Operation Manual
easyTone

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All available operation manuals can be found in the download center on the MAICO homepage:

Germany:

International:

Compliance

MAICO Diagnostics is an ISO 13485 certified corporation.

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

Trademark Notice

Android is a trademark of Google LLC.

Windows is a registered trademark of Microsoft Corp.

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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 easyTone is a screening audiometer designed to perform a hearing screening. The instrument is intended for all patient populations over 3 years of age and able to respond to a test signal in a rational way.

1.2 Indications for Use Statement

The easyTone is a portable or standalone audiometer intended to be used for the identification of hearing loss and the factors that contribute to the occurrence of the hearing loss in the age range of children to adults. It is used as part of a total test battery to determine hearing acuity by audiologists, ENTs, hearing healthcare professionals, or other trained technicians under the supervision of a professional such as an audiologist, doctor or nurse in a hospital, clinic, healthcare facility or other suitable quiet environment as defined in ISO 8253-1 or ANSI S3.1 or equivalent.

1.3 Contraindications of Use

The patient is too young, sick or uncooperative to perform the tasks.

1.4 Features and Benefits of easyTone

1.4.1 General information about the easyTone

The easyTone gives you the benefit of:

- Portable headphone audiometer with tablet
- Air Conduction screening audiometry
- Site specific screening protocol creation
- Pass or Refer result with report
- Guided workflow
- Start screen adaptability
- Import / export screening lists
- Quick reporting (e-mail, printer, drive)
- Noise monitoring

1.4.2 easyTone Companion Software

The easyTone Companion Software allows you to:

- Import screening list to easyTone app
- Download subject results for easy result management

1.5 Description

The easyTone audiometer is designed to be a device for screening for hearing loss. Output 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 screening for hearing loss using this kind of audiometer 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 MANUAL BEFORE ATTEMPTING TO USE THIS SYSTEM!

Use this device only as described in this manual.

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

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

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

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

2.2 Customer Responsibility

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

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

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

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

Customer responsibility includes proper maintenance and cleaning of the device.

Section 3.3 Maintenance

Section 3.4 Cleaning and Disinfection Recommendations

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

Section 2.3 Manufacturer's Liability

Section 3.1 Warranty

NOTE: In the unlikely case of a serious incident, inform MAICO as well as the competent authority in the country where the user is established.

2.3 Manufacturer's Liability

Usage of 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 disregarding the operation manual, the operation of the device by underqualified personnel as well as making unauthorized alterations on the device.

2.4 Regulatory Symbols

SN	Serial number
	Date of manufacture
	Manufacturer
	Caution, consult accompanying documents
	Warning, consult accompanying documents
	Information sign (reference for more detailed information)
	Return to authorized representative, special disposal required
REF	Reference number
MD	Medical Device
(01)04260176127444 (11)201020 (21)MA0123456	UDI information: (01) GTIN (Global Trade Item Number), (11) Date, (21) Serial number
	Patient applied part type B according to IEC 60601-1
	Refer to operation manual (mandatory)
	Keep away from rain
	Transport and storage temperature range
	Transport and storage humidity limitations
	Transport and storage atmospheric pressure limitations
CE 0123	CE label with notified body ID
	Non-ionizing electromagnetic radiation
	Direct Current (DC)
ETL CLASSIFIED Intertek	ETL listed mark
MAICO	Logo

2.5 General Precautions

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

Use and store the device indoors only. For operation, storage and transport conditions see Table in Section 6 Technical Data.

For operation in certain places, a recalibration may be necessary.

No modification of this equipment is allowed.

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

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.

Uncalibrated devices may lead to faulty measurements and may cause the examinee to be exposed to loud sounds.

Ensure that the device does not come into contact with liquids. 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.

2.6 Electrical and Electrostatic Safety

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

In Case of Emergency

In case of emergency, disconnect the audiometer headphone from the tablet.

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

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 WiFi or USB connection.

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

Section 4.3 Establishing a PC Connection

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

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-enriched environment, such as a hyperbaric chamber, oxygen tent, etc. If the device is not used switch it off and disconnect it from the power supply.

Never short-circuit the terminals.


WARNING

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


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 easyTone Hardware


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 easyTone, 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

To ensure data protection it is essential to follow common practice in terms of cyber security. This involves:

1. Ensure operating systems are security patched
2. Keep your software up to date.
3. Install only apps and software from trusted sources.
4. Install an antivirus protection and anti-malware software and a firewall from a trusted vendor and keep them up to date.
5. Utilize the tablet/PC password settings and use safe passcodes.
6. Ensure secure physical and network access to computers with local data storage.
7. Implement an appropriate backup policy.
8. Do not use public WiFi.
9. Learn about phishing scams: Be very suspicious of emails and calls.

Permanent Deletion of Test Data

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

To permanently delete test data, proceed as follows:

Figure 1

Press the easyTone app icon until the info selection dialog box opens (Figure 1). Open the ***App info*** and press ***Storage & cache*** (Figure 2).

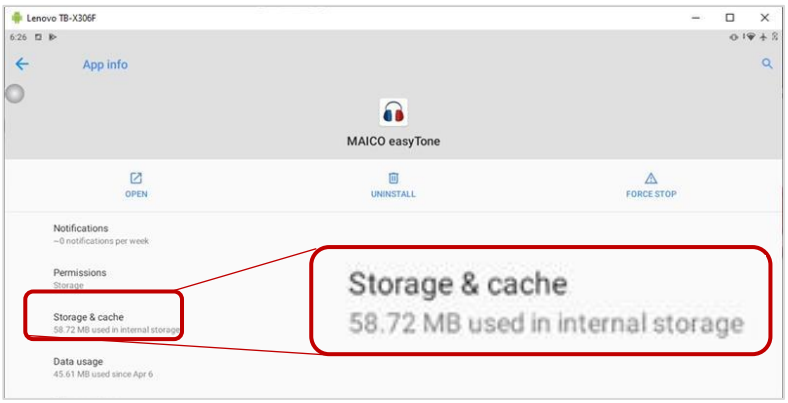


Figure 2

Press ***CLEAR STORAGE*** and ***CLEAR CACHE*** to permanently delete all test data (Figure 3).

Figure 3

2.9 Device Control

The user of the device should perform a subjective device check once a week according to ISO 8253-1.

For a checklist see:

Section 6.6 Checklist for Subjective Audiometer Testing

For annual calibration please see sections:

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 one 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, please enclose evidence of purchase with the device.

3.1.2 Ownership, Warranty and Disclaimer (Software)

Ownership

The easyTone Software (hereinafter the “SOFTWARE”) is 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 in the ***About*** screen.

	Section 5.13	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

In order to ensure that the device works properly, it has to be checked and calibrated at least once every 12 months.

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

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

3.4 Cleaning and Disinfection Recommendations

It is recommended that parts (device and accessories like headphones, 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 switch off the tablet and disconnect the headphones from the tablet.
- For cleaning the headphones use a lightly dampened cloth with soap water solution. For cleaning the tablet follow the instructions of the manufacturer of the tablet.
- Disinfect the plastic housing of the easyTone and its accessories by wiping the surfaces with wet disinfectant wipes. Follow the instructions on the specific disinfection product.
    - Wipe before and after each patient
    - After contamination
    - After infectious diseases
- Disinfect tablet, computer, keyboard, etc. with wet disinfection wipes:
    - once a week
    - after contamination
    - when polluted

To avoid damage of the device and its accessories, please 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 easyTone 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 2002/96/EC on waste electrical and electronic equipment (WEEE), MAICO has changed their sales policy. To avoid additional distribution costs we assign the responsibility for the proper collection and treatment according to legal regulations to our customers.

Non-European countries

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

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

Reporting Imperfections

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

Report Immediately any Faults

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

Keep Packaging for Future Shipment

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

Components

The easyTone comes with different components (see Table 1). The availability of configurations with the following components is country specific. Contact your local distributor for more information.

Table 1 Components

Components
easyTone Audiometer Headphones*
easyTone App
Patient Response Switch*
Tablet
Power Supply Unit USB-C for Tablet UES18LCPU-050200SPA
USB-C Splitter
Tablet Case
Carrying Case
Operation Manual
Quick Guide

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

4.2 Hardware Orientation

4.2.1 easyTone Device

Figure 4 shows the easyTone headphones, the tablet, the optional patient response switch and the carrying bag.

Figure 4

4.2.2 Connections

CAUTION

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

The audiometer headphones are connected to the tablet via the USB-C connection (Figure 5). Insert the plug of the optional patient response switch into the socket on the handset (Figure 6).

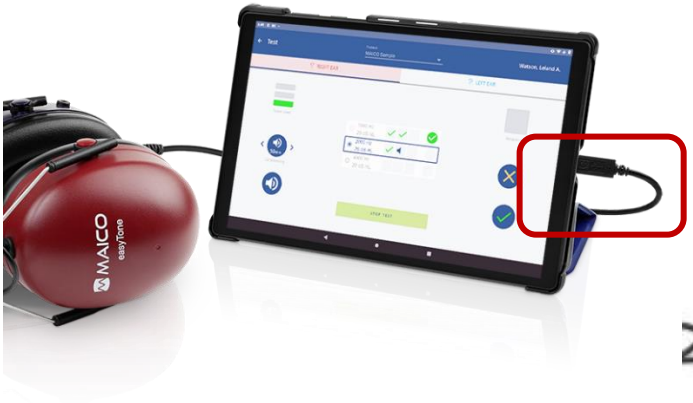


Figure 5

Figure 6

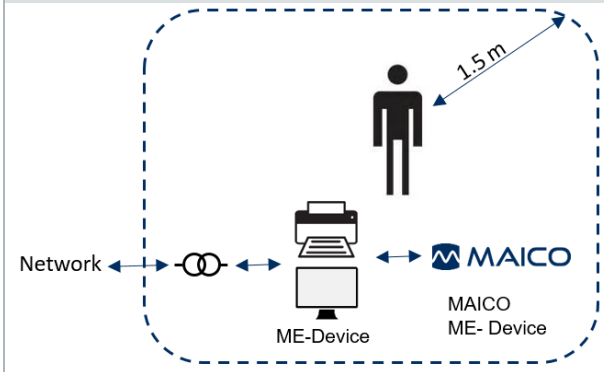
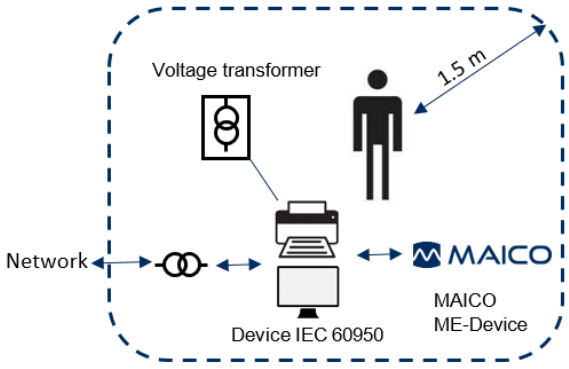
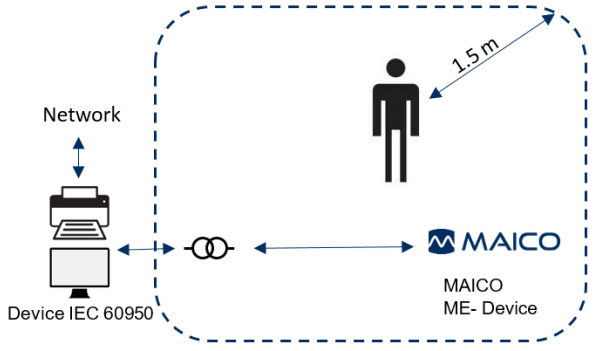
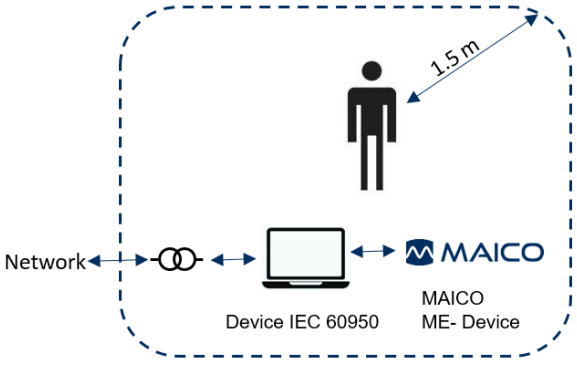
4.3 Establishing a PC Connection

Data transfer to a PC can be done via USB connection. If the easyTone is used with office equipment that is not a medical device itself (see Table 2, PC Connection 1), make sure to establish the PC connection in one of the following ways (see Table 2, PC Connection 2, 3 or 4).

