



Operating Instructions ERO•SCAN™





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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. ⑤) 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 (DPOAE and TEOAE) Test Instrument is designed to 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 MAICO ERO•SCAN™ instrument probe tip must not be inserted into any ear at any time without a disposable eartip properly affixed.

Precautions

- READ THIS ENTIRE MANUAL BEFORE ATTEMPTING TO USE THIS UNIT.
- 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 disposable alkaline 1.5V AA batteries only. 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 expose this instrument or its accessories to temperatures below 40°F (4°C) or above 100°F (38°C), or to relative humidity of more than 75%.
- Do not attempt to open or service the instrument. Return the instrument to the manufacturer for all service. Opening the instrument



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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 parameters 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 passing 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.

Printer Rechargeable Battery Precautions



- Do Not Attempt to Open the Battery Pack! The printer battery pack contains Nickel-Cadmium 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.



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- Disconnect the printer power supply before removing or replacing the battery pack.



- Observe local regulations for handling, transport, and disposal of Nickel-Cadmium cells. Regulations in many areas prohibit the disposal of Nickel-Cadmium cells. Complete battery packs may be returned at the user's risk and expense to the manufacturer for ecological recycling.

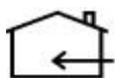
- The battery pack must be charged for a minimum of five hours before using the printer for the first time. Failure to fully charge the battery pack before use may reduce the lifetime of the battery pack.

Printer Power Supply Precautions

READ THIS SECTION CAREFULLY BEFORE USE!



- The printer power supply converts main voltage (230V~) to a safe low voltage (12V DC) for charging the printer battery pack. Use only the power supply supplied for this purpose.



- This product is for indoor use only. Do not expose to water or excessive dust.

- Do not cover the power supply body as it may result in excessive heating. The power supply 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.



3 Description

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.



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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.

3.1 Description of Otoacoustic Emissions

3.1.1 What Are DPOAEs?

Distortion product otoacoustic emissions 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 $2 f_1 - f_2$.

3.1.2 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.

3.1.3 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 re-screened and/or referred for additional audiological testing.

3.1.4 How Does the MAICO ERO•SCAN™ Device Measure DPOAEs?

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

3.1.5 How Does the MAICO ERO•SCAN™ Device Measure TEOAEs?

The MAICO ERO•SCAN™ instrument generates a series of clicks, directs them into the ear canal, and then analyses the spectrum of the returning signal, separating the noise and emission. By using bandpass filters, the MAICO ERO•SCAN™ device provides an estimate of outer hair cell



function over a wide range of frequencies.

3.2 How Does the MAICO ERO•SCAN™ Device Work?

The digital signal processor in the instrument generates two pure tones (f_1 and f_2) 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 average 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 **MAICO ERO•SCAN™** instrument.

3.2.1 What Frequency Range of Hearing is Estimated?

DPOAEs: Roughly 1 kHz to 6 kHz. 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 Getting started

4.1 Unpacking your instrument

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 **MAICO ERO SCAN™** Hand-held Unit.....



- 1 Cradle.....



- 1 Printer.....



- 1 Printer Power Supply.....



- 1 Printer Cable.....





- 1 Headphones.....
- 1 Kit with 156 Eartips (12 sizes).....
- 4 Probe Tips.....
- 4 AA/UM-3/R6 Alkaline batteries (already installed in instrument)
- 1 Thermal printer paper roll (already installed in printer)
- 1 Operating instruction manual

4.2 Connecting 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 two cables into the slots ③ provided on the bottom of the cradle.
- Return the cradle to right side up (Figure 2).
- The long end of the cable ① should be plugged firmly into the inlet at the rear of the printer ①. 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 short end ③ of the cable ① into the printer power supply. Plug the power supply cord into an electrical outlet. The printer indicator light ④ (located on the front of the printer) will shine a steady orange. This indicator will turn to green once the battery pack is sufficiently charged and if paper is installed. The printer must be



Figure 1
Installation printer cable



Figure 2
Connector power supply



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charged for 5 hours prior to use. See the precautions for the printer power supply at chapter 2.

NOTE: The printer runs on a Ni-Cad 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.

4.3 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.

4.4 Quick start

These steps will allow you to quickly start using the **MAICO ERO•SCAN™** 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.

- Place an eartip as far down as possible on the probe tip.
- Turn on the **MAICO ERO•SCAN™** instrument by pressing the large ? down arrow button ⑩.
- 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



Figure 3 Eartips



Figure 4 Keys



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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.
- 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 5 Testing



Figure 6
Printout of test result



4.5 Installing the optional external probe

- Remove the protective cover of the external probe plug ⑯ at the top of the **MAICO ERO•SCAN™** using a tool or the fingernail (see figure 7).
- Turn off the **MAICO ERO•SCAN™** and put the external probe connector ⑰ into the plug ⑯ on the top of the **MAICO ERO•SCAN™** (figure 8). The connector ⑰ will fit only in one direction. The arrows on the connector ⑰ should face the display ⑧ on the **MAICO ERO•SCAN™**.
- Turn on the **MAICO ERO•SCAN™**. The yellow TEST light ⑥ on the display will light shortly, indicating the **MAICO ERO•SCAN™** has detected the presence of the external probe. Disconnect and reinsert the connector ⑰ if the yellow light ⑥ is not seen.



Figure 7
Removal of Cover



Figure 8
Connection of
External Probe

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

4.6 Testing with the optional external probe

- The external probe uses the same disposable eartips as the **MAICO ERO•SCAN™** probe. Place the eartip ⑳ fully onto the probe tip ㉑ (see Figure 9).
- Never use the probe without an eartip installed. Use the shirt clip on the external probe housing ㉒ to secure the probe to clothing or bedding.
- Check the ear canal for cerumen or vernix before inserting the probe.
- Turn on the **MAICO ERO•SCAN™** and select the ear to be tested.*
- Insert the probe into the ear canal (Figure 10). Lift gently on the outer ear during insertion to straighten the ear canal and ensure proper placement.



Figure 9
Correct Placement
of the Eartip



Figure 10
Correct inserted
External Probe



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- The AUTO-START function automatically begins the test when the probe is inserted correctly. If the **MAICO ERO•SCAN™** does not start the test, reposition the probe.

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



Figure 11
The External Probe



5 Performing the DPOAE or the TEOAE test

5.1 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 **MAICO 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.

5.2 The control buttons

- The **MAICO ERO•SCAN™** instrument uses four buttons to control all functions of the instrument. These buttons are arranged in a directional cursor format. The arrows on the keys (= left ⑨, < right ⑫, > up ⑪, ? down ⑩) correspond to the arrows that are used on the screen ⑧. The screen ⑧ will indicate which button to push by showing the appropriate arrow.
- NOTE: The > up key ⑪ will always bring the instrument back to either the previous menu or the Main Menu. The > up key ⑪ will also turn the unit off when the instrument is at the Main Menu.



Figure 12 Control buttons and displays

5.3 Turning On the Instrument

- To turn on the **MAICO ERO•SCAN™** instrument, press the large ? down key ⑩ located below the instrument's display screen ⑧. Three small lights (red ⑤, yellow ⑥ and green ⑦) will appear for a short moment just above the display



Figure 13 Turn on



Figure 14 Start display

screen. The green ready light ⑤ will remain on. On the display ⑧ the text shown in figure 14 will appear shortly when DPOAE is set or selected. If



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TEOAE is set or selected the text at the bottom will be TE instead of DP.

- If the batteries have sufficient power, the **MAICO ERO•SCAN™** instrument will automatically check the date and time settings. If there are no date/time errors detected, the Main Menu (Figure 15) will appear on the display.



Figure 15
Main menu

- NOTE: If this is the first time the **MAICO ERO•SCAN™** instrument is being used, or if you wish to change the date or time, see Setting the Clock in chapter 7.3 for instructions on setting the correct date and time.
- The **MAICO ERO•SCAN™** instrument has an automatic shutdown feature, designed to prolong battery life. The unit will automatically shut down after 2 minutes (default) of inactivity. To turn it again on, simply press the large ? down key ⑩. This feature can be re-programmed to various periods of inactivity before shut-down. (See chapter 7.6 for further information on this feature.)

5.4 Testing in the “Default” Mode

- The **MAICO ERO•SCAN™** instrument can use a default protocol or a custom test protocol for DPOAE and/or TEOAE. The default protocol will be used unless a custom protocol is selected. See Changing Instrument Settings in chapter 7.6. Chapter 7.7 contains information on custom protocols, and the Advanced Options menu allows the user to change test protocols.
- The settings for DPOAE testing in the default mode are as follows:
Number of Frequencies Tested = 3 Averaging Time = 2 Seconds
Frequency Range = 2 kHz to 4 kHz “PASS” SNR (Signal-to-Noise Ratio) = 5 dB
P1 (Intensity of f1) = 65 dB_{SPL} Number of PASSing Frequencies for Test “PASS” = 3
P2 (Intensity of f2) = 55 dB_{SPL}
- The settings for TEOAE testing in the default mode are as follows:
Number of Frequencies Tested = 6 Averaging Time = 16 Seconds
Frequency Range = 1 kHz to 4 kHz “PASS” SNR (Signal-to-Noise Ratio) = 4 dB
Click Presentation Level = 65 dB_{SPL} Number of PASSing Frequencies for Test “PASS” = 3



5.5 To Begin Testing

To begin testing in the default mode, place an eartip ① as far down as possible on the probe tip ② (see figure 17). For proper eartip attachment refer to chapter 7.3.



