Operation Manual
ERO•SCAN®

Screening and Diagnostic Version

MAICO Diagnostics GmbH, Sickingenstr. 70-71 , D-10553 Berlin, Tel. +49 30 / 70 71 46-50, Fax -99

Table of Contents

Title: Operation Manual ERO•SCAN® Screening and Diagnostic Version

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MAICO Diagnostics GmbH
Sickingenstr. 70-71
10553 Berlin
Germany
Tel.: + 49.30.70 71 46-50
Fax: + 49.30.70 71 46-99
E-mail: sales@maico.biz
Internet: www.maico.biz

Compliance

MAICO Diagnostics is an ISO 13485 certified corporation.

Caution for USA: Federal Law restricts this device to sale by or on the order of a licensed medical professional.

Trademark Notice

ERO•SCAN® is a U.S. registered trademark of Etymotic Research, Inc.

HearSIM™ is an unregistered trademark of OtoAccess A/S for use in the USA.

OtoAccess is a trademark of OtoAccess A/S registered in the USA and Europe.

Sanibel Supply® is a trademark of Interacoustics A/S registered in the USA and Europe.

1 Introduction

This Section offers you important information about:

- **the intended use of the device**
- **indications and contraindications of use**
- **features and benefits**
- **a description of the device**

1.1 Intended Use Statement

The ERO•SCAN® Hearing Test System 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.

1.2 Indications for Use Statement

The OAEs are generated by a series of clicks that are directed into the ear canal.

Otoacoustic emissions are low level audio-frequency sounds that are produced by the cochlea as part of the normal-hearing process. Available evidence suggests that otoacoustic emissions are generated by the cochlea’s outer hair cells and that the presence of OAEs is an indication that the outer hair cells are viable. Clinical evidence indicates that these emissions normally occur with normal hearing, or at most, mild hearing loss (usually 30-40 dB HL). The majority of hearing-impaired individuals will be identified by a simple OAE test.

1.3 Contraindications of Use Statement

Testing should not be performed on patients with one of the following symptoms without a medical doctor’s approval:

- Recent stapedectomy or other middle ear surgery
- Discharging ear
- Acute external auditory canal trauma
- Discomfort (e.g. severe otitis externa)
- Occlusion of the external auditory canal

Visual inspection for obvious structural abnormalities of the external ear structure and positioning as well as the external ear canal should be performed before testing.

1.4 Features

1.4.1 General Information About the ERO•SCAN®

The ERO•SCAN® features:

- Screening and diagnostic measurements with TEOAE and/ or DPOAE
- Fast automatic OAE screening with Pass/Refer results and graphical displays
- 2 predefined protocols for screening version, 5 DP and 3 TE protocols for diagnostic devices
- High noise immunity for operation in normal clinical environment
- Lightweight, small ear probe
- Sharp, colored OLED display
- Wireless printing
- Various software solutions available

1.4.2 Licenses

The ERO•SCAN® is available in versions (each with or without printer):

- ERO•SCAN® Screener DPOAE
- ERO•SCAN® Screener TEOAE
- ERO•SCAN® Screener DPOAE + TEOAE (2 DP and 2 TE protocols with fix parameters)
- ERO•SCAN® Diagnostic DPOAE
- ERO•SCAN® Diagnostic TEOAE
- ERO•SCAN® Diagnostic DPOAE + TEOAE (5 DP and 3 TE protocols (4 DPOAE and 2 TEOAE are customizable)

1.4.3 Printing Options

Printing test results from the ERO•SCAN® is accomplished in a variety of ways:

- Print directly from ERO•SCAN® using the optional wireless label printer that is available from MAICO.
- Transfer test data into a PC Software and print results using your standard printer attached to the PC.

1.4.4 PC-Software

The ERO•SCAN® can be connected to the following PC software:

- MAICO Sessions Standalone
- MAICO Sessions with OtoAccess® Database
- MAICO Sessions with Noah Database
- MAICO Sessions with your existing Practice Management Software via GDT or XML interface
- HearSIM™ Software with OtoAccess® Database (ERO•SCAN® Screener only)

1.5 Description

1.5.1 General

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.

1.5.2 TEOAE

Transient Evoked Otoacoustic Emissions (TEOAE) technology uses a click stimulus to screen patients' ears for cochlear hearing loss. The emissions are clearly related to the stimulus and therefore can be measured via a sensitive microphone placed in the patient's ear canal. The responses can be divided into frequency bands for assessment.

1.5.3 DPOAE

Distortion product otoacoustic emissions (DPOAE) technology uses pairs of pure tones presented in sequence to screen patients for cochlear hearing loss. The emissions are clearly related to the stimulus and therefore can be measured via a sensitive microphone placed in the patient's ear canal.

1.5.4 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 device 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.

2 For Your Safety

This Section offers you important information about:

- **how to read the operation manual**
- **where to spend special attention**
- **the customer responsibility**
- **the explanation of all regulatory symbols used**
- **important cautions and warnings that have to be considered during the whole time handling and operating your device**

2.1 Reading this Operation Manual

This operation manual contains information pertinent to the use of the ERO•SCAN® system including safety information as well as maintenance and cleaning recommendations.

It is highly recommended that users read the operation manual in its entirety prior to use of the ERO•SCAN® device on a patient.

READ THIS ENTIRE OPERATION MANUAL BEFORE ATTEMPTING TO USE THIS SYSTEM!

Use this device only as described in this operation manual.

All images and screenshots are only examples and may differ in appearance from the actual device settings.

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

The information sign displays alternative documents or sections in this operation manual that provide more detailed information.

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

2.2 Customer Responsibility

All safety precautions given in this operation manual must be observed at all times. Failure to observe these precautions could result in damage to the equipment and injury to the operator or subject.

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 device, the more stringent rules should take precedence.

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.

NOTE: Customer responsibility includes proper maintenance and cleaning of the device.

Section 3.2 Maintenance
Section 3.3 Cleaning and Disinfection Recommendations

Breach of the customer responsibility can lead to limitations of Manufacturer's Liability and Warranty.

Section 2.3 Manufacturer's Liability
Section 3.1 Warranty

NOTE: In the unlikely case of a serious incident, inform MAICO as well as the competent authority of the Member State in which the user and/or the patient is established.

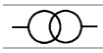
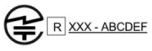
2.3 Manufacturer's Liability

Usage of the device in a way deviant from the intended use will lead to a limitation or termination of the manufacturer's liability in case of damage. Improper use includes disregarding the operation manual, the operation of the device by underqualified personnel as well as making unauthorized alterations on the device.

2.4 Regulatory Symbols

The following Table 1 gives an explanation of the symbols used on the device itself, on the packaging and the accompanying documents including the Operation Manual.

Table 1 Regulatory Symbols

REGULATORY SYMBOLS SYMBOL	DESCRIPTION
SN	Serial number
	Date of manufacture
	Manufacturer
	Caution, consult accompanying documents
	Warning, consult accompanying documents
	Information sign (reference for more detailed information)
	Return to authorized representative, special disposal required
REF	Reference number
MD	Medical Device
GTIN	Global Trade Item Number
	Patient applied part type B according to IEC 60601-1
	Refer to operation manual (mandatory)
	Keep away from rain
	Transport and storage temperature range
	Transport and storage humidity limitations
	Transport and storage atmospheric pressure limitations
	Voltage transformer
	Do not reuse
CE	Conforms to European Medical Device Directive 93/42/EEC
FC	FCC marking with ID
	Non-ionizing electromagnetic radiation
	Label Marking of Radio Equipment based on Certified Type
	Direct Current (DC)
	ETL listed mark
	Underwriters Laboratories, Inc. Label
MAICO	Logo

2.5 General Precautions

Before starting a measurement make sure, that the device works properly.

Use and store the device indoors only. For operation, storage and transport conditions see table in Section 6.1.

Do not drop or otherwise cause undue impact to this device. If the device is dropped or otherwise damaged, return it to the manufacturer for repair and/or calibration. Do not use the device if any damage is suspected.

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

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

No parts of the equipment can be serviced or maintained while in use with the patient.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

The list of accessories, transducers and cables can be found in:

Section 6.3 Electromagnetic Compatibility

Do not immerse the device in any fluids. Should the user suspect fluids have contacted the system components or accessories, the device should not be used until deemed safe by a MAICO certified service technician.

2.6 Electrical and Electrostatic Safety

This device complies with part 15 of the FCC Rules. Operation is subject to the condition that this device does not cause harmful interference

This icon indicates that patient applied parts of the device conform to IEC 60601-1 Type B requirements.

The system is internally powered.

In case of emergency, disconnect the device from the computer.

In Case of Emergency

WARNING

In Case of Emergency

In case of emergency, disconnect the device from power supply.

Position the device in such a way that it can be easily disconnected from the USB cable at any time.

Do not use the device if the mains cable and/or the plug is damaged.

WARNING

To transfer data to a PC, establishing a PC-connection via USB is required.

To learn how to safely establish a connection with a power supplied PC or laptop (medical device/non-medical device) or to a battery-driven laptop see:

Section 4.5 Establishing a PC-Connection

This equipment is intended to be connected to other equipment thus forming a Medical Electrical System. External equipment intended for connection to signal input, signal output or other connectors shall comply with the relevant product standard e.g. IEC 60950-1 for IT equipment and the IEC 60601-series for medical electrical equipment. In addition, all such combinations – Medical Electrical Systems – shall comply with the safety requirements stated the general standard IEC 60601-1, edition 3, clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment i.e. at least 1.5 m from the patient support or shall be supplied via a separation transformer to reduce the leakage currents. Any person who connects external equipment to signal input, signal output or other connectors has formed a Medical Electrical System and is therefore responsible for the system to comply with the requirements. If in doubt, contact qualified medical technician or your local representative. If the device is connected to a PC (IT equipment forming a system) ensure not to touch the patient while operating the PC. Do not touch the patient and the printer at the same time.

If the device is connected to a PC (IT equipment forming a system) assembly and modifications shall be evaluated by qualified medical technician according to safety regulations in IEC 60601.

The consequence of not following this warning could be a too high leakage current to the patient.

WARNING

Do not touch the contacts on the bottom of the device and the patient at the same time. When connected to computer equipment do not simultaneously touch the computer equipment and the patient at the same time. The consequence could be a too high leakage current to the patient.

The device is not intended for operation in areas with an explosion hazard. Do NOT use the device in a highly oxygen-enriched environment, such as a hyperbaric chamber, oxygen tent, etc. If the device is not used switch it off and disconnect it from the power supply.

Never short-circuit the terminals.

To avoid the risk of electric shock, this equipment must only be connected to the medical power supply originally delivered by MAICO. Using another power supply can also lead to electrical damage on the device.

Prevent cable breakage: cables must not be bend or buckled.

Before performing any service to the insert earphones, such as disconnecting the transducer boxes from the cable, you must uncouple the ERO•SCAN® transducers and electrodes from the patient.

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

2.7 Electromagnetic Compatibility (EMC)

The device fulfills the relevant EMC requirements. 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.

Also refer to EMC consideration in:

Section 6.3 Electromagnetic Compatibility

The ERO•SCAN® 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 device in proximity with other devices or equipment that may emit or be susceptible to electromagnetic interference, including mobile phones. If the device 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. It may be necessary to take mitigation measures, such as reorienting or relocating the ERO•SCAN® or shielding the location.

2.8 Battery Safety and Capacity

2.8.1 Battery Safety

Explosion hazard

The internal battery must be only replaced by an authorized service representative. Damage to the electronics resulting from an attempt to change the battery by someone other than an authorized representative will not qualify for repair under the product warranty.

2.8.2 Battery Capacity

The capacity of the battery will degrade over time with repeated charging/discharging cycles. The need to replace the battery due to diminishing capacity depends on usage patterns.

To extend battery capacity, do not allow the battery to fully discharge. To learn how to charge the device correctly see:

Section 4.4 Battery Charging

3 Warranty, Maintenance and After-Sales Service

This Section offers you important information about:

- **warranty conditions**
- **maintenance**
- **cleaning and disinfection recommendations**
- **accessory and replacement parts**
- **recycling and disposal of the device**

3.1 Warranty

The MAICO ERO•SCAN® is guaranteed for at least one year.

This warranty is extended to the original purchaser of the device by MAICO through the distributor from whom it was purchased and covers defects in material and workmanship for a period at least one year from date of delivery of the device to the original purchaser.

The device shall only be repaired and serviced by your distributor or by an authorized service center. Opening the device case voids the warranty.

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

3.2 Maintenance

In order to ensure that the device works properly, it has to be checked and calibrated at least once every twelve months.

The service and calibration must be performed by your dealer or to a service center authorized by MAICO.

