

Maico Diagnostics



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Inc.

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Operating Instruction

ERO•SCAN®

Screener Plus

Diagnostic Plus





ERO•SCAN[®] Operating Instruction

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1 Standards Compliance

Standard	Issue Date	Title
ANSI/ASA 3.6	2010	Specification for Audiometers
IEC 60601-1	2007	Medical Electrical Equipment – General Requirements for Basic Safety and Essential Performance, Ed. 3
IEC 60645-1	2004	Electroacoustics – Audiological equipment – Part 1: Pure-tone audiometers
IEC 60645-3	2007	Electroacoustics – Audiometric equipment – Part 3: Test signals of short duration
IEC 60645-6	2010	Electroacoustics – Audiometric Equipment – Part 6: Instruments for the measurement of otoacoustic emissions
ISO 14971	2007	Application of Risk Management to Medical Devices
ISO 10993	2009	Biological Evaluation of Medical Devices
EN 60601-1-2	2007	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and Tests
FCC Part 15		FCC 47CFR, Part 15.247 & 15.249 (Bluetooth®)
UL 60601-1	2005	Clause 8.9.1.8; Pollution Degree Classification: 2



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2 Warranty

MAICO Diagnostics warrants that this product is free from defects in material and workmanship and, when properly used, will perform in accordance with applicable specifications. If this instrument does not meet these criteria within one year of original shipment, it will be repaired, or at our option, replaced at no charge when returned to our service facility.

NOTE: Changes in the product not approved by MAICO Diagnostics shall void this warranty. MAICO Diagnostics shall not be liable for any indirect, special or consequential damages, even if notice has been given of the possibility of such damages.

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

For assistance with this ERO•SCAN® Otoacoustic Emission Test System contact your Special Equipment Distributor or contact MAICO Diagnostics by phone at 888.941.4201 or by fax at 952.903.4100.

2.1 Intended Use

The ERO•SCAN® OAE Test Instrument is indicated for testing of cochlear function in infants, children, and adults by measuring otoacoustic emissions (OAEs). This instrument is suitable for use in all settings, including hospitals, schools, physician's offices, and audiologist practices. Factory defined protocols allow for simple screening measurements and user customizable protocols allow for diagnostic evaluations.

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



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3 Warnings, Cautions, and Errors

In this manual the following two labels identify potentially dangerous or destructive conditions and procedures.



The WARNING label identifies conditions or practices that may present danger to the patient and/or user.



The CAUTION label identifies conditions or practices that could result in damage to the equipment

NOTE: Notes help you identify areas of possible confusion and avoid potential problems during system operation.



The ERO•SCAN® Otoacoustic Emission Test System should be charged using only the provided power supply. Injury to personnel or damage to equipment can result when a three-prong to two-prong adaptor is connected between the ERO•SCAN® power supply and an AC outlet.

No modifications of the equipment are allowed by anyone other than a qualified MAICO representative. Modification of the equipment could be hazardous.

The ERO•SCAN® product has been verified by an independent laboratory to conform to international standards for EMC (electromagnetic emissions and immunity). The user is advised to avoid installation and use of this instrument in proximity with other devices or equipment that may emit or be susceptible to electromagnetic interference, including mobile phones. If the instrument is used adjacent to other devices or equipment, the user is instructed to verify that no disturbance is found in the operation of this or other equipment in proximity.



This icon indicates that patient applied parts of the instrument conform to IEC 60601-1:2005, Type B requirements.



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Instruments which bear the Underwriters Laboratories, Inc. label should be interconnected with accessories that have the proper electrical compatibility and are listed as meeting the requirements of the UL Medical and Dental Equipment Standard. Connection of accessories not meeting these requirements may result in electrical leakage currents in excess of those allowed by the standard and present a potential electrical shock hazard to the person being tested.

Any program aimed at obtaining reliable measurements of otoacoustic emissions should be staffed and supervised by appropriately-trained individuals.



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3.1 Status/Error Messages

Display Messages:

Attach Probe	No probe is detected at the start of a test.
BT Device Not Found	The paired Bluetooth® device cannot be detected. The device may be turned off or too far away.
BT Error #xxx	There is an error condition with the Bluetooth® device. Check the status.
BT Not Configured	The ERO•SCAN® instrument is not paired with any Bluetooth® device.
Device not Responding	The printer is not responding to queries from the instrument.
Due For Service	Indicates calibration of instrument is recommended. Message will appear upon the calibration due date set in the device. Message appears during device startup once per day.
Fit Error Cannot Obtain L	For a DP test, the desired level (L1 or L2) cannot be obtained within allowable limits. User should refit the probe and retry the test.
Fit Error Too High	For a DP test, the level of the calibration tone is too high. User should refit the probe and retry the test.
Fit Error Too Low	For a DP test, the level of the calibration tone is too low. User should refit the probe and retry the test.
Limit Error	Overflow error during the calculation of the DFTs for a DP test. User should repeat the test.
Memory Almost Full	Saved tests are within 5 tests of the maximum limit.
Memory Full!	The maximum saved test limit is reached. The user will need to clear the memory before any additional tests can be performed.
Power Low!	The battery charge level is too low for operation. The user must charge the battery before additional tests can be performed.
Printer Error	Indicates a problem with the printer. Check the printer status.
Printer Paper Out!	Indicates that printer paper has run out.
Time/Date Error	The clock is checked during power on to ensure it has not lost time and been reset. In the case of clock reset, this message is shown. The user should set the correct date/time.

Indicator LEDs (lights):

NOISE / Orange	The indicator labeled 'NOISE' provides a visual indication (AMBER) that the noise level measured during the test exceeds a nominal threshold. Also used to indicate some error conditions and when the outcome of test is REFER, NOISY, or NO SEAL.
TEST / Yellow	The indicator labeled 'TEST' provides a visual indication (YELLOW) that the selected test is being performed. This indicator will remain on steady state during the test function.
READY / Green	The indicator labeled 'READY' lets the user know that the instrument is not currently performing a test function and that it is available to perform a test function.
CHARGE / Blue	The indicator labeled 'CHARGE' provides a visual indication (BLUE) of the battery recharging function and battery status. The rate of illumination of the indicator provides a means of identifying the status of the charging function.



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4 Customer Responsibility



This product and its components will perform reliably only when operated and maintained in accordance with the instructions contained in this manual, accompanying labels, and/or inserts. A defective product should not be used. Make sure all connections to external accessories are snug and secured properly. Parts which may be broken or missing or are visibly worn, distorted, or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from MAICO.

This product should not be used in the presence of fluid that can come into contact with any of the electronic components or wiring. Should the user suspect fluids have contacted the system components or accessories, the unit should not be used until deemed safe by a MAICO certified service technician.

Do NOT use in the presence of flammable gaseous mixtures. Users should consider the possibility of explosions or fire when using this device in close proximity to flammable anesthetic gases.

Do NOT use the ERO•SCAN® in a highly oxygen-enriched environment, such as a hyperbaric chamber, oxygen tent, etc.

Equipment is not user repairable. Repairs and battery replacement must be performed by a qualified service representative only.



Use and store the instrument indoors only. It is recommended that the instrument be operated within an ambient temperature range of 15 °C / 59 °F to 35 °C / 95 °F and in relative humidity between 30 % and 90 % (non-condensing).

Transport and store the instrument in temperature between +5 °C / +4 °F to +40 °C / +104 °F.

Annual calibration recommended. Have an authorized service technician perform electrical safety checks on the unit in order to maintain continued compliance to IEC and UL 60601-1.



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5 Safety Precautions

The following safety precautions must be observed at all times. General safety precautions must be followed when operating electrical equipment. Failure to observe these precautions could result in damage to the equipment and injury to the operator or patient.

The employer should instruct each employee in the recognition and avoidance of unsafe conditions and the regulations applicable to his or her work environment to control or eliminate any hazards or other exposure to illness or injury.

It is understood that safety rules within individual organizations vary. If a conflict exists between the material contained in this manual and the rules of the organization using this instrument, the more stringent rules should take precedence.

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

5.1 Cautions - General



If the system is not functioning properly, do not operate it until all necessary repairs are made and the unit is tested and calibrated for proper functioning in accordance with MAICO published specifications.

Use only the disposable eartips designed for use with this instrument.

Never insert the probe tube into the ear canal without affixing an eartip.

The eartips are disposable and for single patient use only. Do not clean or reuse eartips.

Probe tubes are disposable and should be replaced when clogged. If a probe tube is reused after removal from the probe head, it will not sit as tight as before.

Do not attempt to clean probe tubes. This may cause damage to the probe.

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.



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5.2 Warning - Electric Shock Hazards



Do not open the case of the ERO•SCAN® Instrument. Refer servicing to qualified personnel.

Do not touch the contacts on the bottom of the instrument and the patient at the same time.

Do not connect the instrument to the patient and the PC at the same time.

5.3 Warning - In Case of Emergency

In case of emergency, disconnect the instrument from the supply mains by removing the micro-USB cable from the connector as shown in Figure 2 on page 15.

5.4 Warning - Explosion



This system is not explosion proof. Do not use in the presence of flammable anesthetics or other gases.

5.5 Warning - Battery Safety



This instrument contains a rechargeable lithium-ion battery. The battery is not user replaceable and must be returned to an authorized MAICO service location for repair.

5.6 Warning - General



Proper use of this device depends on careful reading of all instructions.



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6 Recycling/Disposal



Many local laws and regulations require special procedures to recycle or dispose of electrical equipment-related waste including batteries, printed circuit boards, electronic components, wiring and other elements of electronic devices. Follow all your respective local laws and regulations for the proper disposal of batteries and any other parts of this system.



WARNING

Batteries may explode or cause burns, if disassembled, crushed or exposed to fire or high temperatures.

7 Regulatory Symbols

No.	Symbol	IEC Pub.	Description
		980 & 60601-1	Serial Number
		980 & 60601-1	Date of Manufacture
		980 & 60601-1	Manufacturer
		980 & 60601-1	Caution, Consult Accompanying Documents
		980 & 60601-1	Return to Authorized Representative, Special Disposal Required
		980 & 60601-1	Reference Number
		60601-1	B Patient Applied Part According to IEC60601-1
		980 & 60601-1	Consult Operating Instructions
		60601-1	Keep Dry
		60601-1	Transport and Storage Temperature range
			Logo
		980 & 60601-1	EU Authorized Representative
		980 & 60601-1	Conforms to European Medical Device Directive 93/42/EEC



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MEDICAL - GENERAL MEDICAL EQUIPMENT
AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005, 3rd ed.) and
CAN/CSA-C22.2 No. 60601-1 (2008)



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8 Introduction

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.

The ERO•SCAN® is available as a Screening or Diagnostic version. Please see chapter 18 and 19 for further information.

8.1 How Does the ERO•SCAN® Device Work?



Figure 1

The system consists of the instrument, Micro-Probe, single-use eartips, replaceable probe tubes, and other accessories. The ERO•SCAN® instrument contains the hardware and software for generating the test stimuli, measuring and displaying the OAEs, 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 a rechargeable lithium-ion battery to power the device. The instrument uses an organic light-emitting diode (OLED) display screen and three light-emitting diodes (LEDs) to provide a visual display of test status to the operator. 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.

