EC Declaration of Conformity

It has been demonstrated that:

Product:

Product type:	Objective Audiometer
Class:	IIa
Trademark:	MAICO Diagnostics GmbH
Type No.:	ERO●SCAN™

Manufactured by:

Name:	**MAICO Diagnostics GmbH**		
Address:	**Sickingenstr. 70-71**		
Area code/Area:	**D-10553 Berlin**	Country:	**Germany**
Phone No.:	**(+49) 30 70 71 46 0**	Fax No.:	**(+49) 30 70 71 46 99**

Is in conformity with the following Directives of the European Parliament and of the Council:

- 93/42/EEC of 14 June 1993, including all amendments, concerning medical devices, fulfilling the essential requirements in appendix I through application of a full quality system according to appendix II.3
- 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

The conformity is achieved by the fulfilling of the following main standards:

- IEC 60601-1: 2005 General requirements for basic safety and essential performance
- IEC 60601-1-2: 2007 Electromagnetic compatibility - Requirements and tests (EMC)
- IEC 60645-1: 2017 Audiological equipment
- IEC 60645-3: 2007 Test signals of short duration
- IEC 60645-6: 2009 Instruments for the measurement of otoacoustic emissions

Valid until: 2021-07-08

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstr. 65, D-80339 Munich / Germany
ID No.: 0123

CE 0123

This declaration is made on the sole responsibility of:

Company:	**MAICO Diagnostics GmbH**		
Address:	**Sickingenstr. 70-71**		
Area code/Area	**D-10553 Berlin**	Country:	**Germany**
Phone No.:	**(+49) 30 70 71 46 61**	Fax No.:	**(+49) 30 70 71 46 99**

Signature:

Date: 2017-06-16

Name: **Uwe Ledworuski**
Title: **Regulatory Affairs Manager**

Digitally signed by Jighili Tatiana
Date: 2021.06.08 15:39:48 EEST
Reason: MoldSign Signature
Location: Moldova

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 063429 0017 Rev. 00

Holder of Certificate: **MAICO Diagnostics GmbH**
Sickingenstr. 70-71
10553 Berlin
GERMANY

Certification Mark:

Scope of Certificate: **Design and development, manufacture, sales, distribution, servicing and calibration of audiometric equipment and related applied products**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 063429 0017 Rev. 00

Report No.: 713185782

Valid from: 2021-01-28
Valid until: 2023-07-08

Date, 2021-01-28

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 063429 0017 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

MAICO Diagnostics GmbH
Sickingenstr. 70-71, 10553 Berlin, GERMANY

Design and development, manufacture, sales, distribution, servicing and calibration of audiometric equipment and related applied products