When returning the device for repairs or calibration it is essential to send the acoustic transducers with the device. Please include a detailed description of faults. In order to prevent damage in transit, please use the original packing when returning the device.

3.3 Cleaning and Disinfection Recommendations

3.3.1 General

It is recommended that parts (device and accessories like probe tips) which come in direct contact with the patient be subjected to standard cleaning and disinfecting procedure between patients.

Recommendations for cleaning and disinfection of MAICO device presented in this document are not intended to replace or contradict policies in effect or procedures required for infection control at the facility.

If there is not a high infection potential, MAICO recommends:

- Before cleaning always switch off and disconnect the device from power supply.
- Remove disposable eartips or probes prior to disinfection.
- For cleaning use a lightly dampened cloth with soap water solution.
- Disinfect the plastic housing of the ERO•SCAN® and its accessories by wiping the surfaces with wet disinfection wipes. Follow the instructions on the specific disinfection product.
    - Wipe before and after each patient
    - After contamination
    - After infectious patients

To avoid damage of the device and its accessories, please mind the following:

- Do not autoclave or sterilize the device or probes.
- Do not use the device 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 device should not be used until deemed safe by a MAICO certified service technician.

Do not use hard or pointed objects on the device or its accessories.

For more detailed cleaning recommendations see the following Sections and follow the instructions on the items that are relevant for your system.

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.

3.3.2 Cleaning and Disinfecting the Screen

Use a lens cleaning or microfiber cloth to clean the screen.

Disinfect the screen of the device by wiping the surfaces with wet disinfection wipes.

3.4 Disposables – Eartips

3.4.1 Safe Use of Eartips

Figure 1

Operating the ERO•SCAN® requires the use of eartips (Figure 1) and probe tubes.

Eartips and probe tubes are intended for single-use only. They must be discarded after use. They cannot be cleaned.

WARNING

If you use the same eartips for different patients you enhance the risk of bacterial cross-contamination which can cause serious infections!

Replace the eartips with unused ones at the end of each patient's examination and discard the used ones.

IMPORTANT NOTE: All disposable supplies included with the ERO•SCAN® are produced by Sanibel Supply®. The system has only been tested using disposables supplied by Sanibel Supply®. Use of other supplies could alter the behavior and results obtained with the device and is not recommended. Sanibel disposables are latex, DsEHP and BPA free and have been tested for bio-compatibility. Data sheets are available upon request.

3.4.2 Applying Eartips

The ERO•SCAN® 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.

NOTE: See Section 5.7.2 on how to properly insert a probe into the patient's ear canal.

Figure 2

Choose an eartip that is appropriate for the patient's ear volume.

Push the eartip onto the probe tube until it is flush against the base of the probe tube (Figure 2). Twisting the eartip slightly while pushing it onto the probe is recommended. Be sure the eartip is fully seated on the probe.

Figure 3

There shall be no gaps between the eartip and the collar of the probe head (Figure 3).

3.4.3 Removing Eartips

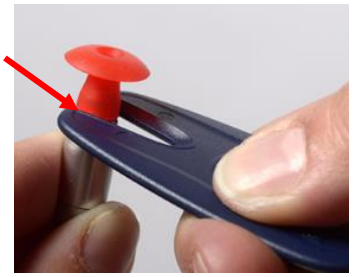


Figure 4

In order to remove the eartip, grasp the eartip at the base using the eartip removal tool and pull it smoothly straight off the probe tube (Figure 4). If you do not have a Removal tool, grasp the eartip at the base with your fingers and twist it while pulling off 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.

3.5 Disposables – Probe Tubes

3.5.1 Safe Use of Probe Tubes

WARNING

If you use the same probe tube for different patients you enhance the risk of bacterial cross-contamination which can cause serious infections!

Replace the probe tube with an unused one at the end of each patient's examination, and discard the used one.

CAUTION

If the probe tube is re-used after it was removed from the probe it can damage the probe head since it will not sit as tight as before.

3.5.2 Probe Tube Removal

Use the Probe Tube Removal Tool for replacement of probe tubes.

Figure 5

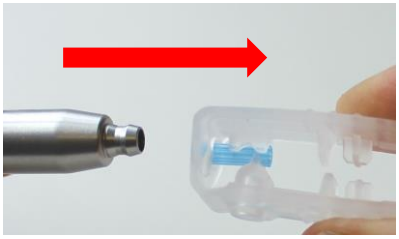


Figure 6

1. Place the front hole of the Probe Tube Tool over the end of the probe, as shown. The probe should be seated against the face of the tool and snap in place.
2. Squeeze the tool closed and hold it.
3. Twist the tool a couple of times while holding the tool closed and pulling away from the probe(Figure 5).
4. The probe tube will pull out from the probe. Discard the probe tube (Figure 6).

3.5.3 Applying a New Probe Tube

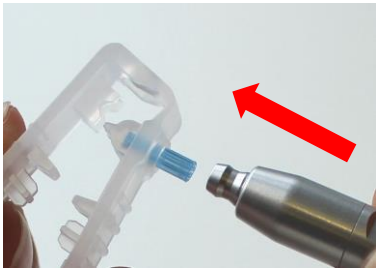


Figure 7

Figure 8

1. Place a new tube into the hole on the top of the tool.
2. Align the probe with the probe tube (Figure 7).
3. Push the probe onto the probe tube until the probe contacts the face of the probe tube tool and a snapping sound is heard (Figure 8).
4. Slide the tool off leaving the tube in place in the probe.

3.6 Troubleshooting

If problems occur while working with your ERO-SCAN®, you can usually easily solve them yourself. Follow the instructions in Table 2 for general problems or Table 3 if display messages are shown.

Contact MAICO for service if a problem persists.

Table 2 Troubleshooting

Problem	Explanation
Device does not turn on	• Press the ***DOWN*** arrow for a full second (the yellow LED (***TEST***) illuminates). • Connect the charger as shown in Figure 2 on page 37. Confirm that the blue LED (***CHARGE***) is illuminating in a slow blink pattern. Wait at least 10 minutes and then attempt to turn on the device.
Test does not start	• 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. • Try if the device starts in your own ear with the proper eartip. If the test does not start or if the AutoStart tones sound unusual, replace the probe tube.
Results are not printed	• 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. • Make sure the printer has paper. • If paper comes out of the printer, but nothing is printed on the paper, the paper roll may have been inserted the wrong way round. • Press the large printer button twice rapidly to run demo print.
Display is frozen and device does not respond to button presses	• Press and hold the ***DOWN*** arrow button for 10 seconds to force the device to power off. The device should function normally the next time it is switched on.
Numerical results show a line rather than a number	Dashes are displayed when there is excessive noise while testing. • Reduce the noise and retest. Dashes are displayed in the DP and SNR column when the signal level is at a minimum of 5 dB over target level. • Reinsert the probe and retest.

Table 3 Display Messages

Display Message	Explanation
Attach Probe	Probe is not detected. • Check that the probe connector is fully seated in the socket. • Disconnect and reconnect the probe. • Restart the device.
Wireless Device Not Found	The paired wireless device cannot be detected. The device may be turned off or too far away. Paired to Printer: • Check that the printer is turned on. • Move closer to the printer. • Recycle printer's power (press Power button until all lights are off, then press Power for steady green). • Try again. Paired to PC or wireless connectivity dongle: • 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®.
Wireless Error #xxx	There is an error condition with the wireless device. • Check wireless device (printer or PC) status. • Attempt to connect to wireless device again.
Wireless Not Configured	Printing has been attempted, but no wireless device is paired with the ERO•SCAN®. • Pair the ERO•SCAN®.with the wireless device.
Device not Responding	The printer is not responding to queries from the device. • Check printer status. • Awaken printer from sleep mode. • Charge printer battery if necessary.
Due For Service	Indicates that the calibration of the device is recommended. Message appears upon the calibration due date set in the device. Message appears during device startup once per day. • Have the device calibrated by a service technician authorized by MAICO.

Display Message	Explanation
Fit Error Cannot Obtain L	For a DP test, the desired level (L1 or L2) cannot be obtained within allowable limits. • Refit the probe and retry the test. • Replace the probe tube.
Fit Error Too High	For a DP test, the level of the calibration tone is too high. • Refit the probe and retry the test. • Replace the probe tube.
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. • Refit the probe and retry the test. • Replace the probe tube.
Limit Error	Overflow error during the calculation of the DFTs for a DP test. • Repeat the test. • Restart the device.
Memory Almost Full	Saved tests are within 5 tests of the maximum limit. • Print or transfer test result to avoid interruption in testing.
Memory Full!	The maximum saved test limit is reached. • Clear the memory before starting a new test.
Power Low!	The battery charge level is too low for operation. • Charge the battery before starting a new test.
Printer Error	Indicates a problem with the printer. Check the printer status.
Printer Paper Out!	Indicates that printer paper has run out. • Replace the paper roll.
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. • Set the correct date/time.

3.7 Recycling/Disposal

Within the European Union it is illegal to dispose of electric and electronic waste as unsorted municipal waste. According to this, all MAICO products sold after August 13, 2005, are marked with a crossed-out wheeled bin. Within the limits of Article (9) of DIRECTIVE 2002/96/EC on waste electrical and electronic equipment (WEEE), MAICO has changed their sales policy. To avoid additional distribution costs we assign the responsibility for the proper collection and treatment according to legal regulations to our customers.

Non-European countries

Outside the European Union, local regulations should be followed when disposing of the product after its useful life.

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

4 Unpacking and Hardware Orientation

This section provides information on:

- **unpacking the system**
- **becoming familiar with the hardware inclusive connections**
- **system assembly**
- **using the printer**
- **how to power the ERO•SCAN®**
- **how to store the device**

4.1 Unpacking the System

Check Box and Contents for Damage

- It is recommended that you unpack your ERO•SCAN® carefully making sure that all components are removed from the packing materials.
- Verify that all components are included as shown on the packing slip included with your shipment.
- If any component is missing, contact your distributor immediately to report the shortage.
- If any component appears to be damaged in shipment, contact your distributor immediately to report it. Do not attempt to use any component or device that appears to be damaged.

Reporting Imperfections

Notify the carrier immediately if any mechanical damage is noted. This will ensure that a proper claim is made. Save all packaging material so the claim adjuster can inspect it as well.

Report Immediately any Faults

Any missing part or malfunction should be reported immediately to the supplier of the device together with the invoice, serial number, and a detailed report of the problem.

Keep Packaging for Future Shipment

Save all the original packing material and the shipping container so the device can be properly packed if it needs to be returned for service or calibration.

Section 3.2 Maintenance

The ERO•SCAN® comes with different components (see Table 4 and Table 5). The availability of configurations with the following components are country-specific. Contact your local distributor for more information.

Table 4 List of Components

List of Components
ERO•SCAN® Device incl. Battery
Micro USB Power Supply for Charging the Lithium-Ion Battery (UES12LCP-050160SPA)
Micro-Probe*
Eartip Removal Tool
Probe Tube Removal Tool
PC Database Software with Operation Manual
Printer Kit incl. Power Supply for Charging Printer (UE15WCP1-120125SPA) and Thermal Printer Paper
Micro USB Cable for PC Communication
Carrying Case
Operation Manual
Quick Guide

***Applied parts according to IEC 60601-1**

Disposables supplied

NOTE: MAICO strongly recommends to use Sanibel eartips for reliable results.

Table 5 Disposables

Disposables
Eartip Kit (120 pc.) including 500 replacement probe tubes and removal tool

4.2 ERO•SCAN® Hardware and Components

The ERO•SCAN® system consists of the following components (configuration-dependent):

1. ERO•SCAN® device
2. Micro-Probe,
3. single-use eartips (for single-use only)
4. probe tubes (for single-use only)
5. Micro-USB cable
6. Thermal Printer

Figure 9 shows the ERO•SCAN® device.