The Micro-Probe houses speaker and microphone 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, which fit onto the probe tube. The disposable eartips are color coded to facilitate easy selection by size.



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8.2 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 is capable of storing up to 250 test results. The results are displayed via the OLED 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.

8.3 Sensitivity and Specificity

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.



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9 Setup

9.1 Unpacking the System

The following is a list of parts shipped with each ERO•SCAN® system:

- ERO•SCAN® Instrument
- Micro-Probe
- Box of Single Use Eartips
- Package of Probe Tubes
- Micro-USB Power Supply for Charging the Lithium-Ion Battery
- Operating Instructions
- PC Database Software with Manual
- Micro B to A USB Cable for PC Communication/Charging
- Protective Carrying Case

Optional:

- Printer
- Printer Power Supply for Charging Printer
- Thermal Printer Paper Roll

If any of these parts are missing, contact your special equipment distributor or MAICO Diagnostics at 888.941.4201. We recommend that you save the shipping box and packing materials in case you need to store or ship the system.

9.2 Battery Charging

The ERO•SCAN® instrument is powered by an integrated rechargeable lithium-ion battery (1800 mAh) providing 20 hours (1000 tests, minimum) of operation between full charging. The battery status is indicated by the battery icon shown in the upper right corner of the Main Menu (Display 1, page 18). Full battery charge is represented by a full battery symbol on the display and reduces to an empty battery in increments corresponding to the discharge of the battery.

NOTE:

- Battery life will vary depending on each product configuration.
 - The maximum capacity of this battery will decrease with time and usage.
 - For maximum battery life, do not completely deplete the battery, but charge when 5-10 % of the battery remains.
-



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Figure 2

The Micro-USB port on the bottom of the instrument is used for charging via the power supply. Connect the charger as shown in Figure 2.

NOTE: Misalignment of the plug and socket can cause damage. The plug and socket should be visually inspected prior to each installation of the charging cable. If damage is observed, contact MAICO Diagnostics.



Figure 3

The indicator labeled 'CHARGE' (Figure 3) provides a visual indication (BLUE) of the battery recharging function and battery status during operation.

During battery charging the indicator will be lit whenever the Micro-USB connector is engaged and powered. The rate of illumination of the indicator provides a means of identifying the status of the charging function, and is defined as follows:

- Steady-state illumination indicates that the battery is fully charged. This identifies that the charging cycle has been completed or was not implemented because the battery was already fully charged.
- Slow blink illumination indicates that the charging function is in process.
- Fast blink illumination indicates a fault condition in which the user would be directed by the user manual to return the instrument for service.

During instrument operation, the user is warned of a low battery condition by the following illumination of the CHARGE indicator:

- Two fast blinks followed by a pause and then repeated until the battery is charged.

9.3 Installing the Micro-Probe



Figure 4

Turn off the ERO•SCAN® and insert the Micro-Probe connector into the socket on the top of the ERO•SCAN® (Figure 4). The plug will fit in only one direction. A MAICO logo is on the probe connector and will align with the instrument control panel.

NOTE: Misalignment of the plug and socket can cause damage. The plug and socket should be visually inspected prior to each installation of the remote probe. If damage is observed, contact MAICO Diagnostics.



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9.4 Attaching Eartips



Figure 5

The ERO•SCAN® instrument comes with a box of disposable eartips that fit a variety of ear canal sizes. The probe tube must have an eartip attached before inserting it into an ear canal. 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. The eartips are disposable and should be replaced after each patient.



Figure 6

After selecting an eartip, push it onto the probe tube until it is flush against the base of the probe tube (Figure 5). Twisting the eartip slightly while pushing it onto the probe is recommended. Be sure the eartip is fully seated on the probe. There should be no gaps between the eartip and the collar of the probe head (Figure 6).

To remove the eartip, grasp the eartip at the base and twist it while pulling it straight off the end of the probe tube. Grasping the base of the eartip will prevent the probe tube from being inadvertently pulled out of the probe head along with the eartip.

NOTE: If the probe tube becomes dirty or clogged, it must be replaced. See the section *Probe Tube Replacement, Chapter 20.3* for further information.



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10 Operating Instructions

10.1 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 a qualified professional for removal of the blockage prior to testing.

Place the patient in a position that will allow easy access to the ear canal. Use the shirt clip on the remote probe to secure the probe to clothing or bedding. The patient should remain still and quiet while the test is being performed.

10.2 Turning On the Instrument

To turn on the ERO•SCAN® instrument, press the ▼DOWN key located below the instrument's display screen (see Figure 7). The yellow 'TEST' light will appear briefly just above the display screen. The green 'READY' light will remain on indicating the instrument is ready for use. The Flash Screen will appear briefly. This display will indicate the type of instrument - Screener (SCR), Screener Plus (SC+), Standard (STD), or Combo (CMB), software version, serial number (for example ME1234567), and a recalibration date.

If the battery is sufficiently charged, the ERO•SCAN® will power on and automatically check the date and time. If there are no date/time errors detected, the **Main Menu** (Display 1, page 18) will appear on the display.

If this is the first time the ERO•SCAN® is being used, or if you wish to change the date or time, see the section *Clock Settings* on page 35. If a time/date error message is indicated, follow the instructions in this section to set the correct date and time.

10.3 Control Panel



Figure 7

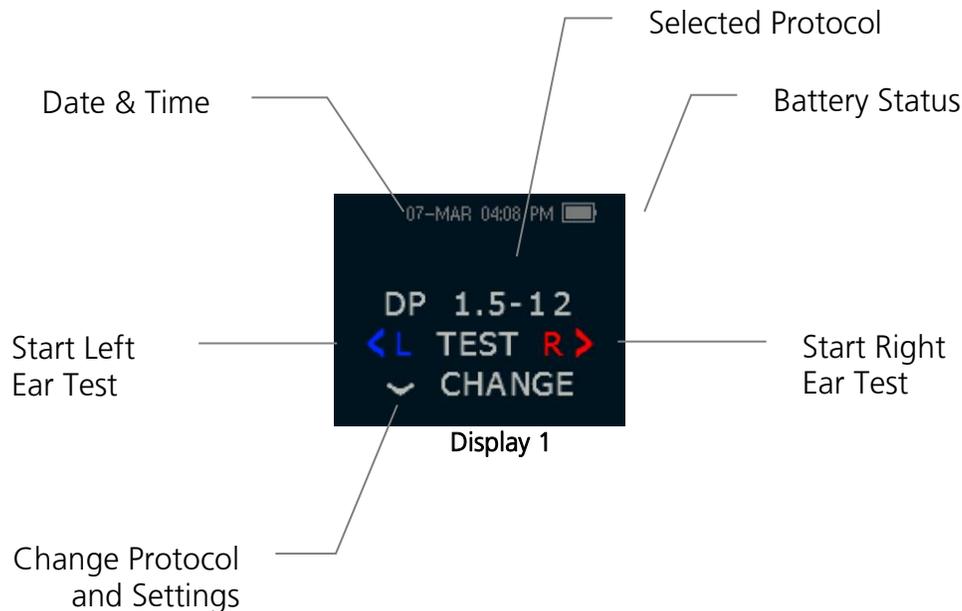
The ERO•SCAN® instrument uses 4 buttons to control all functions of the instrument (Figure 7). These buttons are arranged in a directional cursor format. The arrows on the keypad (◀LEFT, ▶RIGHT, ▲UP, and ▼DOWN) correspond to the arrows that are used on the screen. The screen will indicate which button 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 access the print command from the Main Menu.



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10.4 Main Menu



10.5 Selecting the Test Protocol



The currently selected protocol is shown on the Main Menu (Display 1). To change the selected protocol press ▼CHANGE at the Main Menu. The Change Protocol display will appear (Display 2). Use the ◀CHANGE▶ arrow buttons to change the selected protocol. Press the ▲UP arrow to return to the Main Menu to begin testing. Press the ▼SETUP to enter the setup menus.

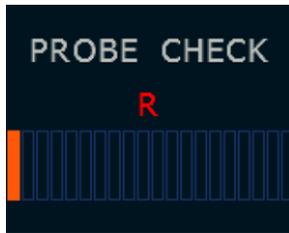
For either DPOAEs or TEOAEs screener devices, there are two default test protocols that vary by averaging time. *Appendix D* contains complete information on protocol settings. For instructions for customizing diagnostic protocols, review chapter 18 and 19.

NOTE: Screener default protocols cannot be customized. Diagnostic protocols are customizable.

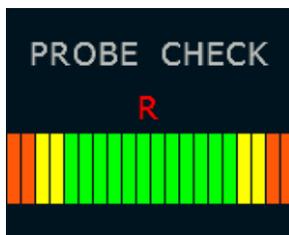


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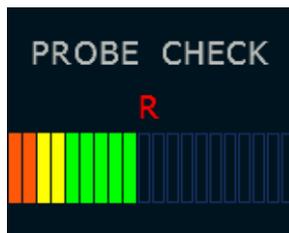
10.6 Probe Check (Beginning a Test)



Display 3



Display 4



Display 5

To obtain a seal and measure emissions, 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. To begin a test, insert the probe into the ear and select either the ◀LEFT or RIGHT▶ arrow key to indicate which ear will be tested.

After the test ear is selected, the Probe Check screen will be shown. This display shows a horizontal bar graph representing the ear canal volume and at the same time the fitting of the probe. When the bars are in the orange to the left (Display 3) this represent a very large ear canal volume or the probe is not inserted into the ear or place properly. When the bars are all the way to the right (Display 4), this represent the volume is too small for the test to begin or probe tip is blocked. Reinsertion and/or inspection of the probe tip is necessary. When the probe check is anywhere in the green area (Display 5), the ear canal volume is in the target area for testing to begin. The test will begin automatically if the probe fit is stable.

Appropriate adjustment of the probe/eartip position and eartip size selection should be made until the indicator falls within the green area and remains stable. If the test will not progress past the Probe Check phase, change the probe tube, check that the probe connector is fully seated in the socket and try again.

NOTE: Do not remove or insert the probe from the probe connector unless the device is off.

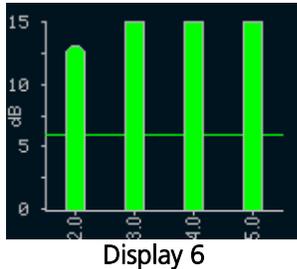
When a seal is obtained, the unit will automatically begin testing (AutoStart) and the yellow 'TEST' LED will illuminate throughout the test.

NOTE: To test children with PE tubes, the AutoStart needs to be disabled. This is accomplished by first inserting the probe 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 ◀LEFT or RIGHT▶ 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.

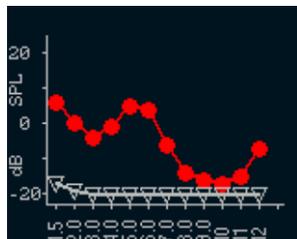


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10.7 Calibration and Test



Display 6



Display 7

The ERO•SCAN® instrument will automatically perform a calibration prior to the start of each test. During calibration a series of tones will be presented to the ear canal to calibrate the levels of the frequencies to be tested.

