Operation Manual
easyDigits

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Compliance

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Android is a trademark of Google LLC.

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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 easyDigits hearing tester is designed to quantitatively measure and monitor an individual's hearing threshold by assessing the speech intelligibility.

1.2 Intended Clinical Benefits

There are no clinical benefits of this device.

1.3 Indications for Use Statement

There are no medical indications of this device.

1.4 Intended Operator

The easyDigits is intended to be used as a self-test device for the target population. The operator should generally be able to operate a tablet.

1.5 Target Population

The target population of easyDigits is children to adults.

1.6 Contraindications

A discharging ear, acute external auditory canal trauma, discomfort (e.g., severe otitis externa) or occlusion of the external auditory canal, or if the patient is too young, sick or uncooperative to perform the tasks. In this context, being sick refers to a state of poor health or the presence of a medical condition that prevents the patient from safely completing the tasks.

1.7 Features and Benefits of the easyDigits

The easyDigits gives you the benefit of:

- Portable tablet hearing test device with headphones or speakers
- Digit Triplet Test (digits-in-noise self-test)
- Scoring methods Digit and Triplet
- Pass or Refer results for testing with headphones, including indicate hearing aid grant eligibility
- Clear result presentation, including a PDF report
- Guided workflow
- XML test result files for further processing

1.8 Description

The easyDigits is a device designed for screening hearing loss.

It features the Digit Triplet Test (DTT). DTT is a speech-in-noise screening test. It uses combinations of three digits, also known as digit triplets, as speech material in French and Dutch (Flemish). The test determines the Speech Reception Threshold (SRT) using an adaptive 1-up-1-down procedure. The SRT is the minimum hearing level for speech at which a person can recognize 50 % of the speech material.

The output and specificity of this type of device are based on the defined test characteristics and may vary depending on environmental and operating conditions. The screening for hearing loss using this kind of device depends on the interaction with the patient. As with any type of hearing screening, a Pass result should not overrule any additional concerns regarding hearing ability. A full audiologic evaluation should be administered if concerns about hearing sensitivity persist.

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 How to Read this Operation Manual

This Operation Manual contains information pertinent to the use of the MAICO device system including safety information as well as maintenance and cleaning recommendations.

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 operation manual, the following labels identify potentially dangerous or destructive conditions and procedures:

WARNING	The WARNING label identifies conditions or practices that may present danger to the patient and/or user.
CAUTION	The CAUTION label identifies conditions or practices that could result in damage to the equipment.
ℹ	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 always observed. Failure to observe these precautions could result in damage to the equipment and injury to the operator or patient.

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

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

⚠️ **WARNING** 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. Defective products 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.

Customer responsibility includes proper maintenance and cleaning of the device.

ℹ️ Section 3.3   Maintenance

Section 3.4   Cleaning and Disinfection Recommendations

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

ℹ️ 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 in the country where the user is established.
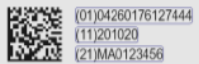
2.3 Manufacturer's Liability

Using the device in a way deviant from the intended use leads to a limitation or termination of the manufacturer's liability in case of damage. Improper use includes failure to follow the operation manual, operation by unqualified personnel, and unauthorized modifications to the equipment.

2.4 Regulatory Symbols

The following Table 1 explains 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
i	Information sign (reference for more detailed information)
	Return to authorized representative, special disposal required
REF	Reference number
MD	Medical Device
(01)04260176127444 (11)201020 (21)MA0123456	UDI information: (01) GTIN (Global Trade Item Number), (11) Date, (21) Serial number
	Applied part type B according to IEC 60601-1
	Refer to operation manual (mandatory)
	Consult (electronic) operation manual (IFU)
	Keep away from rain
	Transport and storage temperature range
	Transport and storage humidity limitations
	Transport and storage atmospheric pressure limitations
CE 0123	CE marking with notified body ID
(((•)))	Non-ionizing electromagnetic radiation
---	Direct Current (DC)
ETL	ETL listed mark
MAICO	Logo

2.5 General Precautions

⚠ WARNING	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:

> 🛈 Section 6.1 easyDigits Hardware and Software

For operation in certain places, recalibration may be necessary.

⚠ WARNING	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.

⚠ WARNING	Do not modify this equipment without authorization of the manufacturer.

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 part of the equipment can be serviced or maintained while in use with the patient.

⚠ WARNING	Calibration of the device: The device and the transducers complement each other and share the same serial number (i.e. MA7663252). Therefore, the device shall not be used with any other transducer prior to recalibration. Recalibration also needs to be conducted, when defected headphones are replaced.

Uncalibrated devices may lead to faulty measurement results and could even damage the hearing of the examinee.

⚠ WARNING	The device is not intended to be used in environments exposed to fluid spills. Ingress of any fluids is considered a single fault condition. No means specified for fluid protection (not IP classed).

⚠ WARNING	Connect only accessories purchased from MAICO to the easyDigits. Only accessories which have been stated by MAICO as being compatible are allowed to be connected to the device.

2.6 Electrical and Electrostatic Safety

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

WARNING

In Case of Emergency

In case of emergency, disconnect the headphones from the tablet.

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

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 power supply at any time.

Do not use the device if the power supply unit and/or the plug is damaged.

WARNING

Data transfer to the PC can be done via USB connection.

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

Section 4.2.2   Establishing a PC Connection via USB

WARNING

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 62368-1 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 in 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 a qualified medical technician or your local representative.

WARNING	A Separation Device (isolation device) is needed to isolate the equipment located outside the patient environment from the equipment located inside the patient environment. In particular such a Separation Device is required when a network connection is made. The requirement for the Separation Device is defined in IEC 60601-1 clause 16.
WARNING	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-series.
WARNING	Do not touch the contacts of the device/tablet and the patient at the same time. If the tablet is connected to a PC (IT equipment forming a system) do not touch the patient and the IT equipment at the same time. The consequence of not following this warning could be a too high leakage current to the patient.
WARNING	The device is not intended for operation in areas with an explosion hazard. Do NOT use the device in a highly oxygen rich 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.
WARNING	To avoid the risk of electric shock, this equipment must only be connected to the medical power supply unit originally delivered by MAICO. Using another power supply unit can also lead to electrical damage on the device.
WARNING	Prevent cable breakage: cables must not be bent or buckled.

2.7 Electromagnetic Compatibility (EMC)

WARNING

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.

The device fulfills the relevant EMC requirements.

Avoid unnecessary exposure to electromagnetic fields, e.g., from mobile phones etc.

WARNING

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.

WARNING

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 6.1   easyDigits Hardware and Software

WARNING

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 easyDigits, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result in improper operation.

2.8 Cyber Security and Data Protection

Connecting the device to a PC or other IT equipment implies connecting the device to an IT network. The connection to an IT network may result in previously unidentified risks to patients, operators or third parties.

Security risks must be identified, analyzed, evaluated, and controlled by the responsible Health Care Provider.

Changes to the IT network could introduce new risks that require additional analysis. Changes include:

- changes in network configuration
- connection of additional items
- disconnection of items
- update of equipment
- upgrade of equipment.

As a part of data protection, ensure to be compliant with all the following points:

- Use only the operating systems specified for the MAICO software in this operation manual. Ensure these operating systems have continued software and security support.
- Ensure operating systems are security patched.
- Install only apps and software from trusted sources and keep them up to date.
- Ensure secure physical and network access to computers. Change any default administration passcodes immediately and use individual user accounts with strong passcodes for PC logins.
- Install antivirus protection, anti-malware software and a firewall from a trusted vendor and keep them up to date.
- Implement appropriate backup and log retention policies.
- Do not use public WiFi.
- Learn about phishing scams: Be very suspicious of e-mails and calls.

Permanent Deletion of Test Data

NOTE: We recommend permanently deleting the test data before selling the easyDigits system to protect personal data to protect personal data from misuse.

To permanently delete test data, proceed as follows:

Open the *Settings* and scroll down to the apps.

Press the easyDigits app icon until the info selection dialog. Open the *App info* and press *Storage & cache* (Figure 1).