DGS Diagnostics Sp. z o. o.
ul. Zeusa 2, 72-006 Mierzyn, POLAND

Manufacturing, distribution, servicing and calibration of audiometric equipment

DGS Diagnostics A/S
Audiometer Allé 1, 5500 Middelfart, DENMARK

Manufacturing, distribution, servicing and calibration of audiometric equipment

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TÜV®

MAICO

ERO•SCAN

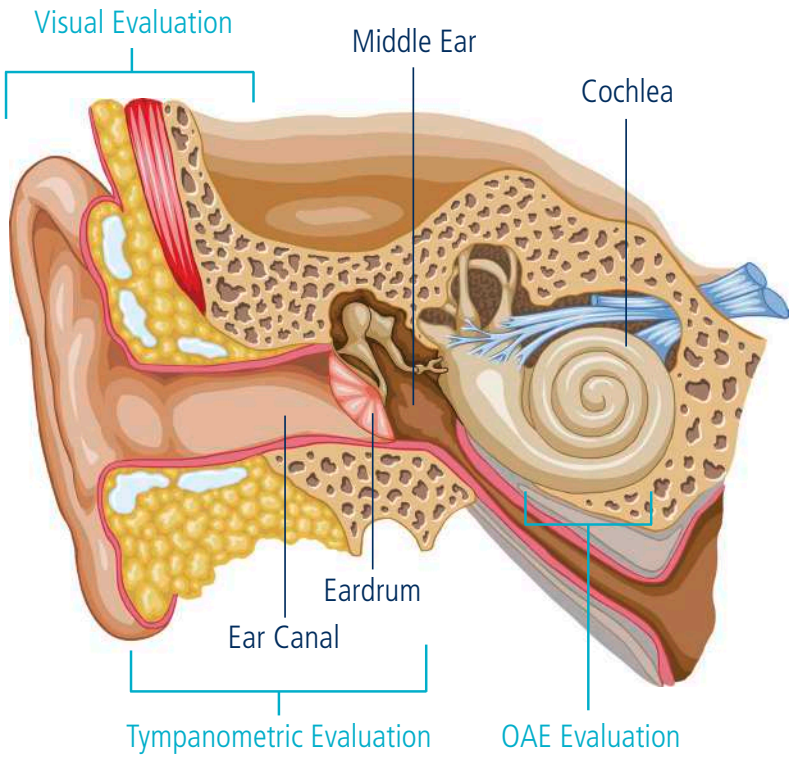
Otoacoustic Emission Testing

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

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.

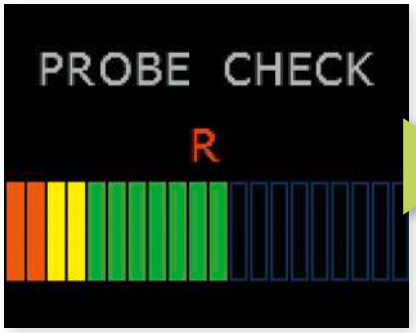
School Screening

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.

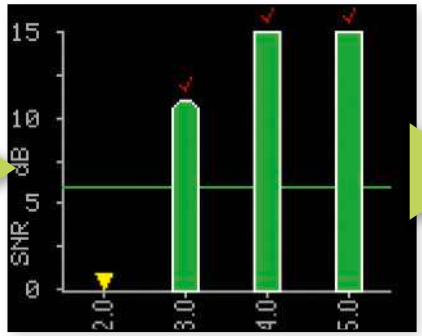
Diagnostic Evaluation for all Ages

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



Feedback on the placement of the probe



Detailled user feedback on the progress of the test

Easyly comprehensible result screen

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.

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.

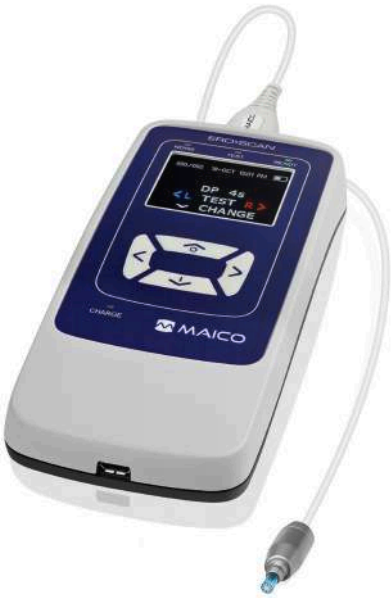
Optimized Probe

The ergonomic micro-probe is perfect for attaining a tight ear seal with no effort. Made of aluminum the probe is extremely endurable. 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 devices. It can be used in various settings and integrate flexible 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 is fully supported by MAICO Sessions PC Software. This provides you the possibility to transfer OAE test data from the device to a PC for the purpose of viewing, archiving, managing and printing OAE reports. 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

Instrument Specifications

Power Supply	Lithium-Ion rechargeable
Battery Life	1000 tests per charge, minimum 15 hours on-time
Dimensions	66 mm x 31 mm x 145 mm
Weight	176 g
User Interface	OLED display 4-button keypad
PC Interface	USB micro