WARNING

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

Table 2 PC Connections

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

4.4 Powering

4.4.1 Powering the easyTone Audiometer Headphones

The easyTone headphone audiometer is powered from the USB connection.

4.4.2 Powering the Tablet

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

Using a non-medical 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 only use the power supply unit supplied by MAICO (UES18LCPU-050200SPA).

Connect the USB-C splitter to the tablet and plug in the connectors for the power supply unit and the easyTone audiometer headphones.

NOTE: When you are not using the easyTone, you should turn off the tablet and disconnect the easyTone headphones from the tablet; otherwise, it will continue to consume power.

4.5 Storage

When the easyTone audiometer headphones and the tablet are not in use, unplug all accessories and power 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 easyTone audiometer headphone and the patient response switch in the carrying case and the tablet in the tablet case.

Store according to the recommended temperature conditions described in:

Section 6.1 easyTone Hardware

5 Operating the Device

5.1 Getting started with the easyTone

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

5.1.2 Where to Setup

The easyTone 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 function of the audiometer. Therefore, it is not recommended to use these devices in close proximity to 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 1 minute before the first measurement. If the device has been cooled down (e.g., during transport), please wait until it has warmed to room temperature before using.

NOTE: For temperature and warm-up time see:

Section 6.1 easyTone Hardware

5.2 Switching On

To switch on the device:

- Connect the easyTone audiometer headphones to the tablet.
- Press the power key on the tablet to boot it up.
- Launch the easyTone app by pressing on the icon. Allow access to the easyTone. The app shows the start screen.

5.3 Switching Off

Press the power key to switch the tablet off and disconnect the easyTone Headphones from the tablet to allow safe storage.

Section 4.5 Storage

5.4 Android™ Navigation

Navigate the Android™ tablet in the navigation bar of the tablet:

	Back	Move backward through the history of screens previously visited.
	Home	Return to main screen of tablet.
	Task Switch	Display all recently opened apps. Launch or close an app running in the background.

NOTE: The navigation bar is an Android™ setting option. It is recommended to leave the setting as all manual and training materials utilize this view.

5.5 Managing Protocols

Manage Protocols allows the test seen to be adapted to the specific screening guidelines of the location. This is one of the first functions that should be completed when easyTone is received to utilize the full benefit of the device.

5.5.1 Entering the Manage Protocols Screen

To enter the ***Manage Protocols*** screen, press:

 to open the menu.

Manage Protocols to open the ***Manage Protocols*** screen (Figure 7).

Figure 7

5.5.2 Creating a New Protocol or Changing a Protocol

You can create your own protocols according to your screening guidelines and modify them later if needed.

Press:

+	to open the ***New Protocol*** screen OR
⋮ and ***Edit***	to enter the ***Edit Protocol*** screen.

Protocol wizard will start and leads you through protocol options (e.g., Figure 8, single steps: Figure 9 to Figure 14).

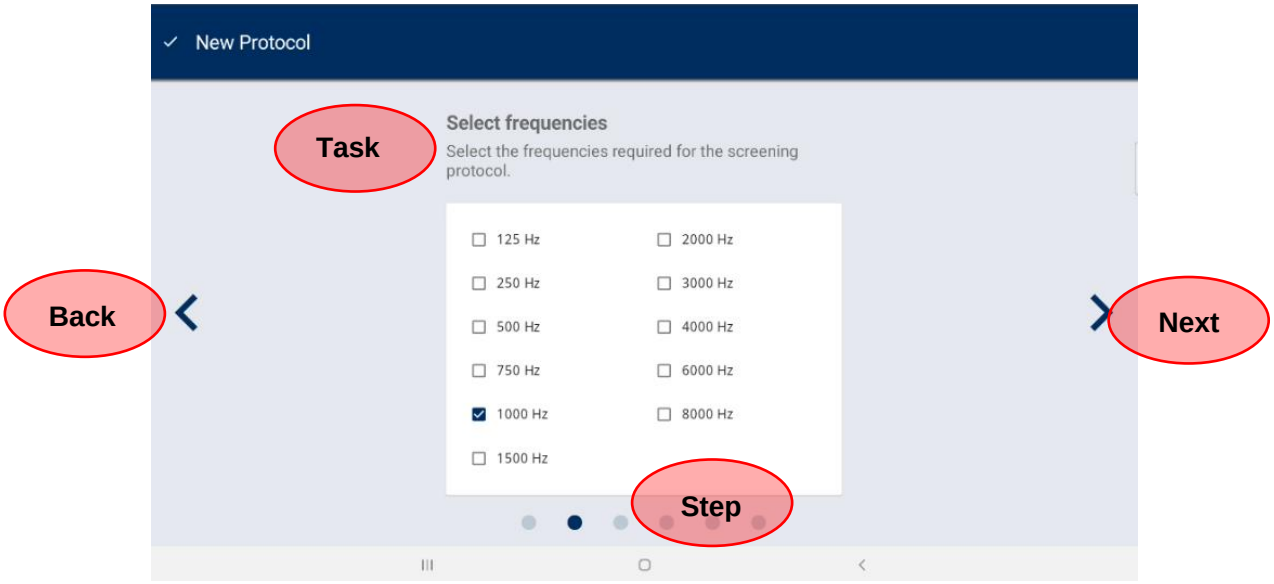


Figure 8

Enter a ***Name*** for the protocol using the built-in keyboard (Figure 9). Press › to proceed.

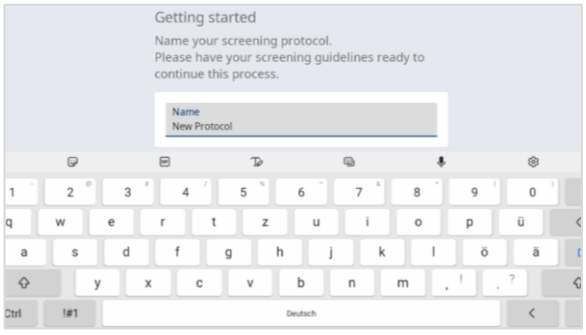


Figure 9

Select/deselect the frequencies (Figure 10). Press › to proceed.

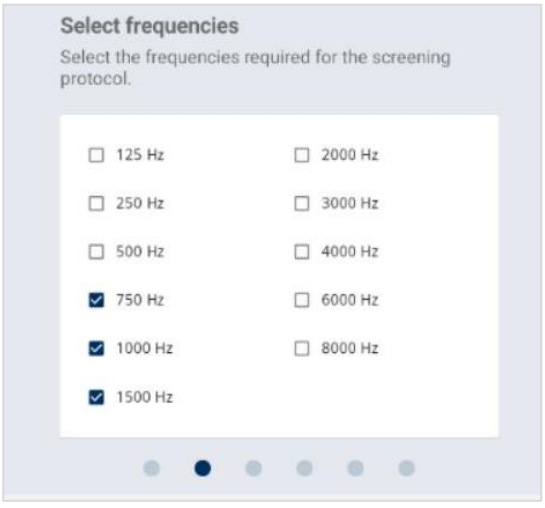


Figure 10

Set the level for each frequency (Figure 11). Press › to proceed.

Figure 11

Choose the frequency order for each ear (Figure 12). Touch ☰ and drag the window with the frequency to the desired position. Press › to proceed.

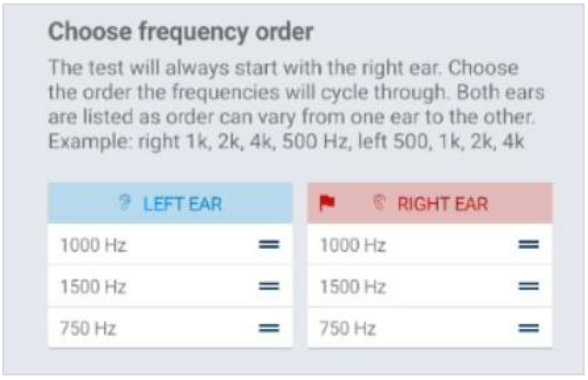


Figure 12

To allow a ***Pass*** result for each frequency (Figure 13):

- after 2 responses: activate setting.
- after 1 response: deactivate setting.
- Press › to proceed.

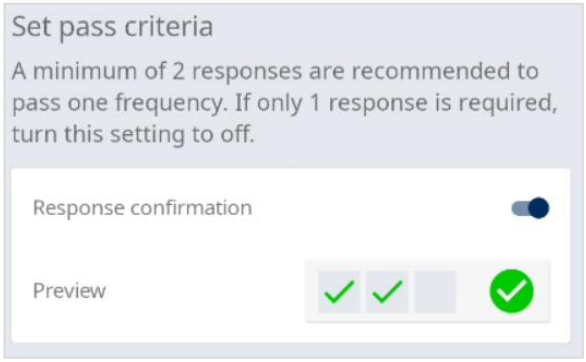


Figure 13

Select the signal type (Figure 14).

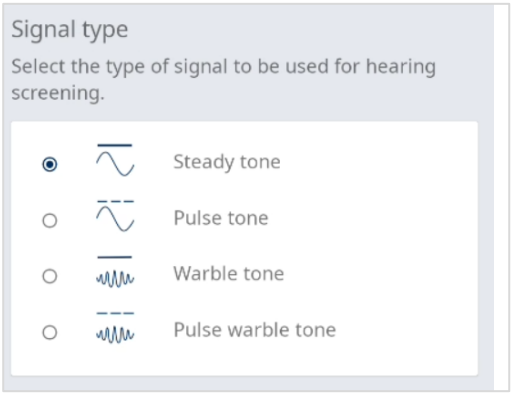


Figure 14

New Protocol:

Press CREATE to save the protocol or press ← to abort protocol creation after further confirmation.

Edit Protocol:

Press ← to save modifications.

5.5.3 Deleting a Protocol

Press:

⋮ and ***Delete*** to delete the protocol.

5.5.4 Sharing a Protocol

NOTE: You can use various apps to share the protocols (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 protocols (XML-format) using the apps installed on the tablet. Press:

⋮ and ***Share*** to share a single protocol.

to share all protocols.

Select the app for sharing (Figure 15) and complete the sharing process in the app or save the file in the directory of the tablet.

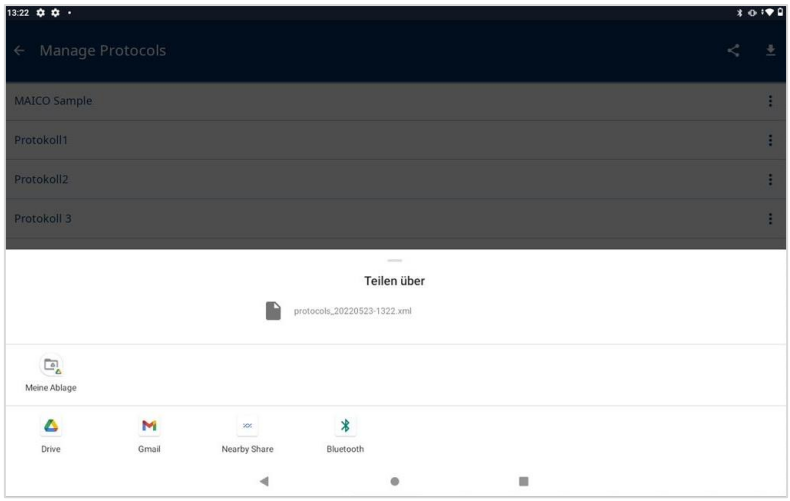


Figure 15

5.5.5 Importing a Protocol from the Tablet

to open the directory of the tablet. Navigate to the location of the protocol file you want to import (Figure 16). Press on the file. You will automatically be returned to the ***Manage Protocols*** screen. The log(s) have been imported.