Figure 1

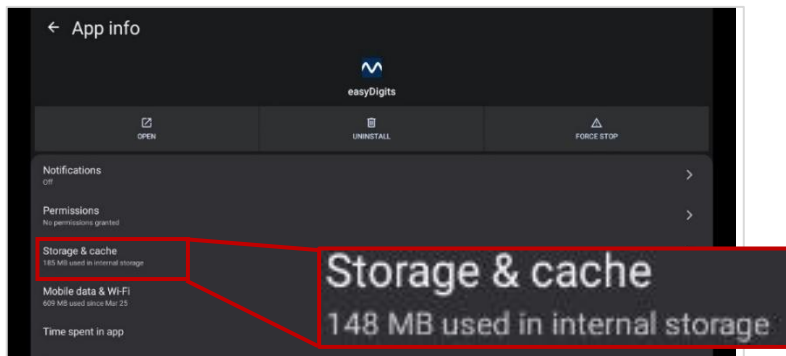Press *CLEAR STORAGE* and *CLEAR CACHE* to permanently delete all test data (Figure 2).
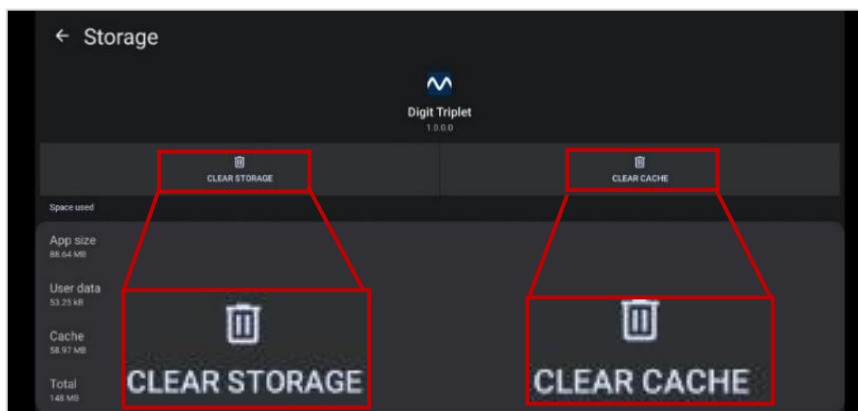

Figure 2

Additionally, all PDF and XML files need to be deleted.

For deletion of the PDF and XML files from the storage, see sections:

i   Section 5.7   Managing Test Results

2.9 Device Control

For annual calibration, see sections:

i   Section 2.5   General Precautions

    Section 3.3   Maintenance

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

3.1.1 General

The MAICO device is guaranteed for at least 1 year. Ask your authorized local distributor for more information.

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 of at least 1 year from date of delivery 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 will void the warranty.

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

3.1.2 Ownership, Warranty and Disclaimer (Software)

Ownership

The easyDigits App (hereinafter the "SOFTWARE") are solely owned by MAICO Diagnostics GmbH, Sickingenstr. 70-71, D-10553 Berlin, Germany. By purchasing the SOFTWARE the buyer is entitled the right of usage, but not ownership of the SOFTWARE. The SOFTWARE is to be used in accordance to the agreed terms of usage provisioned by MAICO.

Copyrights

MAICO's ownership of the SOFTWARE covers worldwide and is therefore, protected against any unauthorized copying of the SOFTWARE. Non conformity of use of the SOFTWARE is strictly prohibited.

Restrictions

You may not:

Reverse engineer or attempt in any manner to discover the source code of the SOFTWARE.

Attempt to defeat any mechanisms in the SOFTWARE, including those mechanisms responsible for password protection of data and limiting the number of concurrent users.

Rent, lease, sublicense or in any manner, copy or transfer (except as permitted above) the SOFTWARE.

Obscure or obliterate any MAICO copyright or trademark notices which appear on the SOFTWARE, the documentation, the screen-display, or otherwise in connection with the SOFTWARE.

MAICO specifically calls your attention to the fact that, any violation or infringement of above restrictions will result in legal action.

The SOFTWARE can be used by any number of users, on any number of computers, and in any place, provided but not on more than one display screen at the same time.

Limited Warranty

MAICO warrants that any physical media and physical documentation provided by MAICO are free of defects in materials and workmanship. This limited warranty is effective for a period of ninety (90) days from the original purchase date.

If MAICO receives notification within the warranty period of defects in materials or workmanship and determines that such notifications are correct, MAICO will replace defective media or documentation.

Do not return any product until you have obtained authorization to do so from your supplier. The entire and exclusive liability and remedy for breach of this limited warranty shall be limited to replacement of defective media or documentation supplied by MAICO, and shall not include or extend to any claim for or right to recover any other damages, including, but not limited to, loss of profit, data, or use of the SOFTWARE, or special, incidental or consequential damages, or other similar claims, even if MAICO has been specifically advised of possibility of such damages. In no event will MAICO's liability for any damages to you or any other person ever exceed the lowest list price or the actual price paid for the license to use the SOFTWARE, regardless of the form of the claim.

Disclaimer

MAICO covers; including but not limited to; all warranties, representations and terms and conditions, either expressed or implied; under specified terms of use and application of the SOFTWARE for its specific purpose. All other terms and conditions shall not apply.

Furthermore, MAICO does not guarantee that the SOFTWARE or Documentation is free of bugs, or fulfill the relevant standards, requirement or needs of a user. In this case, all the warranties, guarantees and terms and conditions on all MAICO delivered physical disk and documentation shall be limited to the 90 days warranty period.

MAICO is not liable for any third party's product, disks, SOFTWARE or documentation that is used in conjunction with MAICO's SOFTWARE or programs, but is not directly manufactured or supplied by MAICO.

NOTE: A list of applied third party's software can be found on the *Over (About)* screen.

ℹ️ Section 5.9.5   easyDigits App – About

General Terms and Conditions

Any change made to this Agreement shall be notified in writing, agreed and signed between both parties, namely the purchaser of the SOFTWARE and a representative of MAICO.

In the event that the essential purpose of the above remedy (limited warranty) is not fulfilled, all other limited liability including the liability limits and exclusions of damage claims shall continue to apply.

This SOFTWARE License Agreement shall be interpreted and construed according to, and governed by, the laws of Jurisdiction of Federal Republic of Germany.

In the event that any legal or commercial dispute or controversy arising out of, or relating to this agreement; provided MAICO is in all case violated of the rights, to the SOFTWARE or other intellectual property protection right related to the SOFTWARE; shall be presented under the Jurisdiction of Federal Republic of Germany in the court of Berlin.

The SOFTWARE is protected under both Copyright Law and the International Copyright Treaties. Copying of the SOFTWARE is strictly prohibited except for copies made of the SOFTWARE for backup purposes to protect data loss.

3.2 End User License Agreement (Tablet)

By using the device, you agree to the End User License Agreement from Android™ and Lenovo.

3.3 Maintenance

To ensure that the device works properly, it must be checked and calibrated at least every 12 months.

The service and calibration must be performed by your distributor, or 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. Include a detailed description of faults. To prevent damage in transit, use the original packaging when returning the device.

3.4 Cleaning and Disinfection Recommendations

It is recommended that parts (device and accessories like headphones, and ear cushions) 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 turn off and disconnect the device from the power supply.

- Remove the headphones from the device.

- For cleaning use a lightly dampened cloth with soap water solution.

- Disinfect the plastic housing of the device and its accessories by wiping the surfaces with wet disinfection wipes or a comparable product. Follow the instructions on the specific disinfectant.

    - Wipe before and after each patient

    - After contamination

    - After infectious patients

⚠️ CAUTION

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

- Do not autoclave or sterilize.

- 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 unit 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.

3.5 Accessories and Replacement Parts

Some reusable components are subject to wear with use over time. MAICO recommends that you keep these replacement parts available (as appropriate for your device configuration). Ask your authorized local distributor when accessories need to be replaced.

3.6 Recycling and 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 2012/19/EU of the European Parliament and of the Council of 4 July 2012 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.

4 Unpacking and Hardware Orientation

This section provides information on:

- **unpacking the device**
- **becoming familiar with the hardware including connections**
- **system assembly**
- **how to power the device**
- **how to store the device**

4.1 Unpacking the System

Check Box and Contents for Damage

- It is recommended that you unpack your easyDigits and the tablet carefully making sure that all components are removed from the packaging 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 packaging so the device can be properly packed if it needs to be returned for service or calibration.

Components

The easyDigits comes with different components (see Table 2). The availability of configurations with the following components is country specific. Contact your local distributor for more information.

