Operation Manual
easyTymp

Contents

Title: **easyTymp** – Operation Manual

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Compliance

MAICO Diagnostics GmbH 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

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

1 Introduction

This section offers you important information about:

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

1.1 Intended Use Statement

The tympanometer is used to obtain information on medical conditions affecting the middle ear and to assess hearing.

Indications for Use

The easyTymp is an electroacoustic test device that produces controlled levels of test tones and signals intended for use in conduction diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders. It features tympanometry and acoustics reflex.

It is intended to be used by audiologists, ENTs, hearing healthcare professionals, or other trained technicians in a hospital, clinic, healthcare facility or preferably other suitable quiet environment as defined in standard ISO 8253-1 or ANSI S3.1.

Target population

The easyTymp 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 infant to adults.

1.2 Contraindications of Use

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

- Recent stapedectomy or other middle ear surgery
- Discharging ear
- Acute external auditory canal trauma
- Discomfort (e.g., severe otitis externa)
- Occlusion of the external auditory canal
- Presence of tinnitus, hyperacusis or other sensitivity to loud sounds may contraindicate testing when high intensity stimuli are used

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

1.3 Features and Benefits of the easyTymp

The purpose of the easyTymp test system is to provide rapid Tympanometry and Acoustic reflex measurements to measure the middle ear status where a pass or no response notation is identified. easyTymp provides an optional 1 kHz probe tone for testing infants. Factory defined protocols allow for simple screening measurements, and different versions are available that provide diagnostic testing functions. As with any type of hearing screening, a “pass” result should not overrule any additional concerns regarding middle ear function. A referral to a physician should be administered if concerns about middle ear function persist.

The easyTymp cradle serves as a docking and recharging station for the handheld device and includes an opening for placement of the ear tip box.

When using the Software, the handheld unit will transfer data to a PC via USB-connection while in the docking station, or it can also transfer data directly via USB cable when no docking station is available.

The easyTymp comes in multiple versions and configurations dependent on the country and service partner. Each version provides specific testing functionalities dependent upon the user needs.

easyTymp

- Rapid tympanometry measurement
- Ipsilateral acoustic reflex measurements at several frequencies
- 1 kHz probe tone for international protocols (option)
- Special protocols for Sweden (option)

easyTymp Plus Version (Purchases until 10/2025, Shoulder Box Cable Required)

- Rapid tympanometry measurement
- Ipsilateral acoustic reflex measurements at several frequencies
- Contralateral acoustic reflex measurements at several frequencies
- 1 kHz probe tone (option)

easyTymp Pro Version (Purchases until 10/2025, Shoulder Box Cable Required)

- Rapid tympanometry measurement
- Ipsilateral acoustic reflex measurements at several frequencies
- Contralateral acoustic reflex measurements at several frequencies
- Acoustic reflex decay (Ipsilateral and Contralateral)
- Eustachian tube function
- 1 kHz probe tone (option)

1.4 Description

1.4.1 General

Dependent on the configuration the easyTymp offers the following Impedance measurements:

- Tympanometry
- Acoustic Reflex
- Contralateral Acoustic Reflex
- Acoustic Reflex Decay
- Eustachian Tube Function Test

Further information on the different tests are given in Sections 1.4.2 to 1.4.6.

1.4.2 Tympanometry

Tympanometry is the objective measurement of middle ear mobility (compliance[1]) and pressure[2] within the middle ear system (Figure 1). During the test, a low-pitched probe tone (226 Hz) is presented to the ear canal by means of the probe. This tone is used to measure the change in compliance in the middle ear system while the air pressure varies automatically from a positive value (i.e. +200 daPa) to a negative value (i.e. -400 daPa max). The compliance is obtained as aural acoustic admittance (Y), which consists of the parts susceptance (B) and conductance (G).