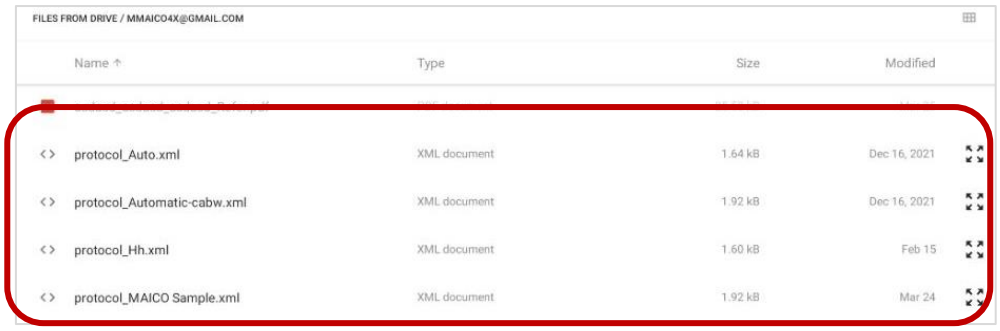


Figure 16

to return to the Manage Protocols screen without importing a file.

5.6 Testing

5.6.1 Preparing for Testing

5.6.1.1 Preparing the Subject

The subject should sit at a distance of at least 1 m from the device.

Prior to hearing threshold level measurements, the following instructions should be given. ***"You will now hear a variety of tones with various loudness levels, raise your hand, or press the response switch, as soon as you hear the tone in either ear."***

NOTE: This is an example of subject preparation. Each state may have their own preparation procedure. Contact your state health department for guidelines in your area.

5.6.1.2 Placement of Headphones

Figure 17

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 17) 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).

5.6.2 Selecting a Screener

NOTE: For learning how to add a screener see:

Section 5.11.5 Settings – Screeners

Press in the upper right corner of the start screen. Select a screener from the list and press ***OK*** (Figure 18).

Figure 18

NOTE: You can add a new screener in ***Menu → Settings → Screeners.***

Press to add a new screener. Enter the screener name and press ***Save***.

5.6.3 Selecting a Subject

5.6.3.1 General

Section 5.11.2 Settings – Basic

According to the settings made, the app starts with

- the ***Screening List*** screen (see Section 5.6.3.3)
- the ***Single Screening*** screen (see Section 5.6.3.2).

NOTE: From both screens it is possible to start a ***Quick Test*** without having created a subject beforehand.

Section 5.6.3.5 Quick Start

5.6.3.2 Entering a Subject in Single Screening Mode

1. Fill in the entry fields.

NOTE: You can start the test as soon as you have filled in at least one field.

2. Clear the entries if needed.
3. Press ***START TEST*** to directly start testing the subject you have just entered.

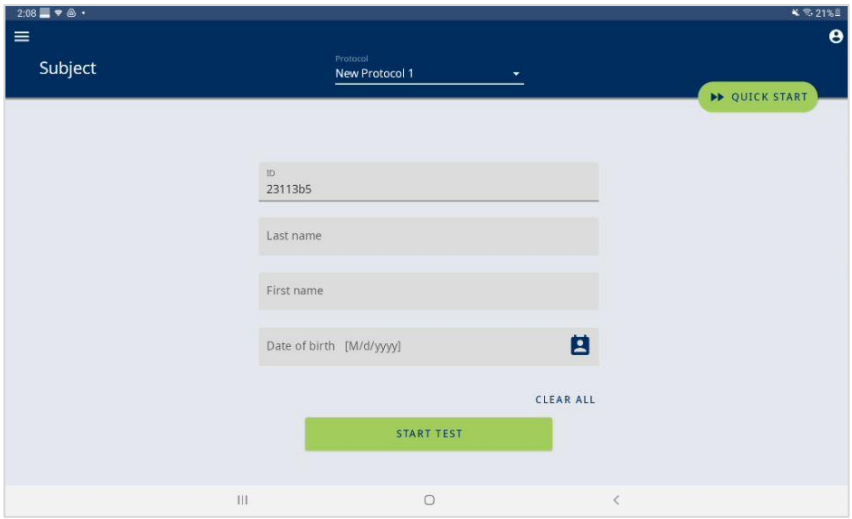


Figure 19

5.6.3.3 Selecting a Subject from the Screening List

Figure 20 shows the Screening List. Table 3 provides further explanations.

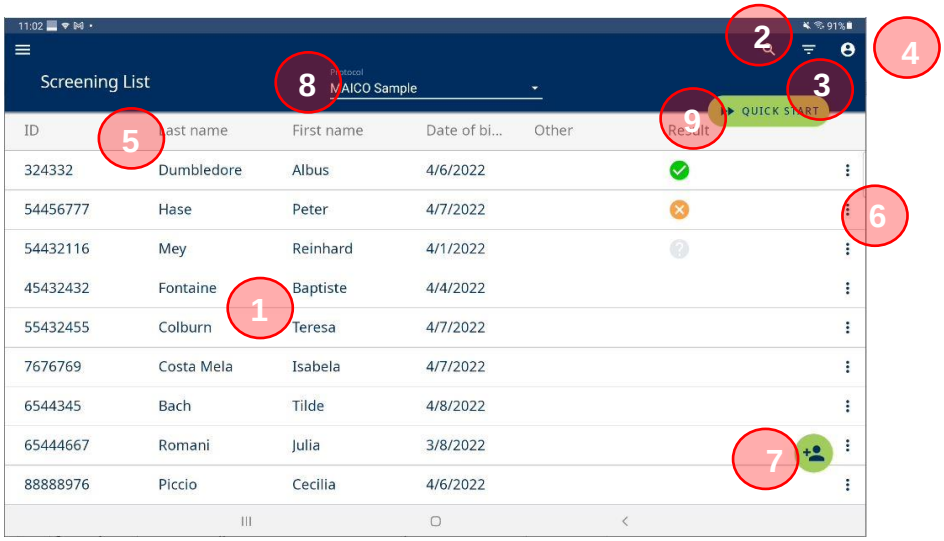


Figure 20

Table 3 Screening List

No.	Item	Information
1	**Screening List**	The Screening List shows the data of the subjects and the overall test result if available. Result symbols: ✓ - ***Pass***, ✗ - ***Refer***, ? - ***Could not test***.
2	🔍	Search the Screening List by ***Id***, ***Last Name***, ***First Name***, or ***Other***.
3	▽	Filter the list by ***No test***, ***Pass***, ***Refer***, or ***Could not test***.
4	👤	ⓘ Section 5.6.2 Selecting a Screener
5	Last Name ▾	Sort the list by ***ID***, ***Last Name***, ***First Name***, ***Date of Birth***., or ***Other***.
6	⋮	Press to expand for further actions. Press: ✎ Edit to edit an existing subject. 🗑 Delete to delete a subject from the list. ? Could not test to mark that a subject could not be tested.
7	👤+	Add a new subject to the Screening List. ⓘ Section 5.6.3.4 Adding a New Subject to Screening List
8	**Protocol**	Select the test protocol. **NOTE**: The protocol can also be changed on the test screen.
9	**Quick Start**	ⓘ Section 5.6.3.5 Quick Start

5.6.3.4 Adding a New Subject to Screening List

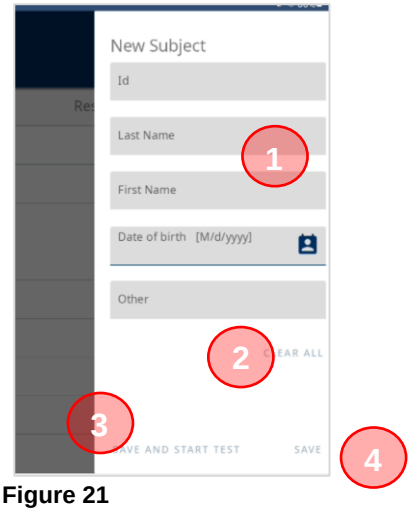


Figure 21

To enter a new subject to the Screening List, press  and proceed as follows (Figure 21):

1. Fill in the entry fields.

   NOTE: You can save the subject as soon as you have filled in at least one of the entry fields.

2. Clear the entries if needed.
3. Press ***SAVE AND START TEST*** to directly start testing the subject you have just entered.
4. Press ***SAVE*** to save the new subject and return to the ***Screening List*** screen.

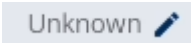
5.6.3.5 *Quick Start*

You can start a test even if the subject information has not yet been entered. You can do this both in Screening List mode and in Single Screening mode.

Press 

to start the test and proceed as normal.

Single Screening:

On the ***Result*** screen you can add the Subject information. Press 

(above Screening Result) to go to the ***New Subject*** screen and add the information.

Screening List mode:

After the test is completed, you will be asked to enter the subject information (Figure 22).

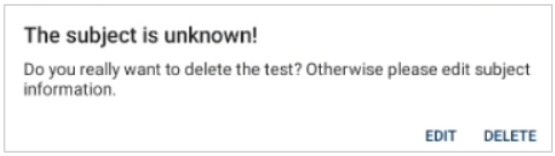


Figure 22

Press ***EDIT*** to enter the ***EDIT SUBJECT*** screen and fill in the data. The new subject will be added to the Screening List.

Or press ***DELETE*** to delete the test data.

5.6.4 Selecting a Protocol

 Section 5.5 Managing Protocols

Select a protocol either in the start screen or in the test screen (Figure 23 and Figure 24). When selecting from the test screen, this must be completed before a screening response is stored as the Protocol selection becomes inactive.

Figure 23

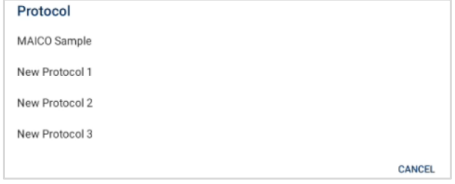


Figure 24

5.6.5 Testing

Figure 25 shows the test screen. For testing proceed as follows:

Figure 25

1. Change the selected protocol if needed.
2. Press RIGHT EAR or LEFT EAR to select the ear. The ear changes automatically once all frequencies have been tested.
3. Check the ***Noise Level*** and improve testing conditions if needed (green = ideal, yellow: okay, red = too loud, testing conditions need to be improved).
4. Condition the subject.

   Section 5.6.6 Conditioning the Subject
5. Present a tone.
6. Press

   if the subject does not respond.

   if the subject does respond.

   Proceed accordingly for further frequencies and the other ear.
7. Review single results for each frequency per ear.
8. Press STOP TEST to stop the test, if testing is not possible anymore (***Could not test***) or you want to save an overall ***Refer*** result (Figure 26).

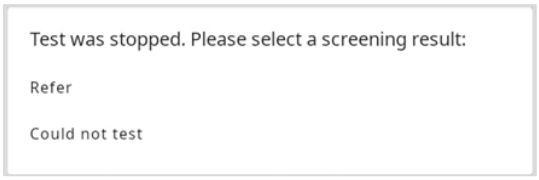


Figure 26

5.6.6 Conditioning the Subject

Conditioning or training the subject on what to listen for is done before the hearing screening begins. This allows the subject to know what to respond to at an elevated hearing level.

Set the preferred conditioning level with the arrows and then select the blue button between the arrows to present the tone.

There are a variety of conditioning levels available to select and even can be used to gradually reduce to the screening level.

NOTE: A conditioning level of 100 dB HL is available for selection. The headphones must not be worn for this presentation level. This should only be used as a training tool to allow the subject and screener to hear the signal together, for training of the response.

5.7 Test Result – Screen Layout

Figure 27 shows the ***Result*** screen. Table 4 gives explanation.