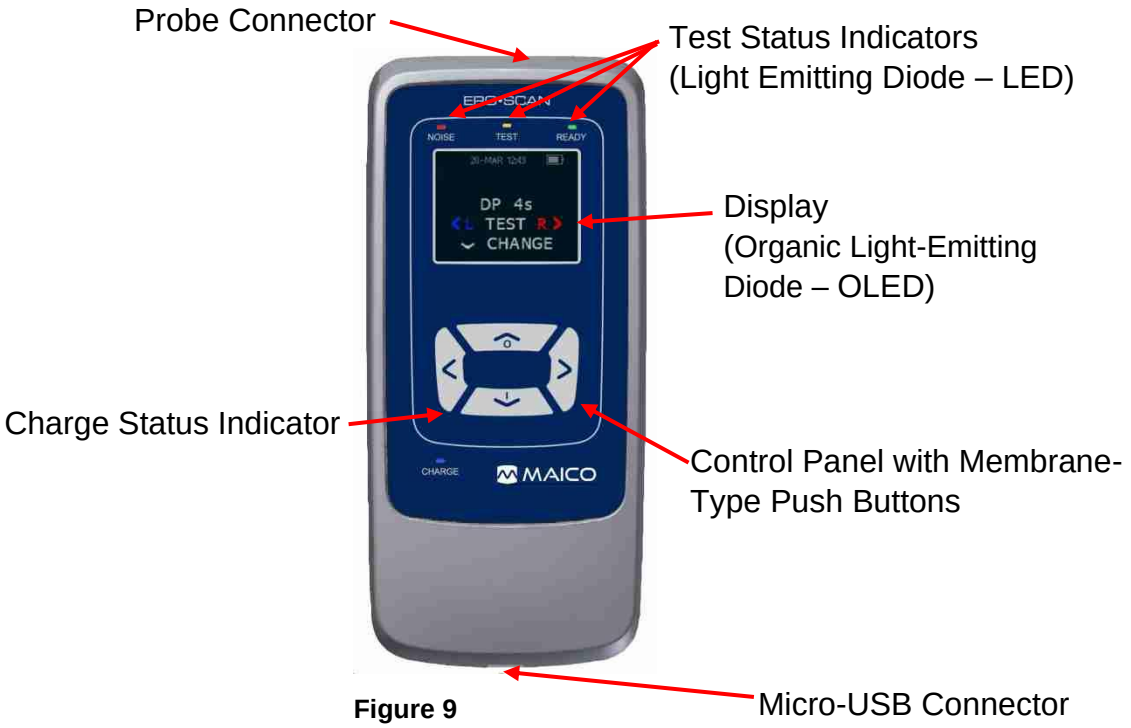


Figure 9

4.3 Handling the Micro-Probe

Attaching a Probe Tube and an Eartip

Figure 10

The Micro-Probe houses speaker and microphone which produce test stimuli and measure the sound pressure level (SPL) present in the sealed ear canal.

Secure placing of the probe in the ear canal is accomplished through disposable eartips, which fit onto the probe tube. The eartips are color-coded to facilitate selection by size.

Section 3.4 Disposables – Eartips

Connecting the Micro-Probe with the ERO•SCAN®

Figure 11

Turn off the ERO•SCAN® and insert the Micro-Probe connector into the socket on the top of the ERO•SCAN® (Figure 11). The plug fits in only one direction. A MAICO logo is on the probe connector and aligns with the device 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.

4.4 Battery Charging

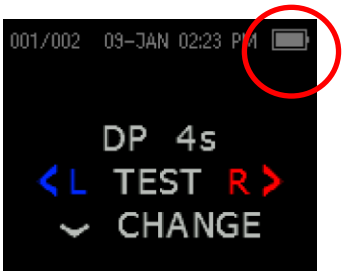


Figure 12

The ERO•SCAN® is powered by an integrated rechargeable lithium-ion battery (1700 mAh) providing 15 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*** (Figure 12).

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 varies depending on the product configuration.

The maximum capacity of this battery decreases with time and usage.

For maximum battery life, do not completely deplete the battery, but charge when 5 % to10 % of the battery remains.

Figure 13

The Micro-USB port on the bottom of the device is used for charging via the power supply. Connect the charger as shown in Figure 13.

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 14

The blue LED (***CHARGE***) (Figure 14) provides a visual indication of the battery status during operation or charging. The status is indicated as follows:

Two fast blinks followed by a pause	Battery is low. Charging is needed.
Slow blinking	Charging is in progress.
Fast blinking	Indicates an error. Contact your local representative or MAICO for help.
Steady	Battery is fully charged.

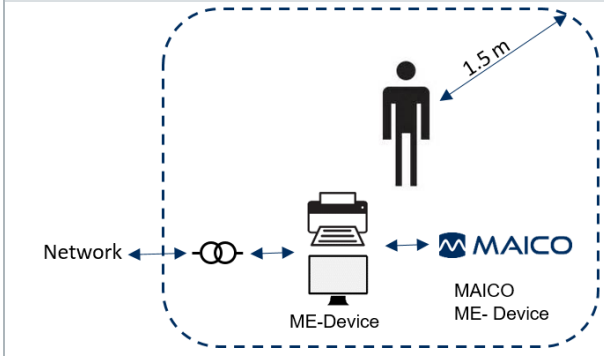
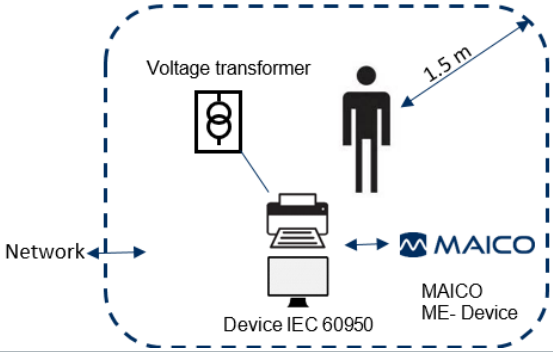
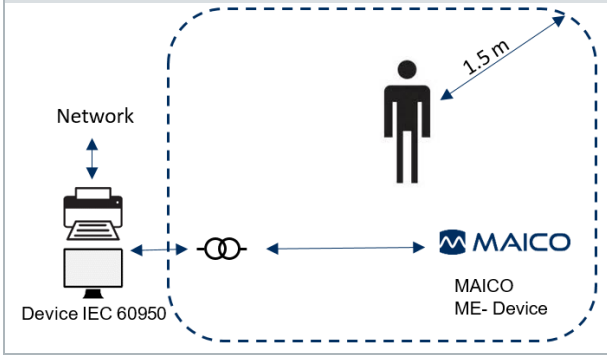
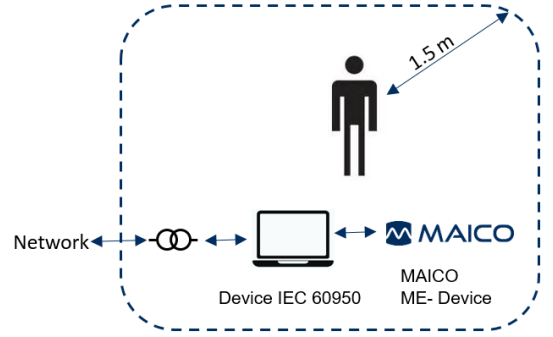
4.5 Establishing a PC-Connection

To transfer data to a PC, establishing a PC-connection via USB is required. If the ERO•SCAN® is used with office equipment that is not a medical device itself (see Table 3, PC-Connection 1), make sure to establish the PC-connection in one of the following ways (see Table 3, PC Connection 2, 3 or 4).

WARNING

Make sure you use only office equipment with the device that is a medical device itself or meets the requirements of IEC 60950. If a non-medical device is used within the patient environment (1.5 m from patient as defined in IEC 60601) a voltage transformer must be used (exception: a battery driven laptop is used).

Table 3 PC-Connections

PC CONNECTIONS	
PC Connection 1: Medical device – Medical Device	PC Connection 2: Medical device – Non-Medical Device
	
PC Connection 3: Medical device – Non-Medical Device	PC Connection 4: Medical device – Laptop (battery-driven)
	

4.6 Using the MPT-IIThermal Printer

4.6.1 Powering the Thermal Printer

Battery pack insertion

Insert battery as shown (Figure 15).

Figure 15

Charging the battery

The thermal printer is powered by a Lithium-ion battery. In order to charge the battery you must insert the plug of the power supply into the laterally placed socket and plug the power supply with the proper plug adapter into an outlet (Figure 16).

Figure 16

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.

Green Power indicator is lit if printer is powered by battery (Figure 17).

Figure 17

NOTE: Selecting Print on the ERO•SCAN® when the printer is off will result in an error message. Printer must be on and in close proximity of the ERO•SCAN® for printing to proceed.

Charging Light Indicators

Table 7 MPT-II Charging Light Indicator

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 powered	-	-
Slow flash	Slow flash	Out of paper	Beep	-
Slow flash	Off	Sleep mode	-	-

Self-test

When 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.

4.6.2 Paper Loading

Open the lid by pushing on the sides (Figure 18), insert paper roll as shown (Figure 19), and close the lid (Figure 20).

Figure 18

Figure 19

Figure 20

Paper feed

When powered press ***paper feed*** button. Paper will feed as long as the button is pressed.

NOTE: Reorder paper from MAICO or your local distributor.

4.6.3 Connecting the MPT-II Thermal Printer to ERO•SCAN®

The connection of the ERO•SCAN® and the printer is made via wireless pairing.

Section 5.10.2.2 Wireless Device Pairing

NOTE: It is possible to pair four devices with one printer. Do not have several printers powered on and within range while searching.

4.7 Storage

When the ERO•SCAN® is not in use, store it in the carry case or in a location where it will be safe from damage to the screen or other sensitive parts. Store according to the recommended temperature conditions.

Section 6.1 ERO•SCAN® Hardware – Device SPECIFICATIONS – Transport & Storage environment

5 Operating the Device

This Section provides information on:

- **how to get started with the ERO•SCAN®**
- **the device layout**
- **the function keys**
- **performing the measurement methods of Audiometry**
- **patient management**
- **documentation of results**
- **changing settings in the user menu**

5.1 Getting Started with the ERO•SCAN®

5.1.1 Use of Equipment After Transport and Storage

Make sure the device is functioning correctly before use. If the device has been stored in a colder environment (even for shorter time) allow the device to become acclimatized. This can take a long time depending on the conditions (like environmental humidity). You can reduce the condensation by storing the device in its original packaging. If the device is stored under warmer conditions than the use conditions no special precaution are required before use. Always ensure proper operation of the device by following routine check procedures for audiometric equipment.

5.1.2 Where to Setup

The ERO•SCAN® should be operated in a quiet room, so that the audiometric examinations are not influenced by outside noises. Ambient sound pressure levels in an audiometric test room shall not exceed the values specified in the norm ISO 8253-1 or ANSI S3.1.

5.1.3 Noise Sources

When the noise level exceeds the noise rejection limit of the device, the orange 'NOISE' light will appear. It is common for the 'NOISE' light 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.

Section 5.2 Indicator Lights

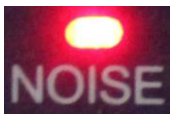
The largest source of noise can come from the patient. This is biological noise, such as movement, coughing, sucking, talking, etc. The patient must be calm and not move or talk. Ambient noise in the testing environment can also be a large source of noise during the test. A properly sealed eartip can block a large amount of this noise, but performing the testing in a relatively quiet environment is recommended.

5.2 Indicator Lights

Figure 21

The device has 4 indicator lights (LED, Figure 21) that help you to know the actual state of the device. Table 8 give explanation to the indication lights.

Table 8 Indicator Lights

Indicator Light	Explanation
NOISE / Red 	The noise level measured during the test exceeds a nominal threshold of 55 dB SPL. Test duration will be prolonged. Section 5.1.3 Noise Sources Also used to indicate some error conditions and when the outcome of test is ***Refer***, ***Noisy***, or ***No Seal***.
TEST / Orange 	The selected test is being performed. This indicator light remains lit throughout the test procedure.
READY / Green 	The device is ready to perform a test.
CHARGE / Blue 	Shows the battery recharging function and battery status. The rate of illumination provides a means of identifying the status of the charging function. Section 4.4 Battery Charging

5.3 Control Panel

Figure 22

The ERO•SCAN® uses 4 buttons to control all functions of the device (Figure 22). 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 you back to either the previous menu or the ***Main Menu***. The ***UP*** key will also access the print command from the ***Main Menu***.

5.4 Turning On the Device

Figure 23

To turn on the ERO•SCAN® press the ***DOWN*** key located below the display (Figure 22). The yellow light (***TEST***) will appear briefly just above the display screen. The green light (***READY***) will remain on indicating the device is ready for use. The Flash Screen (Figure 23) appears briefly. It shows

- the device version – Screening Version (SCR), Screener Plus (SC+), Standard (STD), or Combo (CMB)
- the software version (e.g. 105.05) and
- the serial number (for example ME1234567)

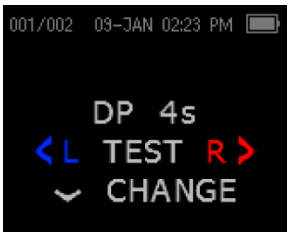


Figure 24

If the battery is sufficiently charged, the ERO•SCAN® powers on and automatically checks the date and time. If there are no date/time errors detected, the ***Main Menu*** is shown (Figure 24).

NOTE: If the date or time shown is wrong you can change it in the device settings menu.

Section 5.10.1 Clock and Date Settings

5.5 Turning Off the Device

Manual Turn-Off

Press ***UP*** to turn off the device.

