



ERO•SCAN

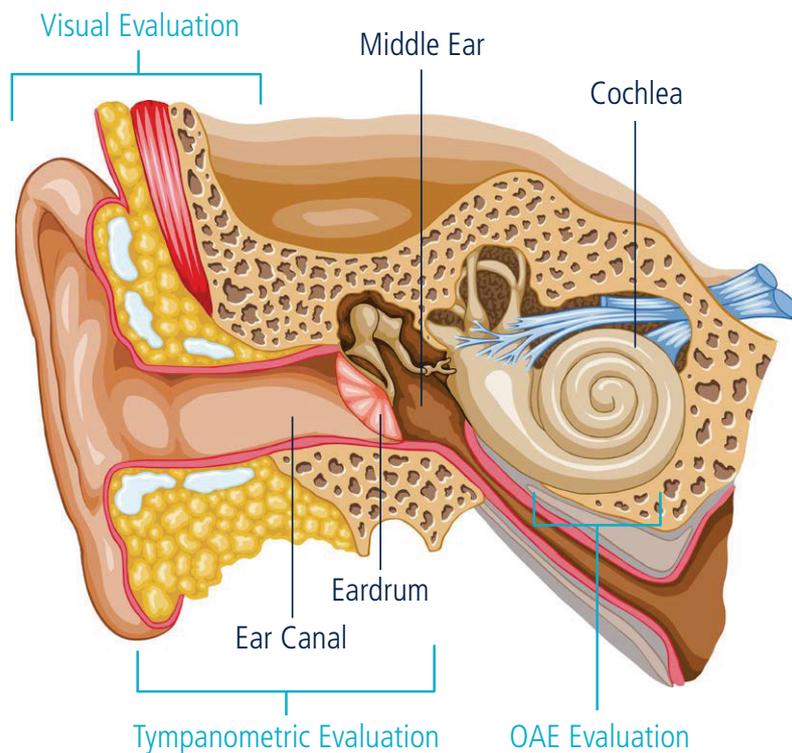
Otoacoustic Emission Testing



ERO•SCAN – Theory

Otoacoustic Emissions

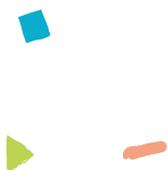
Evoked Otoacoustic Emissions (OAEs) are soft sounds returned by the inner ear as a response to a sound event. The inner ear contains hair cells, which are responsible for transforming the sound signal to a nerve potential, that is processed in the brain. These hair cells respond to sound by vibrating. The vibration produces a very quiet sound, that echoes through the middle ear to the ear canal. With very sensitive microphones, this sound can be measured. TEOAEs are evoked by a transient stimulus, DPOAEs are evoked by a pair of pure tone stimuli.



OAEs only occur in a normal functioning cochlea with normal hearing sensitivity. If there is damage to the cochlea (more specifically to the outer hair cells) or middle ear, OAEs will not be present.

OAEs are measured by placing a small probe into the patient's ear. The probe presents a stimulus and records the soft sounds generated in the cochlea. The test does not need any kind of cooperation of the patient and the test result is shown immediately after the test is finished.

With the ERO•SCAN a test result with a PASS means OAEs were detected. A REFER screening result means, that no clear response could be measured. The patient might be at risk for possible hearing loss and therefore communication difficulties. Further diagnostic assessment of the patient's state of hearing is recommended.



ERO•SCAN – OAE Testing for all ages

Newborns



School Children



Toddlers



Adults



Applications

I.P. Atlikti klininius otoakustinės emisijos klausos tyrimus naujagimiams (iki 1 metų)

Newborn Hearing Screening

Worldwide approximately two of thousand babies are born with permanent hearing loss. The measurement of otoacoustic emissions is a standard procedure to screen newborns for hearing loss. Early detection of babies with hearing loss is essential for providing best possible support to them.