Figure 16
Place eartip



Figure 17
Proper sitting eartip

Turn on the instrument by pressing the ? down button ⑩ and select either the = left ⑨ or < right ⑫ arrow key to indicate which ear will be tested. After the test ear is selected, the text shown on the display ⑧ in figure 20 will appear. This display will verify the test ear and indicates that the unit is in auto-start mode. To obtain a seal and to measure OAEs, gently insert the eartip into the patient's ear canal. It should fit snugly and comfortably. The best test results are obtained when an eartip is inserted deeply into the ear canal instead of flush with the ear canal opening.



Figure 18
Turn on



Figure 19
Select ear

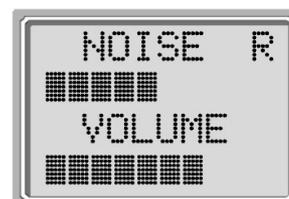


Figure 20
Start screen

The NOISE and VOLUME bar readings (see figure 20) should be used as an indication how the unit seals the ear canal. If the NOISE and VOLUME bars continue to fill the screen, the unit is not sealing the ear canal and the environmental noise is too high. Make appropriate adjustments until a decrease of these bars is seen. Note that for an adult, the VOLUME bar will decrease to about half, while for a newborn or child, the VOLUME bar will decrease further to the left. The NOISE bar will show a decrease from the original reading. When a seal is obtained, the unit will automatically begin testing and the yellow TEST LED ⑥ will illuminate throughout the test.

5.5.1 Testing children with PE Tubes

To test children with PE tubes, the auto-start needs to be disabled. This is accomplished by first inserting the **MAICO ERO•SCAN™** with the



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appropriate ear tip into the ear canal and obtaining proper seal. To disable auto-start, at the Main Menu select the ear by HOLDING DOWN the = left ⑨ or < right ⑫ arrow key for 3 seconds until the green test light ⑥ turns off. Once the key is released, the **MAICO ERO•SCAN™** will calibrate and test as described below.

5.6 Auto Calibration and test

- The **MAICO ERO•SCAN™** instrument will automatically perform a calibration at the start of each test and the text shown in figure 21 will briefly appear on the LCD ⑧. During calibration a series of tones will be presented to the ear canal to calibrate the levels of the primary tones at the frequencies to be tested. It is very important that the **MAICO ERO•SCAN™** unit is held steady in the patient's ear canal while the yellow TEST LED ⑥ is illuminated.



Figure 21
Calibration

- Following the automatic calibration of the test tones, a set of bars should appear on the display (figure 22). These are the test results which are displayed as the emissions are measured. Two bars are used to represent each of the test frequencies (DPOAE) or in each of the frequency bands (TEOAE).

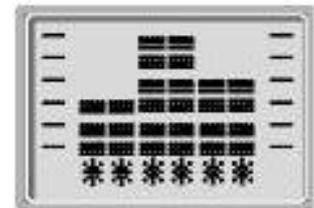


Figure 22
Test in progress

- Testing is completed when the green "READY" light ⑦ is illuminated. Both the tester and patient should remain as still and quiet as possible until the green light ⑦ turns on. The graphic display is explained in chapter 6 „Interpreting Test Results“.

5.7 Reviewing the test results

- When testing is completed, a display similar to figure 23 will appear.

as soon as the test is complete. The results will be saved even if the unit turns off or the batteries are temporarily removed.

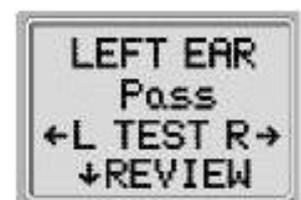


Figure 23
Test result

- This screen again indicates the test ear and further gives the results of the



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- 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.
 - The tester can determine from the display 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 ⑩ to return to the Main Menu.
 - Once the instrument returns to the Main Menu and a new test for that ear is started, the previous results may not be viewed again unless a printout of the results has been obtained.
 - If a patient did not pass, testing can be repeated by selecting the same test ear and starting the procedure again.
 - By default, the **MAICO 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 **MAICO 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 Print Mode/Storing Test Results in chapter 7.6 to set up the device to save 50 tests in memory.

5.8 Printing the test results

- It is recommended that the results be printed after each patient. The **MAICO 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. If the printer is operating on the battery pack, turn



Figure 24
Printout of test result



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it on by pressing the green button (F) before placing the instrument in the cradle. The test results that are stored will print out automatically. If the printer is plugged into main power, it is already on. The results of the most recent test from each ear will continue to be stored in memory until another test is completed.

- NOTE: The **MAICO 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" print mode, only the most recent test results for each ear will be printed. If it is set to the "50" print mode the printer will print all tests stored in the **MAICO ERO•SCAN™** memory. For ease of record keeping, it is recommended that you print test results after each patient.
- The **MAICO ERO•SCAN™** instrument can be configured to store up to 50 tests in memory before printing. See the chapter 7.6 for instructions to save more than two tests in memory.

5.9 Test Technique

- As with other otoacoustic emission test instruments, there is a technique to learn when using the **MAICO ERO•SCAN™** instrument, especially for newborns and infants. Experience with existing OAE systems suggests that it may take up to three months to become completely proficient at screening newborns with emissions.
- When testing a newborn or infant with the **MAICO 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



Figure 25
Newborn test



Figure 26 Newborn
test with pacifier



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straighten out the ear canal. Prepare the **MAICO 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 **MAICO 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.
- Warming the eartips prior to insertion helps to keep the baby calm.
- Deeper insertion into the ear canal allows for the measurement of larger emissions due to the reduced ear canal volume.
- The small green and yellow mushroom-shaped eartips can also be used, however, the selected eartip should enter the ear canal, rather than just sitting flush with the ear canal opening.

5.10 Noise Sources

- When the noise level exceeds the noise rejection limit of the instrument, the red ERROR light ⑤ will appear. The ERROR light ⑤ 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 that must be measured by the microphone in the probe. 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 biological noise can come from the patient (movement, coughing, sucking, talking, etc.). The patient must be calm and should not move or talk.
- Ambient noise in the testing environment can also be a large source of noise during the test.



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- 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 **MAICO 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.



6 Interpreting test results

6.1 Understanding the Display

- The display on the **MAICO ERO•SCAN™** test instrument will indicate the results of the test with a graphical display.
- The display will be generated and shown during the test and can be reviewed after the test is completed.
- The display might differ depending on the settings used for the test.

- The display shows a 6-column graph. Each frequency (DPOAE) or frequency range (TEOAE) is indicated by one or two adjacent columns, depending on how many frequencies are tested (e.g., in the default mode where only three frequencies are tested each frequency will be represented by two columns). 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 higher (6 rows of 2 dB each).

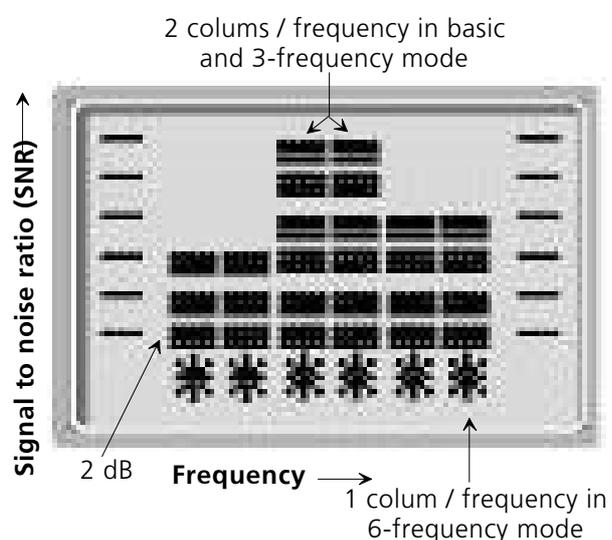


Figure 27 Result display

- The display is shown while the test is being performed. To review the display after the test is finished, press the REVIEW key $\text{\textcircled{10}}$ to look at the display.
- For 3-frequency tests, two columns for each frequency are used (and will be identical).
- For 6-frequency tests each column represents an individual frequency.



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6.2 Understanding the DPOAE Printed Results

- Each test will generate its own printout. Described below is the FULL printout, text or graph printouts will be abbreviated.

- 1 = The test number.
- 2 = The ear selected.
- 3 = The time and date of the test, based on the setting of the internal clock.
- 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} .

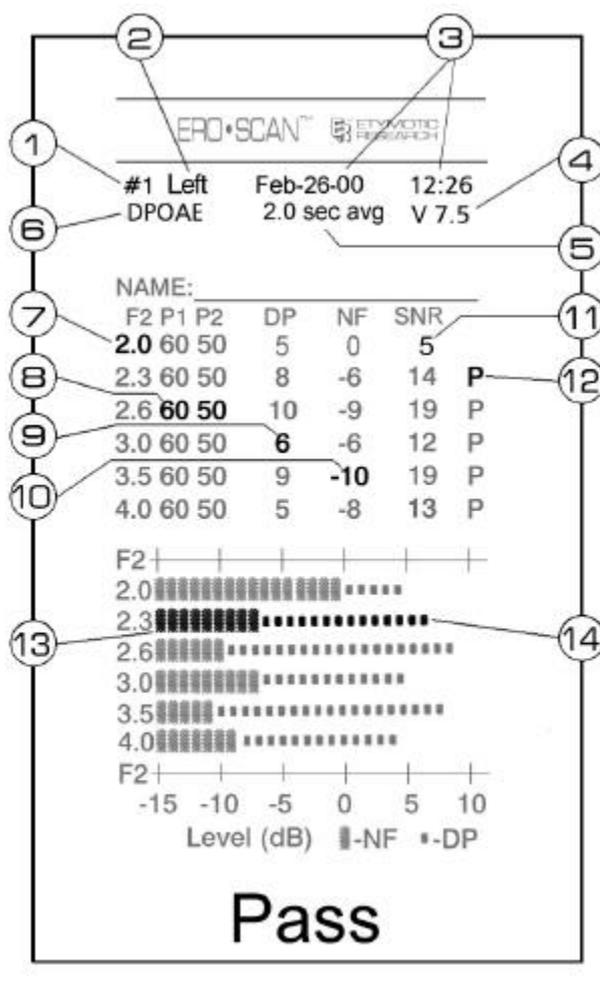


Figure 28 Full result printout



6.3 Understanding the TEOAE Printed Results

- Each test will generate its own printout. Described below is the FULL printout, text or graph printouts will be abbreviated.