Automatic Shutdown

The ERO•SCAN® has an automatic shutdown feature, designed to prolong battery life.

The device automatically shut down after 1 minute (default) of inactivity. To turn it back on, press the ***DOWN*** key.

NOTE: You can change the time for automatic shutdown in the device settings menu.

Section 5.10.2.4 Auto Shutdown Time

5.6 Main Menu

Figure 25 gives explanation to the ***Main Menu***.

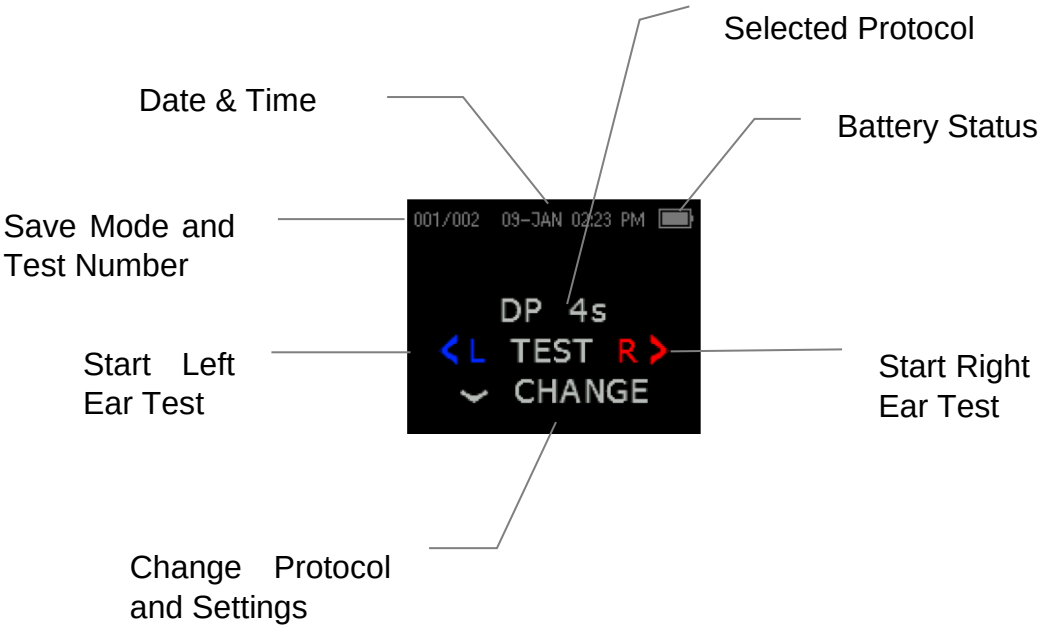


Figure 25

5.7 Testing Procedure

5.7.1 Calibration and Test

The ERO•SCAN® automatically performs a calibration prior to the start of each test. During calibration test signals are presented to the ear canal to calibrate the levels of the frequencies to be tested. After calibration the test phase starts automatically.

NOTE: The testing procedure can be stopped. Press: ***UP*** to stop testing.

No record of an aborted test is saved in the internal memory.

The ERO•SCAN® allows the user to select from two options for viewing the results:

- the ***Graph SNR*** view
- the ***Graph Value*** view.

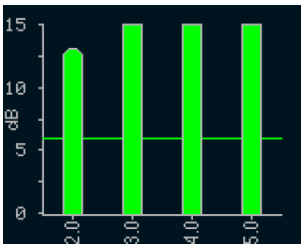


Figure 26

Graph SNR view

The ***Graph SNR*** view (Figure 26) shows the signal-to-noise ratio for each DP test frequency or TE test band.

The set of bars display the emissions measured. This can be reviewed after a measurement. Each column represents one test frequency (DP) or frequency band (TE).

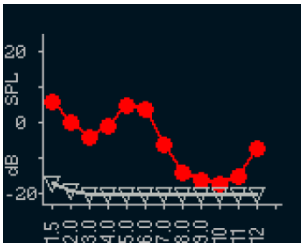


Figure 27

Graph Value view

The ***Graph Value*** view shows the absolute emission and noise levels for each DP test frequency or TE test band (Figure 27).

Section 5.10.2.8 Graph Style (Settings)

5.7.2 Selecting the Test Protocol

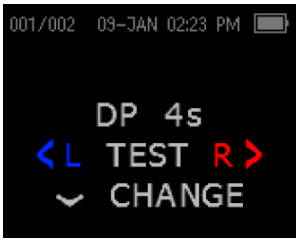


Figure 28

The currently selected protocol is shown on the ***Main Menu*** (). To select another protocol press:

CHANGE to proceed to the next screen ().

CHANGE to select another protocol.

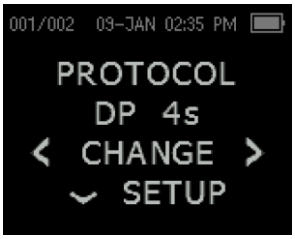


Figure 29

UP to return to the ***Main Menu*** and start testing OR

SETUP to enter the ***Setup*** menu.

NOTE: Some protocols of the Diagnostic Version are customizable.

Section 6.5 Configurations and Test Protocols

Section 5.10.3 Advanced Settings Menus (Diagnostic Version only)

5.7.3 Preparing the Patient


WARNING

Keep in mind the indications and contraindications of use given in

Section 1.2 Indications for Use Statement

Section 1.3 Contraindications of Use Statement

During the testing process it is important that the patient is calm and relaxed. This is often difficult to achieve when testing babies. The following suggestions can help you prepare a baby for the testing process:

Hearing screening is most successfully and efficiently performed on a quiet, sleeping baby. If the baby is awake but quiet or sucking intermittently, testing is possible though the test time may be affected. If the baby is crying, moving or sucking vigorously and constantly then the test will be prolonged and the chance of a Refer result will be increased. In this case it would be best to terminate the screening and return when the baby is sleeping.

Screening can be performed when the baby is lying in a crib, in a car seat or is being held by the screener or parent. The key is to make the baby comfortable and quiet for the screening. Swaddling the baby in a blanket with the arms wrapped inside is recommended. This will calm the baby and keep the baby from interfering with the screening device components.

Otoscopic examination

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.

Attaching a Probe Tube and an Eartip


WARNING

If you insert the OAE probe tip into the patient's ear without having an eartip applied, the adapter can scratch the the patient's ear.

Always apply an eartip before you insert the OAE probe tip into the patient’s ear!


WARNING

If you use the same probe tube and eartip for different patients you enhance the risk of bacterial cross-contamination which can lead to infections.

Always use a new probe tube and a new eartip for a new patient and discard the used ones.

Select an earplug that is appropriate for the patient's ear. Apply the eartip onto the OAE probe tip

Figure 30

NOTE: Use MAICO's special tools for attaching and/or removing the eartips and probe tubes:

Section 3.4 Disposables – Eartips

Section 3.5 Disposables – Probe Tubes

Placing the Probe in the Ear Canal

Figure 31

Insert the eartip into the patient's first ear to test. For newborn hearing screening do this by pulling gently down and out on the patient's ear lobe to open the ear canal, for older patients pull the patient's ear lobe up and back. Hold the probe and aim and twist (gently) the eartip into the ear canal. The fit of the eartip should be secure; not superficial. Release the earlobe. You should not hold the OAE probe during the measurement since this can cause acoustic noise (Figure 9).

5.7.4 Starting a Test (Probe Check)

IMPORTANT NOTE: To test children with Pressure Equalizer (PE) tubes, the Probe Check needs to be omitted. Proceed as follows to disable the ***AutoStart*** function:

- Hold down the ***LEFT*** or ***RIGHT*** arrow keys for 3 seconds until the green LED (***READY***) turns off.

Once the key is released, the ERO•SCAN® will calibrate and test as normal.

Probe Check

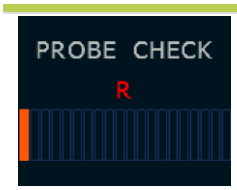
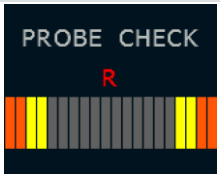
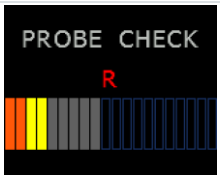
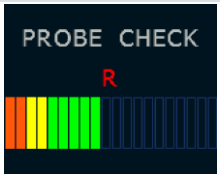
To start a test, insert the probe into the ear and select either the ***LEFT*** or ***RIGHT*** arrow key to indicate which ear will be tested.

After the test ear is selected, the ***PROBE CHECK*** screen is shown. This screen shows if

- you have selected a proper eartip size for the patient`s ear canal volume.
- if you have placed the probe and the eartip well to obtain a seal.

See Table 9 for the various status displays on the ***PROBE CHECK*** screen.

Table 9 PROBE CHECK Screen

Screen	Explanation
 **Figure 32**	The ear canal volume of the patient is too large or the probe is not inserted into the ear or in place properly (Figure 32).
 **Figure 33**	Volume is too small for the test to begin or probe tip is blocked (Figure 33).
 **Figure 34**	The ear canal volume is in the target area for testing, but the bars stay grey until the seal is also detected (Figure 34).
 **Figure 35**	The ear canal volume is in the target area for testing and a seal is detected. The test starts automatically (***AutoStart***) as soon as the probe fit is stable (Figure 35).

When a seal is obtained, the device will automatically begin testing (***AutoStart***), and the yellow LED (***TEST***) lights up during the test procedure.

If the probe check is not successful try the following:

1. Select an eartip that fits the ear canal of the patient better.
2. Try once more to place the probe (see description above).

If you can still not start the test proceed as follows:

- Turn off the device.
- Change the probe tube.
- Make sure that the probe connector is seated properly in the socket.
- Try again to start a test.

5.7.5 TEOAE and Pause Function

The ERO•SCAN® incorporates a pause function within the TEOAE test when a leak is detected. When the detection occurs, all three LED lights at the top of the device (Noise, Test and Ready) will illuminate to display the device is in pause mode. The pause mode will wait for up to 30 seconds. This allows the tester to reposition the probe without starting the test all over. If the seal is not able to be obtained within the 30 seconds a ***No Seal*** error will display and the probe should be repositioned and test restarted.

5.7.6 Viewing Test Results

Figure 36

When testing is complete, a result screen (e.g. Figure 36) appears. The result screen shows the tested ear as well as one of the following test results:

Pass	The patient passed the screening. No further action necessary.
Refer	The patient did not pass the screening. Review the test result (see below) and consider whether the test should be repeated.
Noisy	Excessive noise was present during the test. Reduce noise and repeat the test. Section 5.1.3 Noise Sources
No Seal	A seal was not maintained throughout the test. Try another eartip size and retest.
FIT ERR	Probe placement in the ear canal is inadequate to produce target stimulus intensities. Try to achieve a better probe fit and retest.

NOTE: The results of the test are automatically saved in the memory as soon as the test is complete. The results are saved even if the device turns off or the batteries are temporarily depleted.

Section 5.9.2 Saving Results

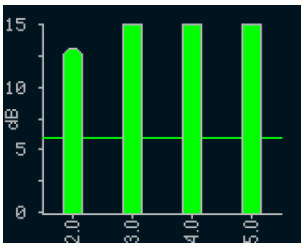


Figure 37

Reviewing Test Results

It is possible to review the test results in two ways:

- **Review on the screen**: Press

  Review to see the graph view of the test result (Figure 36 and e.g. Figure 37).

- **Review the printout**: see

Section 5.8.2 Interpreting Printed Results

5.8 Interpreting Test Results

5.8.1 Understanding the Test Result Screen

The ERO•SCAN® shows the test results as a graph. The screen is being generated and shown during the test and can be reviewed after the test is complete (see Section 5.7.6).

The ERO•SCAN® allows the user to select from two options for viewing the results.

- **SNR graph style**: shows the signal-to-noise ratio for each DP test frequency or TE test band.
- **Value graph style**: shows the absolute emission and noise levels for each DP test frequency or TE test band.

NOTE: The graph style can be changed in the ***Settings***.

Section 5.10.2.8 Graph Style

SNR Graph View

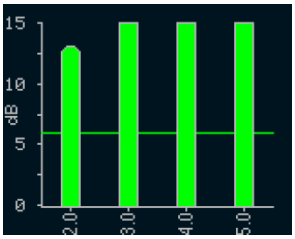


Figure 38 shows the SNR bar graph view. You see the signal-to-noise ratio (SNR) test results which are displayed as the emissions and noise floor are measured. Each column represents one DP test frequency or TE frequency band. The height of each column represents the SNR measured in dB.

Figure 38

If you have selected a protocol with a ***Pass*** criterion, you see a horizontal green line at the decibel level corresponding to the SNR required for a pass. Green vertical bars represent a ***Pass*** result, a yellow bar is a ***Refer*** result at the frequency band.