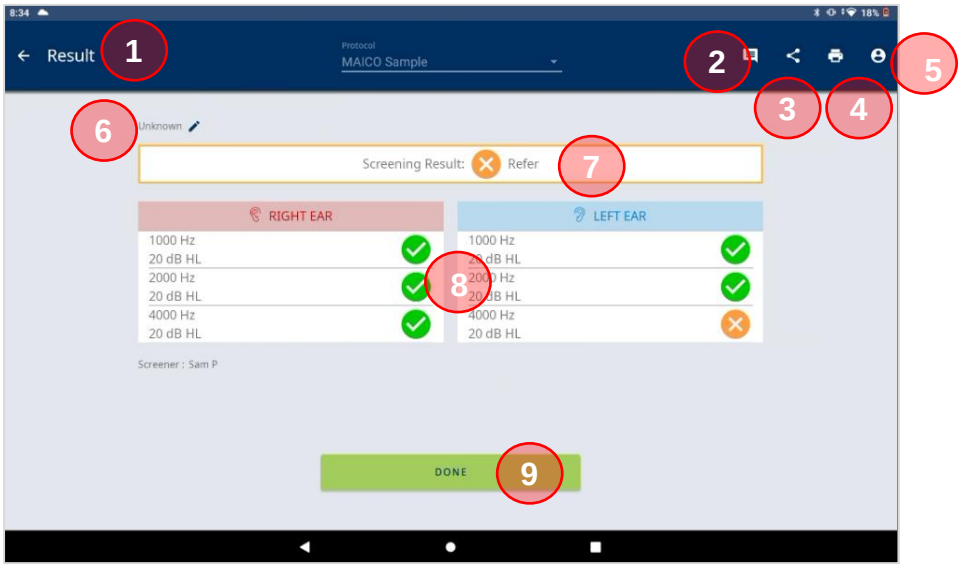


Figure 27

Table 4 Explanation of Test Result Screen

#	Name(s) / Function (s)	Description
1		To return to test screen (e.g., if you want to continue a stopped test).
2		To add a comment to the printout and excel export of the Screening List.  Section 5.8 Add Notes
3		Opens Android™ menu with sharing apps.  Section 5.10.2.2 Sharing Test Results
4		Opens Android™ printing application.  Section 5.10.2.3 Printing Test Results
5		 Section 5.6.2 Selecting a Screener
6	Subject/ Edit	Displays subject. An ***Edit*** icon is displayed only for subjects entered within the easyTone App. Subjects imported from the easyTone Companion Software cannot be edited.
7	Overall Result	The overall result is displayed as ***Pass*** or ***Refer***. When ***No Response*** is collected for just one frequency, the overall result is displayed as ***Refer***.
8	Individual Results	Display all frequency result for both ears.
9	Done	To exit Result Screen and return to start screen.

5.8 Add Notes

To add a note to a test result, press the icon in the app bar.

The ***Add Notes*** field will display. Tap the box to expand the keyboard for entry (Figure 28). Once a note is entered, the icon displays a green dot.

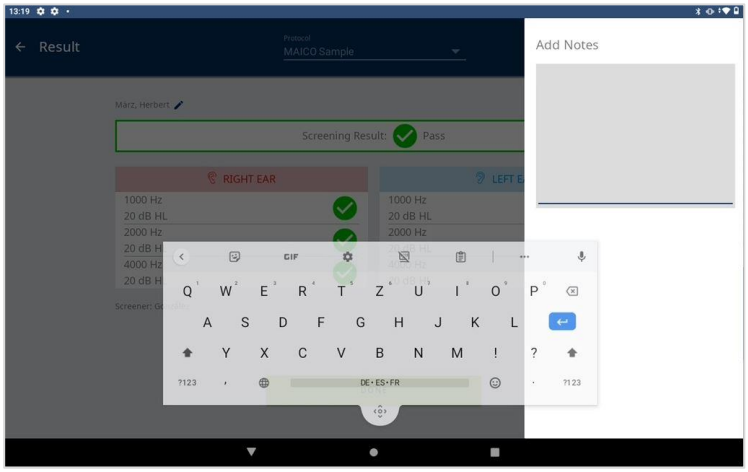


Figure 28

5.9 easyTone Companion Software

5.9.1 General

NOTE: The easyTone Companion software must be installed separately for each PC/Mac user. The settings are managed centrally. The settings are shared among all users.

The easyTone Companion Software allows for Screening Lists to be loaded onto the tablet. This is for ease in a mass screening and in the documentation process.

5.9.2 Installing the easyTone Companion Software

NOTE: Before installation check the system requirements:

Section 6.1 easyTone Hardware – EASYTONE COMPANION SOFTWARE – SYSTEM REQUIREMENTS

easyTone Companion Software for download under:

www.easytone.app

Installing on Windows®

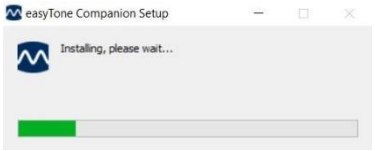


Figure 29

Close all open or running programs. To start the installation process, double-click ***easyTone Companion Setup.exe***.

The application will be installed (Figure 29) and opens automatically after installation is completed.

Installing on Mac

Double-click on the installation file. Move the app to the ***Applications*** folder by drag and drop (Figure 30).

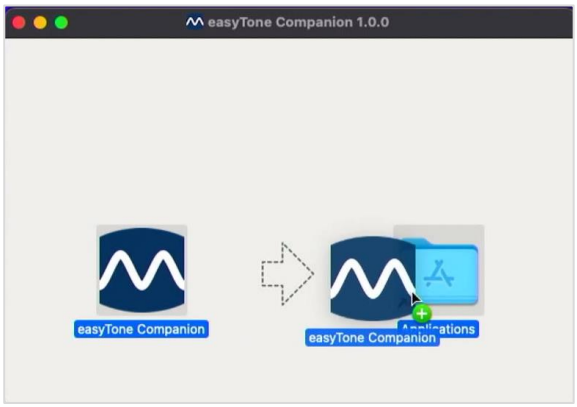


Figure 30

Follow the installation progress in the Applications window (Figure 31).

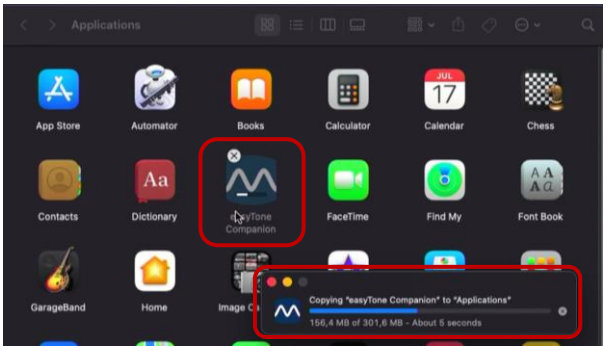


Figure 31

To start the easyTone Companion Software, open the Applications window under ***Go*** → ***Applications*** (Figure 32) and double-click the App icon. The app icon is now displayed in the taskbar.

Figure 32

5.9.3 easyTone Companion Software – Screen Layout

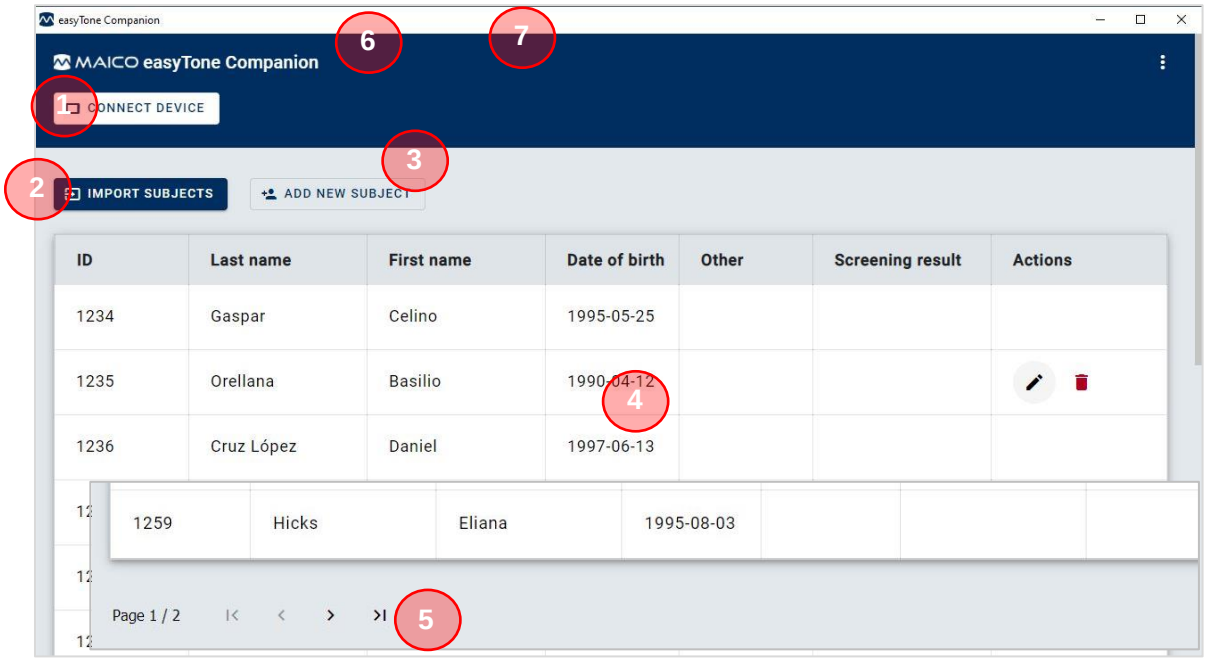


Figure 33

Table 5

#	Name(s) / Function (s)	Description
1	Connection	***CONNECT DEVICE*** button or connected device (IP address) Section 5.9.4 Connecting the Tablet to the easyTone Companion Software
2	IMPORT SUBJECTS	Select to find subject file to import in the directory. Section 5.9.5 Import Subject to easyTone Companion Software
3	ADD NEW SUBJECT	To manually add subject. Section 5.9.6 Add New Subject
4	Screening List	Shows imported/created subjects.
5	Page navigation	To navigate to other subjects.
6	DOWNLOAD	To download a Screening List from tablet. Section 5.9.9 Download Screening List to the easyTone Companion Software
7	UPLOAD	To upload the Screening List to the tablet. Section 5.9.8 Upload Screening List to Tablet

5.9.4 Connecting the Tablet to the easyTone Companion Software

Connect the easyTone Companion Software via

- WiFi (Mac and Windows® PCs) or
- USB (Windows® PCs/laptops only).

Connection via WiFi

1. Connect the tablet and the PC to the same WiFi network.
2. Start the easyTone App on the tablet and make sure the tablet does not enter standby mode.
3. Start the easyTone Companion Software on the PC.
4. Press CONNECT DEVICE and select ***WiFi*** (Figure 34).

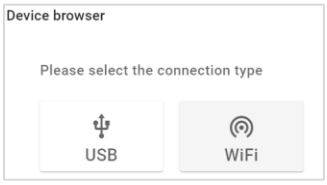


Figure 34

5. Enter the IP address and press ***SEARCH*** or search the tablet by pressing ***SCAN NETWORK*** (Figure 35).

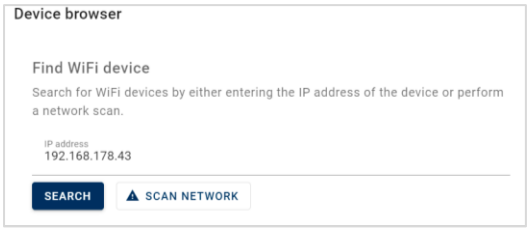


Figure 35

6. Select the tablet's IP address (Figure 36). The IP address can be found in the tablet settings. Use the tablet's search function to find. The successful connection is indicated by a green check mark.