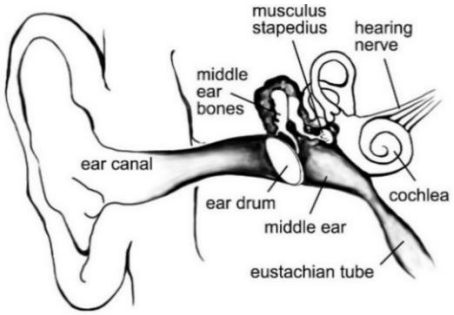


Figure 1

Maximum compliance of the middle ear system occurs, when the pressure in the middle ear cavity is equal to the pressure in the external auditory canal. This is the highest peak of the curve as it is recorded on the chart. The position of the peak on the horizontal axis and on the vertical axis of the chart will provide diagnostic information regarding the function of the middle ear system. Gradient calculations are reported as the Tympanogram width at half of peak compliance expressed in daPa. A normative box is available on both the display and printout to aid in diagnosis.

NOTE: 1 mmho ≙ 1 ml for 226 Hz probe tone

1.4.3 Acoustic Reflex

An ***Acoustic Reflex***, or contraction of the stapedial muscle, occurs under normal conditions when a sufficiently intense sound is presented to the auditory pathway. This contraction of the muscle causes a stiffening of the ossicular chain which changes the compliance of the middle ear system. As in ***Tympanometry***, a probe tone is used to measure this change in compliance.

When the stimulus presentation and measurement are made in the same ear by means of the probe, this acoustic reflex is referred to as an ***Ipsilateral Acoustic Reflex.*** When the stimulus presentation is made in the opposite ear of where the measurement is made, this acoustic reflex is referred to as a ***Contralateral Acoustic Reflex***.

For best results, this reflex measurement is automatically conducted at the air pressure value where the compliance peak occurred during the ***Tympanometric*** test. Stimulus tones of varying intensities at 500 Hz, 1000 Hz, 2000 Hz or 4000 Hz are presented as short bursts. If a change in compliance greater than the selected value is detected, a reflex is considered present. Because this is an extremely small compliance change, any movement of the probe during the test may produce an artifact (false response). The test result is recorded as Pass/No Response, and in graphical form.

If the ***Tympanometric*** results display any abnormal findings, the results of the Acoustic Reflex testing may be inconclusive and should be interpreted with care. Theoretically, a compliance peak is necessary to observe a reflex at peak pressure.

[1] Compliance is measured with respect to an equivalent volume of air, with the scientific quantity milliliter (ml).
[2] Air pressure is measured in deca-Pascals (daPa).

1.4.4 Contralateral Acoustic Reflex (Devices Purchased until 10/2025)

A ***Contralateral Acoustic Reflex*** is available with the easyTymp Plus and Pro Version. When the stimulus presentation and measurement are made in the different ears by means of the shoulder box, probe and contra transducer.

1.4.5 Acoustic Reflex Decay (Devices Purchased until 10/2025)

An ***Acoustic Reflex Decay*** is available with the easyTymp Pro Version. Acoustic reflex decay, also known as adaptation, is the measurement of the ***Acoustic reflex*** response during sustained stimulus presentation. ***Ipsilateral*** and ***Contralateral Reflex Decay*** can be performed.

1.4.6 Eustachian Tube Function Test (Devices Purchased until 10/2025)

The Eustachian tube connects the middle ear with the nasopharynx. Its function is to equalize pressure between the middle ear and the atmosphere.

The ***Eustachian Tube Function*** test is available with the easyTymp Pro Version. It can be used to determine if the Eustachian tube is functioning properly in patients with an intact tympanic membrane or in patients who have a perforated TM or pressure equalization tubes.

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

The WARNING label identifies conditions or practices that may present danger to the patient and/or user.

The CAUTION label identifies conditions or practices that could result in damage to the equipment

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 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 operation 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 operation 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.

NOTE: Customer responsibility includes proper maintenance and cleaning of the device (see Sections 3.2 and 3.3). Breach of the customer responsibility can lead to limitations of Manufacturer's Liability and Warranty (see Sections 2.3 and 3.1).