Power Supply Specifications

Output	5.0 V DC, 1.6 A
Input	100 V-240 V AC, 50/60 Hz, 400mA

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

Test Specifications

Measurement Type	DPOAE (Distortion Product Otoacustic Emissions) TEOAE (Transient Evoked Otoacoustic Emmisions)
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: 80 dB SPL peak equivalent (±3 dB)

Optional Wireless Printer

Type	Thermal printer
Speed	50 to 80 mm / second
Operating Noise	< 50 dB SPL
Power Supply	7.4 V lithium battery or mains 100 V to 240 V 50/60 Hz
Weight	200 g
Data Transfer	Wireless

Standards

IEC 60645-6 2009 Type 2,
IEC 60601-1 Type B, IEC 60601-1-2,
according to the class IIa of the EU medical directive 93/42/EEC,
medical directive 93/42/EEC, FDA 510 (k) #980533 23.31998

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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 achive optimal test results.

MAICO Sanibel
Only Sanibel disposables are designed to ensure reliable test results with MAICO products.

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

MAICO

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09/2020

ERO•SCAN
For OAE Screening and Diagnostic Testing

Frequency Specific OAE Evaluation

The ERO•SCAN for frequency specific TEOAE and / or DPOAE comes with a real plus: The sharp organic LED display allows direct evaluation via SNR and value graph, thus making the handling even more comfortable. Appropriate to your needs you can choose between the ERO•SCAN with screening or diagnostic functions.

ERO•SCAN with Screening Function

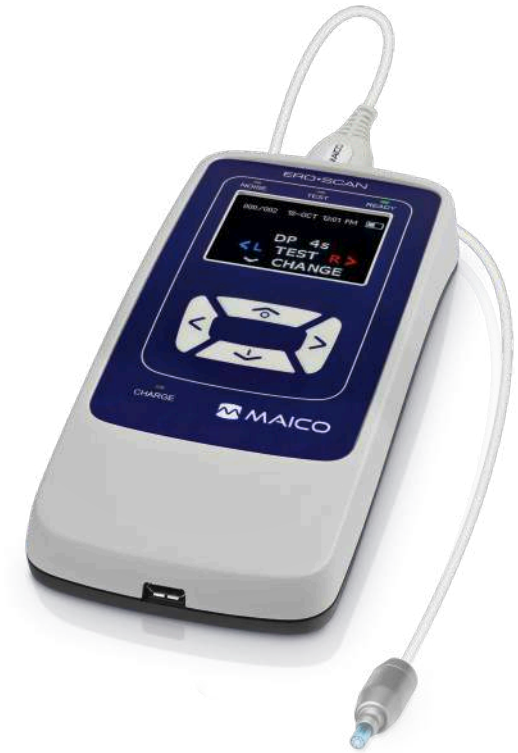
The ERO•SCAN with screening functions comes with automated evaluation and is the ideal solution for screening newborns, infants, pre-school and nursery children.

ERO•SCAN with Diagnostic Function

The ERO•SCAN with diagnostic functions offers advanced applications – suitable for pediatricians, occupational health services and audiologists. Customizable protocol parameters and an extended frequency range makes it ideal for preschool screening and testing people of all ages.

Features at a Glance

- Performing screening and diagnostic measurements of TEOAE and / or DPOAE
- Sharp, colored organic LED display
- Fast automatic testing with Pass / Refer outcome and graphical test result display
- 2 DP and 2 TE screening protocols
- 5 DP and 3 TE diagnostic protocols of which 4 DP and 2 TE are customizable protocols
- High noise immunity for operation in normal clinical environment
- Lightweight, small earprobe
- Wireless communication to PC and optional thermal printer
- Optional with MAICO Sessions PC Software, OtoAccess® Database, Noah Database, HearSIM™ PC Software



Technical Data

ERO•SCAN Specifications

Power Supply	Lithium-Ion rechargeable
Battery Life	1000 tests per charge, minimum 15 hours on-time
Dimensions	66 mm x 31 mm x 145 mm
Weight	176 g
User Interface	OLED display 4-button keypad
PC Interface	USB micro