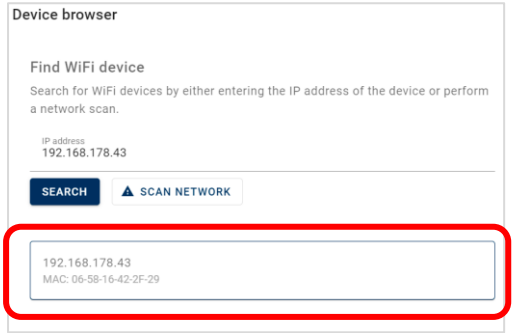


Figure 36

7. Press ***Close***. The IP address of the connected tablet is displayed in the easyTone Companion Software (Figure 37).

Figure 37

USB Connection

NOTE: You must establish the USB connection before each transfer.

Make sure to use the USB-C cord delivered by MAICO. Other USB cords might be for charging only.

When connecting the tablet to your PC or laptop, proceed as follows:

1. Connect the tablet to the PC with the USB cord.
2. Allow access on the tablet.
3. Swipe down from the top to display the ***Silent Notifications*** and locate the Android™ System notification about USB connection. Tap for other USB options (Figure 38).

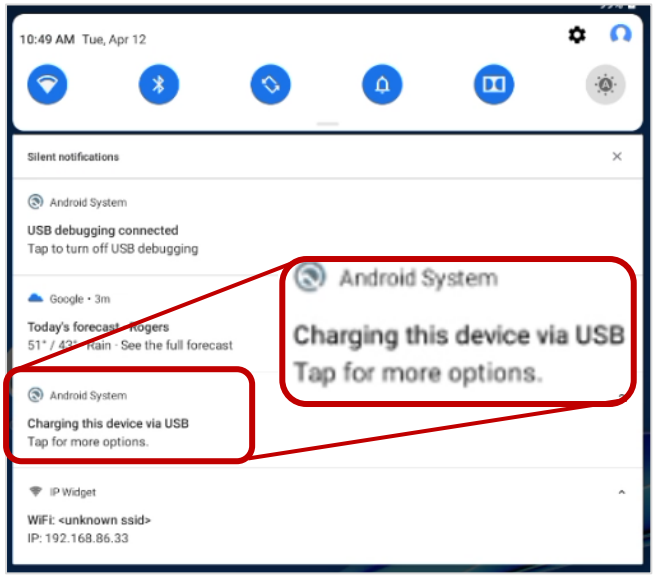


Figure 38

4. Select ***File Transfer*** (Figure 39) and leave the ***USB settings*** menu.

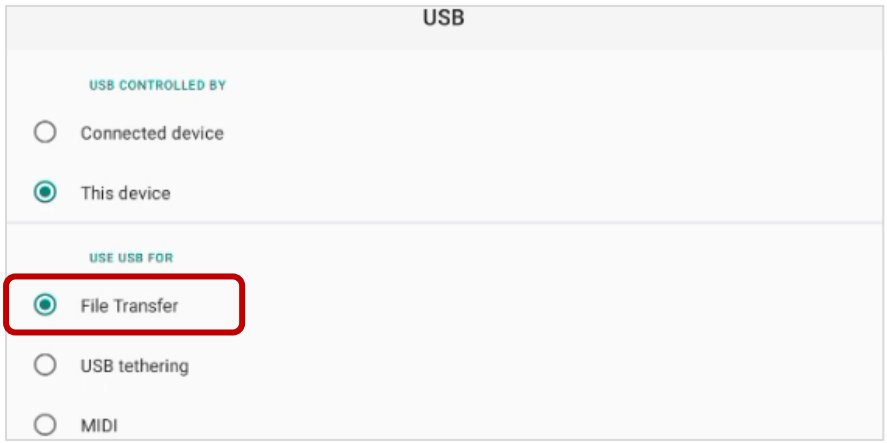


Figure 39

5. Start the easyTone App on the tablet.
6. Start the easyTone Companion Software on the PC.

7. Press CONNECT DEVICE and select ***USB*** (Figure 40).

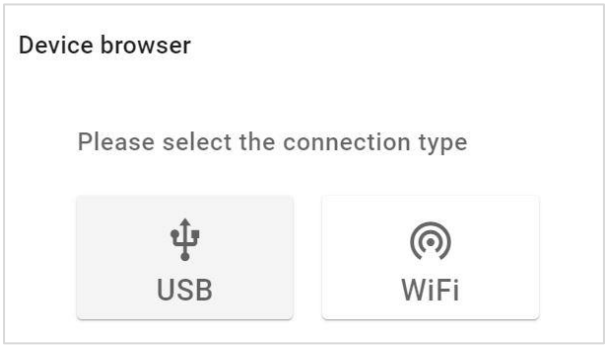


Figure 40

8. Select the USB device (Figure 41). The successful connection is indicated by a green check mark.

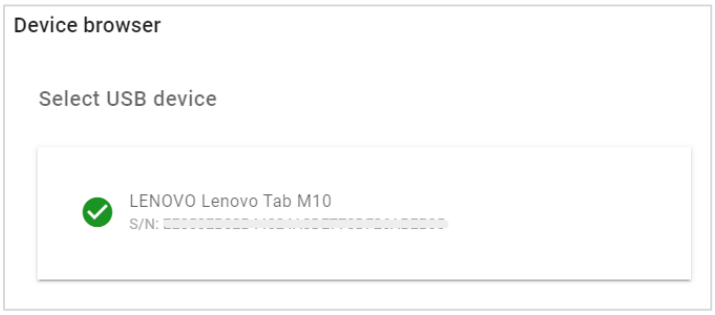


Figure 41

9. Press Close. The connected tablet is displayed in the easyTone Companion Software (Figure 42).

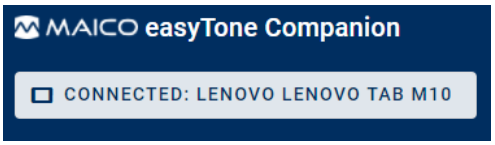


Figure 42

5.9.5 Import Subject to easyTone Companion Software

NOTE: Allowed file formats for Screening Lists: *.XLS, *.XLSX and *.CSV.

This file can be exported from an already utilized database or manually created.

Proceed as follows:

1. Press IMPORT SUBJECTS.
2. Select the file in the directory and press ***Open***.
3. Associate import file columns to subject columns in the easyTone Companion Software by selecting from the drop-down menu and press ***IMPORT*** (Figure 43).

NOTE: Columns that are not associated will not be imported.

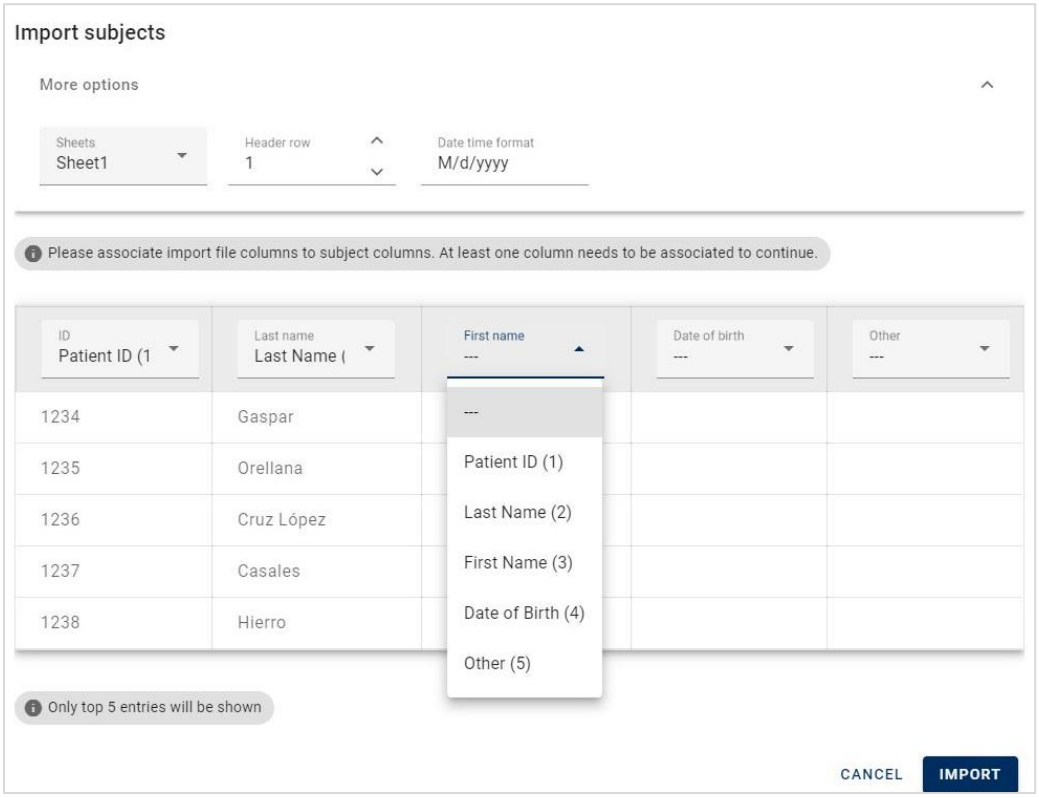


Figure 43

5.9.6 Add New Subject

Press ADD NEW SUBJECT to add a subject to the Screening List. Enter at least one field and press ***Save*** (Figure 44).

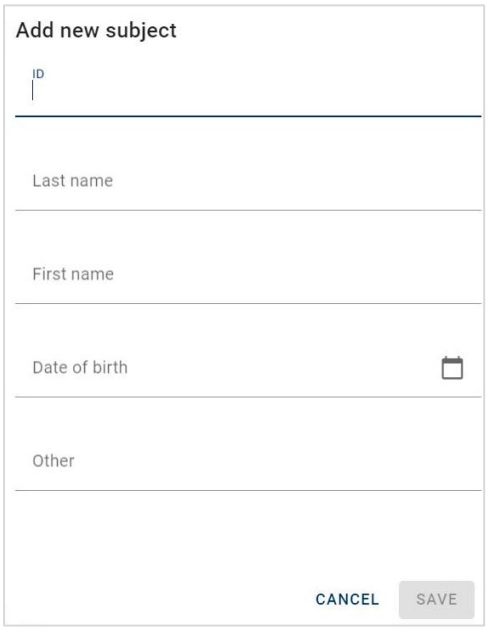


Figure 44

5.9.7 Edit or Delete a Subject from the Screening List

It is possible edit or delete subjects by pressing the icons in the ***Actions*** column (Figure 45).

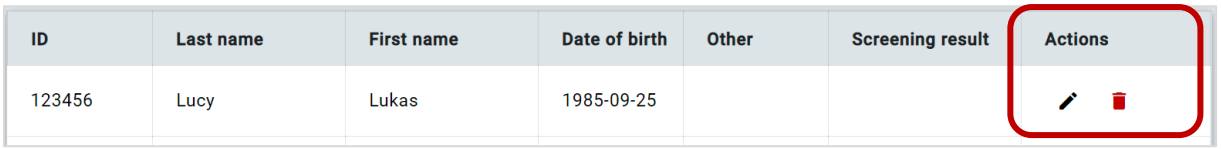


Figure 45

Press to delete a subject after further confirmation.

Press to edit the subject in the ***Edit Subject*** window which is structured like the ***Add New Subject*** window.

NOTE: You can also delete a subject in the Screening List in the easyTone App. Furthermore, it is possible to start a Quick Test and save the result to the Screening List.

Section 5.6.3.3 Selecting a Subject from the Screening List

Section 5.6.3.5 Quick Start

5.9.8 Upload Screening List to Tablet

NOTE: Make sure the Screening List in the easyTone App on the tablet is empty before importing or creating a new list from the easyTone Companion Software.

Press UPLOAD to upload the Screening List from the easyTone Companion Software on the PC or Mac to the easyTone App on the tablet. Successful update is confirmed in the bottom right corner of the easyTone Companion Software (Figure 46).