Table 2 Components

Components
easyDigits App
Tablet
AC Headphones DD65 v2*
Power Supply Unit USB-C® for Tablet UES60LCP-200300SPC
USB-C® to USB-C® Cable US286 for Power Supply Unit
USB-C® to USB-A Cable for PC Transfer
Tablet Case
Operation Manual**

*Applied part according to IEC 60601-1
**As download from the download center – see accompanying leaflet

4.2 Hardware Orientation

4.2.1 Connections

⚠️ CAUTION   Insert plugs with care into the appropriate connection. Do not wiggle the plug or pull with force while connected. Disconnect plugs cautiously.

Figure 3 shows the connections of the tablet. The connections are explained in Table 3.

Figure 3

The headphones are connected to the tablet via the headphones jack plug (**1**). This connection is also used for data transfer to a PC.

Table 3 Connections on Backside of Device

CONNECTIONS	
1	USB-C® Socket for Power Supply Unit
2	Connection for Headphones

4.2.2 Establishing a PC Connection via USB

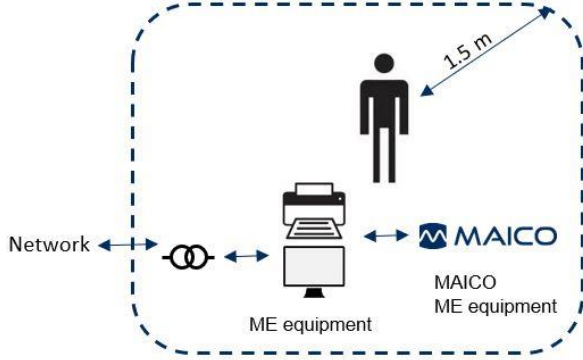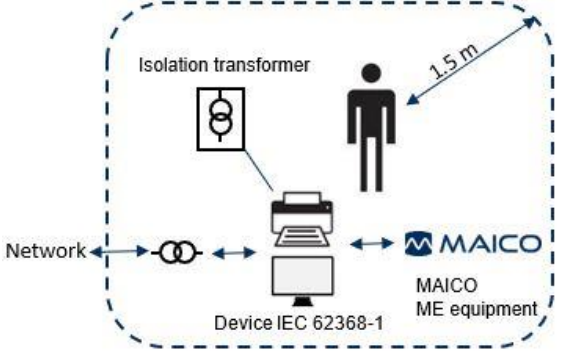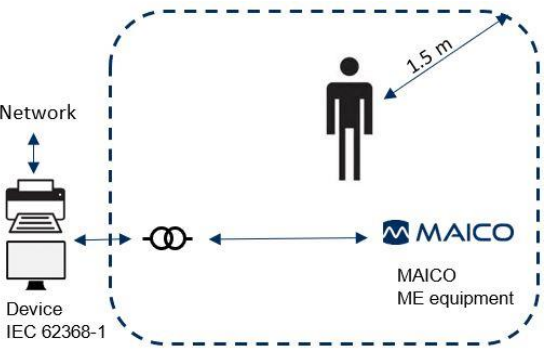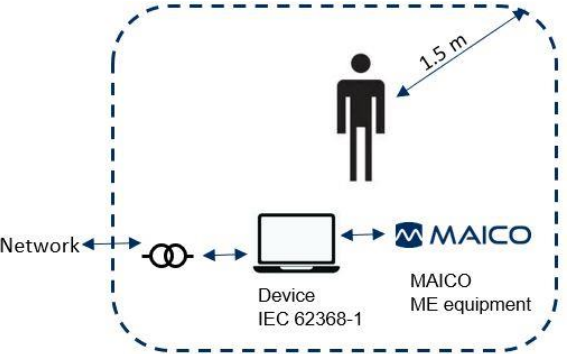Data transfer to a PC can be done via USB connection.

If the easyDigits is used with office equipment that is not medical electrical equipment (ME equipment) itself (see Table 4, PC Connection 1), make sure to establish the PC connection in one of the following ways (see PC Connection 2, 3 or 4).

⚠️ WARNING — Make sure you use only office equipment with the device that is medical electrical equipment itself or meets the requirements of IEC 62368-1. If nonmedical electrical equipment is used within the patient environment (1.5 m from patient as defined in IEC 60601-1) an isolation transformer must be used (exception: a battery-driven laptop is used).

Table 4 PC Connections

PC CONNECTIONS	
PC Connection 1: ME equipment – ME equipment	PC Connection 2: ME equipment – Non-ME equipment
PC Connection 3: ME equipment – Non-ME equipment	PC Connection 4: ME equipment – Laptop (battery-driven)

4.3 Powering

4.3.1 Powering the Tablet

Charge the tablet by using the power supply unit delivered with the tablet. Charging is also possible while testing.

⚠ WARNING	Using a nonmedical power supply unit while testing, leakage current enhances risks of harm or death (e.g., caused by macro or micro shocks).
	If you charge the tablet while testing, you must use only the power supply unit supplied by MAICO.

4.4 Storage

When the headphones and the tablet are not in use, unplug all accessories and turn off the tablet.

Store it in a location where it will be safe from damage to the sensitive components such as the acoustic transducers and cables. It is best to store the headphones in the carry case and the tablet in the tablet case.

Store according to the recommended temperature conditions described in:

ⓘ   Section 6.1   easyDigits Hardware and Software

5 Operating the Device

This section offers you information about:

- **how to get started with the easyDigits**
- **performing testing**
- **managing the test results**
- **settings to be made**

5.1 Getting started with the easyDigits

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 precautions 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 easyDigits 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 ISO 8253 series or ANSI S3.1.

Electronic devices, which emit strong electromagnetic fields (e.g., microwaves or radiotherapy devices), can influence the audiometric function. Therefore, it is not recommended to use these devices near the audiometer as it may lead to incorrect test results.

The test room must be at a normal temperature, usually from 15 °C/59 °F to 35 °C/95 °F, and the device should be switched on approximately 10 min before the first measurement. If the device has been cooled down (e.g. during transport), wait until it has warmed up to room temperature before using.

NOTE: For temperature and warm-up time see:

(i)   Section 6.1   easyDigits Hardware and Software

5.2 Switching On

To turn on the device:

- Connect the headphones or speaker to the tablet.
- Press the power button on the tablet to boot it up.
- easyDigits App launches automatically.

NOTE: If no headphones are connected to the tablet, the output is via the tablet's speakers. However, the test only provides valid results when headphones are used.

5.3 Turning Off

Press the power button to switch the tablet off and disconnect the headphones from the tablet to allow safe storage.

![i] Section 4.4   Storage

5.4 Screen Layout

Figure 4 shows the main screen layout. Table 5 explains.
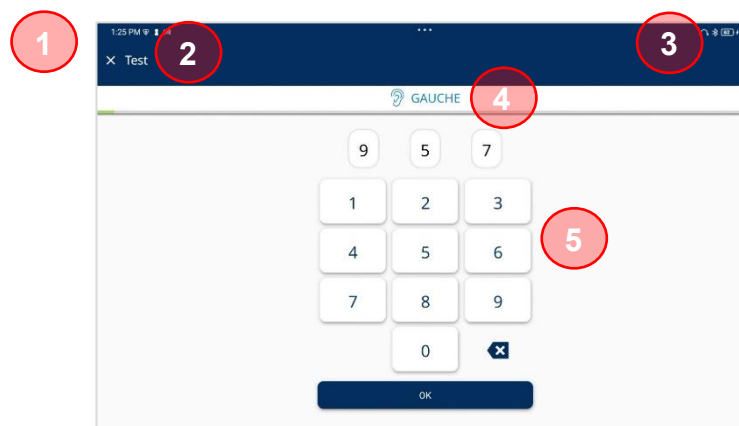
Figure 4

Table 5 Screen Layout

#	Name(s) / Function (s)	Description
1	X	Cancel button
2	Screen name	Shows current screen name.
3	Left/Right/ Aided/Unaided	With DD65 v2: shows the ear currently tested. With speakers: shows *Aided/Unaided*.
4	Fields and buttons	Enter fields and buttons for process.

5.5 Preparing for Tdeesting

5.5.1 Preparing the Patient

The patient should sit at a distance of at least 30 cm to 50 cm from the device.

The necessary instructions are given to the patient on the tablet. After confirmation, the further test procedure starts.