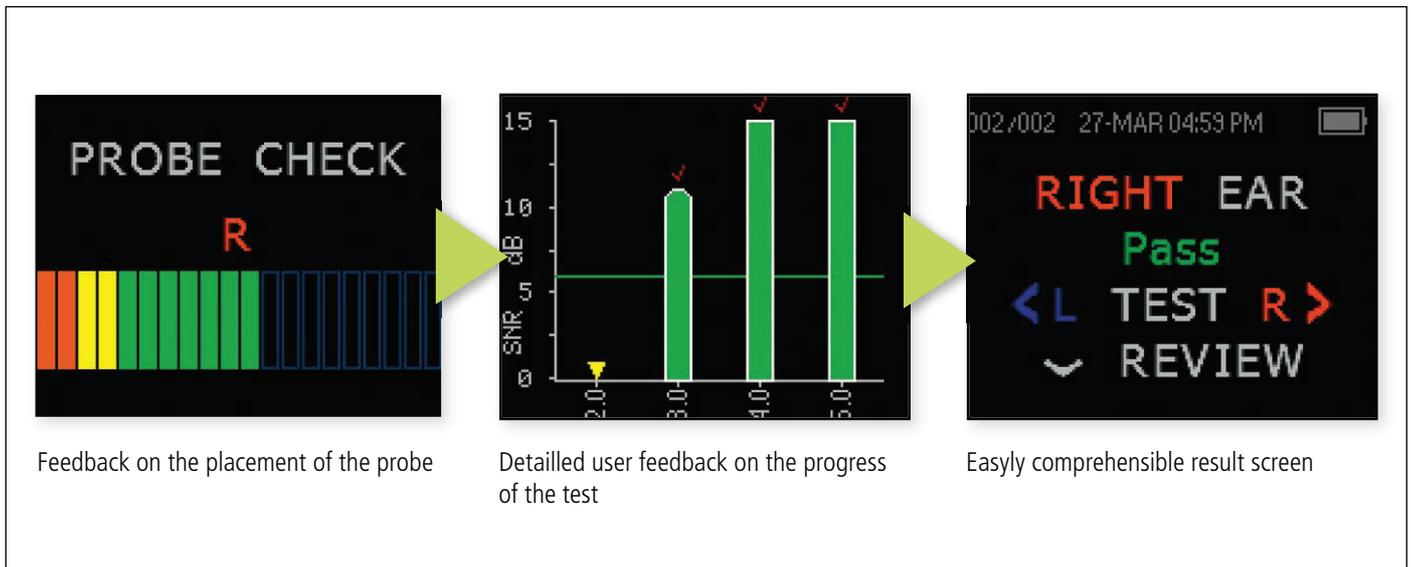
School Screening

When entering the school, children need to be screened for hearing impairment again since it is possible that the children developed a hearing impairment over the years. The measurement of otoacoustic emissions offers a fast and objective method to evaluate children's hearing. Detecting children with hearing loss prevents them from speech, language or learning problems.

Diagnostic Evaluation for all Ages

In combination with pure tone audiometry, immittance testing and auditory evoked potentials, otoacoustic emissions are used for detailed diagnostics of hearing impairments. Otoacoustic emissions provide important information on the patient's auditory system to make a reliable diagnosis.

ERO•SCAN Features & Benefits



Results are Displayed as PASS or REFER

The ERO•SCAN's automated test procedure provides easy to read results. The operation of ERO•SCAN is extremely intuitive and tests can be conducted in less than 30 seconds per ear.

Reliable, Objective Testing

The patented ERO•SCAN noise rejection algorithm allows for reliable testing even in moderate background noise. This leads to fewer false refer results.

3.P. Įrenginys nešiojamas

Portability

The small and lightweight ERO•SCAN is a hand-held unit with rechargeable battery. The battery lasts for more than thousand tests between charges. It allows you to move from room to room with ease.



Optimized Probe

The ergonomic micro-probe is perfect for attaining a tight ear seal with no effort. Made of aluminum the probe is extremely durable. The single-use probe tubes prevent the system from being clogged. The system can be used with a wide range of different ear tip in different sizes.

Managing and Reporting Data

Results can be printed via a wireless printer directly from the ERO•SCAN or a connected computer, by using the optional Sessions PC software. The dedicated HearSIM™ database allows managing of newborn hearing screening results as well as exporting of screening results to HiTrack or Oz .

ERO•SCAN Versions



Screening

The ERO•SCAN with screening functionality provides rapid measurement and documentation of DPOAEs or TEOAEs at multiple frequencies. It is an ideal choice for professionals involved in a hearing screening program. It provides a quick assessment of the inner ear with easily readable PASS or REFER outcomes. The ERO•SCAN can be used for all age groups and is mostly dedicated for screening newborns, infants, pre-school and nursery children.

- Qualified protocols built into the device
- 2 predefined protocols for DPOAE or TEOAE screening
- Optional HearSIM™ database with data export to state tracking systems, HiTrack or Oz.

