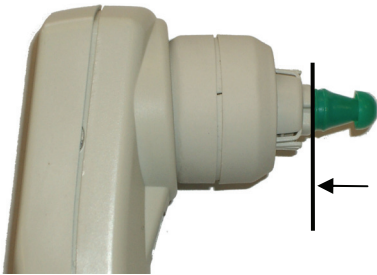


MAICO ERO•SCAN™

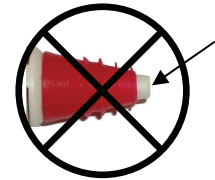
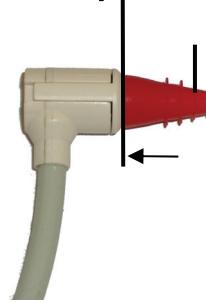
First steps with the OAE-measuring system

1. Preparation of the measurement

The ERO•SCAN offers 2 measurement possibilities:
Probe at the instrument (for children and adults):



External probe (for babies)



Wrong!

Before each measurement the probe tip must be checked for occlusion.
(See point 6. Possible sources of errors)

- Select suitable ear tip corresponding to age of the patient and size of the ear canal
- Recommendation for babies: red ear tip (4mm)
- Push the ear tip through slightly turning on the probe tip until limit stop. The ear tip should **exceed the probe tip for approx. 1 mm**, the probe tip must not stand out of the ear tip, it must be covered.

2. Preparation of the patient

Children and adults:

The room should be quiet. Please do not talk during the measurement.

Babies:

Ideally the baby should sleep respectively it should be very calm and not hungry.
Check the ear canal for occlusion. Danger of blocking the probe!

3. Insert probe into the ear canal

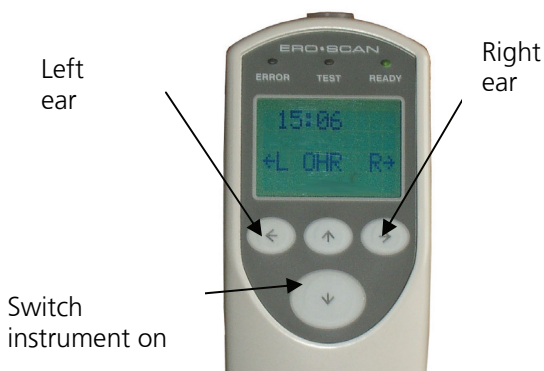
Children and adults:

- Switch the instrument on (see point 4).
- Through slightly pulling the auricle get easy access to the ear canal and push the probe into the canal as far as possible. Slight rotation movement of the instrument eases the insertion. After that do not move the instrument any more.

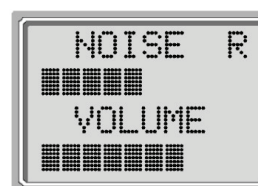
Babies:

- Through slightly pulling the auricle get easy access to the ear canal and push the probe into the canal as far as possible. Slight rotation movement of the instrument eases the insertion. If necessary keep holding the external probe to avoid that it slips out.

4. Start of the measurement



- Switch ERO•SCAN on
- Select ear

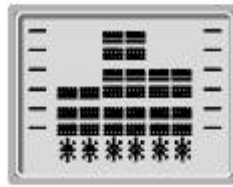


Automatic calibration:

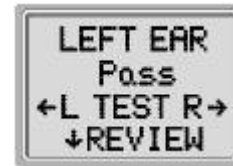
Two bars indicate the background noise and the rest volume in the ear (correct fit of the probe). The automatic calibration is only carried out, if the values are in the tolerance range (ideally: centre of the display).



Start of the measurement



Measurement in operation



Result: Pass or refer

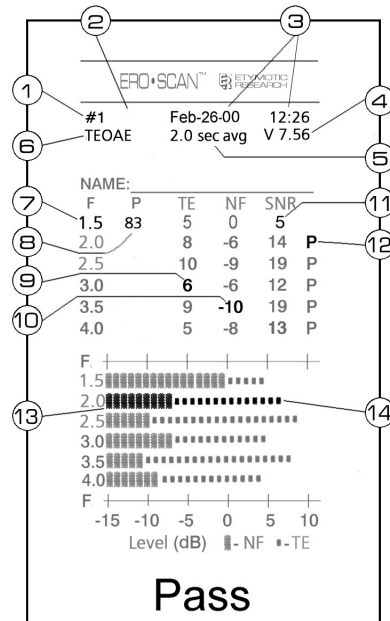
The measurement is stored automatically. The measurement for the other ear can now be carried out as described.

5. Print the result

- Put the ERO•SCAN onto the cradle
- Switch the printer on (green push-button)
- Print starts automatically

- 1 Number of test (up to 50 tests can be stored)
- 2 right ear / left ear
- 3 Time / date of the test
- 4 Software version
- 5 Averaging time
- 6 Test program (TEOAE or DPOAE)
- 7 Frequency range
- 8 Sound pressure level / dB_{SPL}
- 9 Emission level (OAE) / dB_{SPL}
- 10 Background noise / dB_{SPL}
- 11 Signal/noise ratio dB_{SPL}
- 12 P = Pass for individual frequency
- 13 Background noise (thick bar)
- 14 Emission level (OAE)

Data transmission to PC see user manual.



6. Possible sources of error



Measurement does not start Occluded probe tips can block a measurement.

- Removal of the probe tip see user manual
- Check: Are all three openings free of occlusion?
- Exchange the probe tip with new probe tip
- Do not use pointed objects for mechanical cleaning of the probe tip!

On patients with PE-tube or perforation of the ear drum the measurement does not start.
→ see user manual

Error message: „no seal“

- Is the probe positioned correctly? → Insert probe again.
- Is the ear tip chosen correctly? The ear tip must seal the ear canal completely.
- Check the size of the ear tip, change ear tip.

Error message: „too noisy“

- The ear tip must seal the ear canal to protect the measurement against background noise.
- Reduce background noise.
- Insert the probe again.
- Change ear tip



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