Power Supply Specifications

Output	5.0 V DC, 1.6 A
Input	100 V-240 V AC, 50/60 Hz, 400mA

Printer optional

Type	Thermal printer
Speed	50 to 80 mm / second
Operating Noise	< 50 dB SPL
Power Supply	7.4 V lithium battery or mains 100 V to 240 V 50/60 Hz
Weight	200 g
Data Transfer	Wireless

Test Specifications

Measurement Type	DPOAE (Distortion Product Otoacustic Emissions) TEOAE (Transient Evoked Otoacoustic Emmisions)
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: 80 dB SPL peak equivalent (±3 dB)

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

Standards

IEC 60645-6 2009 Type 2, IEC 60601-1 Type B, IEC 60601-1-2, according to the class IIa of the EU medical directive 93/42/EEC, FDA 510(k) K150491

CE 0123

Standard Components

ERO•SCAN device with rechargeable battery and probe, Eartip set (120 pcs.), Eartip removal tool, Replacement probe tubes, Probe tube removal tool, Carrying case, Power supply

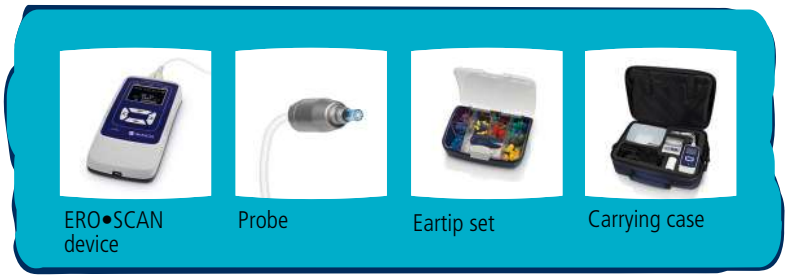
Optional Accessories

Wireless thermal printer, MAICO Sessions PC Software, OtoAccess® Database, Noah Database, HearSIM™ PC Software

Sanibel

We highly recommend to use Sanibel disposables in order to guarantee optimal test results.

MAICO Sanibel
Only Sanibel disposables are designed to ensure reliable test results with MAICO products.



ERO•SCAN device | Probe | Eartip set | Carrying case

Specifications are subject to change without notice.

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HearSIM™

The Solution to manage your Hearing Screening Instruments

Designed for Newborn Hearing Screening

HearSIM™ is our state-of-the-art PC application to manage newborn hearing screening data and devices. The intuitive user interface helps you to focus on the important steps.
It provides you the full picture of the screening status and allows you to quickly extract the needed details by multiple filter options.
In combination with the easyScreen, MAICO's most flexible newborn hearing screening device, this integrated solution is the first choice for screening programs.
If you're using MAICO's ERO·SCAN OAE Screener, you can benefit from the comprehensive data management options HearSIM™ is offering as well.

Tracking is the Key to Success

HearSIM™ ensures that screening results can be forwarded to dedicated tracking centers for follow-up on babies who need further evaluation of their hearing status. With the possibility to enter and export all required details, your screening program will be a full success!

EMR Integration

The OtoAccess® Database is used as backend to store all data securely. This database allows use of add-ons for EMR integration options via HL7 or GDT.
New patients get seamlessly added to the database and are immediately ready for screening. This reduces your workload and allows you to focus even more on the patients.
With a few steps full lists of patients who require screening can be imported from a file and transferred to your screening device.

Prepared for the Future

HearSIM™ provides full flexibility. The data management solution can be either installed on a local PC or on a server, to allow all departments to share their hearing screening data in one database. More client computers can be added if needed.

Features at a Glance

- Store, view and manage patient, test and tracking information
- Intuitive user interface
- Patient transfer to easyScreen and ERO·SCAN Screener
- Configure easyScreen devices
- HiTrack, OZ, CSV and XML tracking export
- Built on OtoAccess® Database
- Server client installation option
- EMR integration via Worklist HL7

Devices shown are not part of the scope of delivery.