> (i) Section 5.6.3   Instructions

5.5.2 Placement of Headphones

Eliminate any obstructions which will interfere with the placement of the ear cushions on the ear (i.e., hair, eyeglasses).

Ensure that the headphones (Figure 5) are positioned correctly: red phone on the right ear, blue phone on the left ear. Adjust the headband of the headphones so that the earphones are positioned at the correct height (i.e. the sound output grid exactly facing the ear canal).

Figure 5

5.6 Performing the Digit Triplet Test

5.6.1 General Test Description

The easyDigits Digit Triplet Test is designed as a self-test.

After a preparation and training phase, up to 27 digital triplets are presented to the patient monaurally for each ear together with noise. The patient is asked to recognize and enter these triplets.

Start levels for training and the first test trial are dependent on the selected scoring method:

- **Triplet scoring**: Speech and noise are both initialized at an SNR of 0 dB, corresponding to either the default presentation level or the level selected on the start screen.
- **Digit scoring**: Speech and noise are initialized at an SNR of -2 dB, with the speech set 2 dB below the noise level.

During the test, the noise level remains constant, and the speech level varies.

The level for presenting the next triplet is determined based on the correctness of the patient's responses in the previous trial, according to the scoring method:

- **Triplet scoring**: If at least one digit in a triplet is entered incorrectly, the entire triplet is scored as incorrect.
- **Digit scoring**: The number of correctly entered digits (0, 1, 2, or 3) is recorded, allowing more granular scoring.

> (i) Section 5.9.2.5   Test Settings

The test stops automatically if the speech level for the next trial would reach or exceed 75 dB SPL, and the result is recorded as ***Incomplete***.

The algorithms are briefly described below:

Triplet Scoring

While the noise level is kept constant, the speech level changes as follows:

- If all digits in the triplet are correct, the entire triplet is scored as correct. The speech level decreases by a defined step size for the next trial.

- If at least one digit in a triplet is entered incorrectly, the entire triplet is scored as incorrect. The speech level increases by the same step size for the next trial.

The step size refers to the fixed amount in dB, by which the speech level is adjusted between trials.

Digit Scoring

This method dynamically adjusts the speech level for the next trial, based on the number of correctly identified digits in a triplet. The number of correctly entered digits (0, 1, 2, or 3) is recorded, allowing more granular scoring.

- **Initial Phase (Trials 1-6):** Adjusts step size based on the accuracy of each response, ensuring precise measurement.

- **Main Phase (Trials 7-18):** Fine-tunes step size for even more accurate adjustments.

For both methods, the Speech Recognition Threshold (SRT) is calculated as the average Signal-to-Noise Ratio (SNR) from the 7th trial to the last trial, including 1 final virtual trial. The standard deviation (SD) is also computed over this same set of trials. This adaptive method ensures the test is both challenging and accurate, tailored to individual performance.

For further details on the algorithm, see:

![info icon] Section 6.1   easyDigits Hardware and Software – DEVICE SPECIFICATIONS – Precision

5.6.2 Start the Test

NOTE: The start screen shows the

i Section 5.9.2.5 Test Settings

1. Fill in the input fields (**1**):
   - ID (required)
   - Date of Birth (open the widget 📷 or type into the input field)
2. **Only with displayed test options:** Select the test language (**2**).
3. **Only with displayed test options:** Select the ear(s) to be tested for testing with headphones or *Aided/Unaided* for testing with speakers (**3**).
4. **Only with displayed test options:** Select the noise level (**3**).
5. Press *START TEST* to directly start testing the entered patient (Figure 6).
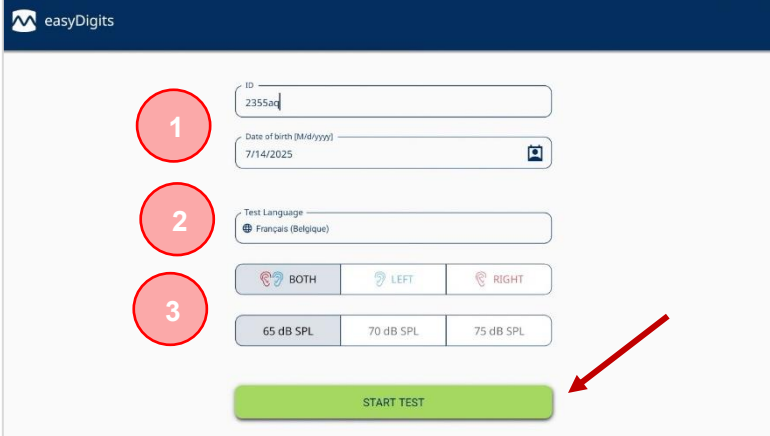
Figure 6

5.6.3 Instructions

The patient shall read the instructions and press *OK* (Figure 7).

The training starts.
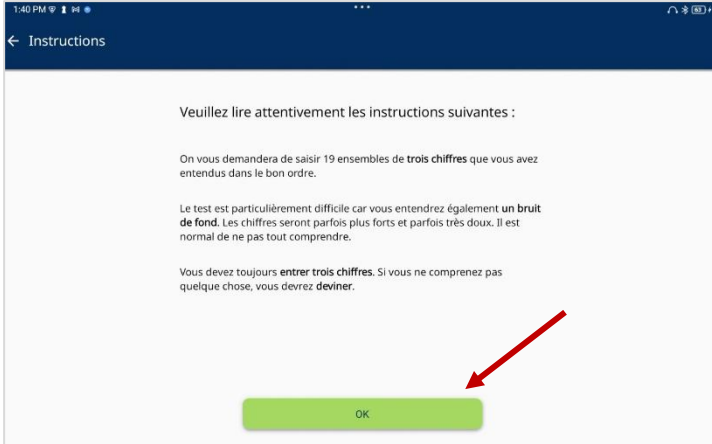
Figure 7

5.6.4 Training

The patient is presented with speech and noise at a fixed level. The levels remain constant during the training phase. The training will be conducted

- binaurally or monaurally (right or left) according to the test options selected on the start screen

- binaurally if test options are hidden on the start screen.

ℹ️ Section 5.9.2.5   Test Settings

Figure 8 shows the training screen.
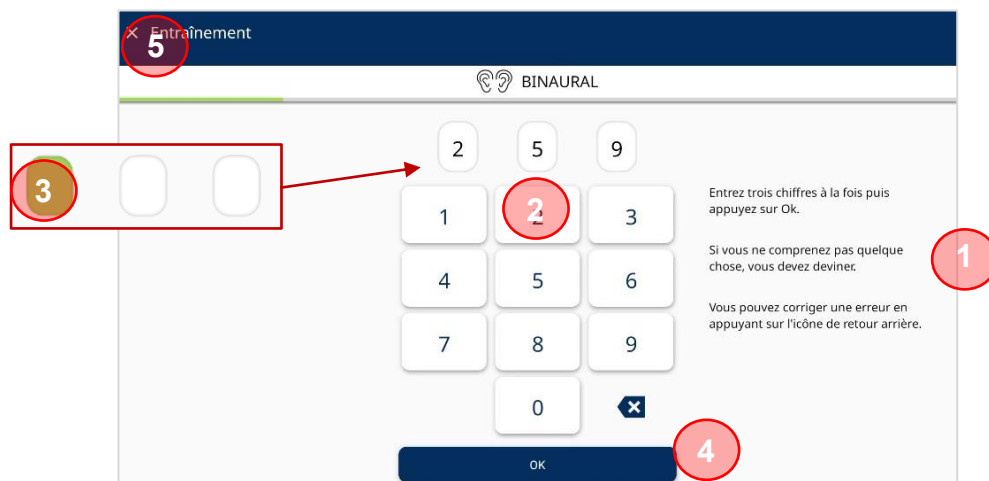
Figure 8

- The test procedure is provided as an aid (**1**).
- The patient enters the perceived sequence of numbers (**2**) and presses *OK* (**4**). The field of the digit currently being presented lights up green (**3**).
- The patient can cancel the process by pressing **x** (**5**).