- 1 = The test number.
- 2 = The ear selected.
- 3 = The time and date of the test, based on the setting of the internal clock.
- 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} .

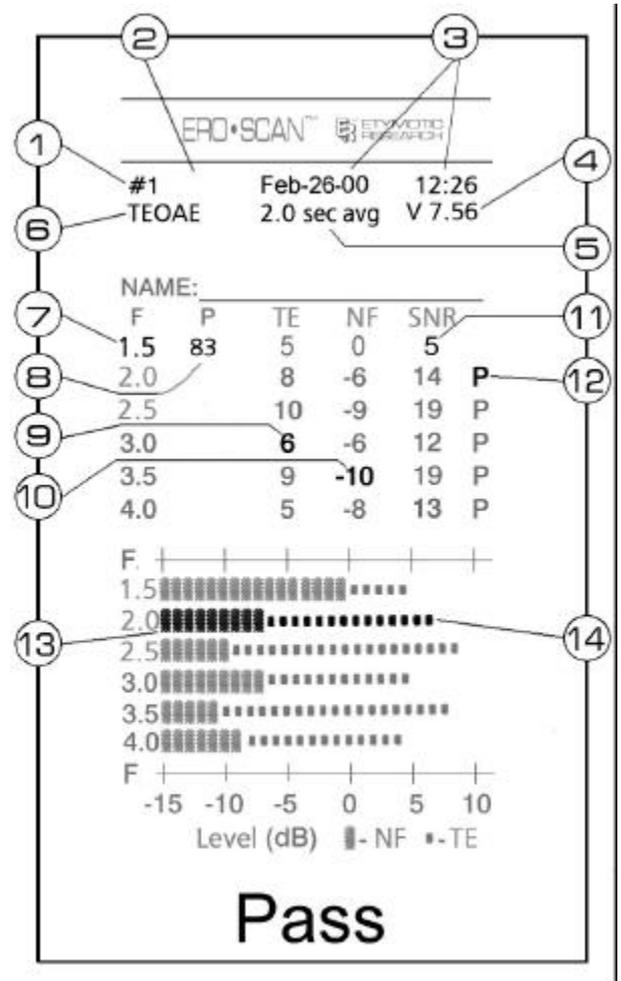


Figure 29 Full result printout



6.3 A Note About Rounding of 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 distortion (DP) 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, figure 28, the actual values were assumed at 2.0 kHz for DP = 4.5 dB, NF = -0.4 dB, which results in SNR = 4.9 dB. The printout values are rounded up to the nearest integer and are shown as DP=5, NF=0, SNR=5, which seems to be an error (since no 'P' appears) but is in fact correct.
- A similar apparent problem can occur for the "PASS" criterion. If the "PASS" criterion is 5 dB while the actual SNR = 4.9, the printed value for the SNR will be 5 but a 'P' will NOT be printed, as shown in figure 24. Again, the "PASS" criterion is based on the full precision of the results, and not the rounded values that are printed. The full precision value for the SNR must be equal to or higher than the "PASS" criterion (5 dB in this example) for the 'P' to be printed.



7 Quick reference guide

7.1 Battery installation

- The **MAICO 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.



Figure 30 Opening of the battery cover

7.2 Changing printer paper

- Open the cover ③ of the printer by pulling up and back. Orient the paper roll so that the paper ④ will feed from the bottom of the roll (see Figures 31 and 32). Place the roll of paper into the printer by holding the white paper-holder lever ① back against the case. Allow the lever ① 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 ② forward until it snaps in place to disengage the roller ⑤. Slide the end of the paper ④ under the roller ⑤; it will come out from the front of the roller ⑤. Pull the paper end ④ through the roller ⑤ until it extends about 3 inches above the roller ⑤.

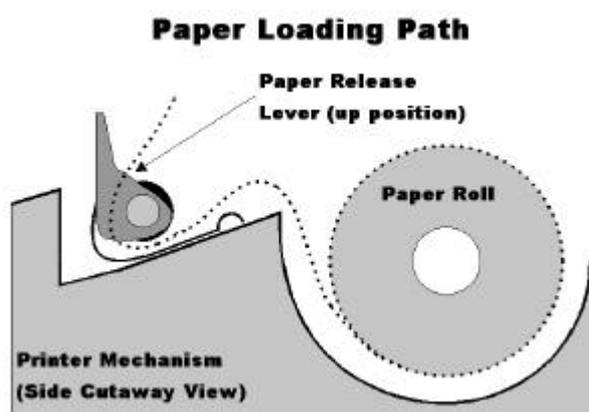


Figure 31 Paper loading

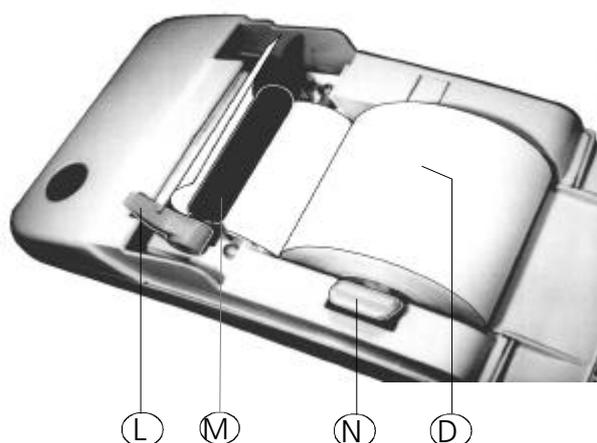


Figure 32 Printer with open cover

Push the paper-release lever ② back. Feed the loose end of the paper through the slot of the printer cover. Close the printer cover ③. Push the green button ⑥ on the top of the printer to advance the paper. The printer



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indicator light ⑤ on the front of the printer will now flash green if the paper was properly installed. Pressing the green button ⑤ twice rapidly will print a test run.

7.3 Attaching the Eartips

- The **MAICO 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 colour-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.



Figure 33 Box with eartip set

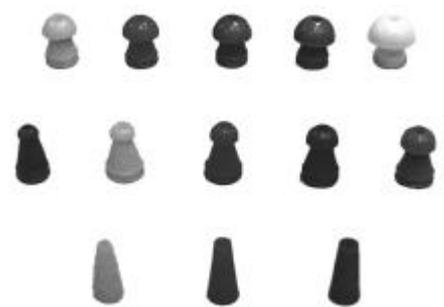


Figure 34 Different eartip sizes

-  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 in chapter 11 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 following section Probe Tip Replacement 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.

7.4 Probe Tip Replacement

- The probe tip should be replaced when it becomes clogged. Four replacement probe tips are included with this instrument.



- Do not attempt to clean the probe tip, the probe tips are disposable and must be replaced when they become clogged.

(See the Replacement Parts section at chapter 11).

- To replace the probe tip, squeeze the tabs as shown in figure 35. The tabs should audibly snap off the probe assembly. Pull the probe tip directly off the probe and discard it.
- Obtain a replacement probe tip and orient the tip as shown in figure 36. 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 35 Removing the probe tip



Figure 36 Replacing the probe tip



7.5 Probe Tip Replacement for the external probe

- The probe tip should be replaced when it becomes clogged. Four replacement probe tips are included with this instrument.
- **Do not attempt to clean the probe tip, the probe tips are disposable and must be replaced when they become clogged.**



(See the Replacement Parts section at chapter 11).

To remove:

Use 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 37).

Slide the probe tip off the front of the probe and discard (Figure 38).

To replace:

1. Align a replacement tip with the front of the probe (Figure 39). 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.

The tabs should be flush with the outside of the probe (Figure 40).