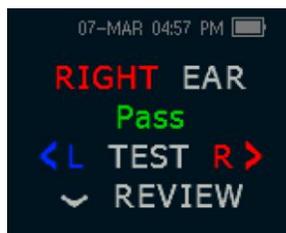
Following calibration of the test tones, the test phase will begin automatically. During the test phase, a set of bars should appear on the display (Display 6). These are the test results which are displayed as the emissions are measured and can be reviewed after the test is complete. Each column represents one test frequency (DP) or frequency band (TE).

The ERO•SCAN® allows the user to select from two options for viewing the results. The (SNR) graph view (Display 6) shows the signal-to-noise ratio for each DP test frequency or TE test band. The Value graph view (Display 7) shows the absolute emission and noise levels for each DP test frequency or TE test band. For additional information review the section *Interpreting Results* on page 30.

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.

NOTE: The ▲UP arrow key can be used to abort a test in progress. No record of an aborted test will be saved in memory.

10.8 Viewing Results



Display 8

When testing is complete, a display similar to Display 8 will appear. The results of the test are automatically saved in memory as soon as the test is complete. The results will be saved even if the unit turns off or the batteries are temporarily depleted. This screen again indicates the test ear and further gives the results of the test.

- "PASS" on the screen indicates that 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.



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- “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 graph. After reviewing the results, again push the ▼DOWN arrow key to return to the Main Menu (Display 1, page 18).

NOTE: Completed tests are automatically saved. By default (Save L/R Mode), the ERO•SCAN® instrument will save only the last test for each ear. Starting a new test for the same ear will overwrite the existing test.

NOTE: Once the review screen is exited, results are no longer viewable within the device. Printing or transferring to the PC is required for continued viewing options.

See the next section *Managing Results* on page 23 for more information on how the ERO•SCAN® saves results.

See the section *Instrument Settings - Save Mode* on page 38 for more information on the ERO•SCAN® save mode options.

10.9 Test Technique

As with other otoacoustic emission test instruments, there is a technique to learn when using the ERO•SCAN® instrument, especially while testing infants. Experience with existing OAE systems suggests that it may take up to 3 months to become completely proficient at screening infants.

When testing an infant with the ERO•SCAN® instrument, the infant has to be relatively quiet and calm; it is usually preferred for the infant to be asleep. A pacifier may be used to calm the infant, however, sucking will add noise to the test and decrease the likelihood of a passing result. Pull gently down and back on the pinna to straighten out the ear canal. Gently place the probe tube into the infant’s ear canal.

When testing children and adults, pull gently up and back on the outer ear during insertion to straighten the ear canal and ensure proper placement.



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10.10 Noise Sources

When the noise level exceeds the noise rejection limit of the instrument, the orange 'NOISE' light will appear. It is common for the 'NOISE' light (See Figure 1, page 12) to 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.

10.11 Turning Off the Instrument

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 "shutdown". (See the Changing *Instrument Settings – Auto Shutdown Time* on page 37.)

NOTE: The ▲UP arrow can be used to manually power off the instrument.



ERO•SCAN® Operating Instruction

11 Managing Results

Users have the option of printing to the thermal printer or transferring results to the ERO•SCAN® PC Database. Each ERO•SCAN® system will include one or more of these options. Your specific options will vary depending on the configuration of the system purchased.

11.1 Saving Results

The ERO•SCAN® instrument automatically saves the results of completed tests in the non-volatile memory (meaning tests are saved even if the battery is temporarily discharged). However, the ERO•SCAN® is not intended for long-term storage of test results.

NOTE: Users are strongly encouraged to print/transfer all test results at the completion of testing to avoid potential loss of data.

When operating in the default "Save L/R" mode, the ERO•SCAN® instrument will save the most recent test results for each ear and print/transfer only these results. This allows the user to retest a patient after a "REFER" result and to print/transfer only the most recent test result for each ear. It is recommended that the results be printed after each patient in the default mode.

When operating in the "Save 250" mode, the ERO•SCAN® will save up to 250 tests. There are two options in the Save 250 mode:

1. The ERO•SCAN® will automatically number each test from 1 to 250. This allows the user to save all tests for each patient (tests of the same ear are NOT overwritten) and to test multiple patients before printing or transferring results. In this mode, it is important to keep a record of the test number(s) for each patient.
2. The ERO•SCAN® Database Software is used to transfer patient names to the ERO•SCAN® and the ERO•SCAN® will display the names. When patient names are used (patient names are uploaded from the ERO•SCAN® Database Software to the ERO•SCAN® unit) the patient names are displayed on the ERO•SCAN® Unit in the same order as displayed on the Database Software. To move to a different name than the one displayed on the ERO•SCAN® screen, use the <LEFT or RIGHT> arrows to cycle through the names until the desired name is on the display. A patient named "Unnamed" is always included at the beginning of the ERO•SCAN® list for instances when a patient is being tested but the patient name was not transferred to the ERO•SCAN®. The "Unnamed" selection can be used multiple times when transferring to the Database Software.

See *Instrument Settings - Save Mode* on page 38 for information on changing the save mode settings.



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11.2 Deleting Results

The ERO•SCAN® holds data in non-volatile memory. The data stays in the memory even after data is printed by the thermal printer or downloaded to the ERO•SCAN® Database Software. Data can be deleted through a few methods, depending on the Save mode.

Save L/R Mode:

- A single test for the Left ear and a single test for the Right ear are held in memory. Data is deleted when a new test for the left or right ear is acquired.

NOTE: Following printing or data transfer to the PC software, all tests saved in memory are marked for deletion and will be permanently deleted when a new test is started. It is not necessary to manually clear the results.

Save 250 Mode:

- Data is deleted when new Patient Names are uploaded from the Database Software to the ERO•SCAN® (a warning is provided that data will be deleted).
- Data can be deleted using the Clear function in the System Menu (page 37).

Data can be deleted in the ERO•SCAN® from the Database Software when the device is connected to the PC and ERO•SCAN® Database Software is opened. When Names is selected, the window allows data to be deleted via the Clear Instrument button. See the *ERO•SCAN® Database Software Manual* for further instruction.

11.3 Printing to a Thermal Printer



Display 9

Printing to an optional thermal printer is by way of Bluetooth® connection. First establish Bluetooth® pairing between the ERO•SCAN® instrument and the printer by following the instructions in the section *Instrument Settings - Bluetooth® Device Pairing* on page 36.

NOTE: See the printer operating manual for instructions on using the printer or chapter *MPT-II SANIBEL Mobile Thermal mini printer*.

Following instructions provided with your printer, be sure the printer is on and ready for communication/printing. From the ERO•SCAN® instrument Main Menu (Display 1, page 18), press the ▲UP button to enter the device connection screen (Display 9). Press the <CONNECT> button.



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Display 10

The ERO•SCAN® will search for the paired printer showing Display 10 while searching. When the printer is found, all the test results that are stored in memory will print out automatically.

The ERO•SCAN® instrument will power off when printing is complete.

NOTE: All printed test results are marked for deletion, but will continue to be stored in memory until a new test is started at which time all tests in the memory will be erased. This allows the user to reprint the tests if printing is unsuccessful (for example, the paper runs out before printing is complete).

NOTE: See the ERO•SCAN® Database Software Manual for instructions on printing from the Database Software.

11.4 Connecting to the PC Database Software

Connection to the PC database software is achieved by using the provided Micro-USB to USB-A cable or via Bluetooth®.

USB Connection:

Plug the correct end (USB-A) of the cable into an available USB port on the computer and the correct end (Micro-USB) of the cable into the port found on the bottom of the ERO•SCAN® instrument.

The ERO•SCAN® instrument will detect the connection to the PC and wait for an action or communication from the PC database software.

Bluetooth® Connection:

Refer to the ERO•SCAN® Database Software Manual for connection via Bluetooth®.

NOTE: See the ERO•SCAN® Database Software Manual for instructions on using the application.



ERO•SCAN® Operating Instruction

12 MPT-II SANIBEL Mobile thermal mini printer

Cautions

- RISK OF EXPLOSION IF BATTERY IS REPLACED BY AN INCORRECT TYPE.
- DISPOSE OF USED BATTERIES ACCORDING TO LOCAL REGULATIONS.
- Do not place the battery in fire or heat the battery.
- Do not connect the positive terminal and the negative terminal of the battery to each other with any metal object.
- Do not place the batteries in microwave ovens, high-pressure containers, or on induction cookware.
- In the event that the battery leaks and the fluid gets into one's eye, do not rub the eye. Rinse well with water and immediately seek medical care. If left untreated the battery fluid could cause damage to the eye.
- This equipment is for professional use only.
- Do not open the cover while printing. The printer head might be hot.
- Do not expose the printer to any liquid.
- Do not disassemble the printer.
- If printer is stored for a longer period of time, store the battery separately.
- For correct battery charging make sure to follow charging instruction.

General information

MPT-II printer kit includes:

- MPT-II printer
- MPT-II rechargeable battery pack
- Thermal printer paper
- Printer Power supply/charger with plug adapters



ERO•SCAN® Operating Instruction

12.1 Operation

Paper loading:

Open the lid by pushing on the sides, insert paper roll as shown, and close the lid (Figure 8).



Figure 8

NOTE: Reorder paper from Maico or your local distributor.

Battery pack insertion:



Figure 9

Insert battery as shown (Figure 9).

Power on:

Push POWER BUTTON  for two seconds in order to power ON or OFF.

One short beep will be heard at power ON, two short beeps at power OFF.



Figure 10

Green Power indicator will be lit if printer is powered by battery (Figure 10).



ERO•SCAN® Operating Instruction

Indicators:

Green LED indicator	Blue LED indicator	Status	Sound	Note
Off 	Fast flash 	Charging	-	Power On
Off 	On 	Charging	-	Power Off
Off 	Slow flash 	Battery nearly discharged	-	-
Off 	On 	Charging completed	-	Power On
Off 	Off 	Charging completed	-	Power Off
On 	Off 	Power ON, battery	-	-
Slow flash 	Slow flash 	Out of paper	Beep	-
Slow flash 	Off 	Sleep mode	-	-

Self-test:

While printer is powered OFF, press and hold PAPER FEED  button, then press and hold POWER BUTTON  simultaneously. When beep is heard after approx. 3 seconds, release both buttons, and a test page will print with information on current status and character samples.

Paper feed:

When powered press PAPER FEED  button. Paper will feed as long as the button is pressed.

Bluetooth® setup:

Pairing with the instrument is necessary before printing via Bluetooth® is possible.

Pairing process:

Power on printer

- Let the instrument / PC search for other Bluetooth® devices.
- A device called MPT-II should occur in the list of devices.
- When prompted enter password "1234."
- Finish pairing.



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NOTE: Do not have several printers powered on and within range while searching.

It is possible to pair up to 8 instruments with one printer. If more instruments are paired the oldest will be deleted.