5.6.5 Testing

Figure 9 shows the *Test* screen.
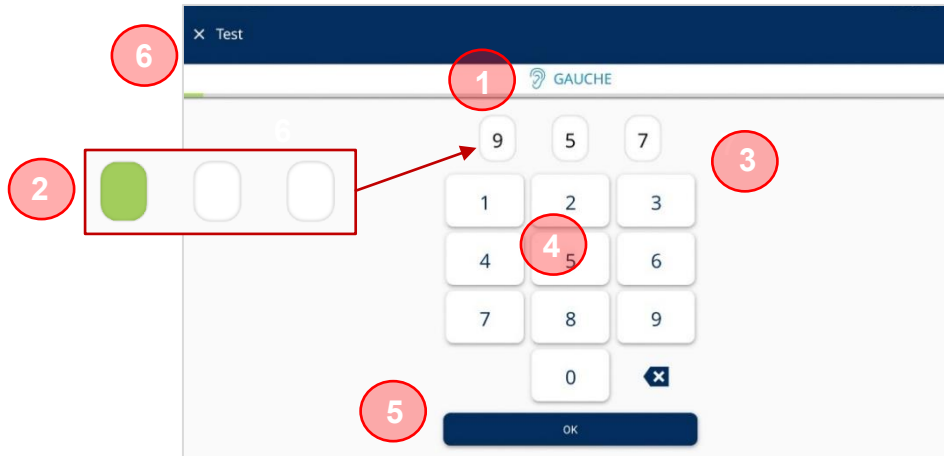
Figure 9

- The current ear or test type is displayed (**1**).
- The field of the digit currently being presented lights up green (**2**). The patient enters the perceived sequence of numbers (**3** and **4**) and presses *OK* (**5**).
- The patient can cancel the process by **x** (**6**).
- The test procedure is saved automatically after the last digit triple is presented and confirmed.

NOTE: The number of trials depends on the test language and the scoring method. It is 27 for Triplet (both languages) and 17 (Dutch) / 19 (French) for Digits.

Upon completion of the test, the system will display one of the following screens, depending on the settings:

- **Complete Screen**: The patient will not see the test results.
- **Result Screen**: The patient can view their results.

Complete Screen

Figure 10 shows the Complete screen.

Press ***KLAAR/TERMINÉ (DONE)*** (**1**) to finally end the test. The test result can no longer be accessed via the easyDigits app.
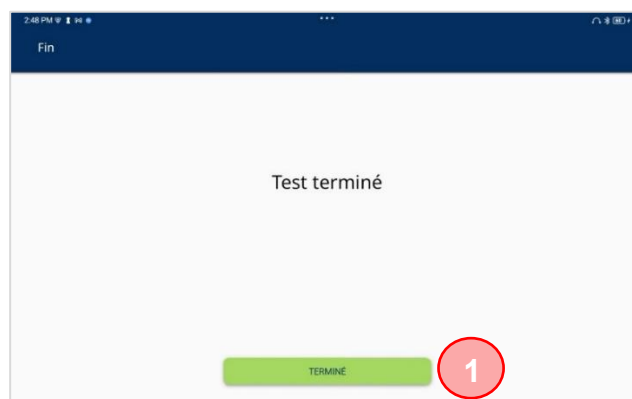
Figure 10

Result Screen

Figure 11 shows the Result screen.

Figure 11

- Select (**1**) to show the result for the left, the right or both ears respectively *Aided/Unaided/Both* (**2**).

- The result screen shows the ***Pass/Refer/Not tested*** result (for testing with headphones) and the speech recognition threshold (SRT). An ***Eligible for hearing aid grant*** result indicates that hearing ability is more than 3 dB worse than the reference value, and the health insurance may provide a subsidy for a hearing aid.

- **Test/Retest**: Select

  - *GAUCHE/LINKS (LEFT)* or

  - *DROITE/RECHTS (RIGHT)* or

  - *Sans appareil auditif/Zonder hoortoestel(len) (Aided*) or

  - *Avec appareil auditif/hoortoestel(len)) (Unaided)* (**1**)

  and press ***TESTER LA SÉLECTION/TEST DE SELECTIE (TEST SELECTION) (3)*** to test/retest. The test restarts with the training phase and can be stopped by pressing ***x***. In this case, the test result of the original test will remain unchanged.

- Press (**4**) ![share icon] to share or ![print icon] to print the test results.

  ![info icon]   Section 5.7   Managing Test Result

- Press ***KLAAR/TERMINÉ (DONE)* (5)** to finally end the test. The test results can no longer be accessed via the easyDigits app.

5.7 Managing Test Results

You can manage your test results in the following ways:

- Share test results via the tablet's Share function.

- Print test results via the tablet's print function.

- Download or delete PDF and XML files via USB.

Sharing and printing via the Android Function

Press ![share icon] to share or ![print icon] to print the test results on the result screen. Select the app for sharing (Figure 12) or printing (Figure 13) and complete the sharing process (i.e. via the email client) or print to a configured printer.
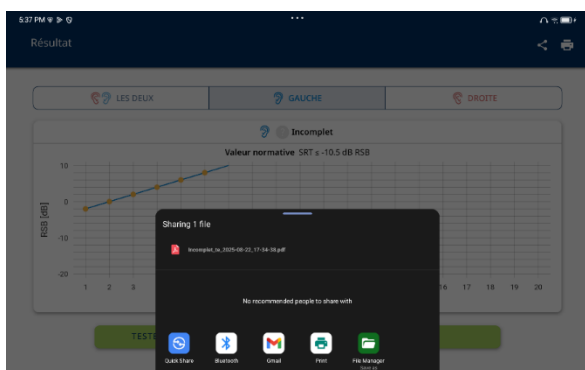
Figure 12
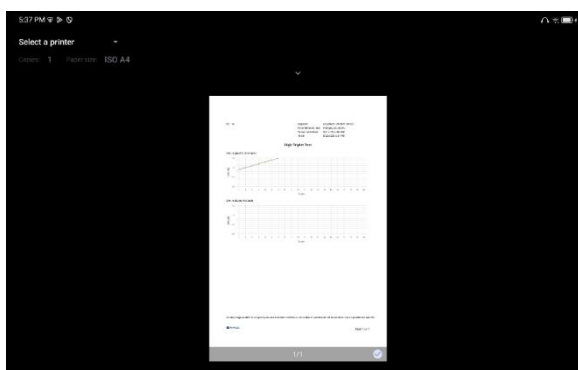
Figure 13

Download or delete PDF and XML files via USB

Test results are saved as XML files under the following path:

This PC\[Tablet Device Name]\[Internal shared storage] Android\data\biz.maico.easyDigits\files\Subjects

Connect the tablet to the PC via USB to retrieve the data via this path.

NOTE: The tablet must be set to use USB for file transfer. The exact path may vary depending on the device name and the system language of the tablet.

5.8 Important Information About Tablet Settings

5.8.1 General

- Swipe down from the top and tap the settings icon to open the tablet settings.

- Swipe left to right to return to the easyDigits software.

The tablet settings have been factory-optimized to ensure reliable performance during screenings with the easyDigits software. While it is technically possible to modify the tablet settings, it is essential that the following configurations remain unchanged to guarantee accurate and consistent screening results:

- Dolby Atmos

- High Volume Warning Suppression

- Gesture settings

See the following sections for more information.

5.8.2 Dolby Atmos

Activating Dolby Atmos alters the stimulus and can lead to inaccurate screening results. You can tell that Dolby Atmos is active if the Dolby symbol appears in the top right corner of the screening screen during the presentation.
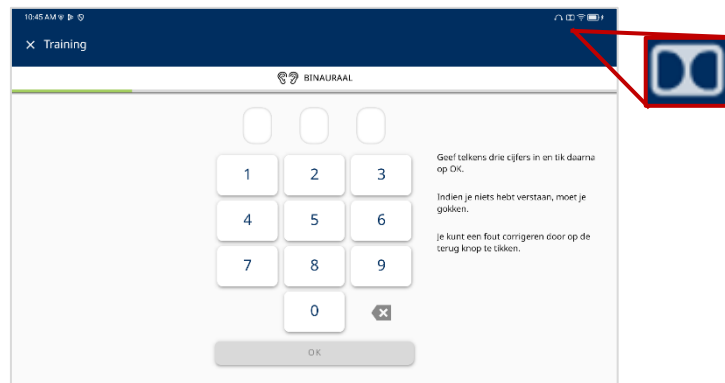
Figure 14

In *Settings > Sound > Dolby Atmos*, *Dolby Atmos* must be deactivated.
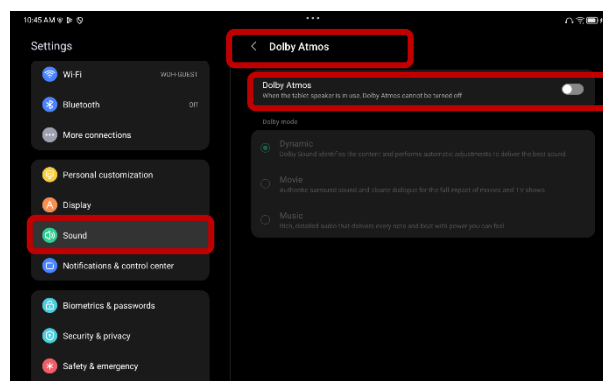
Figure 15

5.8.3 High Volume Warning Suppression

Tablets include a High Volume Warning Suppression feature designed to protect users from potential hearing damage. By default, the system limits the volume to 80 % when headphones are connected. However, for screening purposes, 100 % volume is required to ensure proper levels.