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 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
	Return to authorized representative, special disposal required
REF	Reference number
MD	Medical Device
(01)04260176127444 (11)201020 (21)MA0123456	UDI information (example): (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)
	Keep away from rain
	Transport and storage temperature range
	Transport and storage humidity limitations
	Transport and storage atmospheric pressure limitations
	Isolation transformer
	Do not reuse
CE 0123	CE marking with notified body ID
	Non-ionizing electromagnetic radiation
R XXX - ABCDEF	Label Marking of Radio Equipment based on Certified Type
	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.

For operation in certain places, recalibration may be necessary.

Do not open the case of the easyTymp. Refer servicing to qualified personnel.

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.

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.

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.

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).

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

2.6 Electrical Safety and Electrostatic Safety

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

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

In Case of Emergency

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

In Case of Emergency

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 cable and/or the plug is damaged.

To transfer data to a PC, establishing a PC connection via USB is required. See Section 4.2.5 on how to safely establish a connection with a power supplied PC or laptop (medical electrical equipment/non- medical electrical equipment) or to a battery-driven laptop.

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.

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.

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.

Do not touch the contacts of the device and the patient at the same time.

If the device 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.

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.

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

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

Remove batteries both in the handheld device and the cradle if the device will not be used for some time.

2.7 Electromagnetic Compatibility (EMC)

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.

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.

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 6.5.

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 easyTymp, 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.

2.9 Device Control

The user of the device should perform a subjective device check once a week according to ISO 8253-1. For annual calibration see Section 3.2.

See Section 0 for volume check.

2.10 Battery Safety

Observe the following precautions at any times:

- Keep the battery fully charged.
- Do not place the battery in fire or apply heat to the battery.
- Do not damage the battery or use a damaged battery.
- Do not expose the battery to water.
- Do not short-circuit the battery or reverse the polarity.
- Use only the power supply unit provided with the easyTymp.

3 Warranty, Maintenance and After-Sales Service

This section offers you important information about:

- **warranty conditions**
- **maintenance**
- **cleaning and disinfection recommendations**
- **handling disposables**
- **troubleshooting**
- **recycling and disposal of the device**

3.1 Warranty

The MAICO Updated 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.

3.2 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.

3.3 Cleaning and Disinfection Recommendations

3.3.1 General

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 turn off and disconnect the device from power supply.
- For cleaning use a lightly dampened cloth with soap water solution.
- Disinfect the plastic housing of the easyTymp and its accessories by wiping the surfaces with disinfectant wipes. Follow the instructions on the specific disinfectant.
    - Wipe before and after each patient
    - After contamination
    - After infectious patients
- Disinfect computer, keyboard, transport trolley etc. with disinfectant wipes:
    - once a week
    - after contamination
    - when polluted

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 device should not be used until deemed safe by a MAICO certified service technician.

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

For more detailed cleaning recommendations see the following Sections 3.3.2 to 0.

3.3.2 Cleaning the Case and Cables

Use caution while cleaning.

Use a damp cloth to clean the plastic parts of the easyTymp.

If disinfection is required, use a disinfectant wipe rather than a spray product. Make sure that excess liquid from the wipe does not seep into any sensitive areas such as connectors and seams where plastic pieces connect such as the edges around the screen.

Follow the instructions on the disinfection product.

3.3.3 Cleaning the Probe Tip

Also, check out our training videos:

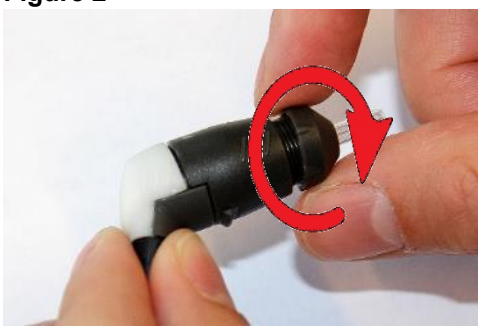
easyTymp Tympanometer | MAICO Training | Hearing Screening Diagnostic Tests – Cleaning the Probe

https://youtu.be/MEQrEK2YVmQ?si=crwHhruaQ9RKSnzY&t=583

To secure correct impedance measurements, it is important to make sure that the probe system is always kept clean. Therefore, clean the probe on a periodic basis. It is indispensable to remove cerumen from the probe tip's small acoustic and air pressure channels. Therefore, follow the illustrated instructions below.