For detailed instructions how to initiate Bluetooth® search, please refer to your device's user manual.

NOTE: See the chapter *Bluetooth® Device Pairing* for more detailed information.

Technical specifications

Print mode:

- Thermal line dot print
- Printing width: 48 mm (1.9 in.)
- Resolution: 8 dots/mm (203 dots per in. (dpi))
- Dots per line: 384 dots

Thermal paper:

- Paper width = 56mm +/- 1 mm (2.2 in. +/- 0.04 in.) max. 40 mm (1.6 in.) diameter

Battery pack:

- 2-cell Li-Ion battery pack 7.4 V-1500 mAh

Power supply / charger:

- 12 V/1 A UE15WCP1-120125SPA
- Maximum current consumption 0.5 A
See also Figure 11



Figure 11

Physical properties:

- Size: 102 mm x 75 mm x 45 mm (4.02 in. x 2.95 in. x 1.77 in.) (W x L x H)
- Weight: 205 g including battery, without paper

Environmental specifications:

- Operational temperature range: -10 °C to +50 °C (+14 °F to +122 °F)
- Operational humidity range: 20 % to 85 %
- Storage temperature range: -20 °C to +70 °C (-4 °F to +158 °F)



ERO•SCAN® Operating Instruction

13 Interpreting Results

13.1 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.

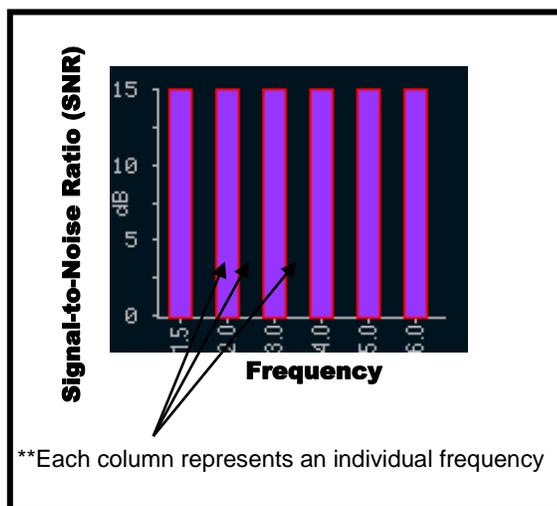


Figure 12

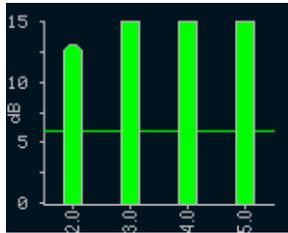
The display above shows a 6-column graph (Figure 12). Each frequency (DPOAEs) or frequency band (TEOAEs) is indicated by one column.

The ERO•SCAN® allows the user to select from two options for viewing the results. The SNR graph view shows the signal-to-noise ratio for each DP test frequency or TE test band. The Value graph view shows the absolute emission and noise levels for each DP test frequency or TE test band.



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13.2 SNR Graph View



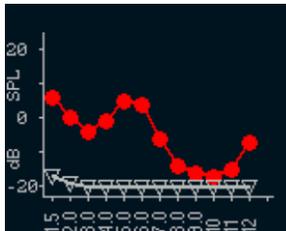
Display 11

Display 11 shows the SNR bar graph view. These are the signal-to-noise ratio (SNR) test results which are displayed as the emissions and noise floor are measured. Each column represents one DP test frequency or TE frequency band. The height of each column represents the SNR measured.

When a protocol with a "PASS" criteria has been selected, the user will see a horizontal green line at the decibel level corresponding to the SNR required for a pass. Green vertical bars represent a pass, a yellow bar is a non-Pass at the frequency band.

NOTE: Diagnostic protocols can display green or purple bars. Green is displayed when a "PASS" criteria is set in the device. For more information on this see *Setting the PASS SNR Level* on page 42.

13.3 Value Graph View



Display 12

Display 12 shows the Value graph view for right ear test. Red circle symbols represent the absolute emission levels at each DP test frequency or TE frequency band. For the left ear, dark blue "X" symbols will represent the absolute emission levels at each DP test frequency or TE frequency band. White upside-down triangles represent the noise floor at each DP test frequency or TE frequency band.

Refer to page 39 for instructions to switch the default setting of the graphs between the SNR Bar Graph and Value Graph.



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14 Interpreting Printed Results

Results from the ERO•SCAN® can be transferred to a portable thermal printer or the ERO•SCAN® Database Software for a full page printout. The information, as specified in section 14.1 and 14.2, is included on both printouts. For instruction on printing from the database, see the ERO•SCAN® Database Software Manual.

14.1 Understanding the DPOAE Printout

The following information is provided for each test (Figure 13):

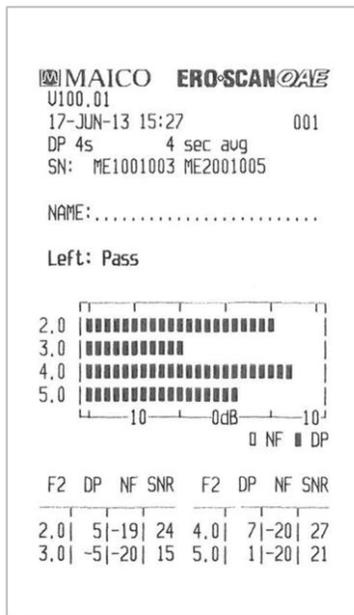


Figure 13

- 1) The software version number (e.g.: V100.01)
- 2) 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
- 3) The test number (if operating in "Save 250" mode) (e.g.:001)
- 4) The protocol selected (e.g.: DP 4s)
- 5) The averaging time used for this test (e.g.: 4 sec avg.)
- 6) Instrument/Probe serial number (SN)
- 7) The ear selected (Right or Left)
- 8) A PASS/REFER indication if there is a criterion set for the selected protocol
- 9) The open blocks indicate the noise floor in dB SPL
- 10) The solid blocks indicate the emission level in dB SPL
- 11) The f2 frequency in kHz (e.g.: 2.0, 3.0, 4.0, 5.0)
- 12) The level of the emission in dB SPL (DP)
- 13) The noise floor in dB SPL (NF)
- 14) The signal-to-noise ratio (SNR) = DP – NF



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14.2 Understanding the TEOAE Printout

The following information is provided for each test (Figure 14):

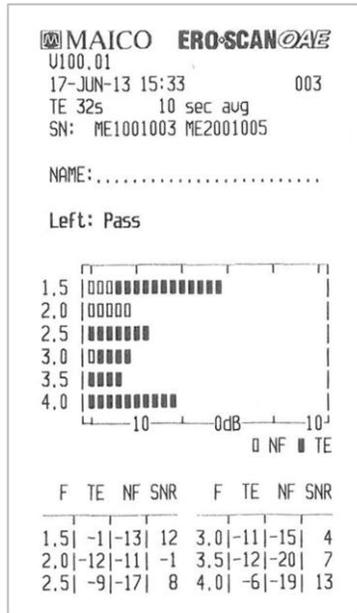


Figure 14

- 1) The software version number (e.g.: V100.01)
- 2) 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
- 3) The test number (if operating in "Save 250" mode) (e.g.:001)
- 4) The protocol selected (e.g.: TE 32s)
- 5) The averaging time used for this test (e.g.: 10 sec avg.)
- 6) Instrument/Probe serial number (SN)
- 7) The ear selected (Right or Left)
- 8) A PASS/REFER indication if there is a criterion set for the selected protocol
- 9) The open blocks indicate the noise floor in dB SPL
- 10) The solid blocks indicate the emission level in dB SPL
- 11) The frequency band center (F)
- 12) The level of the emission in dB SPL (TE)
- 13) The noise floor in dB SPL (NF)
- 14) The signal-to-noise ratio (SNR) = TE – NF



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15 Rounding Results

The user needs to be aware that the SNR and single PASS criteria 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 SNR = 4.9 dB. The printout values are rounded up to the nearest integer and are shown as TE = 5, NF = 0, and SNR = 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 SNR = 4.9, the printed value will be 5, but a "P" will NOT be printed.

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 SNR 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 SNR value appears to be incorrect. If the actual values were TE = 4.5 dB, NF = 0.4 dB, resulting in SNR = 4.1 dB, the printed values would be TE = 5 dB, NF = 0, SNR = 4. The printed SN value of 4 dB appears to be an error, but is in fact correct.



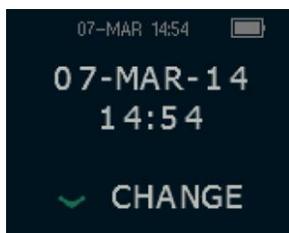
ERO•SCAN® Operating Instruction

16 Clock and Date Settings

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 day-month-year (e.g., 07-MAR-14). 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 Saving Time will also require resetting the clock. If the instrument is being powered on for the first time or if the instrument's battery is completely discharged and the battery is not charged within approximately one hour a "TIME/DATE ERROR" message will occur. If this message appears, reset the time and date.

16.1 Accessing the Clock Menu



Display 13

To change the time and date press ▼CHANGE at the main menu (Display 1, page 18) and then press ▼SETUP at the protocol selection display (Display 2, page 18). The current date and time presently set in the unit will be shown (Display 13). If the time and date are correct, press the ▲UP key to escape back to the main menu.

NOTE: When a Teal arrow is displayed for a ▼DOWN arrow, this represents an alternative menu is available. To access, hold the ▼DOWN arrow for 3 seconds until the 'READY' light (green LED) turns off and release the key.

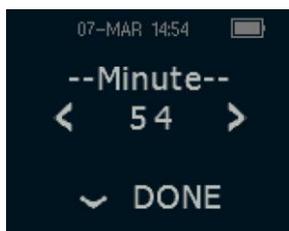
16.2 Changing the Date/Time



Display 14

If either the date or time is incorrect, press the ▼CHANGE key to access the menu to change the month (Display 14). Press the <LEFT or RIGHT> keys to scroll forward or backward through the months.

You will see the abbreviated name for each month (Display 14). When the desired month appears on the display, press the ▼NEXT key to enter the day selection screen. Pressing the <LEFT or RIGHT> keys will scroll through the days of the month. Repeat this process for the year, hour, and minute using the <LEFT or RIGHT> arrow keys to make the selection and the ▼NEXT key to advance to the next display.



Display 15

When the correct minute is selected, pressing the ▼DOWN arrow key (Display 15) will return to the Main Menu. The time and date changes are automatically saved.



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17 Instrument Settings

The ERO•SCAN® instrument allows the user to change many of the instrument's settings or functions. These settings include Bluetooth® Device Pairing, Clearing Test Results, Auto Shutdown Time, Minimum Amplitude Value, Save Mode, Clock Mode, Language, and Reset to Default Settings.

To access the menus to change these functions, press ▼CHANGE at the main menu (Display 1, page 18) and then press ▼SETUP at the Protocol Change (Display 2, page 18) to enter the Clock menu (Display 13, page 35). At the Clock menu, **hold down** the ▼CHANGE key for 3 seconds until the 'READY' light (green LED) turns off and release the key.