NOTE: During the presentation, a dialog may appear asking to deactivate the High Volume Warning Suppression. If this happens, make sure to reactivate it.
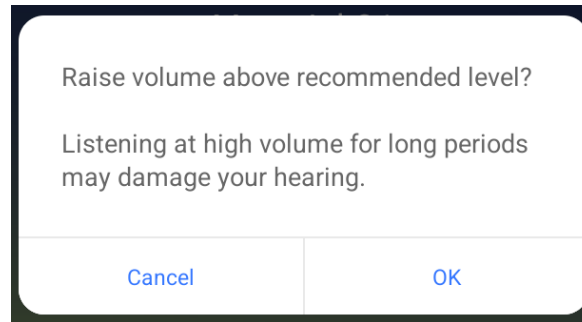

Figure 16

In **Settings > Accessibility, Use High volume warning suppression** must be set **On** (Figure 17and Figure 18).
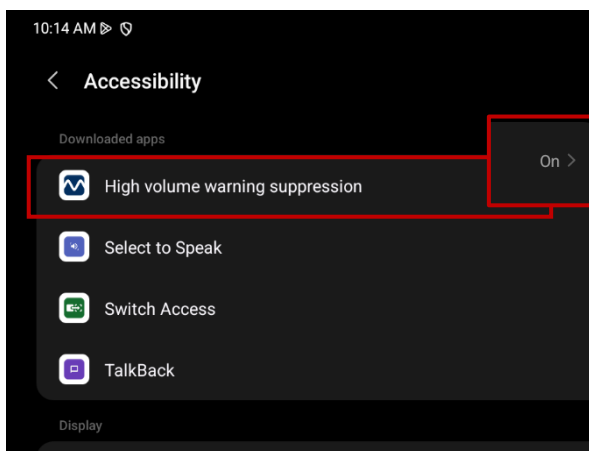
Figure 17
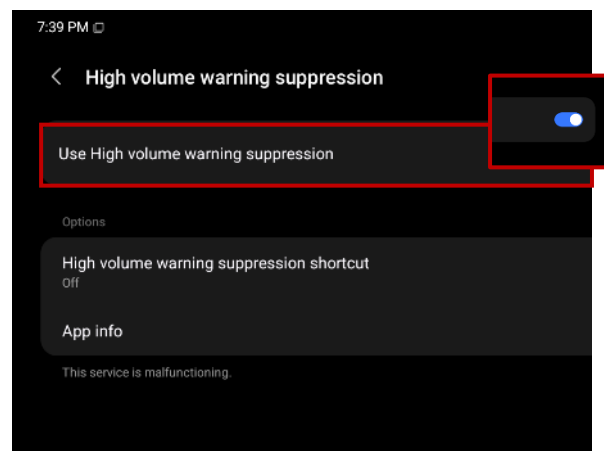
Figure 18

NOTE: If the Setting **High Volume Warning Suppression** is not working or malfunctions due to an error, restart the tablet and confirm that the setting is **On**.

5.8.4 Gesture Settings

The easyDigits software requires gesture navigation to be activated.

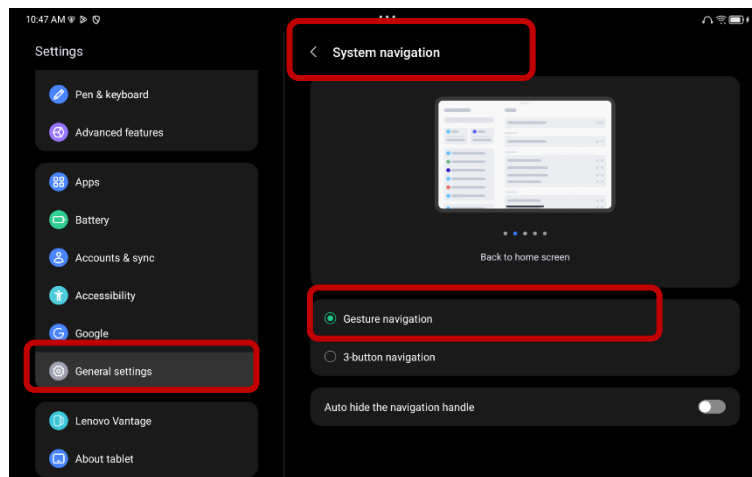In *Settings > General Settings > System navigation*, *Gesture navigation* must be selected (Figure 19).

Figure 19

5.9 easyDigits Menu

5.9.1 General

Briefly press the symbol 3 times to open the hidden *easyDigits* menu (Figure 20 and Figure 21). Select:

- *Settings*

- *Service*

- *Device Information*, or

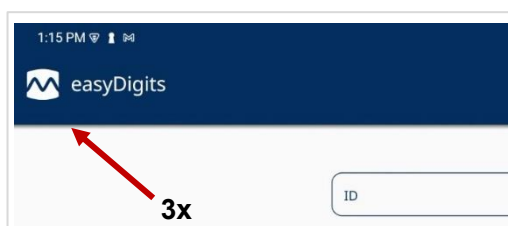- *About*

Note: *Service* is for service personnel only.
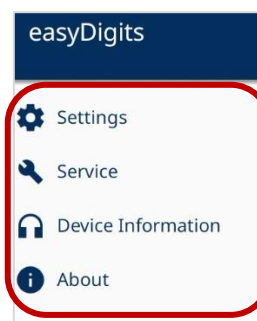

Figure 20

Figure 21

5.9.2 Settings

5.9.2.1 General

Press **Settings** and enter the password **!2776** (Figure 22). The **Settings** menu opens. Select **Basic**, **Test** or **Report** to open the submenus. (Figure 23).
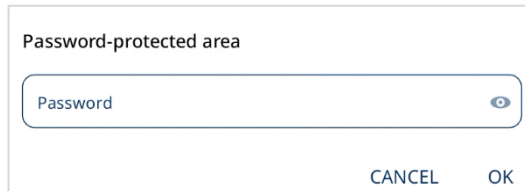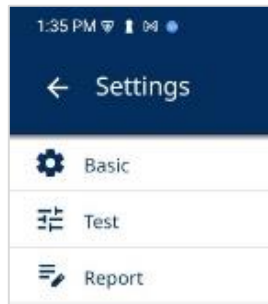

Figure 22

Figure 23

5.9.2.2 Sharing Settings

NOTE: You can use various apps to share the settings (e.g., e-mail or cloud drives). Apps can be installed according to your needs. Keep in mind general recommendations on Cyber Security and Data Protection.

 Section 2.8   Cyber Security and Data Protection

Share settings (file name: **easyDigits.settings.package**) using the apps installed on the tablet. Press:

    to share the settings.