NOTE: Diagnostic protocols can display green or purple bars. Green is displayed when a ***Pass*** criterion is enabled and set in the device.

Section 5.10.3.2 Advanced Options for DPOAE Testing – Setting the PASS SNR Level and Setting the Number of Frequencies for PASS

Value Graph View

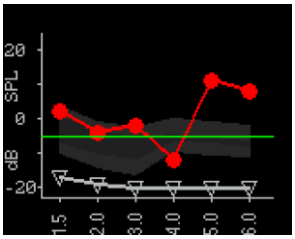


Figure 39

Figure 39 shows the ***Value graph*** view for right ear. 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 represent the absolute emission levels at each DP test frequency or TE frequency band. White upside-down triangles (i.e. ▽) represent the noise floor at each DP test frequency or TE frequency band.

Only for DPOAE protocols: Additional display features include the grey shaded area representing the Boys Town Norms. The green line represents the minimum amplitude setting has been turned on. Both of these settings are optional to be displayed and are independent from one another. These settings are defaulted off.

5.8.2 Interpreting Printed Results

Results from the ERO•SCAN® can be printed in multiple ways. It is up to the examiner to select the appropriate method for their practice needs. The printing options include:

- **Thermal Printout**: An optional wireless printer can be purchased for immediate printing to a thermal printer.
- **Software**: You can transfer the test results to your PC software and print from it.

Respective Software Manual

5.8.2.1 Understanding the Thermal Printout (DPOAE)

The following information is provided for each test (Figure 15):

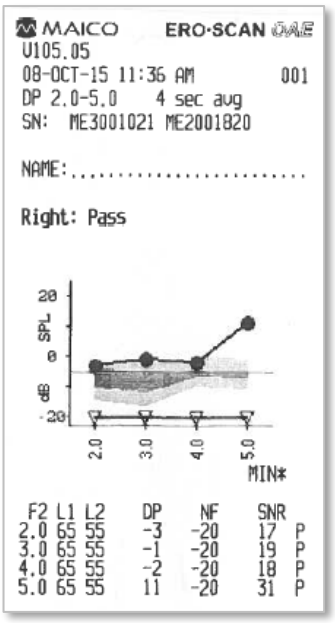


Figure 40

1. Manufacturer Logo
2. The software version number (e.g.: V105.05)
3. The time and date of the test, based on the setting of the internal clock; if the clock is set correctly, this time and date will be correct
4. The test number (if operating in ***Save 500*** mode) (e.g.:001)
5. The protocol selected (e.g.: DP 2.0 - 5.0)
6. The averaging time used for this test (e.g.: 4 sec avg.)
7. Device/Probe serial number (SN)
8. The ear selected (Right or Left)
9. A PASS/REFER indication if there is a criterion set for the selected protocol
10. Graphic display of results
11. Printout notification when Minimum Amplitude is ‘On’ (e.g.: MIN*)
12. The f2 frequency in kHz (e.g.: 2.0, 3,0, 4.0, 5.0)
13. SPL of presented tones (L1, L2)
14. The level of the emission in dB SPL (DP)
15. The noise floor in dB SPL (NF)
16. The signal-to-noise ratio (SNR) = DP – NF
17. A “P” indicates that the frequency passed based on the criterion settings within the selected protocol

5.8.2.2 Understanding the Thermal Printout (TEOAE)

The following information is provided for each test (Figure 41 – TEOAE printout with ***Value Graph*** view, Figure 42 – TEOAE Printout with ***SNR Graph*** view.

Section 5.10.2.8 Graph Style

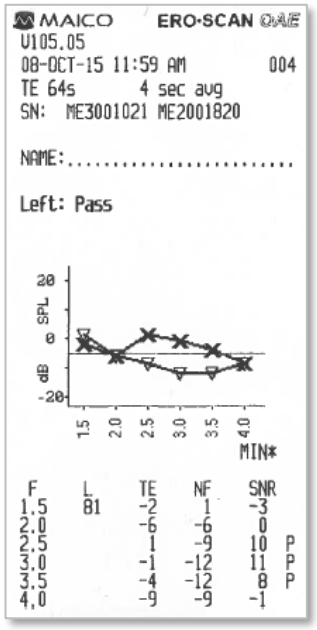


Figure 41

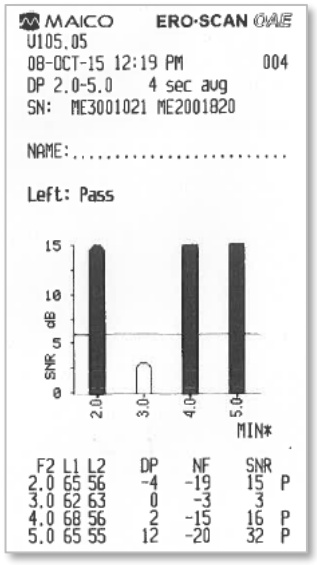


Figure 42

1. Manufacturer Logo
2. The software version number (e.g.: V105.05)
3. The time and date of the test, based on the setting of the internal clock; if the clock is set correctly, this time and date will be correct
4. The test number (if operating in ***Save 500*** mode) (e.g.:001)
5. The protocol selected (e.g.: TE 64s)
6. The test time used to complete the test (e.g.: 4 sec avg.)
7. Device/Probe serial number (SN)
8. The ear selected (Right or Left)
9. A PASS/REFER indication if there is a criterion set for the selected protocol
10. Graphic display of results (SNR or Value graph)
11. Printout notification when Minimum Amplitude is ‘on’
12. The frequency band center (F)
13. SPL peak equivalent of presented click (L)
14. The level of the emission in dB SPL (TE)
15. The noise floor in dB SPL (NF)
16. The signal-to-noise ratio (SNR) = TE – NF
17. A “P” indicates that the frequency passed based on the criterion settings within the selected protocol

5.9 Managing Test Results

5.9.1 General

Dependent on the configuration there are different possibilities to manage test results. It is possible to delete test results, print the session directly with the thermal printer or transfer the data to a PC for further processing.

Users have the option of printing to the thermal printer or transferring results to the PC.

5.9.2 Saving Results

The ERO•SCAN® 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.

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

How the test results are saved depends on the save mode.

Section 5.10.2.5 Save Mode/Storing Test Results

Choose between:

Save L/R mode: only the most recent test results for the left and right ear are saved for printing and/or transfer to a PC.

Save 500 mode: The last 500 test results are saved for printing and/or transfer to a PC.

If patient data are transferred from a connected database, patients can be selected on the ERO•SCAN® using the ***LEFT*** or ***RIGHT*** arrow keys. You may use "***Unnamed***" if the patient is not found in the device and use it for saving results and transfer to the database.

If no patients are transferred to the device the tests are automatically numbered from 1 to 500. It is important to keep record of the test numbers for each patient.

5.9.3 Deleting Test Results

The ERO•SCAN® holds data in non-volatile memory. Deletion of test results depend on the saving mode.

Section 5.9.2 Saving Results

You can delete test data in the following ways:

Automatic Deletion

Save L/R Mode: A single test for the ***Left*** ear and a single test for the ***Right*** ear are saved. Test data are deleted as soon as a new test for the left or right ear is started.

Save 500 Mode: Test data are deleted as soon as new Patient Names are uploaded from the PC Software to the ERO•SCAN® (a warning is provided that data will be deleted).

Printing: As soon as test data are printed via the thermal printer or transferred to the PC software all tests are marked for deletion. You finally delete them by starting a new test.

Manual Deletion

To learn how to manually delete test results in the ERO•SCAN® device see:

Section 5.10.2.3 Clearing Test Results

5.9.4 Transferring Test Results to a PC

It is possible to transfer data from the ERO•SCAN® to the following PC software:

- MAICO Sessions Standalone
- MAICO Sessions with OtoAccess® Database
- MAICO Sessions with Noah Database
- MAICO Sessions with your existing Practice Management Software via BDT/GDT interface
- HearSIM™ Software with OtoAccess® Database (only results of the test protocols TE 32s, TE 64s, DP 4s and DP 2s)

Connecting the ERO•SCAN® to a PC

Connection to the PC software is achieved by using the provided Micro-USB to USB-A cable.

Before transferring data to a PC make sure that you have installed the PC software properly according to the separately delivered operation manual. Before establishing the PC-connection you will have to consider the recommendations given in Section 4.2.4 in case the ERO•SCAN® is connected to a non-medical device.

NOTE: The actual transfer process to the PC software depends on the used Software product.

Respective Software Manual

5.9.5 Printing Test Results

5.9.5.1 Printing to a Thermal Printer

NOTE: Make sure you have successfully paired your ERO•SCAN® device with the printer before trying to start the print process.

Section 5.10.2.2 Wireless Device Pairing

Figure 43

Figure 44

To start the printing process, press:

UP	in the ***Main Menu*** to enter the ***Connect to printer*** screen (Figure 43).
CONNECT	to connect to the printer. Printing process starts as soon as the printer is found. The screen shows ***PLEASE WAIT*** (Figure 44).
CANCEL	to cancel the printing process if wanted.

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).

5.9.5.2 Printing After Data Transfer to PC

The actual printing process from the PC software depends on the used Software product. Printing is possible directly from the following PC Software products.

- MAICO Sessions
- OtoAccess® Database
- HearSIM™
- Your Practice Management Software

Respective Software Manual

5.10 Settings

5.10.1 Clock and Date Settings

NOTE: For changing the ***Clock Mode*** see:

Section 5.10.2.7 Clock Mode

You may want to change the date and/or time

- if you use your ERO•SCAN® the first time.
- if you travel to another time zone.
- due to seasonal time change.
- the device's battery has completely discharged so that the device has automatically reset date and time.

IMPORTANT: 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).

To enter the clock menu proceed as follows:

CHANGE	to enter the ***Protocol Selection Menu***.
SETUP	to enter the ***Clock menu***.

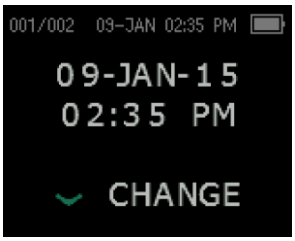


Figure 45

The ***Clock menu*** shows the currently set date and time (Figure 45). Press:

CHANGE (briefly)	to proceed to the next screen.
	NOTE: If you press the ***CHANGE*** too long, you will access the advanced settings.

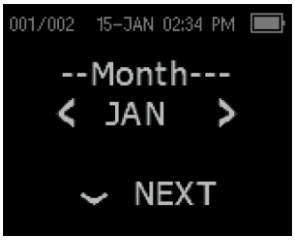


Figure 46

LEFT or ***RIGHT***	to set the ***Month*** (Figure 46), ***Day*** or ***Hour***.
NEXT	to proceed to the next screen.

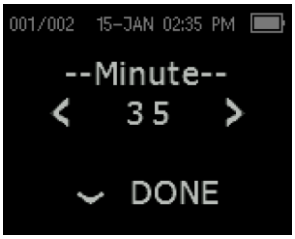


Figure 47

LEFT or ***RIGHT***	to set the ***Minute*** (Figure 47).
DONE	to save the new date and time settings and return to the ***Main Menu***.

5.10.2 General Device Settings

5.10.2.1 General

The ERO•SCAN® allows the user to change many of the device settings or functions. These settings include:

- Wireless Device Pairings
- Clearing Test Results
- Auto Shutdown Time
- Minimum Amplitude Value
- Save Mode
- Clock Mode
- Language
- Reset to Default Settings

Access the General Device Settings Menu

▼***CHANGE*** to access the ***PROTOCOL*** menu.

▼***SETUP*** to access the ***CLOCK*** menu.

▼***CHANGE*** (hold for 3 s) to enter the ***WIRELESS DEVICE*** menu.
Press and hold for 3 s until the green LED (READY) turns off.

Figure 20

NOTE: It is also possible to set advanced options for the DPOAE and TEOAE tests.

Section 5.10.3 Advanced Settings Menus (Diagnostic Version only)

5.10.2.2 Wireless Device Pairing

You can pair the ERO•SCAN® with a thermal printer for printing the test results directly or with a PC to transfer the data to a PC software for further processing:

Pairing with a Wireless Thermal Printer

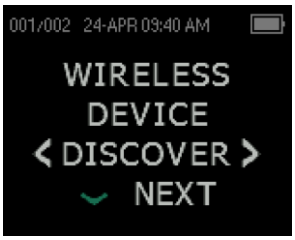


Figure 49

The ***WIRELESS DEVICE*** menu allows the user to pair the ERO•SCAN® with a thermal printer for printing test results (Figure 49).