Diagnostic

The diagnostic ERO•SCAN version is an efficient testing tool for otologists, audiologists, otolaryngologists and pediatricians with need of advanced applications. Additional test protocols are available and customizable. The diagnostic version offers a wide range of application from follow-up diagnosis of 'refer' – screenings to the early detection of noise-induced hearing loss or auditory monitoring.

- DPOAE testing from 1.5 to 12 kHz
- Customizable Pass criteria, stimulus level and averaging time
- 5 DPOAE and 3 TEOAE diagnostic protocols available
- Optional Sessions PC software for electronic data management



ERO•SCAN Software Options

Choose between Sessions and HearSIM™ PC software solutions, depending on the field of application. This extends the functionality of the small and lightweight ERO•SCAN. Sessions is a single patient result viewer for a large range of MAICO device settings and can be integrated easily into patient databases or other EMR systems. Meanwhile HearSIM™ is the dedicated software solution for Newborn Hearing Screening and supports results of the ERO•SCAN Screener version only.

Sessions

The ERO•SCAN device is fully supported by the MAICO Sessions PC software for convenient evaluation and management of ERO•SCAN OAE test results. OAE test data can be easily transferred from the device to a PC via wireless connection or USB cable. All results of your audiometry, tympanometry and OAE assessments are stored together. Sessions can be used along with OtoAccess or NOAH patient databases to also transfer patient lists from your database to the ERO•SCAN. Alternatively use Sessions as standalone solution or to integrate in your EMR system via dedicated interface options. This gives you the means to create detailed reports that can be easily filed or printed. You can also create 'paperless' office by saving the test results as a PDF for electronic filing or email.



HearSIM™

Newborn Hearing Screening results of the ERO•SCAN Screener version can be transferred to HearSIM for review, printing and tracking purposes. HearSIM™ is intuitive to operate and provides you an overview of the screening status of all patients. Depending on your workflow, HearSIM™ allows to transfer patients to the device to select them for testing or to assign tests when stored without patient details. Add the required tracking data for follow-up on referrals and export the screening results in several formats. Choose to print your test results from your PC or store as PDF file.

Features at a Glance

- Store, view and manage patient information
- Store, view and manage test data from ERO•SCAN Screener
- Assign tests to patients after transfer
- Transfer names of patients requiring testing to ERO•SCAN
- Import a patient list from a file
- Print test results on a standard PC-compatible printer
- Export patient and test data (HiTrack, OZ Systems, CSV and XML formats supported)
- Manage user accounts
- Backup and restore the database

Technical Data

Otoacoustic Emissions

Measurement Type	DPOAE (Distortion Product Otoacoustic Emissions) TEOAE (Transient Evoked Otoacoustic Emissions)
Frequency Range	Screening Version DPOAE: 2.0 kHz to 5.0 kHz TEOAE: 1.5 kHz to 4.0 kHz Diagnostic Version DPOAE: 1.5 kHz to 12.0 kHz TEOAE: 0.7 kHz to 4.0 kHz
Stimulus Intensity Range	DPOAE: 40 dB SPL to 70 dB SPL TEOAE: 83 dB SPL peak equivalent (± 3 dB)

12.1.2.P. Dažnių ribose 1500-12000 Hz

12.1.3.P. Lygiai 40-70 dB SPL

Device General

Dimensions	W x D x H: 6.6 cm x 3.1 cm x 14.5 cm
Weight	176 g
Display	OLED display
Languages	English, Arabic, Chinese, French, German, Italian, Japanese, Korean, Portuguese, Polish, Russian, Spanish, Turkish
Storage	Maximum 500 tests
PC Interface	Micro USB, wireless data transfer to Sessions
Battery Life	1000 tests per charge, minimum 15 hours on-time
Power Supply	Output: 5.0 V DC, 1.6 A Input: 100 V-240 V AC, 50/60 Hz, 400mA

4.P. Išoriniai matmenys: plotis: 66 mm, gylis 31 mm, aukštis 145 mm

5.P. Svoris 176 g

7.1.P. Ekranas OLED

8.P. Anglų kalba

10.1.P. 1 vnt. USB

9.P. Vidinė atmintis: galima išsaugoti 500 tyrimų

10.2.P. Belaidis duomenų perdavimas į kompiuterį

11.4.P. Pilnai įkrovus įrenginys atlieka 1000 tyrimų

14.P. Elektros maitinimas iš 230V/50Hz elektros tinklo

Micro-Probe Specifications

Microphone System Noise	-20 dB SPL at 2 kHz (1 Hz bandwidth) -13 dB SPL at 1 kHz (1 Hz bandwidth)
Cable Length	1.1 m
Weight	28 g