Select the app for sharing (Figure 24) and complete the sharing process or save the file in the directory of the tablet for later use (e.g., for later download to a PC).
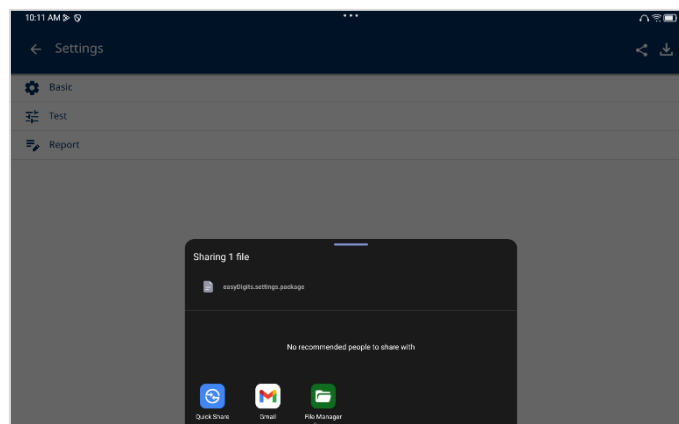

Figure 24

5.9.2.3 Importing Settings from the Tablet

Press:

 to open the directory of the tablet. Navigate to the location of the setting file you want to import (Figure 25).

Press on the file. You will automatically be returned to the **Settings** screen. The settings have been imported.
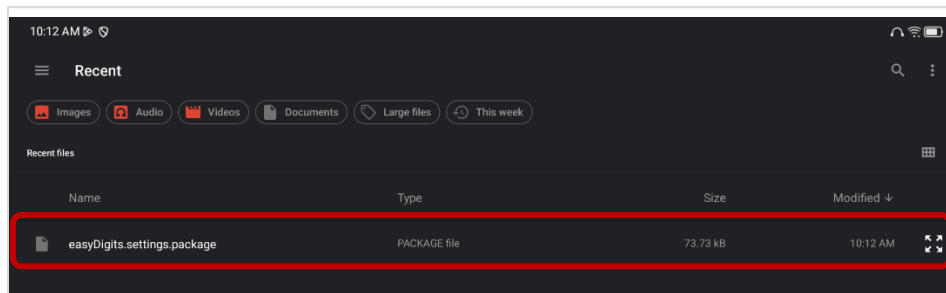

Figure 25

Swipe left to right to return to the easyDigits software without importing settings.

5.9.2.4 Basic Settings

Figure 26

Language

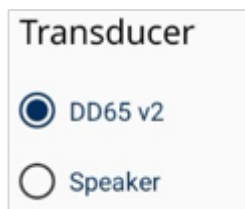Select the application language (**Figure 26**).

Figure 27

Transducer

Select the headphones **DD65 v2** or **Speaker** as transducer (Figure 27). Any speaker with a 3.5 mm jack plug can be used.

NOTE: For tests with speakers, on-site calibration is required.

Pass/Refer results are only for testing with headphones.
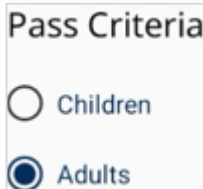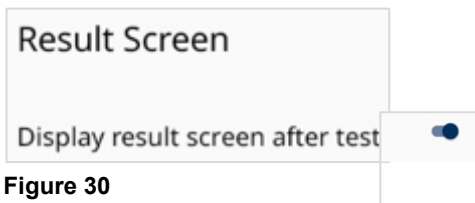
5.9.2.5 Test Settings

Scoring Method

Scoring Method

○ Triplet

◉ Digit

Figure 28

Scoring Method

Select the scoring method: *Triplet* or *Digit* (Figure 36).

i Section 5.6.1 General Test Description

Pass Criteria

Pass Criteria

○ Children

◉ Adults

Figure 29

Pass Criteria

IMPORTANT NOTE: Only valid for testing with headphones!

Select the pass criteria for *Children* or *Adults* (Figure 29). The pass criteria are outlined in:

i Section 6.7 Pass Criteria
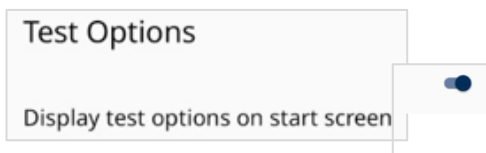
Result Screen

Result Screen

Display result screen after test ●○

Figure 30

Result Screen:

Activated: The *Result* screen is displayed after the test.

Deactivated: Only the completion screen is displayed after the test (Figure 30).

Test Options

Test Options

Display test options on start screen ●○

Figure 31

Test Options

Activated: The *Start* screen displays the test options *Test Language*, ear selection respectively *Aided/Unaided* and *Noise Level* (e.g., for a hearing test shop).
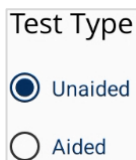
Deactivated: The *Start* screen displays only the input fields *ID* and *Date of birth*. The test options are set to default (e.g., for school screenings, Figure 31).

Test Language

Test Language

Français (Belgique) ▼

Figure 32

Test Language

Select the default language for the instructions, the digits presented and the results (Figure 32).
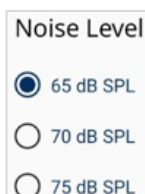
Test Type

Test Type

◉ Unaided

○ Aided

Figure 33

Test Type

Select *Aided* or *Unaided* as default (Figure 33).

Noise Level

Noise Level

◉ 65 dB SPL

○ 70 dB SPL

○ 75 dB SPL

Figure 34

Noise Level

Select the default noise level (Figure 34).

5.9.2.6 Report Settings

Figure 35

Report Language

Select the application language or the test language as report language (Figure 35).

Figure 36

Page size

Select the page size for the report (Figure 36).

NOTE: The page size can still be modified when printing the report.

Figure 37

Facility Information

Enter facility information to be shown in the header of the report (Figure 37). Press:

 to add a logo from the directory.

 to delete the logo again.

5.9.3 Service

For service only.

5.9.4 Device Information

Figure 38

The Device Information screen provides essential information about the device, including its identification and manufacturing specifics (Figure 39).

5.9.5 easyDigits App – About
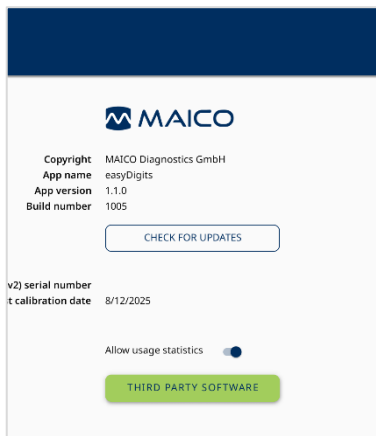
Figure 39

The **About** screen shows diverse information about the software (Figure 39).

It is possible to allow or forbid usage statistics by moving the slider to the left or the right (🟢 = allow, ⚪ = do not allow). Change of this setting requires a restart of the application.

Third-party software is displayed by pressing the arrow.

NOTE: The easyDigits App logs data about the tablet on which it is installed for support reasons. Further, the easyDigits App may log data about its usage patterns and anonymous usage data from test sessions on the manufacturer's servers administered by the manufacturer. They are used for future development.

All data logged is anonymous and is therefore not covered by EU GDPR consent. No individual can be identified and therefore the manufacturer is not able to or obliged to erase data requested by individuals or groups.

You can set **Allow usage statistics** to off.

5.10 Updating the easyDigits App

If the tablet is connected to the Internet and you can check and install updates by pressing the **CHECK FOR UPDATES** in the **About** screen (Figure 40).

Figure 40

Press **INSTALL NOW** to start the update (Figure 41).

If you update the easyDigits App the first time, you may need to allow the app to install updates. Press **Settings** to enter the settings menu (Figure 42).

Figure 41
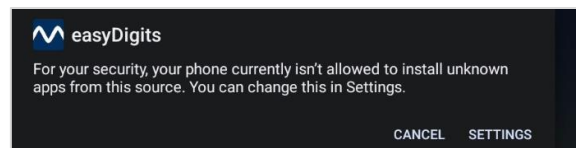
Figure 42

Move the slider to the right to allow updates (Figure 43).
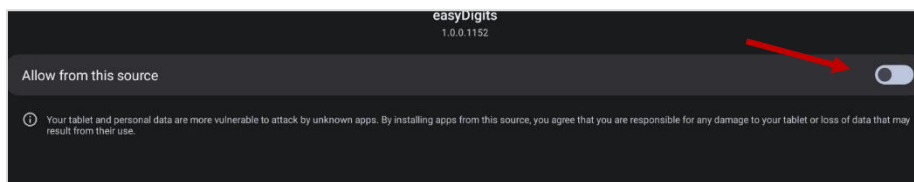
Figure 43

Press **UPDATE** to start the installation (Figure 44).