DISCOVER	to search for wireless devices (approx. 15 s). Display shows "***Please wait***" and yellow LED (TEST) flashes.
CANCEL	to cancel discovery if wanted.

Figure 50

Discovered devices are displayed. A compatible thermal printer is displayed with "***PRT-XX-XX***" (e.g. PRT-e4-8c) (Figure 50).

CHANGE	to select the printer.
PAIR	to pair with the printer.

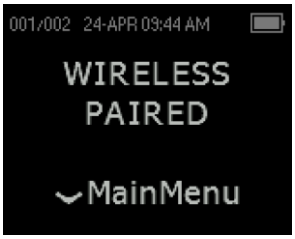


Figure 51

If the display shows "***WIRELESS PAIRED***", the pairing process was successful.

NOTE: If you cannot pair the device with the thermal printer or if any error messages are displayed see

Section 3.6 Troubleshooting

MainMenu	to exit the wireless pairing menu.

Pairing with a PC

Activate the wireless connection on your PC (Figure 52).

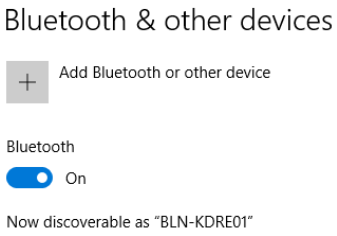


Figure 52

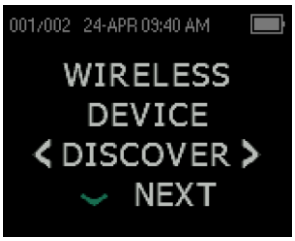


Figure 53

The ***WIRELESS DEVICE*** menu allows the user to pair the ERO•SCAN® with a PC to transfer test results (Figure 53).

DISCOVER to search for wireless devices (approx. 15 s). Display shows "Please wait" and yellow LED (TEST) flashes.

CANCEL to cancel discovery if wanted.

Figure 54

Discovered devices are displayed (Figure 54).

CHANGE to select your PC.

PAIR to pair with your PC.

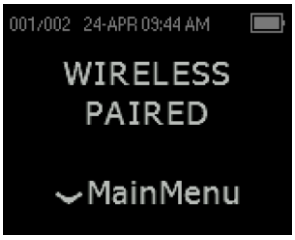


Figure 55

If the display shows "***WIRELESS PAIRED***", the pairing process was successful.

NOTE: If wireless pairing is unsuccessful or if any error messages are displayed see Section 3.6).

MainMenu to exit the wireless pairing menu.

5.10.2.3 Clearing Test Results

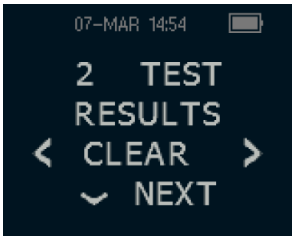


Figure 56

The ***TEST RESULTS*** menu allows the user to clear the test results stored in the device (Figure 56).

NOTE: After printing or transferring the test data to the PC software, all tests saved in memory will be permanently deleted as soon as a new test is started. It is not necessary to manually clear the results using this menu.

CLEAR to clear test results.

YES or ***NO*** to verify clearing or to cancel.

5.10.2.4 Auto Shutdown Time

Figure 57

The ***POWER OFF*** Menu allows you to set a time after which the device shall switch off automatically to prolong battery life (Figure 57).

NOTE: The device will immediately power off after printing regardless of this setting.

CHANGE to select a value between 0.5 and 4 min.

NEXT to proceed to the next screen.

5.10.2.5 Save Mode/Storing Test Results

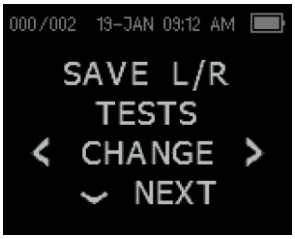


Figure 58

The ERO•SCAN® can store either the most recent test results for the right and left ear (Figure 58) or the last 500 tests (Figure 59).

CHANGE to select ***SAVE L/R TESTS*** or ***SAVE 500 TESTS***.

NEXT to proceed to the next screen.

Figure 59

When using the 500 Tests mode with the ERO•SCAN®, there are two ways of operating.

When a Software is used to transfer patient names to the device, 50 patients can be transferred to the device. The ERO•SCAN® will show the names in an alphabetical order. You can cycle through the names using the left and right arrow. 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®.

When no patient names are transferred to the device, the ERO•SCAN® will automatically number each test from 1 to 500.

NOTE: When 495 tests have been saved, the user will be warned that the memory is almost full. When the ERO•SCAN® device reaches 500 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.

5.10.2.6 Minimum Value (MIN VALUE)

Figure 60

With the MIN VALUE setting (Figure 60) the user is allowed to include the minimum OAE response amplitude to the PASS/REFER criterion for a single frequency. When the MIN VALUE setting is set between -10 dB SPL and + 5 dB SPL the OAE response for the frequency under test needs to be at an equal or higher level than the MIN VALUE set to get a PASS result. If MIN VALUE is set to OFF, the PASS decision is based on the SNR alone for the current frequency measured.
Default MIN VALUE setting is -10 dB SPL.

CHANGE to select a value between -***10 dB SPL*** to ***5 dB SPL*** or to set it ***OFF***.

NEXT to proceed to the next screen.

5.10.2.7 Clock Mode

Figure 61

The ***CLOCK MODE*** menu allows the user to change the clock from a 24 hour mode to a 12 hour mode (Figure 61).

CHANGE to select 1***2 Hour*** or ***24 Hour***.

NEXT to proceed to the next screen.

5.10.2.8 Graph Style

Figure 62

The user can select between two options of displaying the result. (Figure 62). The SNR graph displays the Signal-to-noise ratio as a function of frequency. The value graph view shows absolute OAE levels and noise levels as a function of frequency.

Section 5.7.1 Calibration and Test

CHANGE to select ***GRAPH SNR*** or ***GRAPH VALUE***.

NEXT to proceed to the next screen.

5.10.2.9 Boys Town Norms

The user can chose if the Boys Town[1] will be displayed as comparative normative data if the Graph view setting is set to Value Graph (Figure 63).

CHANGE to select ***NORMS ON*** or ***NORMS OFF***.

NEXT to proceed to the next screen.

Figure 63

5.10.2.10 Reversed Frequency

The reversed frequency setting enables the user to decide on the order of frequencies tested. ON will lead to measure in a descending order (high to low freq.) whereas OFF will lead to measuring in an ascending order (low to high freq.) This setting is only applicable for DPOAE testing (Figure 64).

CHANGE to select ***REV FREQ ON*** or ***REV FREQ OFF***.

NEXT to proceed to the next screen.

Figure 64

5.10.2.11 Auto Stop

The activated ***AUTO STOP*** function stops the DPOAE test automatically as soon as the required number of passed frequencies is reached (for time saving reasons) (Figure 65).

CHANGE to select ***AUTO STOP ON*** or ***AUTO STOP OFF.***

NEXT to proceed to the next screen.

Figure 65

5.10.2.12 Language

The ***LANGUAGE*** menu allows the user to select among several display languages (Figure 66).

CHANGE to select the display language.

NEXT to proceed to the next screen.

Figure 66

[1] Gorga, M.P.,Neely, S.T.,Ohlrich, B., Hoover, B.,Redner, J. And Peters, J. (1997). “From laboratory to clinic: a large scale study of distortion product otoacoustic emissions in ears with normal hearing and ears with hearing loss.” Ear & Hearing, 18, 440-455

5.10.2.13 Reset to Default

Figure 67

In the ***RESET TO DEFAULT*** menu, you can reset the device settings to the factory settings (Figure 67).

NOTE: By resetting the device settings, you delete all existing test results and reset all system and protocol settings. This procedure also separates the ERO•SCAN® from connected wireless devices.

RESET	to reset the device settings to default.
YES or ***NO***	to confirm or stop the reset.
NEXT	to proceed to the next screen.

5.10.3 Advanced Settings Menus (Diagnostic Version only)

5.10.3.1 Customizing Advanced Settings

The Advanced Options menu permits modification of the test parameters and pass criterion for the customizable 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.

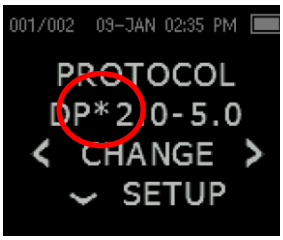
IMPORTANT NOTE: Any change of the parameters Level, SNR for PASS, Number of Frequencies for PASS and Minimum Value has an influence on the Sensitivity and Specificity of the PASS an REFER decision. If the criterion for PASS is set too loose, there is a risk, that the test result is a PASS even if a hearing loss is present. If you choose other settings that the default values, you are responsible.

Section 5.10.3 Advanced Settings Menus (Diagnostic Version only)

Section 5.10.2.6 Minimum Value (MIN VALUE)

The ERO•SCAN® comes with pre-programmed protocol settings. Test protocol changes are saved in the non-volatile memory so the settings will be retained even when the battery is discharged temporarily.

Section 6.5 Configurations and Test Protocols



When a change is made within the Advanced Options menu to a default protocol, an * is place in the protocol name (Figure 68).

Figure 68

To change a parameter of a DPOAE or TEOAE Test Protocol proceed as follows:

CHANGE	to enter the ***PROTOCOL*** menu.
CHANGE	to select the DPOAE/TEOAE protocol (DP 4s and TE 64s protocols are not customizable).
SETUP	to enter the ***Clock menu***.
CHANGE	to enter the ***Setup menu***.
(press for 3 s)	Press and hold for 3 s until the green LED (READY) turns off.
NEXT	to enter the DPOAE/TEOAE menu.
(press for 3 s)	Press and hold for 3 s until the green LED (READY) turns off.
NEXT	to select a protocol parameter to change.
CHANGE	to change a parameter.
DONE	to save the parameters and exit the TEOAE menu.

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.

5.10.3.2 Advanced Options for DPOAE Testing

Selecting the Level of Primary Tones

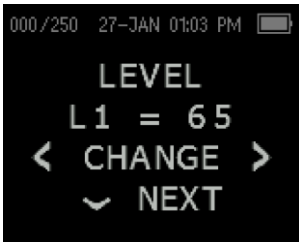


Figure 69

In the ***LEVEL*** menus (***LEVEL L1, LEVEL L2***) you can set the level for the primary tones (L1, L2) (Figure 69).

CHANGE	to set the level L1 to a value between ***40 dB SPL*** and ***70 dB SPL*** (1 dB steps).
NEXT	to proceed to the ***LEVEL L2*** menu.
CHANGE	to set the level L2 to a value between ***40 dB SPL*** and ***70 dB SPL*** (1 dB steps).
NEXT	to proceed to the next screen.

Setting the Averaging Time

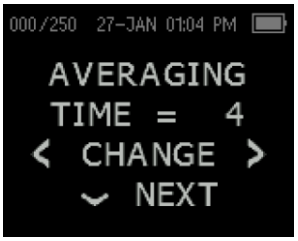


Figure 70

A longer averaging time increase measurement duration and result quality. A shorter averaging time decreases measurement duration and result quality (Figure 70).

CHANGE to set the averaging time to ***0.5 s, 1.0 s, 2.0 s*** or ***4.0 s***.

NEXT to proceed to the ***LEVEL L2*** menu.

Setting the PASS SNR Level

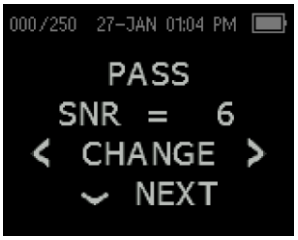


Figure 71

In order to provide a PASS/REFER determination for each test, the PASS SNR must be set. The PASS SNR defines the ratio of how much higher the level of the OAE response has to be compared to the noise. This requirement is used in combination with the number of frequencies to determine an overall PASS/REFER for each test (Figure 71).

CHANGE to select a value between ***3 dB*** and ***10 dB.***

NEXT to proceed to the next screen.

Setting the Number of Frequencies for PASS

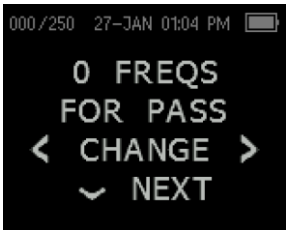


Figure 72

The user can adjust the number of frequencies that have to fulfill the ***SNR PASS*** criterion (and optionally the ***MIN VALUE*** criterion) in order to generate an overall PASS result on the screening measurement. If the defined number of FREQS FOR PASS is not reached, the measurement will result in a REFER.

Setting the ***FREQS FOR PASS*** to ***0*** disables the functionality and no PASS/REFER result will be displayed after measurement (Figure 72).

NOTE: If this function is disabled the bars of the SNR graph are displayed in purple, if enabled in green (PASS) or in yellow (REFER).