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



Figure 37
Release the probe tip

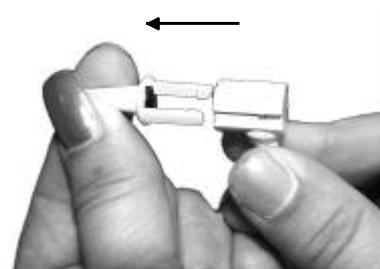


Figure 38
Remove the probe tip

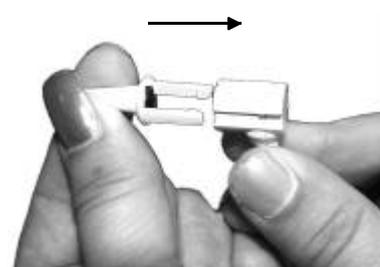


Figure 39
Align the new probe tip

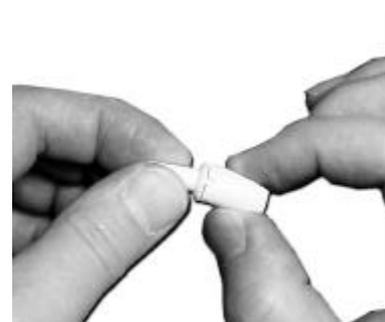


Figure 40
Fastening the probe tip



7.6 Setting the built-in clock

- When the **MAICO 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-26-99).
- 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 are empty and are replaced within approximately one hour, the display as shown in figure 41 may appear. If this message appears, set time and date.
- To change the time and date enter the SETUP by pressing the ? DOWN button ⑩ at the Main Menu. The display ⑧ will show the current date and time presently set in the unit.
- If the time and date are correct, press the > UP key ⑪ to escape back to the Main Menu.
- If either the date or time is incorrect, press the ? DOWN button ⑩ to access the menu to change the month (Figure 43).
- Press the = LEFT ⑨ or < RIGHT ⑫ 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 ⑩ to enter the day selection screen (Figure 44). Pressing the = LEFT ⑨ or < RIGHT ⑫ keys will scroll through the days of the month.
- After the correct day is selected, press the ? DOWN key ⑩ to enter the year selection (figure 45). Pressing the =



Figure 41 Display of time/date error



Figure 42 Display of actual time/date



Figure 43 Changing of the month



Figure 44 Changing of the day



Figure 45 Changing of the year



Figure 46 Changing of the hour



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- LEFT ⑨ or < RIGHT ⑫ keys will scroll through the years.
- When the correct year is selected, press the ? DOWN key ⑩ to enter the hour menu (figure 46). Again use the = LEFT ⑨ or < RIGHT ⑫ keys to set the correct hour.
 - Press the ? DOWN key ⑩ to enter the minute menu (figure 47) and use the = LEFT ⑨ or < RIGHT ⑫ buttons to select the correct minute. When the correct minute is selected, pressing the ? DOWN key ⑩ will return you to the Main Menu.
 - The time and date changes are automatically saved.



Figure 47 Changing of the minute

7.7 Changing Instrument Settings

The **MAICO ERO•SCAN™** instrument allows the user to change many of the instrument's settings or functions. These settings include the Test Mode (DP and DP Custom, or TE and TE Custom - combined instruments allow the choice from all four modes), Clearing Test Results, Auto-Shutdown Time, Headphone Level, Minimum Amplitude Level, Save Mode, Clock Mode, Language and Reset to default Settings. To access the menus to change these functions, press the ? SETUP key ⑩ from the Main Menu (see figure 48) to enter the CHANGE menu (see figure 49). At this menu, hold down the ? CHANGE key ⑩ for three seconds until the Ready light (green LED) turns off. Releasing the ? key ⑩ will then access the menus to change the instrument settings.



Figure 48 Main Menu

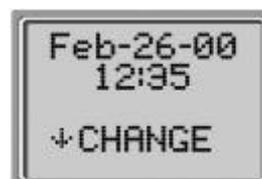


Figure 49 Change Menu

7.7.1 Test Mode

The MODE SET menu (figure 50) allows the user to change the test protocol. The Test Modes that can be selected include either DPOAE and DP Custom or TEOAE and TE Custom. All protocols in the unit come with preset test values (Chapter 11) which can also be customized using the Advanced Option menus. Programming these custom protocols is described in the Advanced Options section in chapter 7.7.

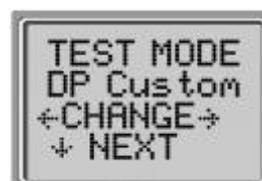


Figure 50 Mode set



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

Pressing the = left ⑨ or < right ⑫ arrow key will scroll through the available choices. When the display shows the setting desired, press the ? NEXT key ⑩.

7.7.2 Clearing Test Results

Test Results Clear menu (figure 51) allows the user to clear the test results stored in the unit without printing them. Select the = left ⑨ or < right ⑫ arrow key to clear the results and select < Yes ⑫ or = No ⑨ to verify clearing (or not clearing) the results (figure 52).

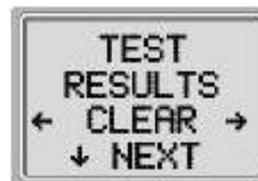


Figure 51
Clear results

7.7.3 Auto-Shutdown Time

The Power Off menu (see figure 53) refers to the Auto-Shutdown time which controls how long the **MAICO ERO•SCAN™** instrument waits before shutting itself off after a period of inactivity. It is not necessary to manually turn off the **MAICO 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 2 minutes have elapsed. The Auto-Shutdown time may be increased or decreased by pressing the CHANGE keys = ⑨ or < ⑫. The times available are 30 seconds, 1, 2, or 4 minutes. Once you have made your selection, press ? NEXT ⑩.



Figure 52
Verify clear

7.7.4 Headphone Level

The Headphone Level menu (see figure 54) is next. Using the headphones provided with the **MAICO ERO•SCAN™** instrument enables the examiner to listen to the calibration and test tones. The headphone plug should be inserted into the jack at the bottom of the **MAICO ERO•SCAN™** instrument. The headphones



Figure 53
Power off menu



Figure 54
Headphone level



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may be used both as a learning tool and for real-time monitoring of the ear canal during the test. Press the CHANGE keys = ⑨ or < ⑫ 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.

7.7.5 Save Mode Storing Test Results

The Print Mode menu is shown in figure 55. The **MAICO 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 ⑨ or < right ⑫ arrow keys to change the menu to 50. It is recommended that you go to the Test Results Clear screen (described in chapter 7.6.2) to clear any previous memory locations after you first select this option. When the **MAICO 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. Upon saving test number 45, the message shown in figure 56 is displayed and the red "ERROR" light ⑤ appear. At this point, five more tests can be stored. Press CONTINUE ⑩ to proceed with testing. When 50 tests are saved, select TEST ⑩ 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 **MAICO ERO•SCAN™** unit will ask to verify your decision to erase all stored tests. To print, select Main Menu ⑩, turn on the printer, and set the instrument on its cradle. All stored tests will be printed.



Figure 55
Save Mode



Figure 56
Message after 44
stored tests



Figure 57
Message after 50
stored tests



7.7.7 Minimum DP Amplitude

Press the ? NEXT button ⑩ to enter this menu. The Minimum DP amplitude screen, as shown in figure 58, 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 DP amplitude at each frequency is equal to or higher than the minimum value programmed into the unit in addition to meeting the other pass criteria including the minimum SNR and the number of passing frequencies for Overall Test "Pass".

The minimum DP amplitude value is: - 5 dB_{SPL}

The minimum TE amplitude value is: - 12 dB_{SPL}



Figure 58
Min Amplitude

7.7.8 Clock Mode

Press the ? NEXT button ⑩ to enter the Clock Mode (Figure 59). The menu allows the user to change the clock from 12 hour mode to 24 hour mode. To change the clock mode, press the CHANGE keys = ⑨ or < ⑫. Once you have made your selection, press ? NEXT ⑩.



Figure 59
Clock mode

7.7.9 Language

The language setting allows the user to select between several languages. Language options include English, French, German and Spanish. To change the language, press the CHANGE keys = ⑨ or < ⑫ until the desired language is shown. Once you have made your selection, press ? NEXT ⑩.



Figure 60
Language Selection

7.7.10 Reset to Default

Selecting the = left ⑨ or < right ⑫ arrow key in the Reset to default menu (Figure 61) will return the instrument settings to their original factory settings. (Note: This does not affect the Custom settings.)



Figure 61
Reset to default



7.8 Advanced Options for DPOAE Testing

The Advanced Options menus permit modification of the test stimuli and measurement values and should be changed 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 **MAICO ERO•SCAN™** instrument comes with pre-programmed settings for the DP and DP Custom protocols. See Chapter 11 for the settings of these custom protocols. Custom settings are saved in the non-volatile memory so the settings will be retained even when changing batteries.

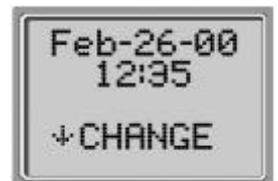
7.8.1 Instructions For Changing Test Protocols:

1. Go to the Main Menu (figure 62). Press the ? DOWN arrow key ⑩ once. CHANGE is displayed (figure 63).



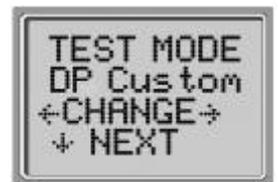
Figure 62
Main Menu

2. Now hold the ? DOWN arrow key ⑩ for 3 seconds (until the green Ready LED turns off). If you push the ? DOWN arrow key ⑩ 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.



Change menu

3. The next display you see is MODE SET (figure 64). Use the = LEFT ⑨ or < RIGHT ⑪ arrow keys to select DP Custom.



Mode set menu

4. Hold the ? DOWN arrow key ⑩ again for 3 seconds (until the green Ready LED turns off).

If you do not hold it for 3 seconds, you will return to 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 as



desired by using the LEFT ⑨ or RIGHT ⑫ arrow keys.

7.8.2 Selecting the Number of Test Frequencies

There are two options for the number of frequencies to be tested. These options are as follows:

3 X 1 = 3 frequencies

6 X 1 = 6 frequencies

The default mode is 3 frequencies. Press the CHANGE keys = ⑨ or < ⑫ to select an option and the ? NEXT key ⑩ to exit.