Optional Printer

Type	HM-E200, 2" portable thermal printer
Printing Time	<5 seconds per test result
Power Supply	100 V-240 V AC, 50/60 Hz
Dimensions	W x D x H: 8.5 cm x 13 cm x 5 cm
Weight	234 g
Data Transfer	Wireless

10.2.P. Belaidis duomenų perdavimas į spausdintuvą

Standards

OAE	IEC 60645-6, Type 2
Test Signal	IEC 60645-1, IEC 60645-3
Safety	IEC 60601-1, Type B
EMC	IEC 60601-1-2
CE 0123	according to Medical Device Regulation (EU) 2017/745, Class II

15.3.P. IEC 60645-6, Tipas 2

15.2.3.P. IEC 60645-3

15.1.1.P. IEC 60601-1, tipas B

15.1.2.P. IEC 60601-2



Standard Components



ERO•SCAN device



Probe



Carrying case



Eartip set

Optional Accessories and Software



Thermal printer



Sessions PC Software



OtoAccess® Database



Noah Database



HearSIM™ PC Software

Disposables

Sanibel™ Supply is the exclusive supplier of MAICO ERO•SCAN disposables.

Use only Sanibel™ disposables to achieve optimal test results.



This brochure contains only a small segment of the comprehensive product portfolio of MAICO. To find out more about other solutions, please contact us.



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Find your local distributor.



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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

2.P. Otoakustinės emisijos klausos tyrimai.
Išrašytos licencijos atlikti:
1. DPOAE tyrimus
2. TEOAE tyrimus

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 thermal 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:

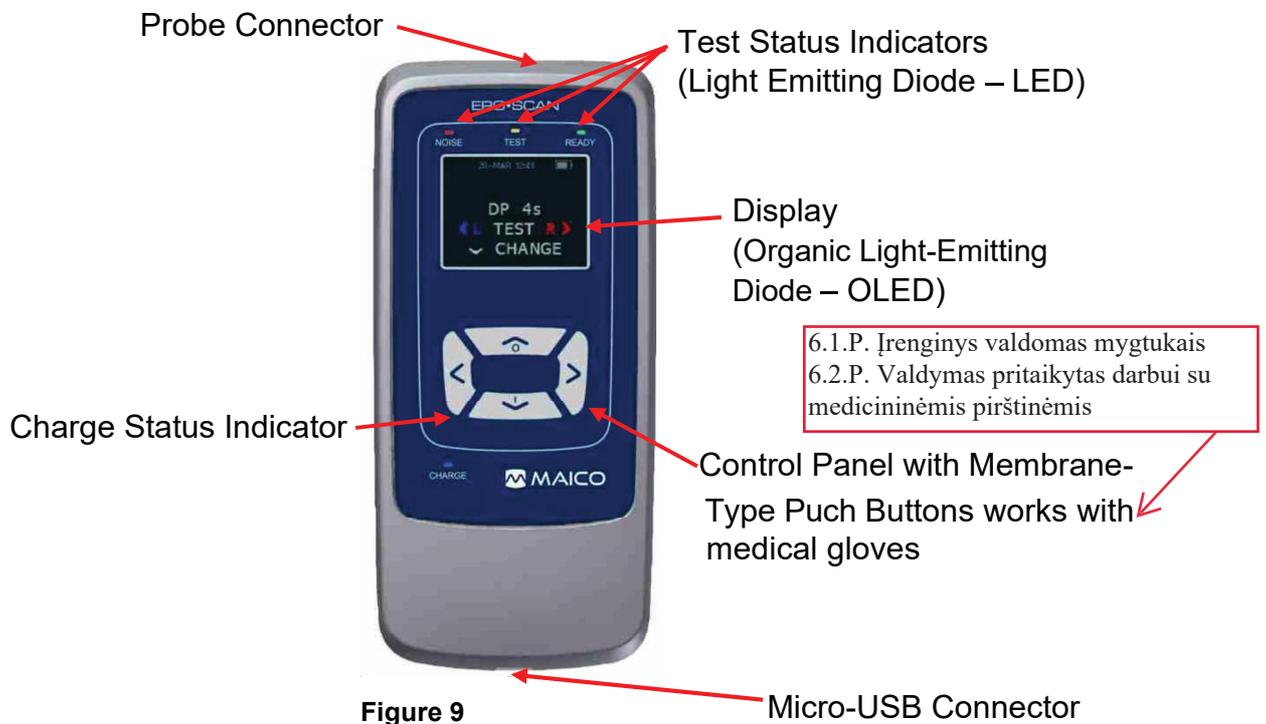
- MAICO Sessions Standalone
- MAICO Sessions with OtoAccess® Database
- MAICO Sessions with Noah Database
- MAICO Sessions with your existing Practice Management Software via GDT or XML interface
- HearSIM™ Software with OtoAccess® Database (ERO•SCAN Screener only)

4.2 Hardware Orientation

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

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

Figure 9 shows the ERO•SCAN device.