17.1 Bluetooth® Device Pairing



Display 16



Display 17



Display 18

The Bluetooth® pairing menu (Display 16) allows the user to pair the ERO•SCAN® unit with a Bluetooth® device, such as a thermal printer or personal computer, for printing test results and data transfer.

The ERO•SCAN® unit can be paired with only one device at any time. To establish Bluetooth® pairing, turn on the device that will be paired with the ERO•SCAN® unit (e.g.: thermal printer). Then select ◀DISCOVER▶ to initiate discovery of available Bluetooth® devices. The ERO•SCAN® will search for available Bluetooth® devices for approximately 15 seconds. During this time the user will see the message "Please Wait" on the display and the yellow 'TEST' LED will flash. Discovery can be canceled by pressing the ▲CANCEL button.

When discovery is complete, all discovered devices will be shown in the order in which they were found (Display 17). A compatible thermal printer will appear as "PRT-##-##" (e.g.: PRT-54-81) and other devices will be shown by their name which can vary depending on the device. Use the ◀CHANGE▶ buttons to select the desired device and then use the ▼PAIR button to pair the ERO•SCAN® to the selected device.

Pairing will be confirmed (Display 18). The pairing process is complete. Select ▼Main Menu to exit the Bluetooth® pairing menu.

NOTE: See the *Troubleshooting* section on page 49 if Bluetooth® pairing is unsuccessful or if any error messages are displayed.



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When pairing to a computer for use with the Database Manager Software, confirm the computer has Bluetooth® availability or a Bluetooth® dongle will be required. Confirm the Bluetooth® settings of the computer 'Allow Bluetooth® devices to find this PC' (See Figure 15).

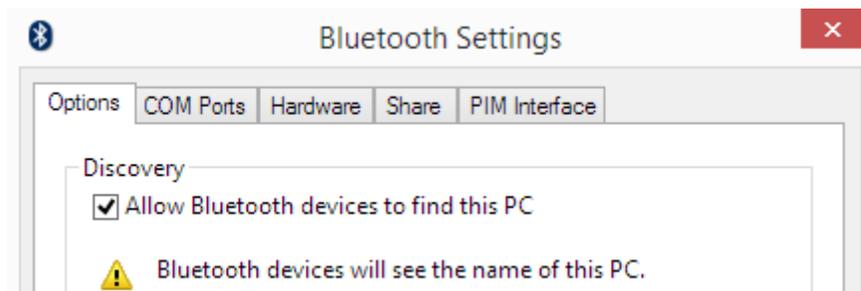
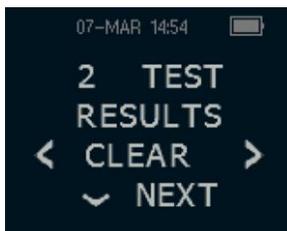


Figure 15 Bluetooth® Settings

Select the Bluetooth® pairing Menu (Display 16, page 36) and press ◀DISCOVER▶ to start the pairing process. When the computer is seen on the device, select ▼PAIR. While the device is pairing to the computer a notification will display on your computer "Add a device". Select this notification on your computer and enter PIN 1234. Once paired, the instrument will show Display 18 on page 36. The first time the ERO•SCAN® Database Manager Software is opened, select 'Detect Com Port' to finalize the ERO•SCAN® connection.

17.2 Clearing Test Results



Display 19

The Test Results Clear menu (Display 19) 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 to cancel. To advance to the next menu without clearing the results, press ▼NEXT.

NOTE: Following printing or data transfer to the PC software, all tests saved in memory are marked for deletion and will be permanently deleted when a new test is started. It is not necessary to manually clear the results using this menu.

17.3 Auto Shutdown Time



Display 20

The Power Off menu (Display 20) 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.



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The Auto Shutdown time may be increased or decreased by pressing the ◀CHANGE▶ keys. The times available are 30 seconds, 1, 2, or 4 minutes. Once you have made your selection, press ▼NEXT.

17.4 Save Mode/Storing Test Results



Display 21



Display 22

The ERO•SCAN® unit automatically stores only the most recent test result for each ear L/R (Display 21), but has the capacity to store 250 individual tests. To change the mode to save up to 250 tests, press the ◀LEFT or RIGHT▶ arrow keys to change the menu to 250. Once you have made your selection, press ▼NEXT.

There are two options in the Save 250 mode (Display 22):

1. The ERO•SCAN® will automatically number each test from 1 to 250
2. The ERO•SCAN® Database Software is used to transfer patient names to the ERO•SCAN® and the ERO•SCAN® will display the names. Up to 50 names can be stored in the device and 250 tests.

When numbers are used (no patient names are uploaded from the ERO•SCAN® Database Software to the ERO•SCAN®), each test is automatically incremented, starting with test number 1.

When patient names are used (patient names are uploaded from the ERO•SCAN® Database Software to the ERO•SCAN® unit) the patient names are displayed on the ERO•SCAN® Unit in the same order as displayed on the Database Software. To move to a different name than the one displayed on the ERO•SCAN® screen, use the left or right arrows to cycle through the names until the desired name is on the display. A patient named "Unnamed" is always included at the beginning of the ERO•SCAN® list for instances when a patient is being tested but the patient name was not transferred to the ERO•SCAN®.

It is recommended that you go to the Test Results Clear screen (Display 19, page 37) to clear any previous memory locations after you changed the save mode setting.

NOTE: When using the 250 test mode, it is important to keep a record of the test number for each patient. When 245 tests have been saved, the user will be warned that the memory is almost full. When the ERO•SCAN® unit reaches 250 saved tests, it will not allow any further testing. At this point either the results must be printed, transferred to the PC software, or they must be cleared from memory.



ERO•SCAN® Operating Instruction

17.5 Minimum Amplitude



Display 23

The Minimum Amplitude setting allows the user to set the unit to include minimum amplitude values in the pass/refer criterion (Display 23). The ERO•SCAN® is set with this feature turned OFF when it is shipped from the factory. 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".

To change the mode to Minimum Amplitude setting, press the ◀LEFT or RIGHT▶ arrow keys to make a selection. Once you have made your selection, press ▼NEXT.

The minimum DP amplitude when ON is -5 dB SPL.
The minimum TE amplitude selections are -5 and -10 dB SPL.

17.6 Clock Mode



Display 24

The Clock Mode menu (Display 24) allows the user to change the clock from a 24 hour mode to a 12 hour mode. To change the clock mode, press the ◀CHANGE▶ keys. Press the ▼NEXT to exit this menu.

17.7 Graph Style



Display 25

The Graph Style menu (Display 25) allows the user to select from two options for viewing the results. The SNR graph view shows the signal-to-ratio for each DP test frequency or TE test band. The Value graph view shows the absolute emission and noise levels for each DP test frequency or TE test band.

See the section *Interpreting Results* on page 30 for further information.



ERO•SCAN® Operating Instruction

17.8 Language



Display 26

The Language setting (Display 26) allows the user to select among several languages. To change the language, press the <CHANGE> keys until the desired language is shown. Press vNEXT to exit this menu.

17.9 Reset to Default



Display 27

The Reset to Default menu (Display 27) will return all instrument settings and protocol settings to their original factory defaults.

Select the <LEFT or RIGHT> arrow keys to reset and select <YES or NO> to verify reset. To exit the System menu without resetting the instrument, press vNEXT to return to the Main Menu.

NOTE: This will un-pair the Bluetooth® device, clear the test results, and reset ALL system and protocol settings.



ERO•SCAN® Operating Instruction

18 Advanced Options for DPOAE Testing

NOTE: The Advanced Options for DPOAE Testing section is reserved for those units purchased as a diagnostic device. Instruments purchased as a screener can skip to Section 20.

The Advanced Options menus permit modification of the test parameters and pass criterion for the customizable DP protocols. 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 protocol settings. See Appendix D 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 the battery is discharged temporarily.

18.1 Instructions for Customizing a Test Protocol

To enter the DPOAE Menu:

- 1) Press ▼CHANGE at the main menu (Display 1, page 18).
- 2) Using the ◀CHANGE▶ buttons, select the DPOAE protocol you want to customize (the "DP 4s" protocol is not customizable).
- 3) Press ▼SETUP at the Protocol menu (Display 2, page 18).
- 4) At the Clock menu (Display 13, page 35) the teal arrow represents a custom protocol menu is available. **Hold down** ▼CHANGE key for 3 seconds until the 'READY' light (green LED) turns off.
- 5) At the New BT Device menu (Display 16, page 36) the teal arrow represents a custom protocol menu is available. **Hold down** the ▼CHANGE key for 3 seconds until the 'READY' light (green LED) turns off.

You will now see the Level L1 screen (Display 28, page 42). You are in the DPOAE menu and will be able to scroll the available protocol parameters with the ▼NEXT button and make changes by using the ◀LEFT or RIGHT▶ arrow keys to CHANGE the selection.

NOTE: 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 custom protocol menus.



ERO•SCAN® Operating Instruction

18.2 Selecting the Level of Primary Tones



Display 28

The intensity of the primary tones (L1, L2) may be changed to any level between 40 dB SPL and 70 dB SPL. The level L1 will change in 1 dB increments by pushing the ◀LEFT or RIGHT▶ arrow keys (Display 28) and press ▼NEXT to move to the L2 screen.

Press the ▼NEXT key to set the level of L2 as with L1 above.

18.3 Setting the Averaging Time



Display 29

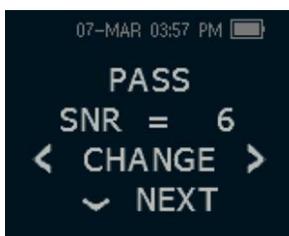
The Averaging Time can be changed to one of four settings. The Averaging Time will have a large impact on the time required to perform the test and on the signal-to-noise ratio (SNR). A 2 second average for 6 frequencies would produce a test in about 18 seconds, which includes the Probe Check sequence. The possible settings for the Averaging Time are as follows:

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

Press the ◀CHANGE▶ keys to select an option and the ▼NEXT key to exit (Display 29).

NOTE: Longer averaging times help to reduce the noise floor which can improve the likelihood of obtaining a passing result, particularly with a noisy patient (like a baby sucking a pacifier) or in a noisy environment. However, shorter averaging times may be preferred for young children and/or uncooperative patients.

18.4 Setting the PASS SNR Level



Display 30

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 (Display 30).



ERO•SCAN® Operating Instruction

18.5 Setting the Number of Frequencies for PASS



Display 31

The number of frequencies required for determining a PASS can be set from 0 to 12. 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 (Display 30, page 42) 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.

NOTE: To disable the PASS/REFER indication set the number of frequencies for pass to 0.

NOTE: Diagnostic protocols display the SNR graph with purple bars. Once the “Number of Frequencies for PASS” is set above zero, green bars display to identify this setting.

Press the <CHANGE> keys to select an option and the vNEXT key to exit (Display 31).

18.6 Reset Protocol



Display 32

Selecting the <RESET> arrow key in the Reset Protocol menu (Display 32) will return the selected protocol settings to their original factory settings. Press the vNEXT key to exit.