Technical Data HearSIM™

SYSTEM REQUIREMENTS

Operating system	Windows® 10 SP1 (x86 and x64)
Required software	OtoAccess® Database 2.0 or higher .NET 4.6.2 is required for the application to run Windows® PowerShell

SUPPORTED MAICO DEVICES

easyScreen ABR/OAE
ERO·SCAN Screener OAE

EMR/EHR INTEGRATION

GDT via OtoAccess® GDT Interface
HL7 via Worklist HL7 add-on for OtoAccess® Database with server installation (order based HL7 2.x is supported)

TYPE OF TRACKING EXPORT

CSV (HearSIM™ format)
XML (HearSIM™ format)
HiTrack
OZ eSP™
Possibility to encrypt or anonymize the data export.

TYPE OF PATIENT DATA IMPORT

XML (HearSIM™ format)
HiTrack

PC REQUIREMENTS

Minimum x86 Processor 1.0 GHz, recommended Intel i5 or AMD A8 or greater.
Minimum x64 Processor 1.4 GHz, recommended Intel i5 or AMD A8 or greater.
Processor Type x64: AMD Opteron, AMD Athlon 64, Intel Xeon with Intel EM64T support, Intel Pentium IV with EM64T support (or newer).
Processor Type x86: Pentium III-Compatible processor or faster.
4 GB RAM
3 GB available disk space
USB port

DISPLAY REQUIREMENTS

The minimum resolution supported is WXGA (1280x768px)

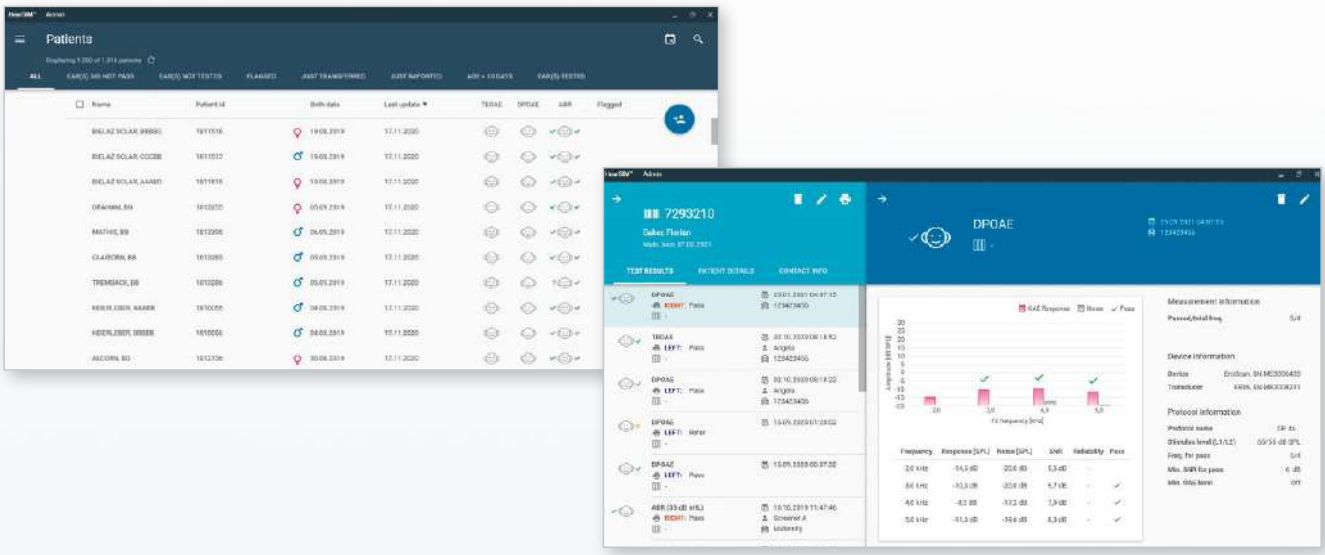
LANGUAGES AVAILABLE

English, Chinese, Czech, German, Greek, French, Italian, Japanese, Korean, Norwegian, Polish, Portuguese, Russian, Slovenian, Spanish, Swedish, Turkish

DATA PRIVACY STANDARDS

GDPR compliant
HIPAA compliant
FIPS compliant

Specifications are subject to change without notice.