DEVICE SPECIFICATIONS

Operation environment 	Temperature	+15 °C to +35 °C / + 59 °F to +95 °F
	Relative Humidity	30 % to 90 % (non-condensating)
	Ambient Pressure	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 7.2.P. Dydis: 42,7 mm x 33,4 mm
Mode of operation		Continuous
Connectors	OAE	HDMI Connector for connection to the Micro-Probe
	USB	Micro USB
Data Interfaces	PC connection	Micro USB, wireless data transfer to MAICO Sessions
	Printing	Wireless connection
	Frequency Range	2402 MHz to 2480 MHz
	Effective radiated power	Up to +12 dBm
	Modulation	GFSK, π/4-DQPSK or 8-DPSK
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

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 23 gives explanation to the **Main Menu**.

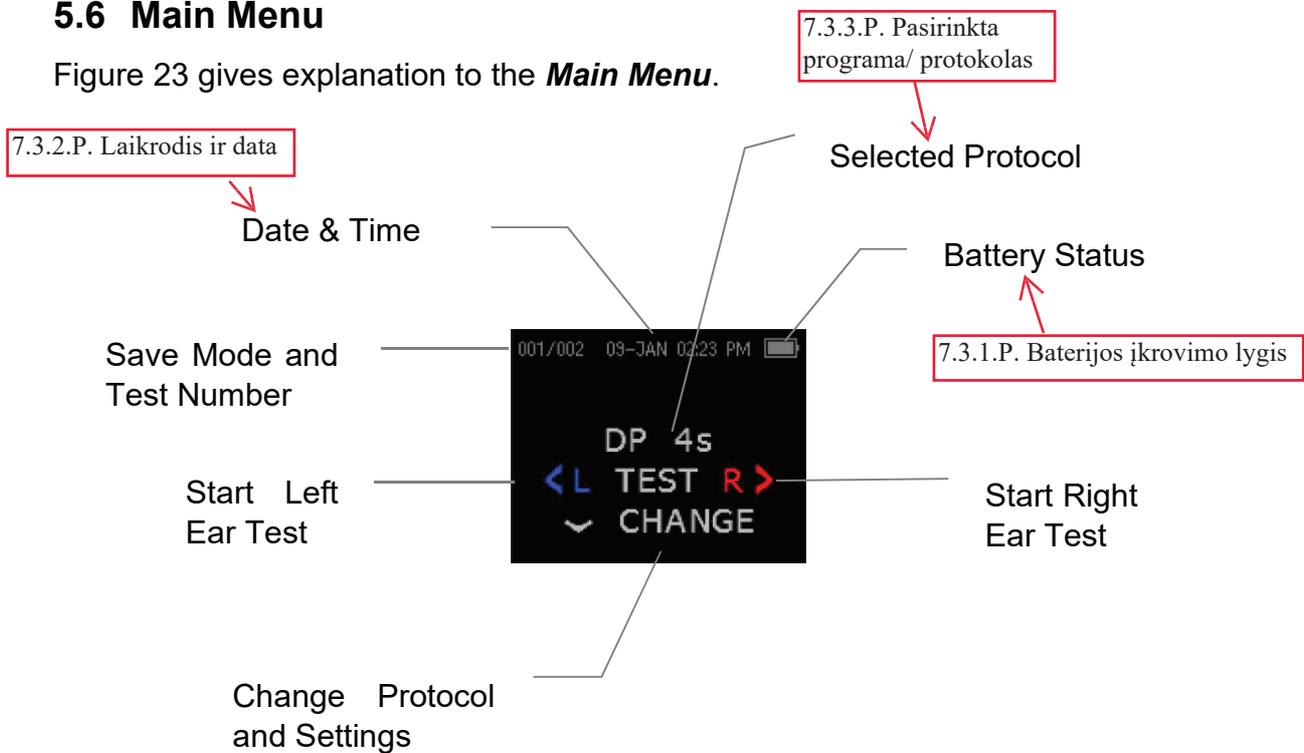


Figure 23

DEVICE SPECIFICATIONS		
Battery	Type	BAKTHNP120, Lithium-Ion battery rechargeable
	Capacity	3.7 V 1800 mAh
	Expected Life Time	Depending on use – typically > 3 years
	Battery Life	500 tests per charge, minimum 15 hours on-time
	Memory	500 tests can be stored
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 UNIT	
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 6.6 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	Micro-Probe
	Recording	Maximum test time
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		12.2.1.P. Pateikimas - nelinijinis klikas
Stimulus	Stimulus type	Non-Linear click (according to IEC 60645-3)
	Default level	83 dB peSPL (peak-to-peak calibrated), auto in-ear calibration 12.2.4.P. Lygis 83 dB peSPL
	Level tolerance	± 3 dB
	Click rate	Approx. 61 /s 12.2.2.P. Kliko dažnis: 61/s
	Transducer	Micro-Probe
Analysis bands	Frequency range	700 Hz to 4000 Hz 12.2.3.P. Analizės dažnių diapazonas ribose 700 - 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		
Micro-Probe	Microphone System	-20 dB SPL at 2 kHz (1 Hz bandwidth)
	Noise	-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

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 Unit for Charging the Lithium-Ion Battery (UES12LCP-050160SPA)

Micro-Probe* ← 13.1.P. Otoakustinės emisijos zondas

Ear Tip Removal Tool

Probe Tube Removal Tool

Printer HM-E200 Kit (Includes 2 Rolls of Thermal Paper, Printer Power supply Unit/Charger with Plug Adapters (5 V/1.6 A) UES12LCP-050160SPA) and Battery Pack

13.3.P. Spausdintuvas

Carry Case

Operation Manual**

Quick Guide**

*Applied parts according to IEC 60601-1

**As download from the download center – see accompanying leaflet

Disposables Supplied

NOTE: MAICO strongly recommends using Sanibel ear tips for reliable results.