Never clean the probe tip while the tip is still attached to the probe (Figure 2).

Figure 2



Unscrew the probe cap by turning it in a counterclockwise direction (Figure 3).

Figure 3

Figure 4

1. Take the plastic probe tip out of the probe (Figure 4).

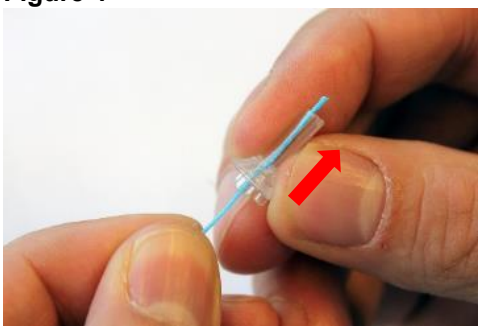


Figure 5

2. Insert the blue end of the floss from back to front through one of the probe channels. Pull the floss along its entire length through the channel (Figure 5).

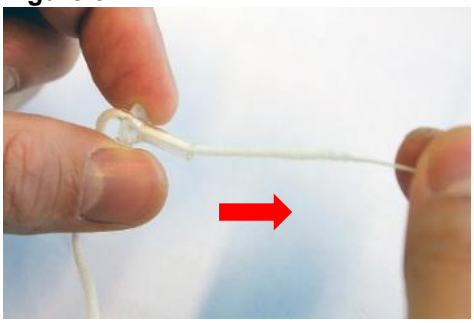


Figure 6

3. Proceed in the same way with all 4 probe channels. Use the floss only once (Figure 6).

Figure 7

4. Place the probe tip back onto the probe. Make sure that the plastic pegs are inserted into the appropriate corresponding cavities (Figure 7).

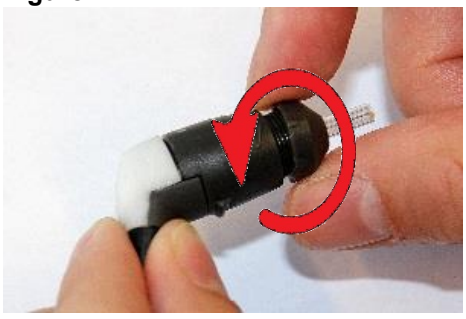
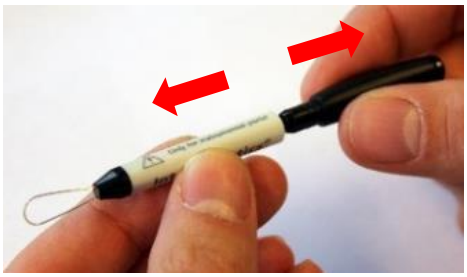


Figure 8

5. Screw the probe cap back on the probe (Figure 8). The force of tightening the cap will tighten the screw sufficiently. Never use tools to fix the probe cap!

If any blockage or damage occurs to the sealing gasket, the probe system can only be serviced by MAICO.

Cleaning alternative:



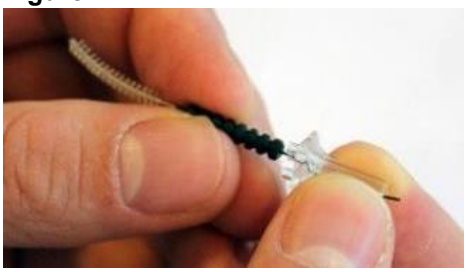
Use the cleaning set from the ear tip box (Figure 9): Take the cleaning tool apart to find the thin brush and thin rigid plastic cord (Figure 10).

Figure 9

Figure 10

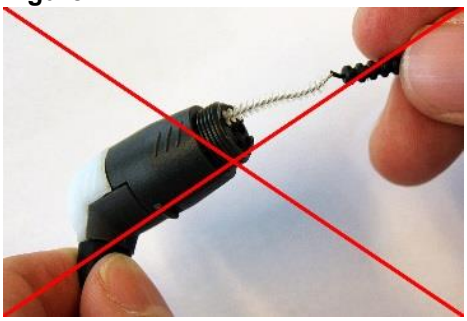
Use the plastic cord or brush to push debris out of the probe tip (Figure 11).