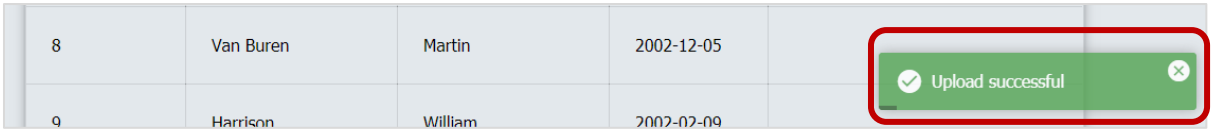


Figure 46

5.9.9 Download Screening List to the easyTone Companion Software

Press DOWNLOAD to download the Screening List from the easyTone App to the easyTone Companion Software (Figure 47).

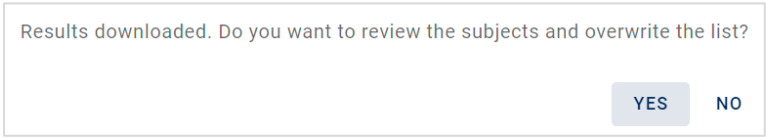


Figure 47

Press ***Yes*** to overwrite the existing Screening List.

Press ***No*** to keep the existing Screening List and only save results to the directory.

After successful download a Quick Link is displayed at the bottom center to open the location (Figure 48).

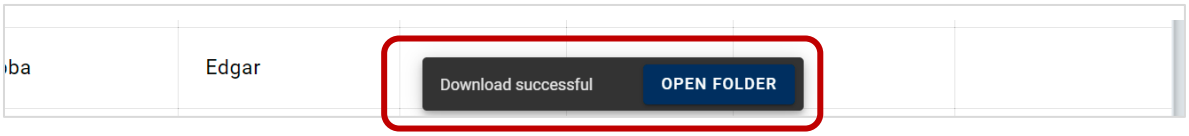


Figure 48

Press ***OPEN FOLDER*** to open the Download folder with the date of download. The folder contains the results in .xlsx and .csv format.

NOTE: The Screening List in the easyTone App is empty after successful download.

5.9.10 easyTone Companion Software – Settings, Feedback and About

Click on the ellipsis in the right upper corner to access the ***Settings***, ***Feedback*** and ***About*** menu (Figure 49).

Figure 49

5.9.11 easyTone Companion Software – Settings

shows the ***Settings*** menu of the easyTone Companion Software (Figure 50).

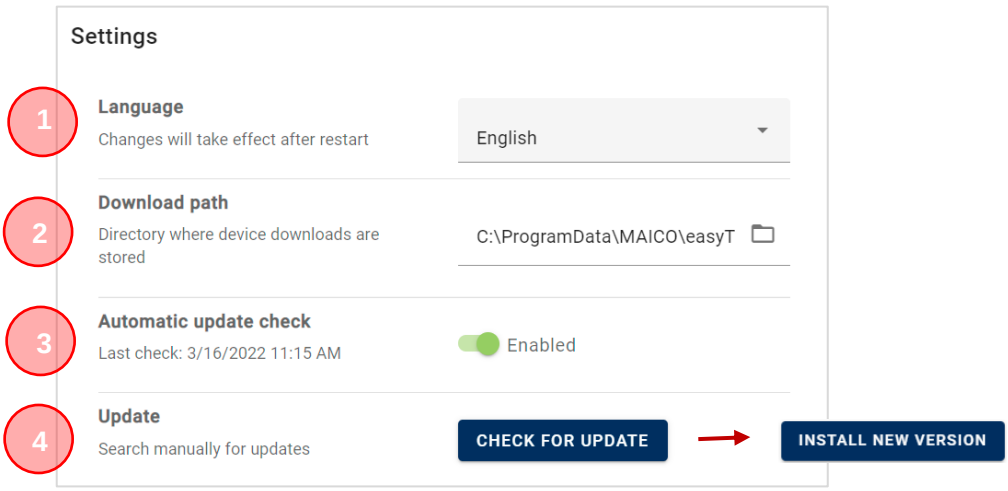


Figure 50

Language (1)

Select a language from the drop-down menu. Restart the easyTone Companion Software to let the change take effect.

Download path (2)

The path where the downloaded results are saved can be changed. Click on the folder icon to create a new download path.

Default: ***C:\ProgramData\MAICO\easyTone Companion\Downloads***

Automatic update check (3)

Enable this feature to automatically check for updates. New updates are displayed after restarting the app. Press INSTALL NEW VERSION (**4**) to perform the update.

Update (4)

Press the CHECK FOR UPDATE button to manually search for updates. Press INSTALL NEW VERSION to perform the update.

5.9.12 easyTone Companion Software – Feedback

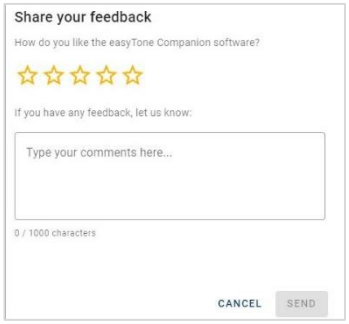
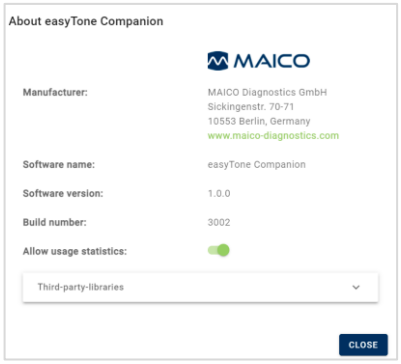


Figure 51

Feedback is always welcomed and encouraged by end users. To share feedback, use the integrated Feedback form. Leave a star rating or let MAICO know how easyTone Companion Software can be improved. Press the ***SEND*** button to share your ideas with MAICO (Figure 51).

NOTE: MAICO is not able to respond to feedback communications. If you need assistance with this software, contact your local representative or MAICO Diagnostics directly.

5.9.13 easyTone Companion Software – About



The ***About easyTone Companion*** screen shows diverse information about the software (Figure 52).

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.

Figure 52

NOTE: The easyTone Companion Software logs data about the tablet on which it is installed for support reasons. Further, the easyTone 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 Managing Test Results

5.10.1 General

The easyTone App and the easyTone Companion Software offer various options for managing test results and test protocols.

5.10.2 Managing Test Results in the easyTone App

5.10.2.1 Deleting Test Results

Delete subjects including test results in the easyTone App or in the easyTone Companion Software:

Section 5.6.3.3 Selecting a Subject from the Screening List

Section 5.9.7 Edit or Delete a Subject from the Screening List

NOTE: If you use the Single Screening Mode the test results will be deleted as soon as the ***DONE*** button is selected. To save a record share or print the test results.

5.10.2.2 Sharing Test Results from the easyTone App

Press  to open the ***Share*** Menu (Figure 53). Select an app to share the test result (PDF file).

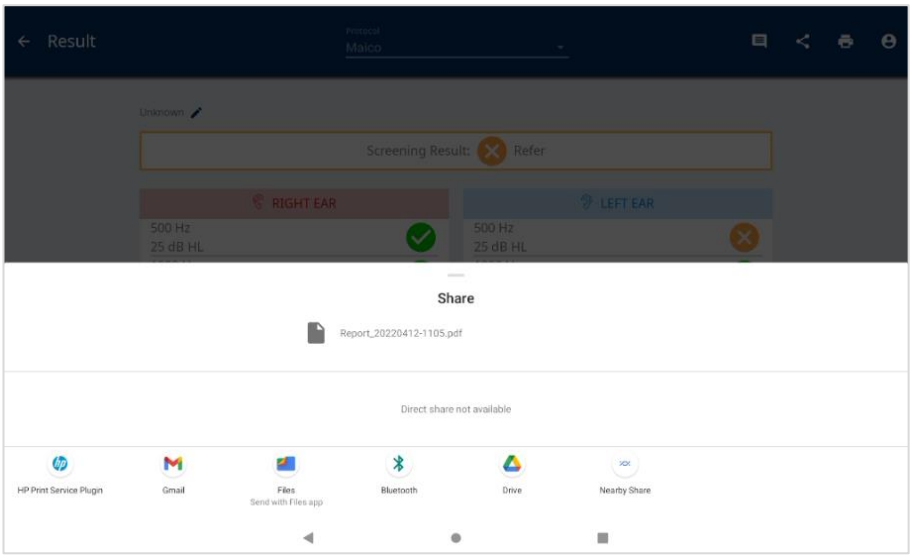


Figure 53

5.10.2.3 Printing Test Results

Press  on the ***Result*** screen and the print preview opens.

Press  (**1**) to open further printer settings if needed.

Save as PDF

Press  (**2**), select the storage location and press ***Save***.

Print on a Printer

Press **3** to select another available printer. Follow the printer instructions.

NOTE: Setup the printer within the Android™ settings before starting to test.

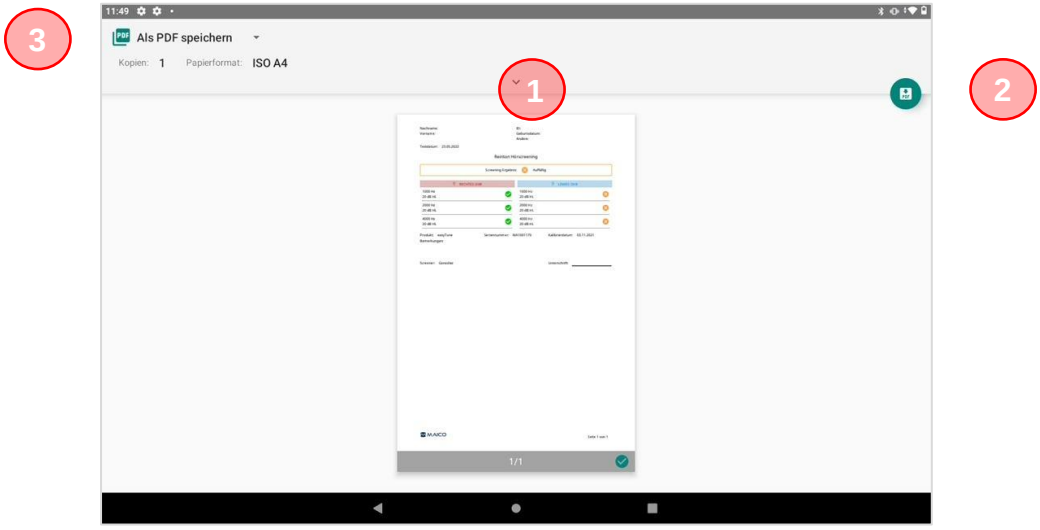


Figure 54

5.10.3 Understanding the PDF Report

Figure 55 gives explanation to the PDF report.