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

18.7 Save Protocol



Display 33

Once all of the settings have been selected for the protocol, these settings can be saved by selecting the <SAVE> keys (Display 33). Press the vDONE key to exit.

Selection of the vDONE before saving will not save the selection made to the protocol.



ERO•SCAN® Operating Instruction

19 Advanced Options for TEOAE Testing

NOTE: The Advanced Options for TEOAE Testing section is reserved for those units purchased as a diagnostic device. Instruments purchased as a screener can skip to Section 20.

The Advanced Options menu permits 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 protocol settings. See Appendix D 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.

19.1 Instructions for Customizing a Test Protocol

To enter the TEOAE Menu:

- 1) Press ▼CHANGE at the main menu (Display 1, page 18).
- 2) Using the ◀CHANGE▶ buttons, select the TEOAE protocol you want to customize (the "TE 64s" protocol is not customizable).
- 3) Press ▼SETUP at the Protocol menu (Display 2, page 18)
- 4) At the Clock menu (Display 13, page 35) the teal arrow represents a custom protocol. **Hold down** the ▼CHANGE key for 3 seconds until the 'READY' light (green LED) turns off.
- 5) At the New BT Device menu (Display 16, page 36) the teal arrow represents a custom protocol menu is available. **Hold down** the ▼CHANGE key for 3 seconds until the 'READY' light (green LED) turns off.

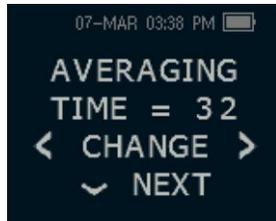
You will now see the Averaging Time screen (Display 34, page 45). You are in the TEOAE menu and will be able to scroll the available protocol parameters with the ▼NEXT button and make changes by using the ◀LEFT or RIGHT▶ arrow keys to CHANGE the selection.

NOTE: 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 custom menus.



ERO•SCAN® Operating Instruction

19.2 Selecting the Averaging Time



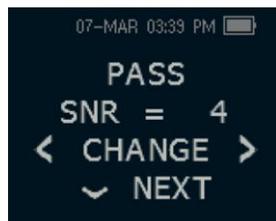
Display 34

The Averaging Time can be changed to one of five 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 4 seconds. A 32 second average would produce a test in about 32 seconds. This timing does not reflect the Probe Check process. 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 **vNEXT** key to exit (Display 34).

19.3 Setting the PASS SNR Level



Display 35

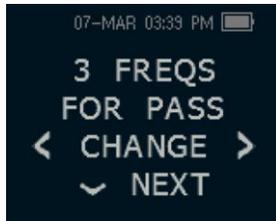
In order to provide a PASS/REFER determination for each test, the PASS SNR must be set. This number refers to the number of decibels that the TEOAE signal must be above the noise to be considered a PASS at that frequency. The limits for the PASS SNR are 3 dB to 10 dB. Pressing the **<LEFT or RIGHT>** 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 **vNEXT** key to exit (Display 35).



ERO•SCAN® Operating Instruction

19.4 Setting the Number of Frequencies for PASS



Display 36

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 **vNEXT** key to exit (Display 36).

NOTE: Diagnostic protocols display the SNR graph with purple bars. Once the “Number of Frequencies for PASS” is set above zero, green bars display to identify this setting.

19.5 Reset Protocol



Display 37

Selecting the **<RESET>** arrow key in the Reset Protocol menu (Display 37) will return the selected protocol settings to their original factory settings. Press the **vNEXT** key to exit.

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

19.6 Save Protocol



Display 38

Once all of the settings have been selected for the protocol, these settings can be saved by selecting the **<SAVE>** keys (Display 38). Press the **vDONE** key to exit.

Selection of **vDONE** before saving will not save the selections made to the protocol.



ERO•SCAN® Operating Instruction

20 Cleaning and Maintenance

20.1 Cleaning and Disinfection

Use a new eartips for each patient. Eartips are for single patient use only. The probe tube, which does not make direct contact with the patient, should be replaced if there is any sign of contamination or if the test will not progress past the Probe Check phase. Disinfection of the probe tube between patients is not required.

External parts of the instrument/probe can be cleaned to remove visible particulate contamination. Do not attempt to insert any object into probe.

This instrument is not designated as a 'sterile' device. Wiping with a clean cloth or towel and a mild non alcohol-based disinfecting solution, provides a suitable form of cleaning and low-level disinfection of the housing and probe exterior. Repeat this weekly, or as often as conditions warrant, to prevent a build-up of grime from normal handling and use.

We believe low-level disinfection is appropriate for this type of instrument. This may not conform to the infection control guidelines of the user's facility. The disinfection materials and procedures applied in the users' facility may be more appropriate for their circumstances than the methods outlined above (see cautions below). The frequency of cleaning and disinfecting is dependent on the facility's risk assessment, usage, and test environment.

Important:

- Do not immerse the instrument or probe in fluids or attempt to sterilize the instrument or any of its accessories.
- Do not allow any fluid to enter the device.
- Do not use autoclave sterilization.
- Do not use alcohol-based disinfectants.
- Take care not to put excessive pressure on the clear display window or allow any utensil to puncture the display window or control panel.

NOTE: Long-term exposure to any disinfecting agents has the potential to alter the material properties of the plastic housing and labeling of the device.

Always follow the safety and disposal guidelines given by the manufacturer of cleaning and disinfectant chemicals.



ERO•SCAN® Operating Instruction

20.2 Maintenance

This instrument requires no regular maintenance beyond routine cleaning and annual calibration. The probe tube requires replacement only when it becomes clogged.

A defective product should not be used. Make sure all connections to external accessories are snug and secured properly. Parts which may be broken or missing or are visibly worn, distorted or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from MAICO.

Equipment is not user repairable. Repairs and battery replacement must be performed by a qualified service representative only.

Annual calibration is recommended. Have an authorized service technician perform electrical safety checks on the unit in order to maintain continued compliance to IEC and UL 60601-1.

20.3 Probe Tube Replacement

Probe tubes are disposable and should be replaced when they become clogged. A package of replacement probe tubes is included with this instrument. Do not attempt to clean the probe tube.



Figure 16

To replace the probe tube, use the eartip to grasp the probe tube (the clear plastic tube) and twist slightly while pulling the probe tube straight out of the probe head (Figure 16).

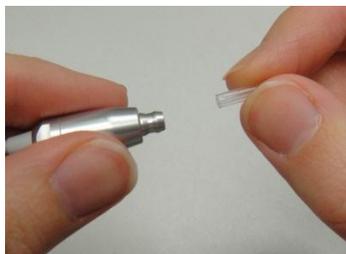


Figure 17

Dispose of the used probe tube immediately to avoid confusing used tubes and new tubes. Take a new probe tube from the package and insert the tube into the probe head until it is fully seated (Figure 17). A properly inserted probe tube will snap securely into place when it is fully seated in the probe head.

NOTE: If the probe tube is re-used after it was removed from the probe head once it will not sit as tight as before.



DO NOT ATTEMPT TO CLEAN PROBE TUBES. THIS MAY CAUSE DAMAGE TO THE PROBE.



ERO•SCAN® Operating Instruction

21 Troubleshooting

Problem	Solutions
Instrument does not turn on	<ul style="list-style-type: none">• The ▼DOWN arrow must be pressed for a full second (the Yellow 'TEST' LED will illuminate).• Connect the charger as shown in Figure 2 on page 15. Confirm that the blue "Charging" LED is illuminating in a slow blink pattern. Wait at least 10 minutes and then attempt to turn on the instrument• Contact MAICO for service if the problem persists.
The test will not start	<ul style="list-style-type: none">• Select a different sized eartip.• Reposition the probe.• Change the probe tube.• Verify that the eartip is sealed in the ear canal via feedback from the PROBE CHECK screen.• Check that the instrument will start in your own ear with the proper eartip for testing yourself. If the test will not start or if the AutoStart tones sound unusual, replace the probe tube.• Contact MAICO for service if the problem persists across several patients.
The results will not print	<ul style="list-style-type: none">• Check the printer status. Turn the printer on (wake from sleep mode) by pressing the large button.• If the printer does not turn on, plug in the power supply to charge the battery.• Be sure the printer has paper.• If paper comes out of the printer but there is no text on the paper then the paper is in backwards.• Press the large printer button twice rapidly to run demo print.• Contact MAICO for service if the problem persists.
Display is frozen and instrument will not respond to button presses	<ul style="list-style-type: none">• Press and hold the ▼DOWN arrow button for 10 seconds to force the instrument to power off. Powering the instrument back on again should reset/restore normal function.• Contact MAICO for service if the problem persists.



ERO•SCAN® Operating Instruction

Message	Solutions
Attach Probe	<ul style="list-style-type: none"> • Probe not detected. Check that the probe connector is fully seated in the socket. • Disconnect and reconnect the probe. • Cycle instrument power. • Contact MAICO for service if the problem persists.
BT Device Not Found	<ul style="list-style-type: none"> • Paired to Printer: <ul style="list-style-type: none"> ○ Check that the printer is turned on. ○ Move closer to the printer. ○ Try again. • Paired to PC Computer or Bluetooth® dongle: <ul style="list-style-type: none"> ○ Check that the serial port is open. Establishing the serial port is handled by the PC and/or the software, not by the ERO•SCAN® instrument.
BT Error #xxx	<ul style="list-style-type: none"> • Check BT device (printer or PC) status. • Attempt to connect to BT device again. • Contact MAICO if the problem persists.
BT Not Configured	<ul style="list-style-type: none"> • Printing has been attempted, but no BT device is paired with the ERO•SCAN® Instrument. Establish Bluetooth® pairing.
Device Not Responding	<ul style="list-style-type: none"> • The printer is not responding to queries from the instrument. Check printer status. • Awaken printer from sleep mode. • Charge printer battery if necessary.
Due for Service	<ul style="list-style-type: none"> • Indicates calibration of instrument is recommended. Message will appear upon the calibration due date set in the device. Message appears during device startup once per day.
Fit Error Cannot Obtain L	<ul style="list-style-type: none"> • For a DP test, the desired level (L1 or L2) cannot be obtained within allowable limits. User should refit the probe and retry the test. • Replace the probe tube. • Contact MAICO for service if the problem persists across several patients.
Fit Error Too High	<ul style="list-style-type: none"> • For a DP test, the level of the calibration tone is too high. User should refit the probe and retry the test. • Replace the probe tube. • Contact MAICO for service if the problem persists across several patients.
Fit Error Too Low	<ul style="list-style-type: none"> • For a DP test, the level of the calibration tone is too low. User should refit the probe and retry the test. • Replace the probe tube. • Contact MAICO for service if the problem persists across several patients.