Figure 65 Number of test frequencies

7.8.3 Selecting the Frequency Range

There are three options for the frequency range to be tested.

These options are as follows:

Frequency Range	3-Frequency Test	6-Frequency Test
2.0 to 4.0 kHz	2, 3, 4 kHz	2, 2.3, 2.6, 3, 3.5, 4 kHz
2.0 to 6.0 kHz	2, 4, 6 kHz	2, 2.5, 3, 4, 5, 6 kHz
1.5 to 6.0 kHz	1.5, 3, 6 kHz	1.5, 2, 3, 4, 5, 6 kHz

The default mode is 2.0 to 4.0 kHz. Press the CHANGE keys = ⑨ or < ⑫ to select an option and the ? NEXT key ⑩ to exit.



Figure 66 Frequency range

7.8.4 Setting the Level of the Primary Tones

The intensity of the primary tones (P1, P2) may be changed to any level between 40 dB_{SPL} and 65 dB_{SPL}. The level P1 will change in 1 dB increments by pushing the = left ⑨ or < right ⑫ arrow keys (figure 67).

The default mode is P1 = 65, P2 = 55.

Press the ? NEXT key ⑩ to set the level of P2 as for P1 (figure 68).

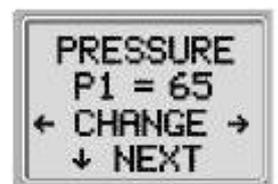


Figure 67 Level of test tone 1

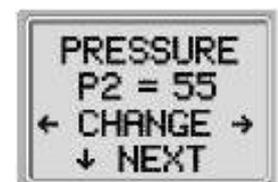


Figure 68 Level of test tone 2



7.8.5 Setting the Averaging Time

The Averaging Time can be changed to several different lengths. 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.

The default setting is 2 seconds. Press the CHANGE keys = ⑨ or < ⑫ to select an option and the ? NEXT key ⑩ to exit.



Figure 69
Averaging time

7.8.6 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 ⑨ or < right ⑫ 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.

The default setting for the "PASS" SNR is 5 dB. Press the CHANGE keys = ⑨ or < ⑫ to select an option and the ? NEXT key ⑩ to exit.

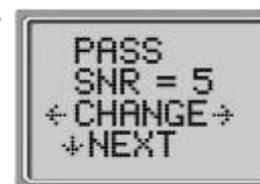


Figure 70
Pass SNR level

7.8.7 Setting the Number of Frequencies for a 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 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

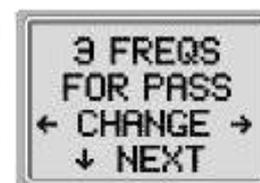


Figure 71
Frequencies for
pass



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 4 when only 3 frequencies are being tested would result in every test being labelled as a "REFER". To disable the "PASS" / "REFER" indication set the number of frequencies for "PASS" to 0.

The default setting for the number of frequencies is 3. Press the CHANGE keys = ⑨ or < ⑫ to select an option and the ? NEXT key ⑩ to exit.

7.8.8 Save Protocol

Once all of these settings have been determined for the customer program, these settings can be saved by selecting the = left ⑨ or < right ⑫ arrow keys (Figure 72). This will save the selected settings as the customer program selected and will be stored in this customer program until new settings are selected and saved.



Figure 72
Save Protocol



7.9 Advanced Options for TEOAE Testing

The Advanced Options menus permit modification of the test stimuli and measurement values and should be changed 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 **MAICO ERO•SCAN™** instrument comes with pre-programmed settings for the TE and TE Custom protocols. See Chapter 11 for the settings of these custom protocols. Custom settings are saved in the non-volatile memory so the settings will be retained even when changing batteries.

7.9.1 Instructions For Changing Test Protocols:

1. Go to the Main Menu (figure 73). Press the ? DOWN arrow key ⑩ once. CHANGE is displayed (figure 74).

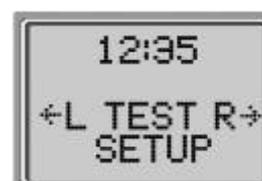


Figure 73
Main Menu

2. Now hold the ? DOWN arrow key ⑩ for 3 seconds (until the green Ready LED turns off). If you push the ? DOWN arrow key ⑩ 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.

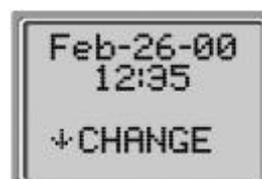


Figure 74
Change menu

3. The next display you see is MODE SET (figure 75). Use the = LEFT ⑨ or < RIGHT ⑫ arrow keys to select DP Custom.

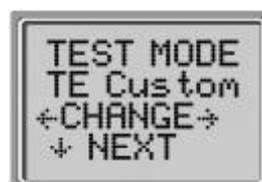


Figure 75
Mode set menu

4. Hold the ? DOWN arrow key ⑩ again for 3 seconds (until the green Ready LED turns off).

If you do not hold it for 3 seconds, you will return to 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 as desired by using the LEFT ⑨ or RIGHT ⑫ arrow keys.



7.9.2 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

The default mode is 0.7 to 4.0 kHz. Press the CHANGE keys = ⑨ or < ⑫ to select an option and the ? NEXT key ⑩ to exit.



Figure 76
Frequency range

7.9.3 Setting the Averaging Time

The Averaging Time can be changed to several different lengths. 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 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 sec., 8 sec., 16 sec., 64 sec.

The default setting is 64 seconds. Press the CHANGE keys = ⑨ or < ⑫ to select an option and the ? NEXT key ⑩ to exit.



Figure 77
Averaging time

7.9.4 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 ⑨ or < right ⑫ 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.

The default setting for the "PASS" SNR is 4 dB. Press the CHANGE keys = ⑨ or < ⑫ to select an option and the ? NEXT key ⑩ to exit.

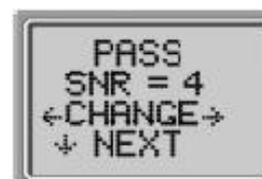


Figure 78
Pass SNR level



7.9.5 Setting the Number of Frequencies for a 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".

The default setting for the number of frequencies is 3. Press the CHANGE keys = ⑨ or < ⑫ to select an option and the ? NEXT key ⑩ to exit.

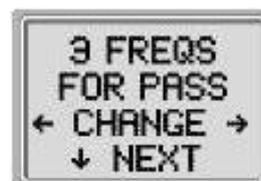


Figure 79
Frequencies for
pass

7.9.6 Save Protocol

Once all of these settings have been determined for the customer program, these settings can be saved by selecting the = left ⑨ or < right ⑫ arrow keys (Figure 80). This will save the selected settings as the customer program selected and will be stored in this customer program until new settings are selected and saved.



Figure 80
Reset to default



8 Recommended literature

Audiometric Interpretation: A Manual of Basic Audiometry

Lloyd, Lyle L., and Harriet Kaplan

Baltimore: University Park Press, 1980

Auditory Disorders: A Manual for Clinical Evaluation

Jerger, Susan, and James Jerger

Boston: College Hill Press, 1981

Handbook of Clinical Audiology

Katz, Jack

Baltimore: William & Wilkins, 1994

Roeser's Audiology Desk Reference

Roeser, Ross J.

New York / Stuttgart: Thieme, 1996

Auditory Diagnosis

Silam, Shlomo and Carol A. Silvermann

San Diego / London: Singular Publishing Group, 1997



9 Care and maintenance of the instrument

Cleaning the instrument

- The instrument and its accessories may be wiped clean with a damp cloth using a mild antiseptic solution. 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

- The instrument requires no regular maintenance beyond routine cleaning and battery replacement.
- The probe tip requires replacement only when it becomes clogged. For Probe tip replacement see chapter 7.4 for the built-in probe or chapter 7.5 for the external probe.



10 Trouble shooting

If you should find that your instrument is no longer working properly during a test run, please check the following points:

10.1 Problems and Solutions

1st Problem:

Instrument does not turn on.

Solutions:

The ? DOWN key ⑩ must be pressed for a full second.

Check that the batteries are installed correctly.

Install new batteries.

2nd 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 error messages.

Reseat or replace the probe tip.

If the patient has a PE-tube refer to chapter 5.5.1

3st 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



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the printer.

Are there any tests in memory to be printed?

“Printer paper low” message appears on LCD. Open printer cover and reposition or replace the paper roll.

If your instrument still does not work properly after this short check, please consult your dealer or service centre.