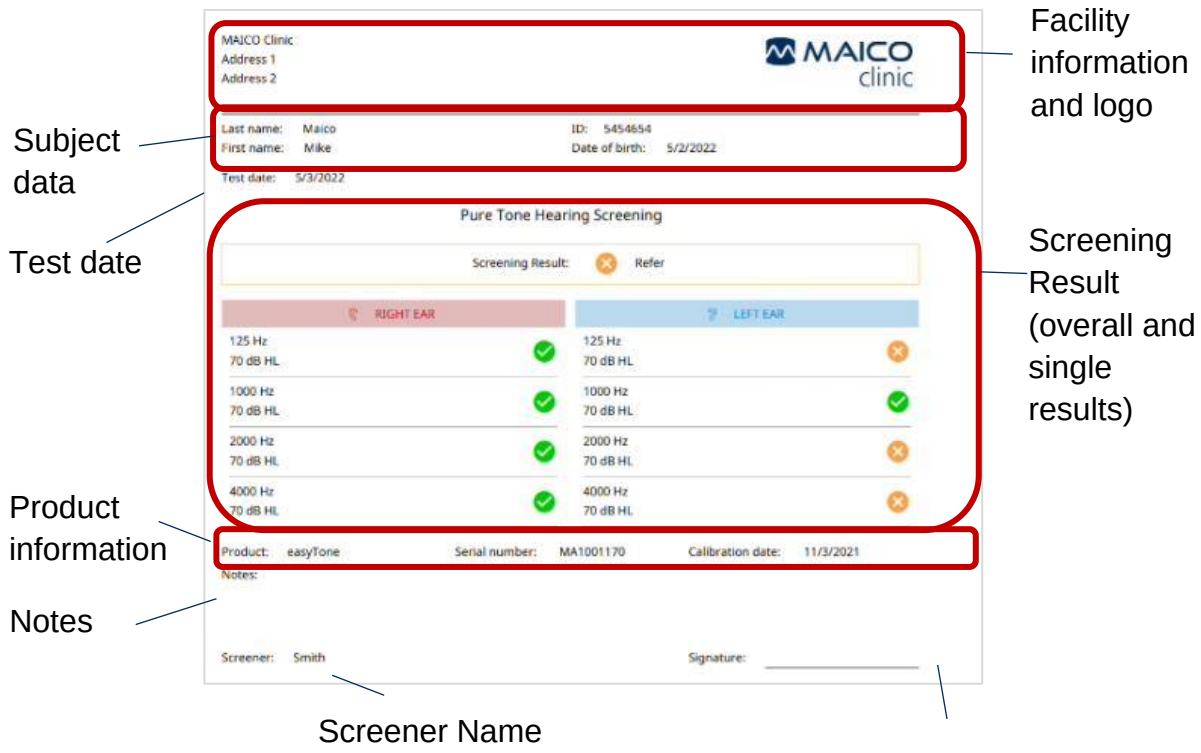


Figure 55

5.11 Settings

5.11.1 General

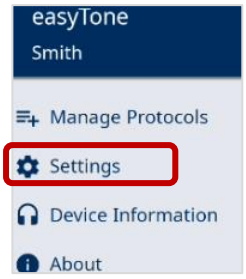
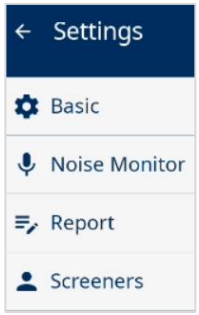


Figure 56

To change settings press (Figure 56 and Figure 57):

to open the menu.

Settings to open the main ***Settings*** menu.



Basic, ***Noise Monitor***, ***Report*** or ***Screeners*** to enter a submenu.

Figure 57

5.11.2 Settings – Basic

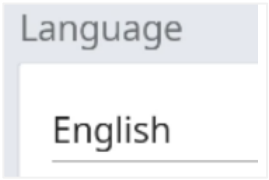


Figure 58

Language

Select a language from the drop-down menu (Figure 58).

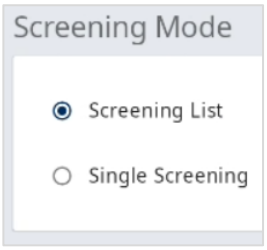


Figure 59

Screening Mode

Select the screening mode (Figure 59):

- ***Screening List***: to start screening by selecting the subject to be screened from a prepared list. This list can be imported from the easyTone Companion Software.
- ***Single Screening***: To screen only a single subject. Subject data are entered on the start screen.

NOTE: When activating the screening mode, the first time, you need to ***ALLOW*** the easyTone App to access photos and media on your device (Figure 60). Otherwise, you will not be able to create screening lists or use the easyTone Companion Software.

Figure 60

Figure 61

Ear Side Representation

Select the order in which the right and left ear shall be displayed on the test screen (Figure 61).

Note: The test always starts with the right ear.

5.11.3 Settings – Noise Monitor

Maximum Permissible Ambient Noise Levels (MPANLs) specifies the limit of how much noise the headphones can be exposed to before noise will infiltrate and might affect the audiometric test. These values are defined in national and international standards.

Select the standard you want to apply (Figure 62).

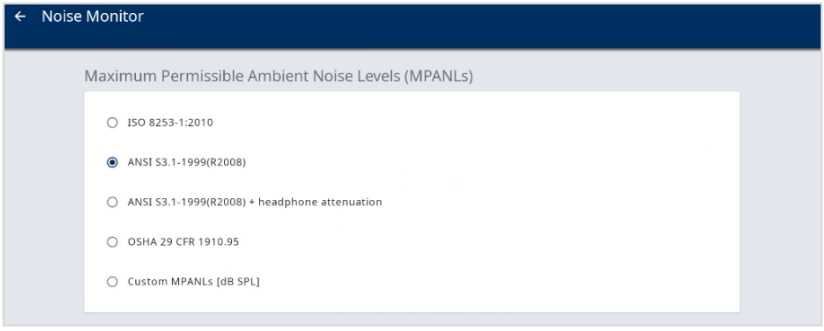


Figure 62

5.11.4 Settings – Report

Figure 63

Figure 64

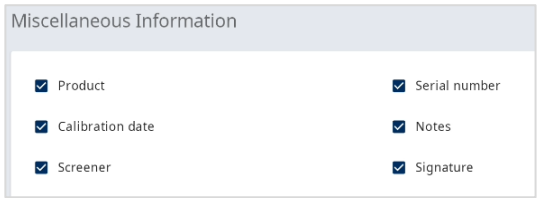


Figure 65

Page size

Select the wanted page size for the report (Figure 63).

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

Facility Information

Enter facility information that be shown in the header of the report (Figure 64). Press:

 to add a logo from the directory.

 to delete the logo again.

Miscellaneous Information

Select/deselect to define the information on the report (Figure 65).

5.11.5 Settings – Screeners

It is possible to create a list of screeners (Figure 66). The name of the screener will be displayed on the PDF report/printout and in the export files and can be selected from the start screen. Furthermore, when starting the easyTone App, a toast message welcomes the screener last selected.

Section 5.6.2 Selecting a Screener

Press ⊕ to add a new screener. Enter the screener name and press ***Save***.

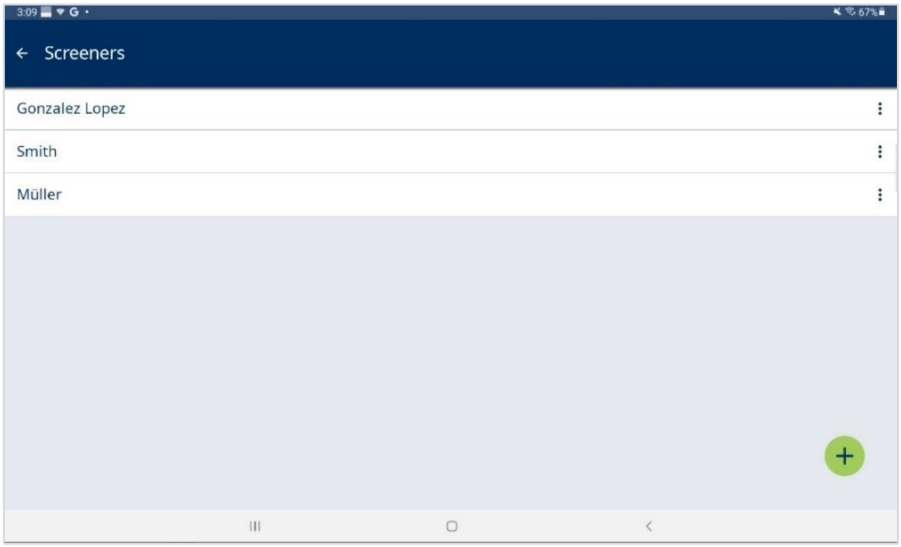


Figure 66

5.12 Device Information

The Device Information screen shows information on the easyTone audiometer headphones (Figure 66).

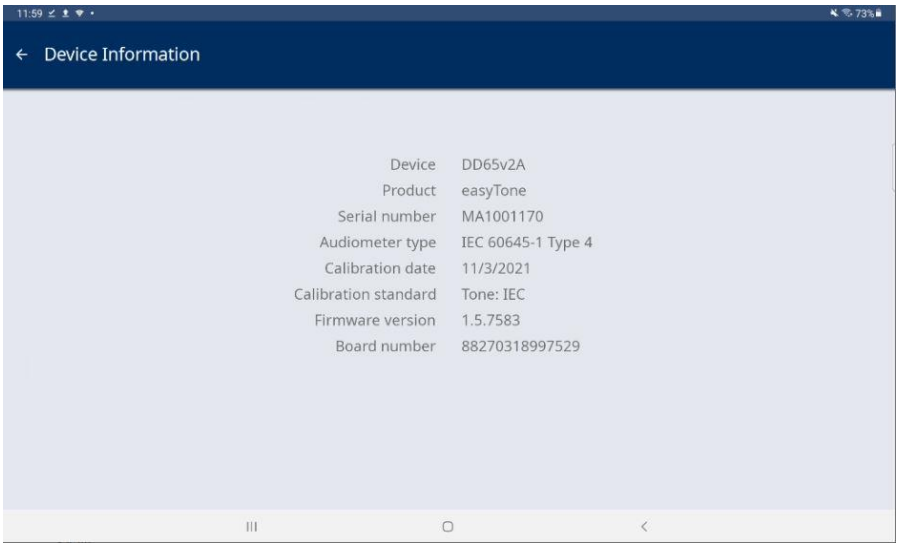


Figure 67

5.13 About

The ***About*** screen shows information about the easyTone App (Figure 68).

NOTE: The easyTone App logs data about the tablet on which it is installed for support reasons. Further, the easyTone 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.

Figure 68

5.14 Updating the easyTone App

If an update is available, it will be offered to you when you start the easyTone app, provided the tablet is connected to the Internet (Figure 69).

Press ***YES PLEASE!*** to start the update.

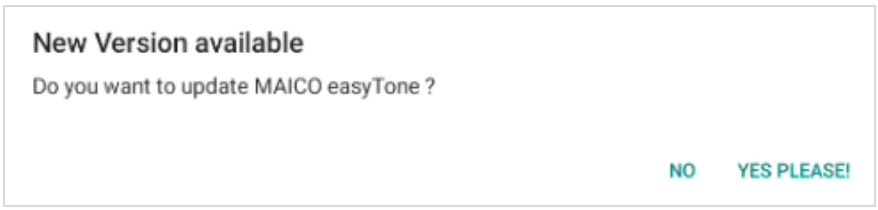


Figure 69

If you update the easyTone App the first time, you will need to allow the app to install updates. Press ***Settings*** to enter the settings menu (Figure 70).

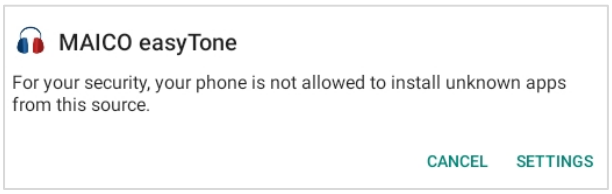


Figure 70

Move the slider to the right to allow updates (Figure 71).

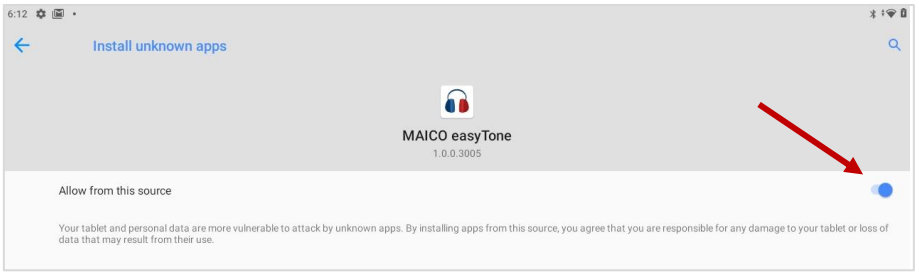


Figure 71

Press ***Install*** to start the installation (Figure 72).

Press ***Done*** to finish the installation process or ***Open*** to open the easyTone App (Figure 73).