Figure 11



Always enter the probe tip from the rear to avoid accumulation of debris inside the vents (Figure 12).

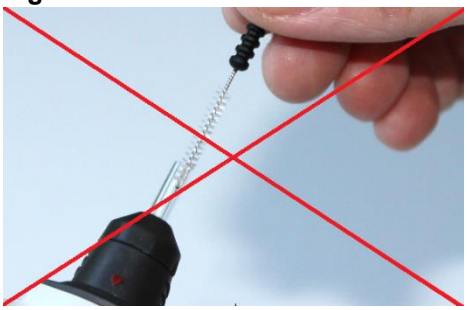
Figure 12



CAUTION

This procedure destroys the probe (Figure 13).

Figure 13



CAUTION

This procedure destroys the probe (Figure 14).

Figure 14

3.3.4 Disposables

Figure 15

Operating the easyTymp will require the use of ear tips – either mushroom shaped (1) or umbrella (2) ear tips (Figure 15). For guidance on selecting the appropriate ear tip for your device setup, see Table 2 below.

Ear tips are intended for single use only. These must be discarded after use. They cannot be cleaned.

WARNING

In case of re-use of the single-use equipment you enhance the risk of cross-infection!

Ear Tip Selection Recommendations

NOTE: MAICO strongly recommends using Sanibel® ear tips for reliable results. Both Sanibel® ADI series and IA mushroom series ear tips are suitable for the easyTymp.

The use of mushroom ear tips requires insertion into the ear canal for a proper seal, which demands more precise placement than umbrella ear tips.

Table 2 Ear Tip Selection Recommendations

Device / Setup	Recommended Ear Tip	Notes
Mounted probe or short extension probe (device held in hand)	 Umbrella	Quick and easy seal by gently pressing probe against ear canal; ideal for screening
Mounted probe or short extension probe (device placed in pocket or on nearby surface)	  Mushroom or umbrella	Frees one hand for ear alignment; more stable and accurate positioning Umbrella: quicker screening process Mushroom: more precise
Diagnostic probes or setups with shoulder box attached to patient	 Mushroom	Required for hands-free, artifact-sensitive measurements; tight fit needed

3.3.5 Components/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 easyTymp device configuration).

3.4 Troubleshooting

Table 3 Troubleshooting

Issue	Solution
White Screen	If the device shows white screen after turning on: • Ensure the battery is fully charged. Charge the battery overnight using the supplied PSU or cradle. • Make sure the probe is properly connected, then restart the easyTymp.
Frozen Display	If the display freezes: • Ensure that the probe is correctly connected so that the retaining latch is fully seated in the recess. Then restart the easyTymp. If the probe was removed while the easyTymp was turned on it needs to be restarted. • Low battery voltage may also cause this issue. Turn off the device and change the battery or charge completely. **NOTE:** Always turn off the device before removing the battery.
Battery charging problem	• Check that the battery connectors (spring contacts) inside the battery compartment are clean and extend fully. • Ensure the battery is properly inserted (gold contacts are aligned), then charge it fully.
easyTymp does not show ready	Make sure the probe is inserted correctly into the probe connector. Otherwise, turn off the easyTymp, unplug and insert the probe again, then restart the easyTymp.
easyTymp shows ready but does not start.	1. Clean the probe tip as described above in 3.1.1. If the system still does not run proceed with step 2. 2. Use a new probe tip. If the system still does not run proceed with step 3. 3. If that does not help, contact your service center.
Device showing leaking	Conduct a system check with calibration cavities. If these tests are not possible contact your service center.
Battery is not charging in cradle slot.	If the spare battery is not charging, check if the battery is properly inserted and the terminal connectors (spring contacts) inside the battery compartment are clean and extend freely. Make sure the battery contacts are clean.
Connection in cradle	Make sure the easyTymp is properly inserted after the test. Improper docking may lead to a bad connection between device and the cradle.
PC Connections	• Make sure the easyTymp has a PC License. • Try to reinstall the PC software. Check the device manager in the PC. If the easyTymp does not appear in the list install the driver again.