11 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: U.S. F.D.A. 510 (k) #980533, 23.03.1998

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: DPOAE 1.5 to 6.0 kHz [2.0 to 4.0 kHz default setting]

TEOAE 0.7 to 4.0 kHz [0.7 to 4.0 kHz default setting]

Intensity Range: 40 to 65 dB_{SPL}

Maximum Output: 90 dB_{SPL}

Microphone Noise: -20 dB_{SPL} @ 2 kHz (1 Hz bandwidth)

-15 dB_{SPL} @ 1 kHz (1 Hz bandwidth)

Sampling Rate: 31,250 Hz

INSTRUMENT SPECIFICATIONS

Power Supply: (4) AA/UM-3/R6 cells - Alkaline (6V total)

Battery Life: Approximately 300 tests

Instrument Weight: 300 g (10.6 oz.) including batteries

Dimensions: W x D x H: 21 x 9 x 5 cm



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PRINTER SPECIFICATIONS

Type:	Thermal dot matrix line printer
Speed:	>10 lines per second
Operating Noise:	<50 dB SPL
Weight:	630 g (1.4 lbs.) including battery pack
Dimensions:	W x D x H: 10 x 15.5 x 8 cm
Power Supply:	Ni-Cad rechargeable battery pack
Recharger:	Plug-in transformer 12V 400mA / 230V~ 50 Hz double-insulated
Paper:	Calculator-type thermal roll - 2.25" wide
Battery Life:	Approximately 300 tests

CRADLE SPECIFICATIONS

Weight:	630 g (1.4 lbs.) including battery pack
Dimensions:	W x D x H: 7,5 x 19 x 10 cm
Interface connector:	9-pin RS-232 connector

PROCESSOR SPECIFICATIONS

Digital Signal Processor:	Motorola 56303 24-bit 66 MHz 3.3 V
Storage:	1 Mbit Flash EEPROM (non-volatile)
Battery Backup:	0.1 F 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



Preset Test Protocols

DPOAE

Number of Frequencies Tested = 3
Frequency Range = 2 kHz to 4 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) = 5 dB
Number of passing Frequencies for Overall Test Pass = 3

DP CUSTOM

Number of Frequencies Tested = 6
Frequency Range = 1.5 kHz to 6 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) = 7 dB
Number of Passing Frequencies for Overall Test Pass = 3

TEOAE

Number of Frequencies Tested = 6
Frequency Range = 0.7 kHz to 4 kHz
Averaging Time = 16 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 = 1.5 kHz to 4 kHz
Averaging Time = 16 Seconds
Pass SNR (Signal-to-Noise Ratio) = 4 dB
Number of Passing Frequencies for Overall Test Pass = 3



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 stops operation and displays an error message (see figure 81). A successful calibration leads to the actual test phase.



Figure 81
Max. Level
reached

The test phase consists in 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 higher 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.



Operating Instructions ERO•SCAN™

Program Flowchart:

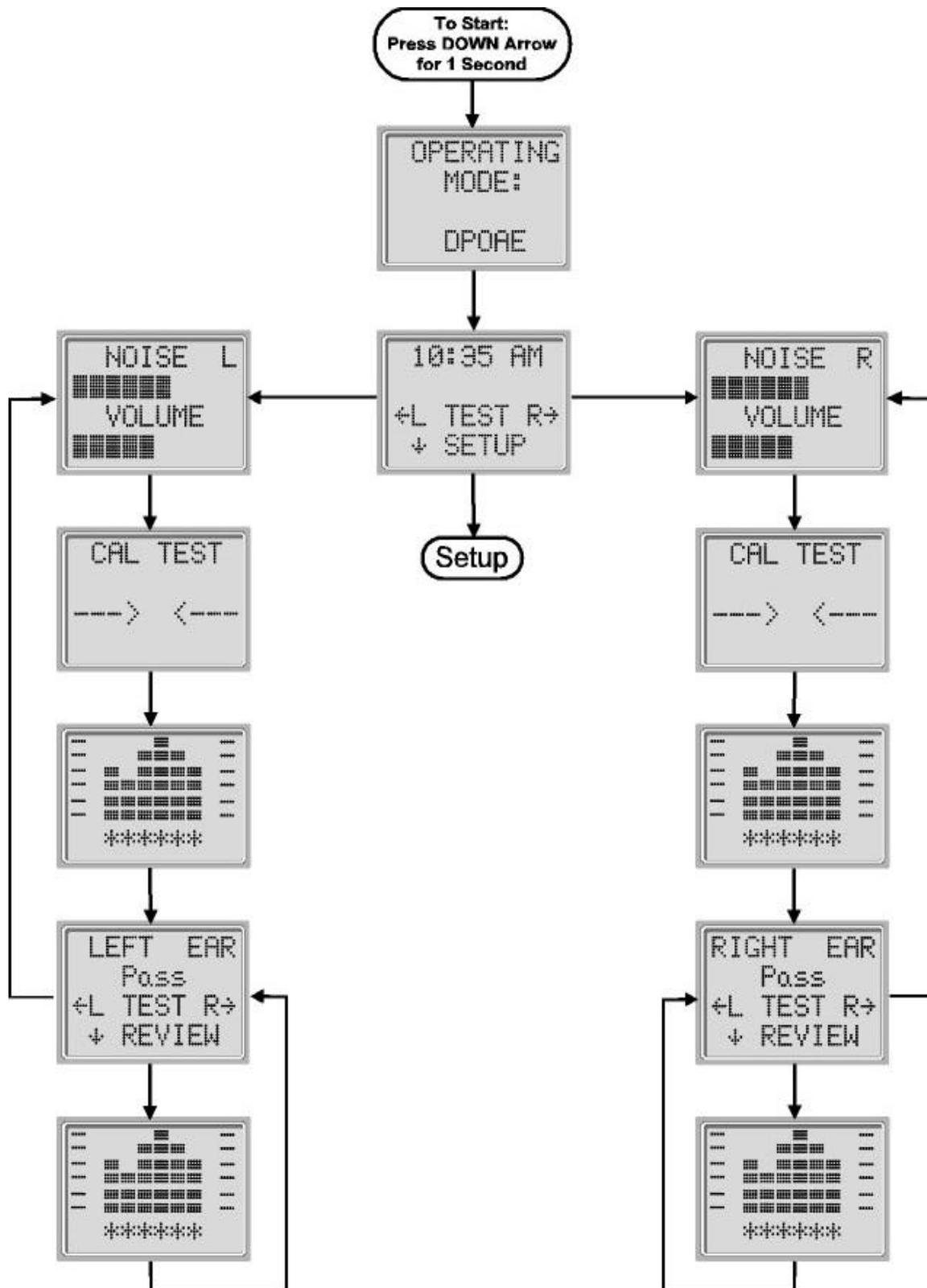


Figure 82 Program flowchart



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Setup Flowchart:

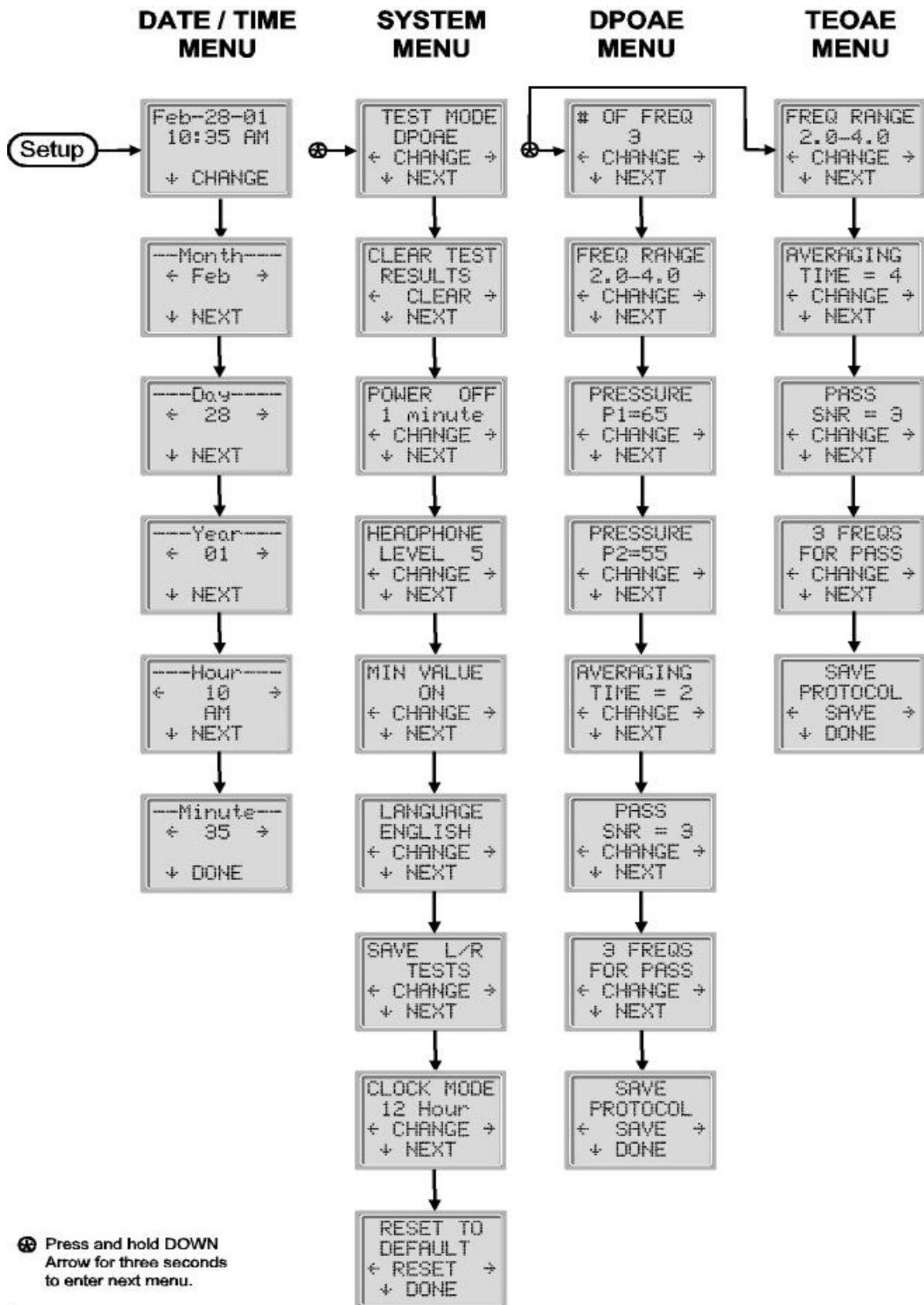


Figure 83 Setup flowchart



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Standard accessories:

- 1 ERO SCAN™ Hand-held unit.....
- 1 Cradle.....
- 1 Printer.....
- 1 Power supply.....
- 1 Printer cable.....
- 1 Headphone.....
- 1 Eartip set.....
- 4 Probe tips.....
- 4 Alkaline AA Batteries (Already installed)
- 1 Printer paper roll (Already installed)

Optional accessories:

1 External probe Part-No. 80 11 27



1 Carrying case heavy duty Part-No. 80 10 69-1





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



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



4 mm
red



5 mm
blue

Figure 84 Eartips



Internal Probe specifications

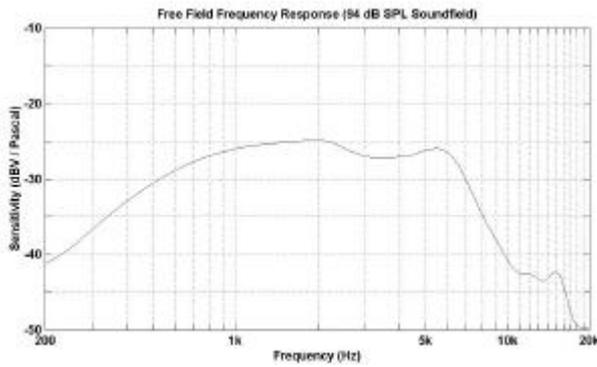


Figure 85 Microphone Frequency Response (nominal)

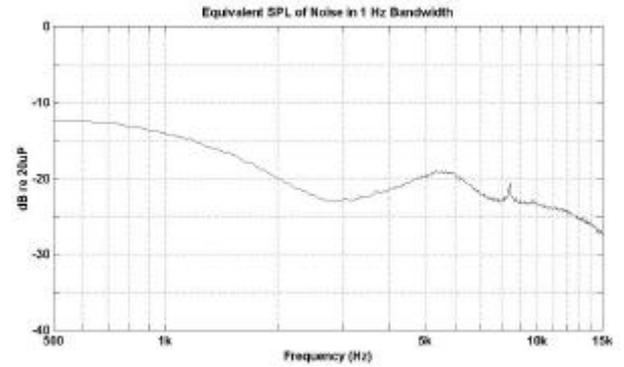


Figure 86 System Noise Floor (nominal)

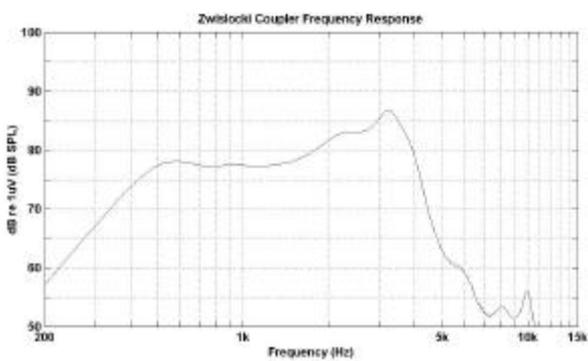


Figure 87 Sound Source Frequency Response (nominal)

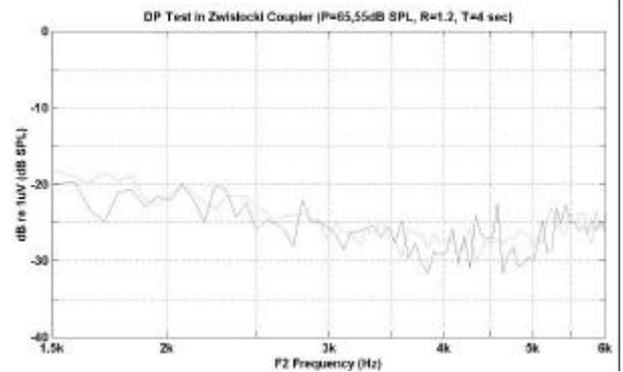


Figure 88 System Distortion + Noise (nominal)



External Probe specifications

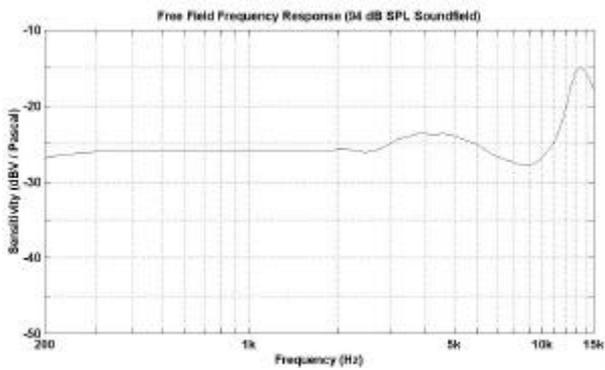


Figure 89 Microphone Frequency Response (nominal)

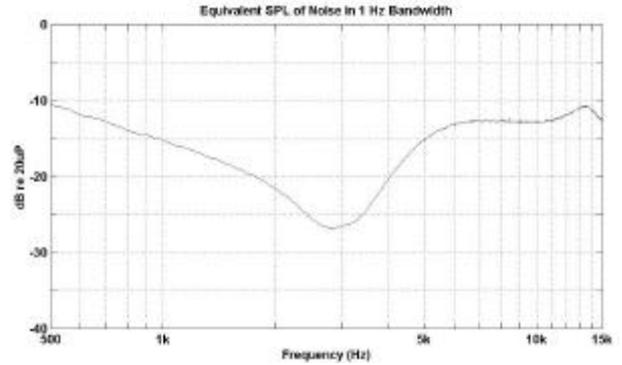


Figure 90 System Noise Floor (nominal)

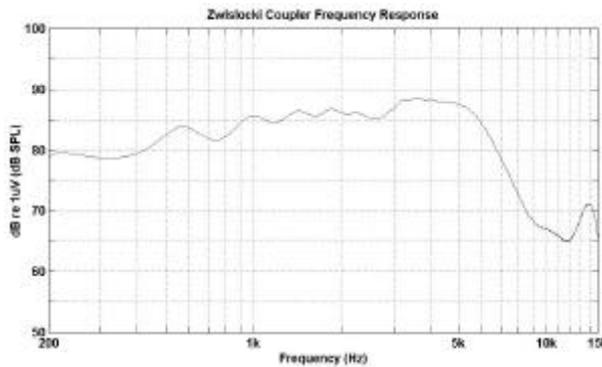


Figure 91 Sound Source Frequency Response (nominal)

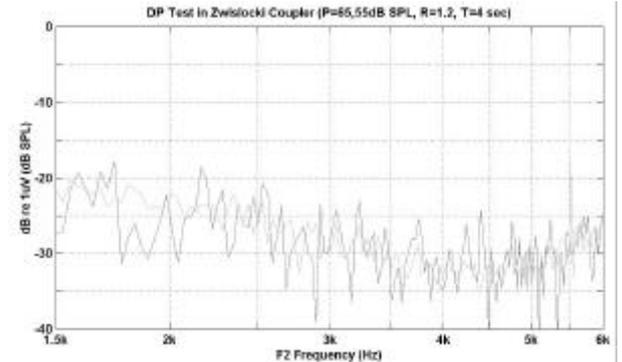


Figure 92 System Distortion + Noise (nominal)



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 4 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 5 dB in 3 out of 3 frequencies drops the probability of passing an ear with significant hearing loss to 1% or less. (In theory, a pass criterion of slightly higher than 4 dB should be adequate, but examination of our cumulative-distribution SNR data suggested choice of a more conservative number.) Note: By the binominal 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 **MAICO 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 need longer. 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), verifying a 99.7% accuracy would require testing hundreds of thousands of babies with a given system. Since the incidence of significant hearing loss is roughly 2 per 1000. Thus to demonstrate that only 3 babies out of 1000



Operating Instructions ERO•SCAN™

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.