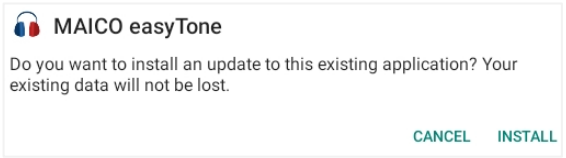


Figure 72

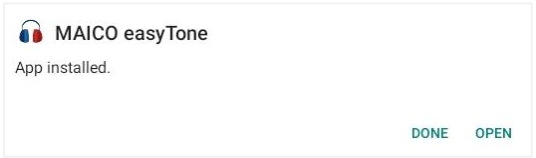


Figure 73

5.15 Calibration Reminder

Section 3.3 Maintenance

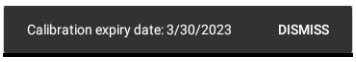


Figure 74

If the device calibration has expired, you will be reminded of the need to recalibrate when you start the easyTone App (Figure 74).

5.16 Troubleshooting

Problem: You cannot create a patient in the Screening List in the easyTone App.

Possible reason: When first using the easyTone App, you have not allowed the easyTone App to access photos and media on your device.

Solution: Allow the easyTone App access to photos and media on your device.

Section 5.11.2 Settings – Basic

Problem: You cannot upload a Screening List from the easyTone Companion Software to the easyTone App.

Possible reason: When first using the easyTone App, you have not allowed the easyTone App to access photos and media on your device.

Solution: Allow the easyTone App access to photos and media on your device.

Section 5.11.2 Settings – Basic

Problem: You cannot update the easyTone App.

Possible reason: Authorization for installation is not given.

Solution: Allow installation on the tablet.

Section 5.14 Updating the easyTone App

Problem: File transfer from tablet to PC/Mac does not work.

Possible reason: File transfer function is not activated.

Solution: Select ***File Transfer*** in the USB settings.

Section 5.9.4 Connecting the Tablet to the easyTone Companion Software (Step 4)

6 Technical Data

This section offers you important information about

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

6.1 easyTone Hardware and Software

CE 0123

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

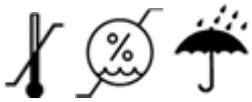
General Information About Specifications

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

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

STANDARDS	
Safety Standards	IEC 60601-1: 2005 + Corr. 1:2006 + Corr. 2:2007 + AM1:2012/ ANSI/AAMI ES60601-1:2005 + A2:2010/ CAN/CSA-C22.2 No. 60601-1:14 Type B applied parts, 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 Standard	IEC 60601-1-2:2014 + AMD1:2020
Audiometer Standards	Tone: IEC 60645-1:2017/ANSI/ASA S3.6-2018, Type 4

DEVICE SPECIFICATIONS

Power supply (tablet)	Type	UES18LCPU-050200SPA
	Input	90 to 264 V AC, 50/60 Hz, 0.5 A
	Output	5.0 V DC, 2.0A MAX
	Safety	IEC 60601-1, Class II
Power supply (easyTone Headphones)	USB-C	
Mode of Operation	Continuous	
Environmental conditions 	Operation:	+15 °C to +35 °C / + 59 °F to +95 °F
		Relative humidity 30 % to 90 % (non-condensing)
		Air pressure 98 kPa to 104 kPa Maximum altitude: 2000 m / 6561 ft above sea level
	Storage:	0 °C to + 50 °C / 32 °F to +122 °F Humidity 10 to 95 % (non-condensing)
	Transport:	-20 °C to + 70 °C / -4 °F to +122 °F Humidity 10 % to 95 % (non-condensing)
Calibration	Calibration information and instructions are located in the easyTone Service Manual.	
Air Conduction	easyTone:	RadioEar Standard Values
Transducers – Headband tension	easyTone:	Headband Static Force: 10.0 N ± 0.7 N
Patient Response switch	One push button	
Inputs	Tone, Warble Tone +5%, 5 Hz (true sine wave frequency modulation)	
Accuracy	Frequency ± 2 %, Level ± 3 dB	
Precision	Available Intensity Steps 5 dB (chosen in Setup Menu)	
Powering	USB-powered; average: 300 mA (Max.: 500 mA)	
Outputs	USB-C	
Stimuli		
Warble Tone	5 Hz sine +/- 5 % modulation	
Pulse Tone	Multiple pulses 250 ms; On/Off; pure tone or warble tone	
Presentation	Manual: Single, Pulse or Warble.	
Intensity	AC: -10 dB HL to 100 dB HL	
Frequency range	125 Hz to 8000 Hz: Frequencies are selected per protocol created.	
Weight	easyTone audiometer headphones: 389g / 0.86 lbs	
Dimensions	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)	
Display	None	

DEVICE SPECIFICATIONS

Language Settings	English, Deutsch, Français, Español
PC Connection	1 x USB C to B for PC Connection
Warm up-time	Less than 1 minute after power on (incl. boot-up time)
Store Function	Stored measurements can be viewed in easyTone App.
Distortion	0.3 % typical at full intensity
Rise/fall Times	~35 ms

EASYTONE COMPANION SOFTWARE – SYSTEM REQUIREMENTS

PC-Requirements	2 GHz Intel Core 2 Duo CPU 2 GB RAM 1 GB available disk space USB drive
Display Requirements	1280 x 960 resolution
Operating System	Windows® 11 Windows® 10 macOS Monterey

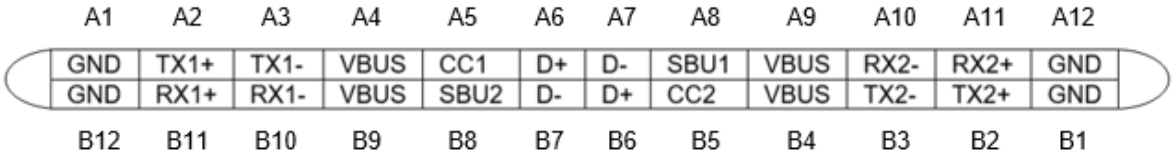
TABLET SPECIFICATIONS

Operating System	Android™
Version	10
Resolution	1280 x 800 px
Screen Size	10”
Input	USB-C
Battery Capacity	Integrated 5000 mAh
Battery Life Time	Dependent on battery age and usage behavior
Weight	480 g / 1.06 lbs
Display	10”

6.2 Connection and Pin Assignment

easyTone Connection

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

6.3 Calibration Values and Maximum Levels

Calibration Values and Max Levels: Headphone easyTone

Coupler IEC 60318-1, PTB Report 2018, AAU Report 2018

Frequency [Hz]	Tone RETSPL dB re 20µPa	Tone Max Level [dB HL]	Sound Attenuation [dB] ISO 8253-1
125	30.5	75	8.3
250	17.0	90	15.5
500	8.0	100	26.1
750	5.5	100	-
1000	4.5	100	32.4
1500	2.5	100	-
2000	2.5	100	43.6
3000	2.0	100	-
4000	9.5	100	43.8
6000	21.0	90	-
8000	21.0	85	45.6

6.4 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 IEC 60601-1-2:2014+AMD1:2020, emission class B group 1.

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

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

To ensure compliance with the EMC requirements as specified in IEC 60601-1-2, it is essential to use only the following accessories (see Table 6). Conformance to the EMC requirements as specified in IEC 60601-1-2 is ensured if the cable types and cable lengths are as specified in Table 6.

Table 6 EMC Requirements – Accessories

ITEM	MANUFACTURER	MODEL	CABLE	
			LENGTH [M]	SCREENED (YES/NO)
Headphone Audiometer	RadioEar	DD65 v2A (easyTone)	1.9	Yes
Patient Response Switch	DGS A/S	APS3	0.85	Yes
Computer (Think Pad)	Lenovo	T410 Type 2537-24G	-	-
Power Supply for Computer	Lenovo	42T4432	1.8	Yes
Power Supply for Tablet	UE / Fuhua	UES18LCP U-050200SPA	1.5	Yes

Portable and mobile RF communications equipment can affect the easyTone. Install and operate the device according to the EMC information presented in this chapter.

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

The use of accessories, transducers and cables other than delivered from MAICO, with the exception of servicing parts sold by MAICO as replacement parts for internal components, may result in increased emissions or decreased immunity of the device.

Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard.

Guidance and manufacturer's declaration - electromagnetic emissions		
The *easyTone* is intended for use in the electromagnetic environment specified below. The customer or the user of the *easyTone* should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The ***easyTone*** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ***easyTone*** is suitable for use in all commercial, industrial, business, and residential environments.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Recommended separation distances between portable and mobile RF communications equipment and the *easyTone*.			
The ***easyTone*** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ***easyTone*** can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ***easyTone*** as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m]**		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17\sqrt{P}$	**800 MHz to 2.7 GHz** $d = 2.23\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **Note 1** At 80 MHz and 800 MHZ, the higher frequency range applies. **Note 2** These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The ***easyTone*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***easyTone*** should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test level**	**Compliance**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	+8 kV contact +15 kV air	+8 kV contact +15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.
Electrical fast transient/burst IEC61000-4-4	+2 kV for power supply lines +1 kV for input/output lines	Not applicable +1 kV for input/output lines	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	+1 kV differential mode +2 kV common mode	Not applicable	Mains power quality should be that of a typical commercial or residential environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5% *U*T (>95% dip in *U*T) for 0.5 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles <5% *U*T (>95% dip in *U*T) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or residential environment. If the user of the ***easyTone*** requires continued operation during power mains interruptions, it is recommended that the ***easyTone*** be powered from an uninterruptable power supply or its battery.
Power frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.
Note: *U*T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity			
The ***easyTone*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***easyTone*** should assure that it is used in such an environment,			
Immunity test	**IEC / EN 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC / EN 61000-4-6	3 Vrms 150kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any parts of the ***easyTone,*** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1{,}2\sqrt{P}$
Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,7 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,7 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ***easyTone*** is used exceeds the applicable RF compliance level above, the ***easyTone*** should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ***easyTone.*** **b)** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

6.5 Electrical Safety, EMC and Associated Standards

- IEC 60601-1: 2005 + Corr. 1:2006 + Corr. 2:2007 + AM1:2012/ ANSI/AAMI ES60601-1:2005 + A2:2010/ CAN/CSA-C22.2 No. 60601-1:14: Medical Electrical Equipment, Part 1 General Requirements for Basic Safety and Essential Performance
- IEC/EN 60601-1-2: 2015 + AMD1:2020: Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and tests
- 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 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE)

6.6 Checklist for Subjective Audiometer Testing

- Clean the ear and head cushion! - Untangle all lines when necessary! - Are the headphone cushions in good condition? If not → replace. - Are plugs and leads in good condition/ undamaged? - Are all controls working properly? - Is the Patient Response Key working properly (if available)? - Check batteries and renew if necessary!	Instrument:..... Manufacturer:..... Serial No.:..... Examiner:.....

Test Signal Quality

All the test frequencies in the below table indicate typical hearing level and can be changed when necessary:
Masking: "B" for Buzz tone, "G" for Noise, "V" for signal distortion, "S" for switching masking noise.

	Right Ear								Level	Left Ear								
kHz	0.25	0.5	1	2	3	4	6	8		0.25	0.5	1	2	3	4	6	8	kHz
AC									30 dB_{HL}									
									50 dB_{HL}									
									70 dB_{HL}									
BC									30 dB_{HL}									
									50 dB_{HL}									

* When noise "B", "G", "V" or "S" is blocked, inform the service center!
* When the test tone is heard at the masking ear, contact the service center!

Air Conduction Audiogram

	Right Ear								Level	Left Ear								
kHz	0.25	0.5	1	2	3	4	6	8		0.25	0.5	1	2	3	4	6	8	kHz
									Should dB_{HL}*									
Left Earpiece									Is dB_{HL}									Left Earpiece
Right Earpiece **									Is dB_{HL}									Right Earpiece **

* Should is the last measurement of the patient
** For inverted measurement please reattach the headphone
If the frequency difference between „Should" and „Is" for one ear averages more than 10 dB, contact the SERVICE CENTER!

Bone Conduction Audiogram

	Right Ear								Level	Left Ear								
kHz	0.25	0.5	1	2	3	4	6	8		0.25	0.5	1	2	3	4	6	8	kHz
									Should dB_{HL}*									
									Is dB_{HL}									

If the frequency difference between „Should" and „Is" for one ear averages more than 10 dB, contact the SERVICE CENTER!

Tested.....
Date:.....

Specifications are subject to change

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