CHANGE to select a number between ***0*** and the maximum number of frequencies of the selected protocol.

NEXT to proceed to the next screen.

Reset Protocol

Figure 73

This ***RESET TO DEFAULT*** menu allows you to reset the settings of the currently selected protocol to the factory settings (Figure 73).

NOTE: If you use this function, you only reset the currently selected protocol. The device settings and settings of other protocols remain unaffected.

RESET to reset the settings of the currently selected protocol to default.

NEXT to proceed to the next screen.

Save Protocol

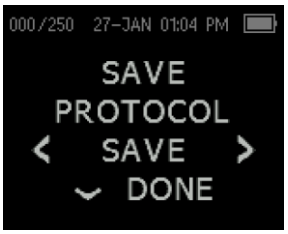


Figure 74

The ***SAVE PROTOCOL*** menu allows you to save the protocol settings made or leave the menu without saving (Figure 74).

SAVE to save the new protocols settings.

DONE to exit the menu.

NOTE: If you press ***DONE*** before saving you lose the settings made.

5.10.3.3 Advanced Options for TEOAE Testing

Selecting the Averaging Time

Figure 75

A longer averaging time increase measurement duration and result quality. A shorter averaging time decreases measurement duration and result quality (Figure 75).

CHANGE to set the averaging time to ***4 s, 8 s, 16 s, 32 s or 64 s.***

NEXT to proceed to next screen.

Setting the PASS SNR Level

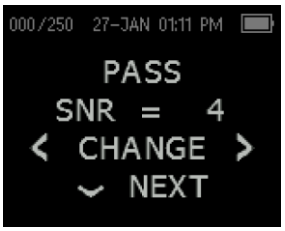


Figure 76

In order to provide a ***PASS/REFER*** determination for each test, the ***PASS SNR*** must be set. The PASS SNR defines the ratio of how much higher the level of the OAE response has to be compared to the noise. This requirement is used in combination with the number of frequencies to determine an overall ***PASS/REFER*** for each test (Figure 76).

CHANGE to select a value between ***3*** and ***10*** (dB).

NEXT to proceed to next screen.

Setting the Number of Frequencies for PASS

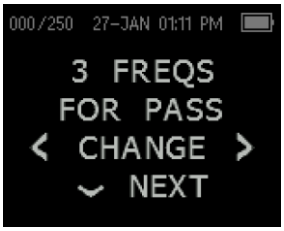


Figure 77

The user can adjust the number of frequencies that have to fulfill the SNR PASS criterion (and optionally the MIN VALUE criterion) in order to generate an overall PASS result on the screening measurement. If the defined number of ***FREQS FOR PASS*** is not reached, the measurement will result in a REFER.

Setting the FREQS FOR PASS to 0 will disable the functionality and no PASS/REFER result will be displayed after measurement (Figure 77).

CHANGE to select a number between ***0*** and ***6***.

NEXT to proceed to the next screen.

Reset Protocol

Figure 78

This ***RESET TO DEFAULT*** menu allows you to reset the settings of the currently selected protocol to the factory settings (Figure 78).

NOTE: Using this function, you only reset the currently selected protocol. The device settings and settings of other protocols remain unaffected.

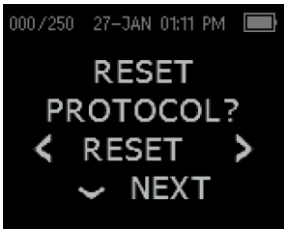


Figure 79

RESET to proceed to the ***RESET PROTOCOL?*** screen (Figure 79).

NEXT to confirm reset of the protocol and proceed to the next screen.

Save Protocol

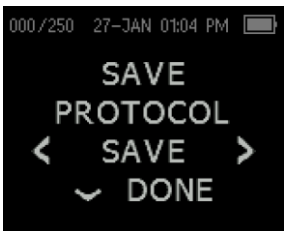


Figure 80

The ***SAVE PROTOCOL*** menu allows you to save the protocol settings made or leave the menu without saving (Figure 80).

SAVE to save the new protocols settings.

DONE to exit the menu.

NOTE: If you press ***DONE*** before saving you will lose the settings made.

6 Technical Data

This section offers you important information about

- **the ERO•SCAN® hardware specifications**
- **the pin assignment**
- **calibration values**
- **electromagnetic compatibility (EMC)**
- **electrical safety, EMC and associated Standards**
- **Configurations and Test Protocols**

6.1 ERO•SCAN® Hardware

CE 0123

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

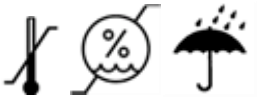
General Information About Specifications

The performance and specifications of the device can only be guaranteed if it is subject to technical maintenance at least once per year.

MAICO Diagnostics puts diagrams and service manuals at the disposal of authorized service companies.

STANDARDS	
Device Safety	IEC 60601-1:2012, Internally power, Type B applies parts ANSI/AAMI ES60601-1:2005/(R)2012 CSA CAN/CSA-C22.2 NO. 60601-1:14
EMC	EN 60601-1-2:2014
Calibration	ISO 389-2 / ISO 389-6
Test Signal	IEC 60645-3:2007
OAE	IEC 60645-6:2009, Type 2

DEVICE SPECIFICATIONS

Operation environment 	Temperature Relative Humidity Ambient Pressure	+15 °C to +35 °C / + 59 °F to +95 °F 30 % to 90 % (non-condensating) 30 % to 80 % recommended 98 kPa to 104 kPa
Transport & Storage environment	Storage Temperature	0 °C to 50°C, 32 °F to 122°F
	Transport Temperature	-20 °C to + 50 °C / -4 °F to +122 °F
	Storage and transport rel. humidity	10 % to 95 % (non-condensating)
Altitude rating	Max. operating altitude	2000 m / 6561 ft. above sea level
Warm-up Time		< 5 s
Boot-up time		< 1 min
Dimensions		65.5 mm x 31.2 mm x 146.0 mm 2.58 in x 1.23 in x 5.78 in
Weight		176 g (6.2 oz.) 204 g (7.2 oz.) (with probe)
Display	Display Size	42.7 mm x 33.4 mm / 1.7 in x 1.3 in
	Resolution	160 x 128
Mode of operation		Continuous
Connectors	OAE	HDMI Connector for connection to the Micro-Probe
	USB	Micro USB
Data Interfaces	PC connection	Micro-USB Wireless connection
	Printing	Wireless connection
User Feedback	Acoustical	Integrated speaker
	Visual	Color display and LED
User Interface		OLED display to provide user information and progress of measurement Control Panel with Membrane-Type Push Buttons
Language Settings		English, Japanese, German, French, Spanish, Russian, Polish, Turkish, Portuguese, Italian, Chinese, Korean, Arabic
Battery	Type	Lithium-Ion battery NP120 rechargeable
	Capacity	3.7 V 1700 mAh
	Expected Life Time	Depending on use – typically > 3 years
	Battery Life	500 tests per charge, minimum

DEVICE SPECIFICATIONS

	15 hours on-time
Memory	500 tests can be stored (each for left and right ear)
Connectors / Communications	Integrated USB communication capability for battery charging and communication with PC-based database programs HDMI Connector for connection to the Micro-Probe Integrated wireless Class 2 + EDR with SPP Protocol for communication with optional printer

POWER SUPPLY

Model No.	UES12LCP-050160SPA
Input	100 to 240 V AC, 50/60 Hz, 0.5 A
Output	5.0V DC, 1.6A MAX
Safety	IEC 60601-1, Class II

DPOAE

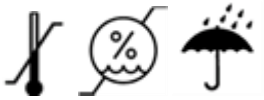
Stimulus	Frequency range	1500 Hz to 12 kHz
	Frequency accuracy	< 1 %
	Default frequencies	See Section 6.5 Configurations and Test Protocols
	Nominal frequency	F2
	F2/F1 Ratio	1.2
	Level range	40 dB SPL to 70 dB SPL
	Level accuracy	± 1.5 dB
	Default level (L1/L2)	65 dB SPL / 55 dB SPL with in-ear calibration
	Transducer	OAE Probe
Recording	Maximum test time	Depends on protocol and device settings
	Artifact rejection level	55 dB SPL
	Probe fit check	Low frequency level loss
	Residual noise	RMS measurement in frequency domain
	Display	SNR bars or line diagram with OAE and noise level per frequency
Pass criteria	SNR criteria	6 dB
	#Freq for pass	3

TEOAE

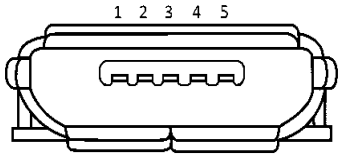
Stimulus	Stimulus type	Non-Linear click (according to IEC 60645-3)
	Default level	80 dB peSPL (peak to peak calibrated), auto in-ear calibration
	Level tolerance	± 3 dB
	Click rate	Approx. 61 /s
	Transducer	OAE Probe
Analysis bands	Frequency range	700 Hz to 4000 Hz
	Default center frequencies	1.5, 2, 2.5, 3, 3.5, 4
Recording	Maximum test time	64 s, depends on averaging time of the selected protocol
	Maximum noise level	55 dB SPL
	Averaging method	Bayesian weighted averaging
	Display	SNR view / value graph view
Pass criteria	SNR criteria	Depends on protocol
	Response criteria	Depends on protocol
	#Freq bands	Depends on protocol

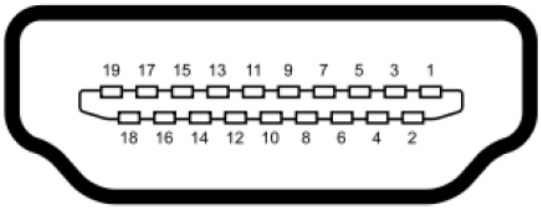
TRANSDUCER

OAE Probe	Microphone System Noise	-20 dB SPL at 2 kHz (1 Hz bandwidth) -13 dB SPL at 1 kHz (1 Hz bandwidth)
	Supported tests	DPOAE, TEOAE
	Cable length	110 cm / 43 in
	Connector	HDMI
	Probe tip	Replaceable
	Weight (incl. cables)	28 g / 1.00 oz

PRINTER	
Print mode	Thermal dot matrix 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 81)  **Figure 81**
Size	02 mm x 75 mm x 45 mm (4.02 in x 2.95 in x 1.77 in)
Weight	Weight: 205 g including battery, without paper
Environment Conditions: 	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)

6.2 Pin Assignment

ERO•SCAN® CONNECTOR MICRO USB B (IN)	
	1. +5 VDC 2. Data - 3. Data + 4. ID 5. Ground

PROBE CONNECTOR TYPE A RECEPTACLE HDMI (FEMALE)			
			
Pin 1	Rcvr +	Pin 11	Unused
Pin 2	Rcvr Shield	Pin 12	Unused
Pin 3	Rcvr -	Pin 13	Unused
Pin 4	Reserved	Pin 14	Reserved
Pin 5	Shield	Pin 15	Comm Power
Pin 6	Reserved	Pin 16	Comm Data
Pin 7	Mic Power +	Pin 17	Ground
Pin 8	Mic Shield	Pin 18	+3.3V
Pin 9	Mic Out	Pin 19	Ground
Pin 10	Mic Power -	-	-

6.3 Electromagnetic Compatibility

This device is suitable in hospital environments except for near active HF surgical equipment and RF shielded rooms of systems for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high.

ESSENTIAL PERFORMANCE for this device is defined by the manufacturer as:

- This device does not have an ESSENTIAL PERFORMANCE.
- Absence or loss of ESSENTIAL PERFORMANCE cannot lead to any unacceptable immediate risk. Final diagnosis shall always be based on clinical knowledge.

Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this device and the other equipment should be observed to verify that they are operating normally.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ERO•SCAN®, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result in improper operation.

This device is in compliance with IEC 60601-1-2:2014, emission class B group 1

NOTICE: There are no deviations from the collateral standard and allowances uses.

NOTICE: All necessary instruction for maintaining compliance with regard to EMC can be found in the general maintenance section in this instruction. No further steps required.

Electromagnetic Compatibility (EMC)

Portable and mobile RF communications equipment can affect the ***ERO•SCAN®.*** Install and operate the ***ERO•SCAN®*** according to the EMC information presented in this chapter.
The ***ERO•SCAN®*** has been tested for EMC emissions and immunity as a standalone ***ERO•SCAN®.*** 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 Interacoustics 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.

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	The ***ERO•SCAN®*** is suitable for use in all commercial, industrial, business, and residential environments.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

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 2.7 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 transmitter, 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.