Press **Done** to finish the installation process or **OPEN** to open the easyDigits App (Figure 45).
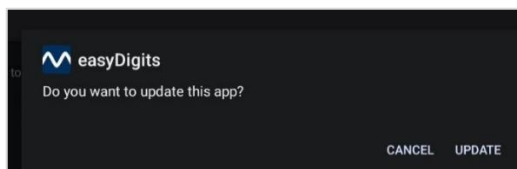
Figure 44

Figure 45

5.11 Calibration Reminder

 Section 3.3   Maintenance
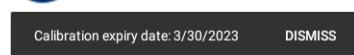
Figure 46

Annual calibration is recommended.

The reminder starts 1 month prior to the expiration of the calibration date for your acoustic transducer (Figure 46).

The user can always dismiss the reminder message and continue with screening.

6 Technical Data

This section offers you important information about

- **the easyDigits hardware specifications**
- **connection ans pin assignment**
- **calibration values and maximum levels**
- **electromagnetic compatibility (EMC)**
- **electrical safety, EMC and associated standards**

6.1 easyDigits Hardware and Software

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The easyDigits is an active, diagnostic medical product according to 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 subjected to technical maintenance at least every 12 months.

MAICO Diagnostics provides circuit diagrams and service manuals to authorized service centers.

| STANDARDS	
Safety Standards	EN IEC 62368-1:2020 + A11:2020 USB powered EQUIPMENT with means of connection to a SUPPLY MAINS complied with CLASS I or CLASS II ME EQUIPMENT requirements when so connected, and when not connected to SUPPLY MAINS with INTERNALLY POWERED ME EQUIPMENT requirements.
EMC	EN 301 489-1 V2.2.3:2019

The easyDigits is not classified according to the standard EN 60645-1 and is not in conformity with this standard.

DEVICE SPECIFICATIONS		
Power Supply Unit (Tablet)	Type	UES60LCP-200300SPC
	Input	90 to 264 V AC, 50/60 Hz, 1.3 A
	Output	5.0~12.0 V DC, 3.0 A MAX
	Safety	IEC 60601-1, Class II

DEVICE SPECIFICATIONS

Mode of Operation	Continuous	
Environmental conditions	Operation	Temperature: +15 °C to +35 °C / +59 °F to +95 °F Humidity: 30% – 90%, non-condensing Ambient pressure: 98 kPa to 104 kPa
	Storage	Temperature: 0 °C to +50 °C / +32 °F to +122 °F Humidity: 10% – 95%, non-condensing
	Transport	Temperature: -20 °C to +50 °C / -4 °F to +122 °F Humidity: 10% – 95%, non-condensing
Altitude Rating	Max operating altitude 2000 m / 6561 ft above sea level	
Calibration	Calibration information and instructions are located in the easyDigits Service Manual.	
Air Conduction	DD65 v2 RadioEar Standard Values	
Transducers – Headband tension	DD65 v2 Headband Static Force: 10.0 N ± 0.5 N	
Test Type	Digit Triplet Test	
Test Signals	Speech-in-noise Triplet method: 27 trials (Dutch (Flemish) / French) Digit method: 17 trials (Dutch (Flemish)), 19 trials (French)	
Levels	Noise: 65 dB SPL, 70 dB SPL, 75 dB SPL (fix)	
	Speech: 30 – 85 dB SPL (adaptive procedure)	
	Speech start level according to scoring method (adaptive procedure):	
	Triplet: 65, 70, 75 dB SPL (0 dB SNR)	
	Digit: 63, 68, 73 dB SPL (-2 dB SNR)	
Accuracy	Level ±3 dB	
Precision	Speech level steps according to scoring method (adaptive procedure):	
	Triplet	Dutch (Flemish) / French: ±2 dB
	Digit	Trial 1 to 6:

Number correct digits:	Level step:
0	+2.0 dB
1	+0.7 dB
2	-0.7 dB
3	-2.0 dB

Trial 7 to 17 (Dutch (Flemish)) / 19 (French)

Number correct digits:	Level step:
0	+3.2
1	+1.8
2	+0.5
3	-0.8

Outputs	Left, Right, Binaural, Aided: Left

DEVICE SPECIFICATIONS

Weight (Headphones)	389g / 0.86 lbs
Dimensions (Headphones)	W x D X H: 19.1 cm x 9.3 cm x 13.4 cm/ 7.5" x 3.6" x 5.3" (excluding connections)
User Interface	Touch screen (tablet)
Language Settings	Test: Dutch (Flemish), French Application/report: English, Dutch (Flemish), French
PC Connection	1 x USB C to A for PC Connection
Stimuli	
Presentation	Automated digits-in-noise test (no time window for responses)
Intensity	AC: 63 dB SPL to 85 dB SPL
Warm-Up Time	Less than 1 min after turning on (incl. boot-up time)
Store Function	Stored as PDF and XML files on the tablet
Distortion	< 0.1 % Total Harmonic Distortion (THD)
Rise/fall Times	~35 ms

TABLET SPECIFICATIONS

Operating System	Android™
Version	15
Resolution	1920 x 1200 px
Screen Size	11"
Input	USB-C®
Battery Capacity	Integrated 7040 mAh
Battery Lifespan	Dependent on battery age and usage behavior
Weight	Around 465 g / 1.03 lbs
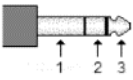
6.2 Connections

Figure 47

CONNECTIONS		
No	**Socket**	**Specification**
1	**Power Supply**	External Power supply, 5.0 V DC, 2.0 A MAX
2	**Headphones**	ZA =10 Ω, UA = 7 Veff

6.3 Pin Assignment

SOCKET	CONNECTOR	PIN 1	PIN 2	PIN 3
Headphones	3.5 mm Stereo	Ground	Signal	-

USB-C® (Out)

Pin	Name	Pin	Name
A1	GND	B12	GND
A2	SSTXp1	B11	SSRXp1
A3	SSTXn1	B10	SSRXn1
A4	VBUS	B9	VBUS
A5	CC1	B8	SBU2
A6	Dp1	B7	Dn2
A7	Dn1	B6	Dp2
A8	SBU1	B5	CC2
A9	VBUS	B4	VBUS
A10	SSRXn2	B3	SSTXn2
A11	SSRXp2	B2	SSTXp2
A12	GND	B1	GND

6.4 Calibration Values and Maximum Levels

Calibration Values and Max Levels: Headphones DD65 v2

Coupler IEC 60318-1

Signal	Max Level [dB SPL]
Speech-filtered noise for Dutch (Flemish) /French DTT	75
Speech (Dutch (Flemish)/French)	85

6.5 Electromagnetic Compatibility (EMC)

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.

This device is in compliance with EN 301 489-1 V2.2.3:2019.

6.6 Electrical Safety, EMC, and Associated Standards

- IEC 62368-1:2014 + A11:2017: Audio/Video, Information And Communication Technology Equipment - Part 1: Safety Requirements
- EN 301 489-1 V2.2.3:2019: ElectroMagnetic Compatibility (EMC) standard for radio equipment and services - Part 1: Common technical requirements - Harmonised Standard for ElectroMagnetic Compatibility
- ISO 14971:2019- Application of risk management to medical devices
- General Safety and Performance Requirements of the current REGULATION (EU) 2017/745
- 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
- DIRECTIVE 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE)

6.7 Pass Criteria

Pass Criteria (Adults) for SRT Values in dB					
	Result				
Language	**Pass**	**Refer**	**Eligible for Hearing Aid Grant**	**Unreliable**	**Incomplete (automatic test stop)**
Dutch	SRT ≤ -11,2	-11,2 < SRT < -8,2	SRT ≥ -8,2	SD ≥ ±3	SRT ≥ 10
French	SRT ≤ -10,5	-10,5 < SRT < -7,5	SRT ≥ -7,5		

Pass Criteria (Children) for SRT Values in dB					
	Result				
Age (years)	**Pass**	**Inconclusive**	**Refer**	**Unreliable**	**Incomplete (automatic test stop)**
9-12	SRT ≤ -8,4	-8,4 < SRT < -6,5	SRT ≥ -6,5	SD ≥ ±3	SRT ≥ 10
13-16	SRT ≤ -9,0	-9,0 < SRT < -8,1	SRT ≥ -8,1		
≥ 17	SRT ≤ -10,0	-10,0< SRT < -8,0	SRT ≥ -8,0		

Specifications are subject to change

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