3.5 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 (13) 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.

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

4 Unpacking and Hardware Orientation

This section provides information on:

- **unpacking the system**
- **becoming familiar with the hardware inclusive connections**
- **how to store the device**
- **becoming familiar with the Probe and the Probe with short extension cable**
- **using the thermal printer**

4.1 Unpacking the System

Check Box and Contents for Damage

- It is recommended that you unpack your easyTymp carefully making sure that all components are removed from the packaging materials.
- Verify that all components are included as shown on the packing list 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 material and the shipping container so the device can be properly packed if it needs to be returned for service or calibration.

The easyTymp comes with different components (see the following tables). The availability of configurations with the following components is country and version specific. Contact your local distributor for more information.

Components
easyTymp Handheld Unit
MAICO Sessions Kit
Probe (Mounted)*
Short Extension Cable for Mounted Probe (350 mm Incl. Cable)*
Short Extension Probe*
Cradle Kit (Component List, See Below)
Printer HM-E200 Kit (Includes 2 Rolls of Thermal Paper, Printer Power Supply Unit With Plug Adapters (5 V/1.6 A) UES12LCP-050160SPA)
Power Supply Unit (5 V/2.5 A) UES18LCP-050250SPA Incl. USB Adapter for easyTymp Handheld Unit
Rechargeable Battery
Ear tip Box (See Below)
Probe Cleaning Kit
Test Cavity
Operation Manual**
Quick Guide**
Carry Case
Wall Mount Kit for Cradle with Integrated Ear tip Box, Power Supply Unit and Additional Rechargeable Battery
Only for Plus and Pro Version (Devices Purchased until 10/2025)
Shoulder Box Cable (1400 mm)*
CIR (Contralateral Earphones)*
DD45C (Contralateral Headphone)*
IP30 Contralateral Insert Earphones*
Quick Guide (Pro or Plus Version)

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

Cradle Kit
Cradle
USB Cable
Power Supply Unit (24 V/1 A) UES24LCP-240100SPA
Rechargeable Battery

Licenses

Licenses
License for International Protocols
License for High Frequency Probe Tone of 1 kHz
License for Plus Version (Devices Purchased until 10/2025): Acoustic Reflexes Contra
License for Pro Version (Devices Purchased until 10/2025): Acoustic Reflexes Contra, Decay and ETF
License for PC Connection (Sessions)

Disposables Supplied

NOTE: MAICO strongly recommends using Sanibel® ear tips for reliable results. Both Sanibel® ADI series and IA mushroom series ear tips are suitable for the easyTymp.

Ear Tip Box
Samples of Sanibel® Ear Tips
Probe Tip
Probe Cleaning Tool
Ear Tip Removal Tool
Allen key SW: s = 2 mm (see Section 4.2.1.3)

NOTE: It is possible to purchase either the whole Ear Tip Box or single items listed.

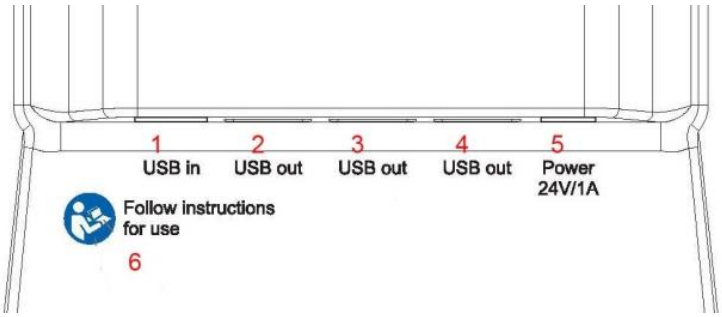
Consumable Material

Consumable Material
Printer Paper
Replacement Ear Tips
Probe Tip
Cleaning Floss

4.2 Hardware and Components

4.2.1 Cradle

4.2.1.1 Installing the Cradle



1 = USB in

2 = USB out

3 = USB out

4 = USB out

5 = Power 24 V

6 = Follow the operation manual

Figure 16

Put the enclosed power cable into the power connection socket #5 and the power connector into a power socket.