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	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 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 IEC61000-4-4	± 2 kV for power supply lines 100kHz repetition frequency ± 1 kV Line-to-line 100kHz repetition frequency	Not applicable ± 1 kV Line-to-line	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	± 1 kV Line-to-line ± 2 kV Line-to-ground	Not applicable	Mains power quality should be that of a typical commercial or residential environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	0% *U*T for 0.5 cycle 0 % UT for 1 cycle and 70% *U*T for 25/30 cycles Single phase: at 0°	Not applicable	Mains power quality should be that of a typical commercial 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 uninterruptable power supply or its battery.
Power frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.

Note: *U*T is the A.C. mains voltage prior to application of the test level.

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 / EN 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC / EN 61000-4-6	3 Vrms 150kHz to 80 MHz 6 Vrms in ISM bands 150kHz to 80 MHz 80 % AM at 1 kHz	3 Vrms 6 Vrms	Portable and mobile RF communications equipment should be used no closer to any parts 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:** $d = 1{,}2\sqrt{P}$
Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,7 GHz 80 % AM at 1 kKz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,7 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 with the following symbol: 
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies NOTE 2 These guidelines may not apply in 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 reorienting or relocating the ***ERO•SCAN®.*** [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

This device is in compliance with IEC 60601-1-2:2014, emission class B group 1.

NOTE: There are no deviations from the collateral standard and allowances uses

NOTE: All necessary instruction for maintaining compliance with regard to EMC can be found in the general maintenance section in this instruction. No further steps required.

To ensure compliance with the EMC requirements as specified in IEC 60601-1-2, it is essential to use only the following accessories (see Table 10).

Table 10 EMC Requirements – Accessories

ITEM	MANUFACTURER	MODEL
OWA Probe	MAICO	-

6.4 Electrical Safety, EMC and Associated Standards

- IEC 60601-1:2005+A1:2012 Medical Electrical Equipment, Part 1 General Requirements for basic safety and essential performance
- ANSI/AAMI ES60601-1:2005/(R)2012 Medical Electrical Equipment, Part 1 General Requirements
- CAN/CSA-C22.2 No. 60601-1: 2014 Medical Electrical Equipment, Part 1 General Requirements for Safety Electrical Equipment for Laboratory Use
- IEC/EN 60601-1-2:2014 Medical Electrical Equipment, Part 1 - Electromagnetic Compatibility - Requirements and Tests
- Essential Requirements of the current European Union Medical Device Directive 93/42/EEC
- 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
- Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE)

6.5 Configurations and Test Protocols

DPOAE Protocols

DEVICE VERSION	NAME	NUM-BER OF FREQ.	F2 FREQ. [KHZ]	L1/L2 [DB SPL]	AVERAGING TIME PER FREQ	PASS SNR	NUMBER OF FREQ. FOR PASS
Screen-ing	DP 4s	4	2, 3, 4, 5	65/55	4 s	6 dB	3
	DP 2s	4	2, 3, 4, 5	65/55	2 s	6 dB	3
Diag-nostic	DP 4s	4	2, 3, 4, 5	65/55	4 s	6 dB	3
	DP 2.0-5.0	4	2, 3, 4, 5	65/55**	4 s**	6 dB**	3**
	DP 1.5-6.0	6	1.5, 2, 3, 4, 5, 6	65/55**	4 s**	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 s**	6 dB**	0
	DP 1.5-12	12	1.5, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12	65/55**	4 s**	6 dB**	0

TEOAE Protocols

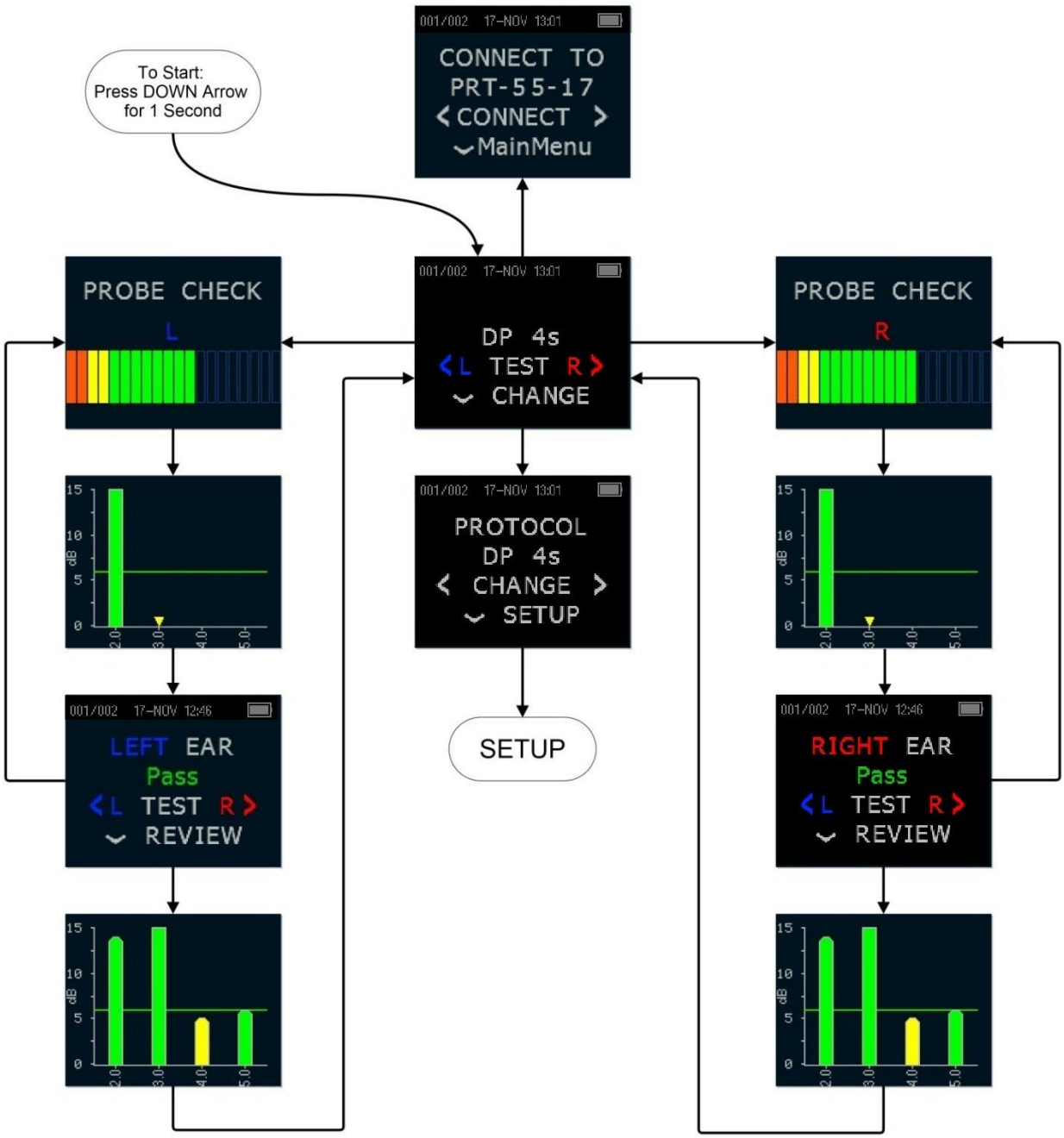
DEVICE VERSION	NAME	NUMBER OF FREQ.	F2 FREQ. [KHZ]	AVERAGING TIME PER FREQ	PASS SNR	NUMBER OF FREQ. FOR PASS
Screen-ing	TE 64s	6	1.5, 2, 2.5, 3, 3.5, 4	64 s	4 dB	3
	TE 32s	6	1.5, 2, 2.5, 3, 3.5, 4	32 s	4 dB	3
Diag-nostic	TE 64s	6	1.5, 2, 2.5, 3, 3.5, 4	64 s	4 dB	3
	TE1.5-4.0	6	1.5, 2, 2.5, 3, 3.5, 4	64 s**	4 dB**	3**
	TE0.7-4.0	6	0.7, 1, 1.4, 2, 2.8, 4	64 s**	4 dB**	0**

** Customizable parameters:

L1/L2:	DP: 40 to 70 dB SPL
Average time:	DP: 0.5, 1.0, 2.0 or 4.0 s
TE:	4, 8, 16, 32 or 64 s
Pass SNR:	DP and TE: 3 dB to 10 dB
Number of Frequencies for PASS:	DP and TE: 0 (no PASS/REFER indication) to Number of Frequencies of the corresponding protocol

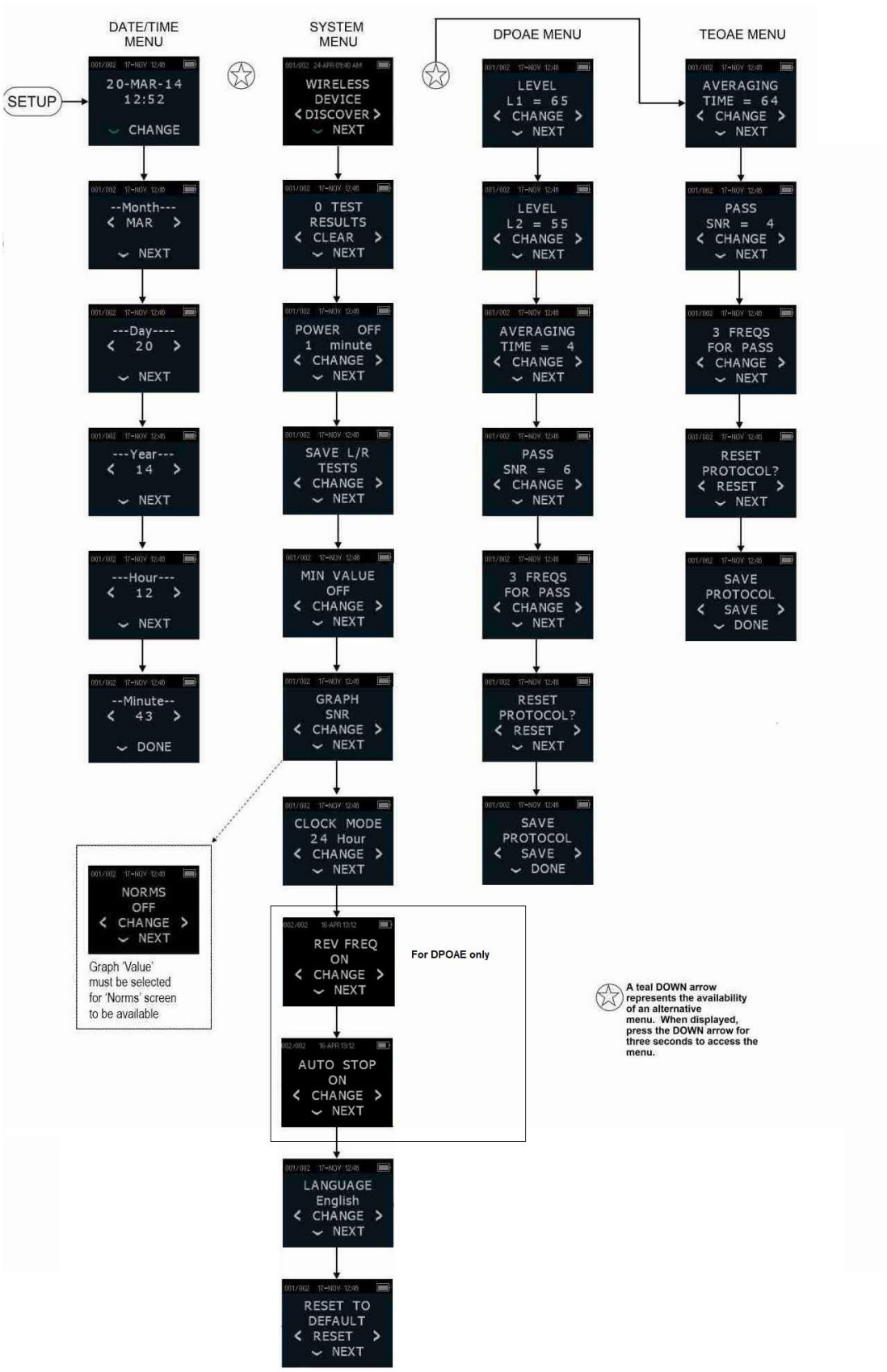
6.6 Flowcharts

6.6.1 Test Operation Flowchart



6.6.2 Setup Menu Flowchart

NOTE: DPOAE/ TEOAE Menu are only accessible in the ERO•SCAN® Diagnostic version.



Specifications are subject to change without notice

MAICO Diagnostics GmbH
Sickingenstr. 70-71
10553 Berlin
Germany
Tel.: + 49 30 / 70 71 46-50
Fax: + 49 30 / 70 71 46-99
E-mail: sales@maico.biz
Internet: www.maico.biz