Table 5 Disposables

Disposables

Ear Tip Kit (120 pcs) including replacement probe tubes and removal tool

13.2.P. Otoakustinės emisijos tyrimo atlikimo priedai (antgaliukai) 120 pacientų

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



The ERO•SCAN is an active, diagnostic medical product according to the class IIa of the Medical Device Regulation (EU) 2017/745.

General Information About Specifications

The performance and specifications of the device can only be guaranteed if it is subject to technical maintenance at least every 12 months.

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

STANDARDS

Device Safety	IEC 60601-1:2005 + Cor. :2006 + Cor. :2007 + A1:2012/ ANSI/AAMI ES60601-1: 2005 / A2:2010/ CAN/CSA-C22.2 No. 60601-1:14 Internally powered, Type B Applied Parts
EMC	EN 60601-1-2:2014
Calibration	ISO 389-2 / ISO 389-6 15.2.1.P. ISO 389-2 15.2.2.P. ISO 389-6
Test Signal	IEC 60645-3:2007
OAE	IEC 60645-6:2009, Type 2

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.

12.1.1.P. 2 gryni tonai

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.

ERO•SCAN® OAE Test System

Features at a Glance

- Performing screening and diagnostic testing with TE and / or DPOAE
- Fast automatic test with Pass / Refer and graphical test result display
- Sharp, colored Organic LED Display
- Direct evaluation via value and bar diagram
- Up to 12 frequencies displayed within the device, DP up to 12 kHz
- 5 DP / 2 TE protocols with user customizable parameters (diagnostic version)
- High noise immunity for operation in normal clinical environment
- Lightweight, small earprobe
- Environmentally friendly due to long life, rechargeable battery
- Wireless communication to optional printer and PC
- Evaluation of results in PC

Frequency specific OAE Evaluation

The new ERO•SCAN® for frequency specific OAE testing (DPOAE and / or TEOAE) comes with a real plus factor: The sharp Organic LED display allows the direct evaluation via value and bar diagram and shows up to 12 frequencies and thus makes the handling even more comfortable. Appropriate to your needs, you can choose between the ERO•SCAN® screener or diagnostic.

Available in two versions:

Screener with 4 frequency DPOAE testing protocols

- Qualified protocols built into the device
- 4 DPOAE test frequencies reported
- Integration to state tracking systems, Hi-Track or Oz

Diagnostic with 4, 6, and 12 frequency DPOAE testing protocols

- 1.5 to 12 kHz frequency range with up to 12 test frequencies reported
- Customizable test protocols
- TEOAE available as an upgradeable option