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Message	Solutions
Limit Error	<ul style="list-style-type: none">• Overflow error during the calculation of the DFTs for a DP test. User should repeat the test.• Cycle instrument power.• Contact MAICO for service if the problem persists.
Memory almost full	<ul style="list-style-type: none">• Saved tests are within 5 tests of the maximum limit. Print or transfer test result to avoid interruption in testing.
Memory Full!	<ul style="list-style-type: none">• The maximum saved test limit is reached. The user will need to clear the memory before any additional tests can be performed.
Power Low!	<ul style="list-style-type: none">• The battery charge level is too low for operation. The user must charge the battery before additional tests can be performed.
Printer Error	<ul style="list-style-type: none">• Indicates a problem with the printer. Check the printer status.• Reset the printer or cycle the printer power.
Printer Paper Out!	<ul style="list-style-type: none">• Replace the paper roll.
Time/Date Error	<ul style="list-style-type: none">• The clock is checked during power on to ensure it has not lost time and been reset. In the case of clock reset, this message is shown. The user should set the correct date/time.



ERO•SCAN® Operating Instruction

22 Specifications

MICRO-PROBE SPECIFICATIONS

Measurement Type:	Distortion Product Otoacoustic Emissions (DPOAE) Transient Evoked Otoacoustic Emissions (TEOAE)
Frequency Range:	Screener Plus version: DPOAE: 2.0 kHz to 5.0 kHz TEOAE: 1.5 kHz to 4.0 kHz Diagnostic Plus version: DPOAE: 1.5 kHz to 12.0 kHz TEOAE: 0.7 kHz to 4.0 kHz
Stimulus Intensity Range:	DPOAE: 40 dB SPL to 70 dB SPL TEOAE: 83 dB SPL peak equivalent (± 3 dB)
Microphone System Noise:	-20 dB SPL at 2 kHz (1 Hz bandwidth) / -13 dB SPL at 1 kHz (1 Hz bandwidth)
Dimensions and Weight:	Length: 1.0 meter (40 in.) Weight: 28 g (1.00 oz.)
Connector:	HDMI

INSTRUMENT SPECIFICATIONS

Power Supply:	Lithium-Ion rechargeable
Battery Life:	1000 tests per charge, minimum 20 hours on-time
Dimensions and Weight:	Dimensions: W X D X H 2.58 X 1.23 X 5.78 in. Instrument Weight: 180 g (6.4 oz.)
User Interface:	OLED display to provide user information and progress of measurement 4-button keypad to control instrument functions
Connectors / Communications:	Integrated USB communication capability for battery charging and communication with PC-based database programs or an optional printer HDMI Connector for connection to the Micro-Probe Integrated Bluetooth® Class 2 + EDR with SPP Protocol for communication with optional printer



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POWER SUPPLY SPECIFICATIONS (use only approved power supply)

Model No:	UE08WCP-050160SPA
Output:	5.0 V DC, 1.6 A
Input	100 V-240 V AC, 50 Hz - 60 Hz, 400 mA

ENVIRONMENTAL REQUIREMENTS

Operating Temperature: 15 ° C to 35 ° C (59 ° F to 95 ° F)

Operating Relative Humidity: 30 % to 90 % (non-condensing)

Maximum Operating Altitude: 2000 meters (6000 feet)

Transport and Storage Temperature: 5 ° C to 40 ° C (41 ° F to 104 ° F)

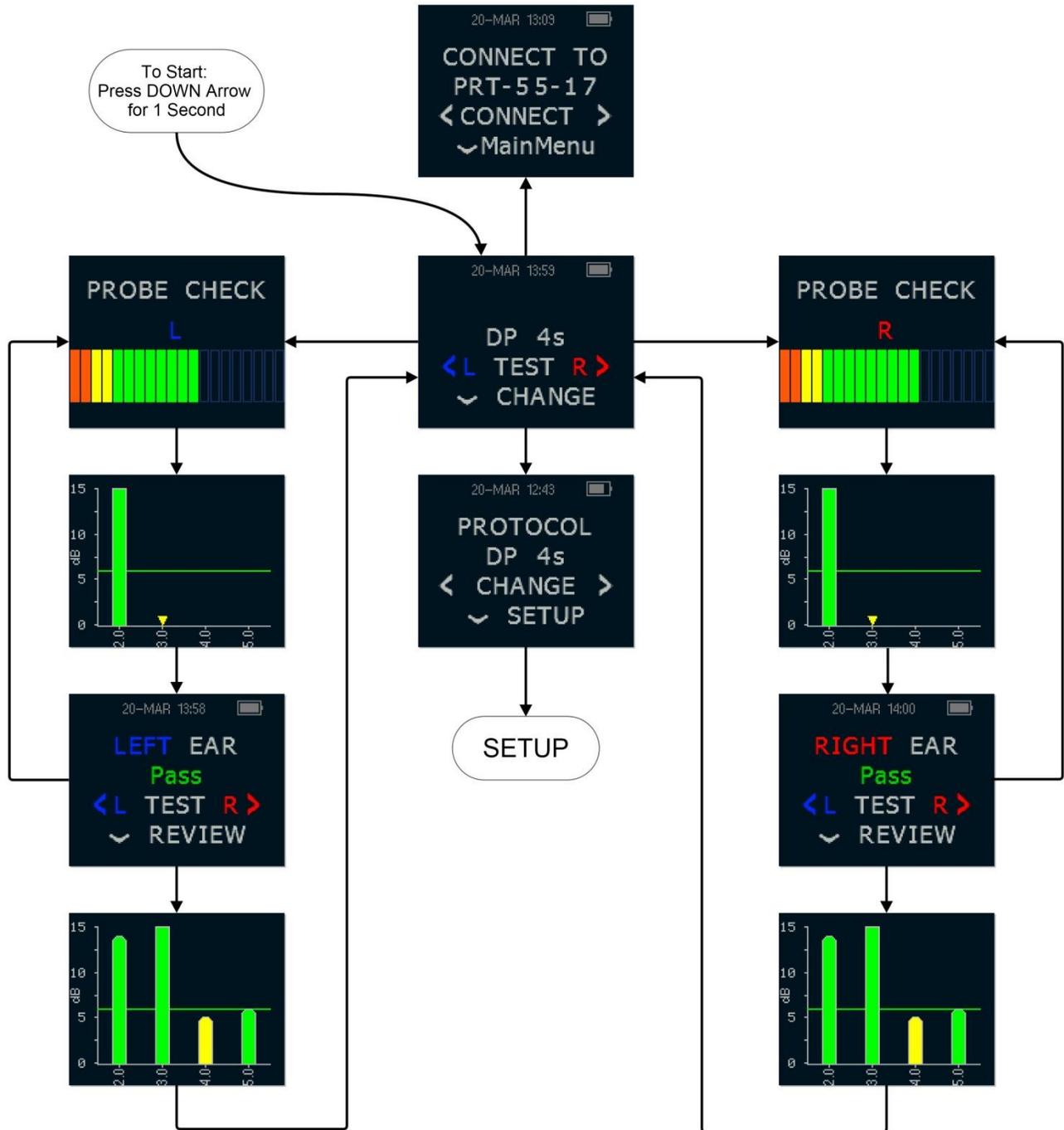




ERO•SCAN® Operating Instruction

Appendix A: Flowcharts

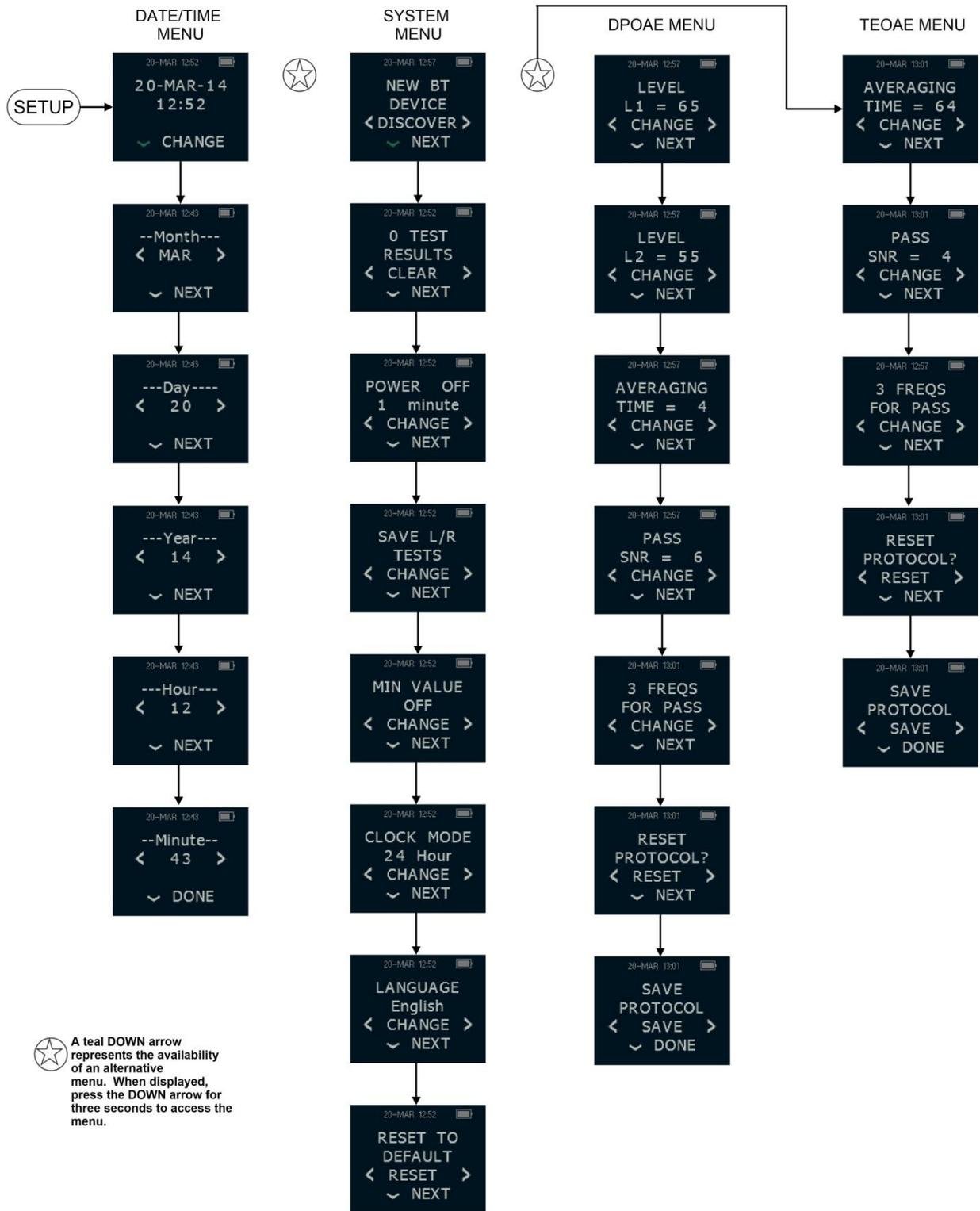
A.1 Test Operation Flowchart





ERO•SCAN® Operating Instruction

A.2 Setup Menu Flowchart



NOTE: DPOAE Menu and TEOAE Menu are not accessible in the ERO•SCAN® Screening version.



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Appendix B: Test Sequence

A complete test sequence consists of a Probe Check, calibration, and test phase. The Probe Check 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 Probe Check phase of the test begins. Probe Check phase 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 the desired peak pressure cannot be obtained, the unit will use the maximum voltage. A successful calibration leads to the actual test phase.