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Sessions
Let Your Data Speak Clearly

Fast and Intuitive Data Management and Visualization for Hearing Screening Tests

Master your Data, Focus on Care
Sessions is designed for fast and intuitive operation, allowing you to focus your attention on the patient. The simple navigation and modern GUI design lets you grasp key details at a glance to explain them clearly.

Advanced Data Transfer
Your data is displayed the same way it is on the device, ensuring a consistent visual appearance.
For our MA 42 and touchTymp, Sessions automatically synchronizes measurements ensuring a seamless transfer of your test data.

Designed for Screening
The clean icon-based user interface enables an efficient workflow and high-speed data management. You can easily customize and print reports to guarantee a professional appearance of your business.

Fit for the Future
Sessions is a long-term solution serving as hub for future MAICO products. Your business will benefit from our sophisticated and ever-expanding solution for years to come.

One Set-Up for All Scenarios
Always the ideal solution – You can link up Sessions to your database with full compatibility or run it standalone. Sessions connects automatically to your existing database. Or integrate it easily to your chosen EMR/ EHR solution via interfaces. Whatever your needs for data handling are, our smart software solution Sessions provides a strong platform to work on.

Boost your Work Process and Number of Patients
Save time by using our patient management support, while working with MA 28, easyTymp or ERO•SCAN and the OtoAccess® Database: Just upload your prepared patient list and later download all test sessions' results easily.

Features at a Glance
- Full OtoAccess® or Noah database support
- EMR/ EHR Integration via XML, PDF and HL7
- Simple and modern user interface
- Icon-based, intuitive navigation
- Automatic device detection
- No training required
- Customizable reports
- One click export as PDF or XML

Technical Data Sessions

SUPPORTED DEVICES

MA 25e
MA 27e
MA 28 (with patient transfer)
MA 42 (2021 model)
PILOT TEST
touchTymp line and RaceCar Module
easyTymp line (with patient transfer)
ERO•SCAN (with patient transfer)

SUPPORTED MEASUREMENTS

Tone Audiometry
High Frequency Audiometry
Speech Audiometry
QuickSIN™
Freiburger Speech Test
Tympanometry and Acoustic Reflexes (Tymp & Reflex)
Eustachian Tube Function (ETF) Intact and Perforated
Reflex Decay
DPOAE
TEOAE

TYPES OF EXPORT

Report as PDF
Session data as XML

SUPPORTED DATABASES

OtoAccess® 2.0 database
Noah 4

PC-REQUIREMENTS

2 GHz Intel Core 2 Duo CPU
2 GB RAM
1 GB available disk space
USB drive

DISPLAY REQUIREMENTS

1024 x 768 resolution
Hardware accelerated DirectX/ Direct3D graphics card

SYSTEM REQUIREMENTS

Windows® 10 SP1 (x86 and x64)
Windows® 8 / 8.1 (x86 and x64)

EMR/ EHR INTEGRATION

XML (patient import / measurement export)
OtoAccess® Worklist HL7 compatible

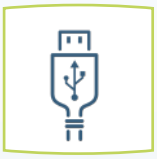
LANGUAGES

English, Chinese, Dutch, French, German, Italian, Polish, Russian, Spanish, Turkish

Specifications are subject to change without notice.

Sessions Kit

Sessions PC-Software


USB Cable


PC-Connection License

Optional Databases

OtoAccess® 2.0 Database

Noah Database

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