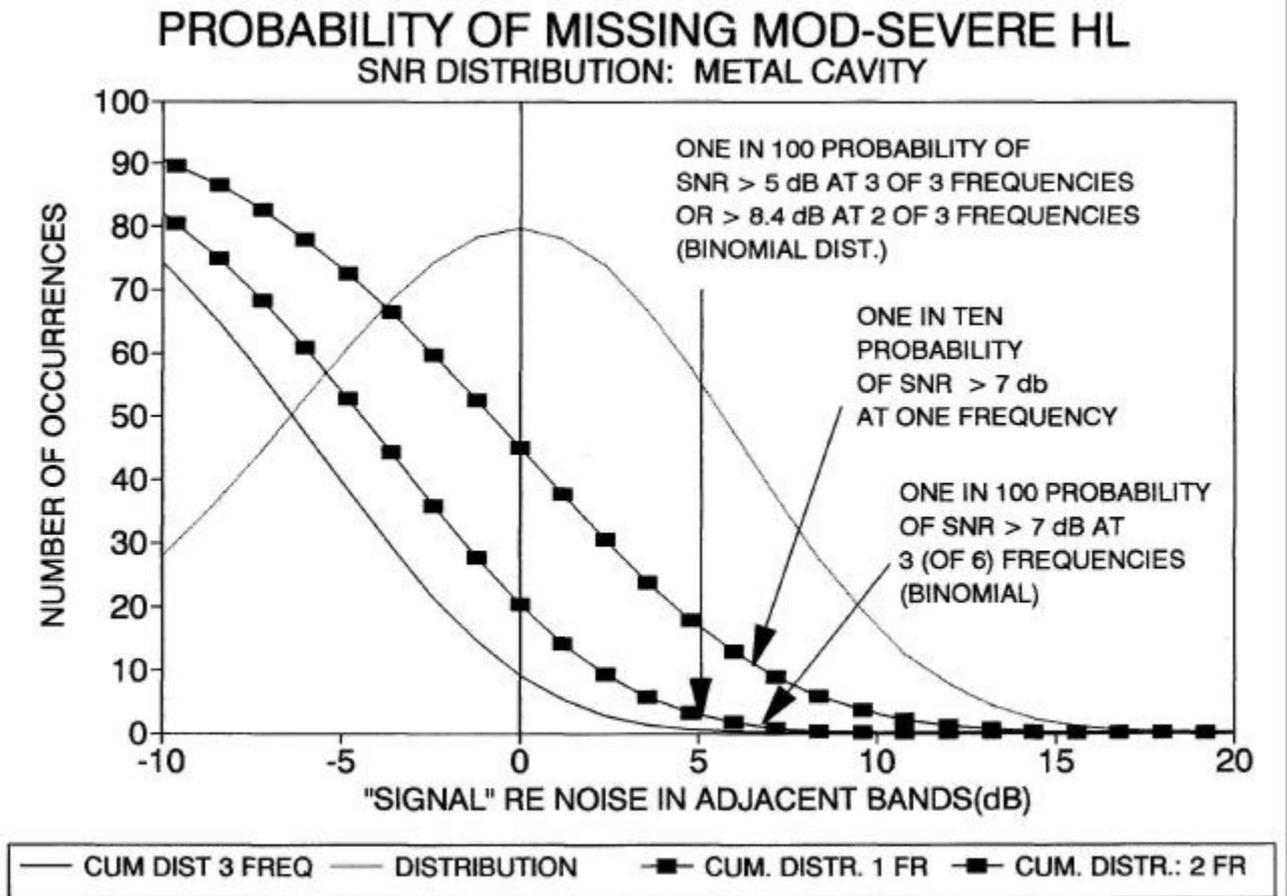


Figure 93 Probability of Missing Mod-Severe HL



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 3 out of the 6 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 **MAICO 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.

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 this case the test result will indicate "noisy."

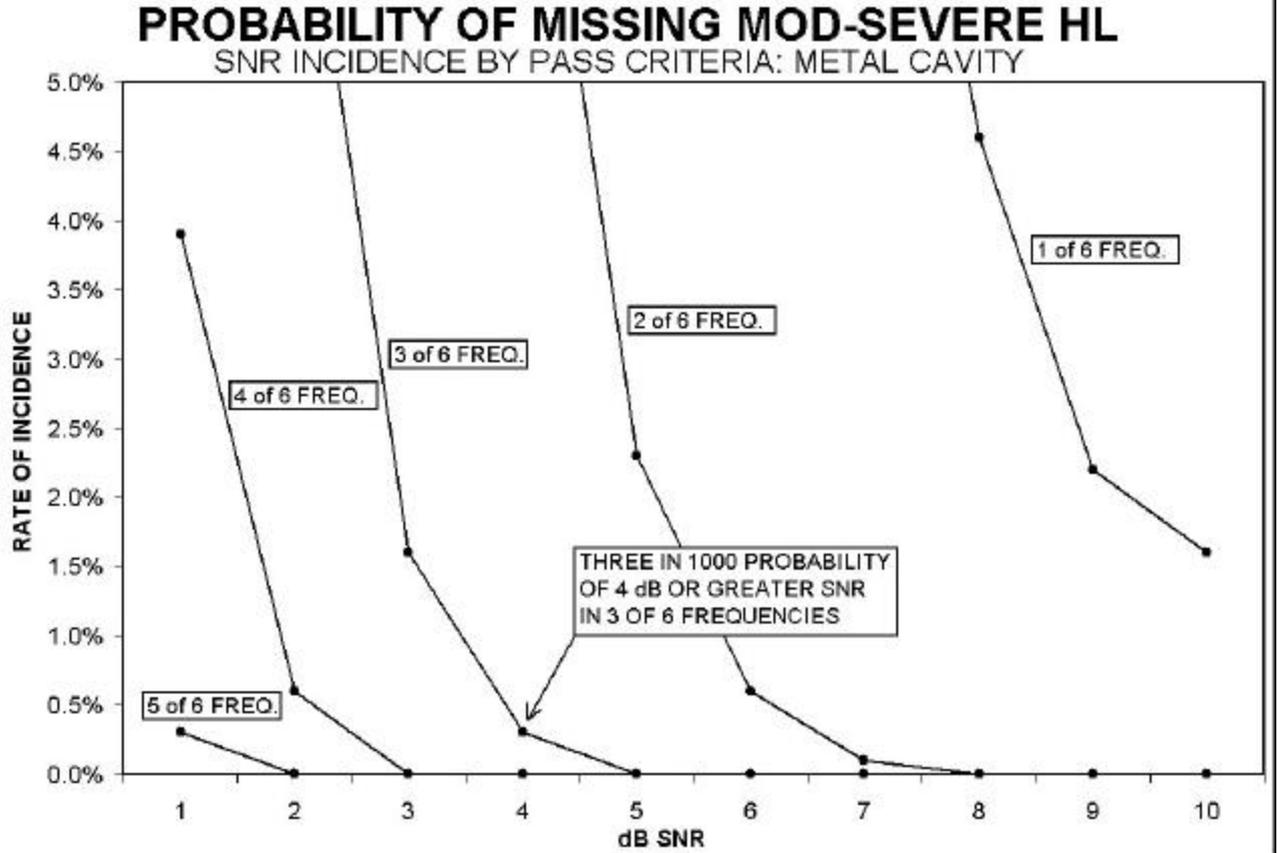


Figure 94 Probability of Missing Mod-Severe HL



12 Warranty, Maintenance and After-Sales 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.



13 Safety Regulations

13.1 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.

13.2 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.

13.3 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.



Certificate of Conformity

We,

MAICO Diagnostic GmbH

Rohrdamm 7

D-13629 Berlin

Germany

certify that the product

MAICO ERO•SCAN™

starting with serial number 181 4001

is produced according to the Medical Directive 93/42/EEC.

U. Ledworuski

Berlin, April 2001

U. Ledworuski

Head of quality department



Operating Instructions ERO•SCAN™

Specifications are subject to change.



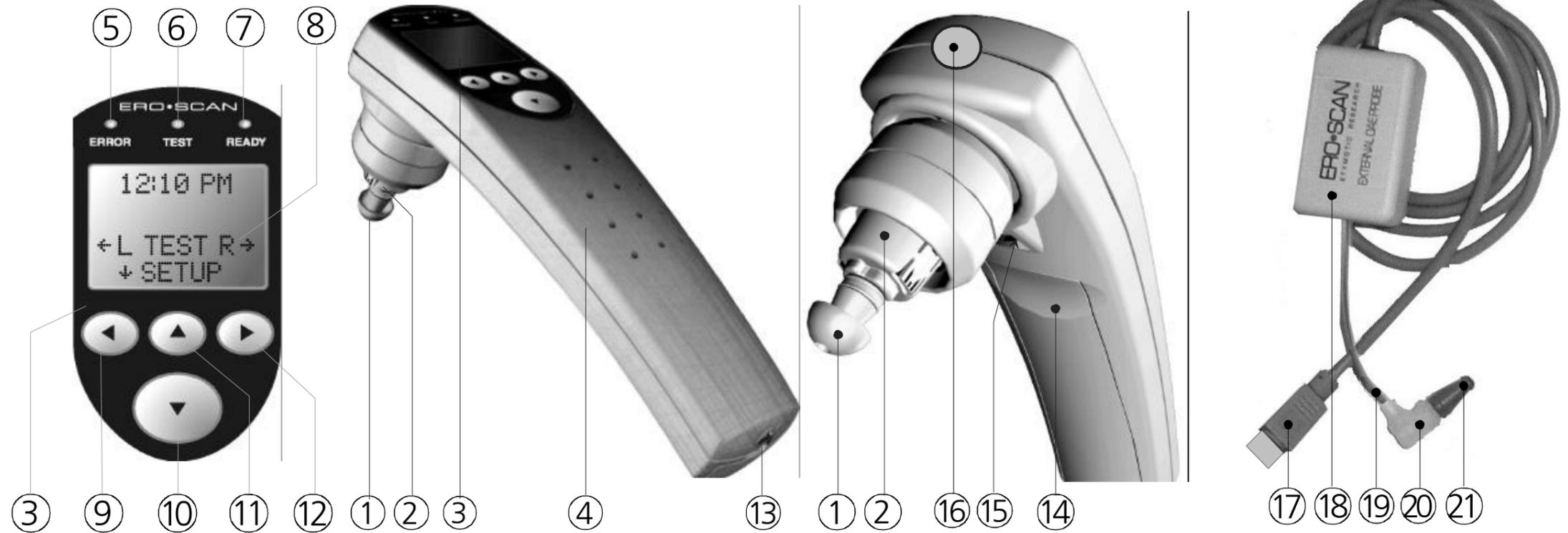
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MAICO ERO•SCAN™ Hand-held unit

- 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
 - Plug for external probe
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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
- Ⓗ Rechargeable battery pack
- Ⓚ Connector

MAICO ERO•SCAN™ Printer cable

- Printer cable
- Ⓚ Cable connector for external power supply