The test phase consists of measuring the response obtained from the pairs of test frequencies (f1, f2) 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 L1, L2, 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



ERO•SCAN® Operating Instruction

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.



ERO•SCAN® Operating Instruction

Appendix C: Pass/Refer Criteria

Pass/Refer Criteria for DPOAE

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

Extended measurements of the noise distributions in both the DPOAE filter channel “DP level” and the rms average of the 4 adjacent channels “N level” indicate that the signal-to-noise ratio (the difference between DP and N) has a standard deviation of 5.5 dB. As shown in Diagram 1 (page 60), 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 infants indicate that the tester’s technique is the single most important variable in the pass rate on normal-hearing infants. Some testers pick up the technique (see *Operating Instructions* section, page 17) with only a couple of day’s practice, producing pass rates comparable to those for other DPOAE equipment they have used for months; other testers take 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), since the incidence of significant hearing loss is roughly 2 per 1,000, 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 1,000 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.



ERO•SCAN® Operating Instruction

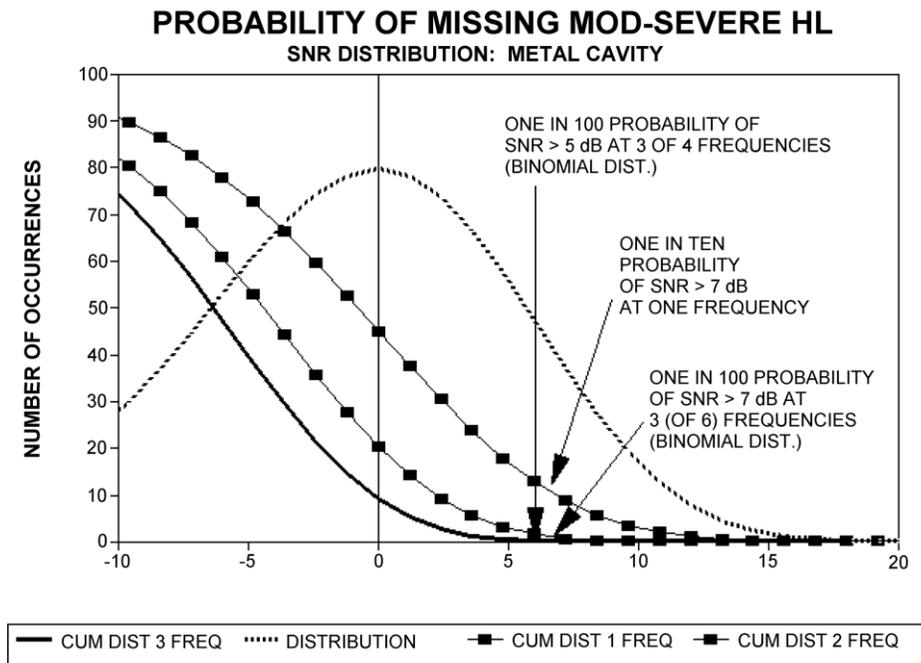


Diagram 1

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.

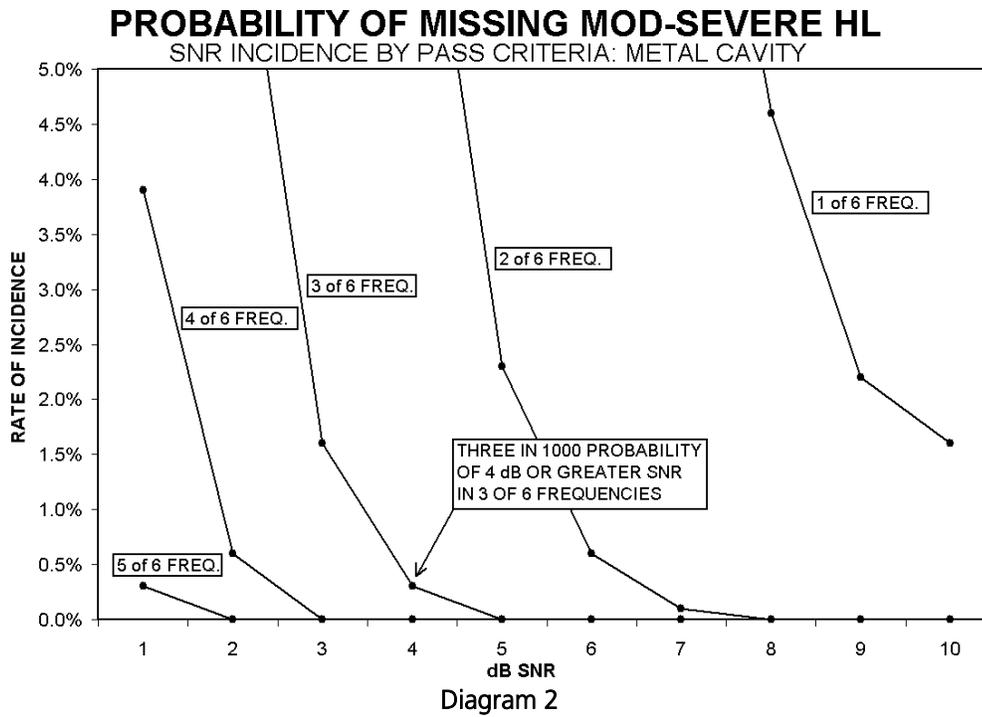
The ERO•SCAN® uses a novel noise-rejection algorithm (patent pending) that permits accurate DPOAE and TEOAE measurements in background noise and babble as high as 55 dB SPL to 65 dB SPL (A-weighted). Briefly explained, use of available memory in the ERO•SCAN® processor permits a post-hoc statistical 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.



ERO•SCAN® Operating Instruction

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”.





ERO•SCAN® Operating Instruction

Appendix D: Configurations and Test Protocols

DPOAE Protocols

	Name	# of Freq.	F2 Freq. [kHz]	L1/L2	Averaging Time	Pass SNR	# Passing Freq. for Test Pass
Screening	DP 4s	4	2, 3, 4, 5	65/55	4 sec	6 dB	3
	DP 2s	4	2, 3, 4, 5	65/55	2 sec	6 dB	3
Diagnostic	DP 2.0-5.0	4	2, 3, 4, 5	65/55**	4 sec**	6 dB**	3**
	DP 1.5-6.0	6	1.5, 2, 3, 4, 5, 6	65/55**	4 sec.**	6 dB**	0**
	DP 1.6-8.0	12	1.6, 2, 2.5, 3.2, 3.6, 4, 4.5, 5, 5.6, 6.3, 7.1, 8	65/55**	4 sec.**	6 dB**	0**
	DP 1.5-12	12	1.5, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12	65/55**	4 sec.**	6 dB**	0**

(Diagnostic version also includes DP 4s screening protocol)

TEOAE Protocols

	Name	# of Freq. Bands	Freq. center bands [kHz]	Averaging Time (max)	Pass SNR	# Passing Freq. for Test Pass
Screening	TE 64s	6	1.5, 2, 2.5, 3, 3.5, 4	64	4 dB	3
	TE 32s	6	1.5, 2, 2.5, 3, 3.5, 4	32	4 dB	3
Diagnostic	TE1.5-4.0	6	1.5, 2, 2.5, 3, 3.5, 4	64 sec**	4 dB**	3**
	TE0.7-4.0	6	0.7, 1, 1.4, 2, 2.8, 4	64 sec.**	4 dB**	0**

(Diagnostic version also includes TE 64s screening protocol)

** Customizable fields:

- L1/L2 : DP: 40 to 70 dB SPL
- Average time : DP: 0.5, 1.0, 2.0 or 4.0 sec, TE 4, 8, 16, 32 or 64 sec.
- Pass SNR : DP and TE: 3 dB to 10 dB
- Passing Freq. for Test Pass : DP and TE: 1 to 12



ERO•SCAN® Operating Instruction

Appendix E: EMC Compatibility

Portable and Mobile RF communications equipment can affect the ERO•SCAN®. Install and operate the ERO•SCAN® according to the EMC information presented on this page and the next 4 pages.

The ERO•SCAN® has been tested for EMC emissions and immunity as a standalone instrument. Do not use the ERO•SCAN® adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, the user should verify normal operation in the configuration.

The use of accessories, transducers and cables other than those specified, with the exception of servicing parts sold by MAICO Diagnostics as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the device. Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard.

Electromagnetic Compatibility

Although the instrument fulfills the relevant EMC requirements precautions should be taken to avoid unnecessary exposure to electromagnetic fields, e.g. from mobile phones, etc. If the device is used adjacent to other equipment it must be observed that no mutual disturbance appears.

Electrical Safety, EMC and Associated Standards

1. UL 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety
2. IEC/EN 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety
3. CAN/CSA-C22.2 No. 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety Electrical Equipment for Laboratory Use
4. IEC/EN 60601-1-1: Collateral Standard, Safety Requirements for Medical Electrical Systems
5. IEC/EN 60601-1-2: Medical Electrical Equipment, Part 1 - Electromagnetic Compatibility - Requirements and Tests
6. Essential Requirements of the current European Union Medical Device Directive 93/42/EEC
7. RoHS (Restriction of the use of certain Hazardous Substance)
8. WEEE (Waste Electrical & Electronic Equipment) Legislation



ERO•SCAN® Operating Instruction

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The ERO•SCAN® is intended for use in the electromagnetic environment specified below. The customer or the user of the ERO•SCAN® should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment - Guidance
RF Emissions CISPR 11	Group 1	The ERO•SCAN® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B Limits	The ERO•SCAN® is suitable for use in all commercial, industrial, business, hospital, and residential environments.
Harmonic Emissions IEC 61000-3-2	Class A Category	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Complies	

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the ERO•SCAN®

The ERO•SCAN® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ERO•SCAN® can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ERO•SCAN® as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.23\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitters, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



ERO•SCAN® Operating Instruction

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The ERO•SCAN® is intended for use in the electromagnetic environment specified below. The customer or the user of the ERO•SCAN® should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment-Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be greater than 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial, hospital, or residential environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial, hospital, or residential environment.
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70 % UT (30% dip in UT) for 25 cycles 5 % UT (>95% dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70 % UT (30% dip in UT) for 25 cycles 5 % UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial, hospital, or residential environment. If the user of the ERO•SCAN® requires continued operation during power mains interruptions, it is recommended that the ERO•SCAN® be powered from an uninterrupted power supply.
Power Frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: *UT* is the a.c. mains voltage prior to application of the test level.



ERO•SCAN® Operating Instruction

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The ERO•SCAN® is intended for use in the electromagnetic environment specified below. The customer or the user of the ERO•SCAN® should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment-Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the ERO•SCAN®, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 1.17\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field Strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a*), should be less than the compliance level in each frequency range (b*). Interference may occur in the vicinity of equipment marked: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

(a*) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ERO•SCAN® is used exceeds the applicable RF compliance level above, the ERO•SCAN® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ERO•SCAN®.

(b*) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.