NOTE: In case you also use the wireless printer make sure you take the right power supply (24 V/1 A), UES24LCP-240100SPA) to connect to the cradle. Otherwise loading times can rise.

4.2.1.2 Cradle Light Indicator

The cradle has 2 light indicators (Figure 17).

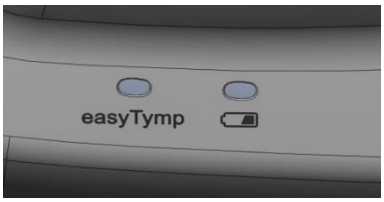


Figure 17

- easyTymp LED shows solid blue when it is placed inside the cradle. The battery will be charged automatically and will be fully charged after approximately 6 hours. The current battery state of charge may be seen on the easyTymp display.
- Battery LED shows solid blue when the spare battery in the cradle is fully charged. The LED will flash while the battery is charging.

NOTE: Upon initial setup, always plug the cradle into the outlet while the easyTymp is out of the cradle.

4.2.1.3 Mounting the Cradle on the Wall (Optional Accessory)

To mount the cradle on the wall, an optional wall mount kit is available (Figure 18)

Figure 18

4.2.2 Adjust the Cradle

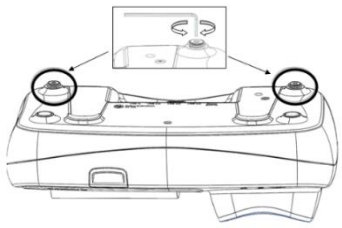


Figure 19

Use the Allen key to adjust the cradle on the Figure 19.

NOTE: An Allen key is enclosed in the packaging of the ear tip box to enable adjustment of the pair of adjustable feet located on the bottom of the cradle.

Ensure that the Allen key is only used to adjust the setting of the adjustable feet on the cradle and that this tool is not used for any other purpose on the easyTymp unit.

4.2.3 easyTymp Plus and Pro Version (Devices Purchased until 10/2025): Connecting the Contralateral Headphones or Insert Earphones

Figure 20

To measure ***Contralateral Reflexes,*** it is necessary to connect the Shoulder Box cable to the easyTymp as described previously.

Find the jack socket labeled "***Contra***" on the Shoulder Box. Insert the ***Contralateral*** transducer into this jack socket (Figure 18).

The Shoulder Box must be calibrated to the selected ***Contralateral*** transducer type. This calibration is already completed if the Shoulder Box cable and transducer are purchased at the same time. Otherwise, the Shoulder Box cable, easyTymp probe and transducer need to be sent to an authorized service center to perform the calibration.

NOTE: Three different contra phones can be purchased for use with the easyTymp. The contra headphone need to be calibrated to the Shoulder Box before use. If a new Contra phone should be used, recalibration of the Shoulder Box is necessary. We strongly advise against using an uncalibrated contra headphone! Uncalibrated devices may lead to faulty measurements and possibly damage the patient's hearing.

4.2.4 Changing Probes

Also, check out our training videos:

easyTymp Extension Probe | MAICO Support

https://youtu.be/XVz9Xq9nN84?si=ijRkar6lxqLLk9kd

Figure 21

Remove the mounted probe by holding down the unlock button on the rear of the device and pulling the probe upward away from the device (Figure 21).

NOTE: Do not pull on the extension cable as this can damage the tubing connection!

Figure 22

Take the short extension probe, line up the arrows on the front of the device and press the rear button to unlock. Push it into place until you hear a click (Figure 22).

Figure 23

To confirm proper fitment of the extension probe, turn on the device. The indicator should light up, and the display shows ***Test Ready*** (Figure 23).

Figure 24

Short extension cable with mounted probe:

The mounted probe can be attached to the short extension cable by correctly lining up the pins and clicking the probe into the end of the extension cable (Figure 24).

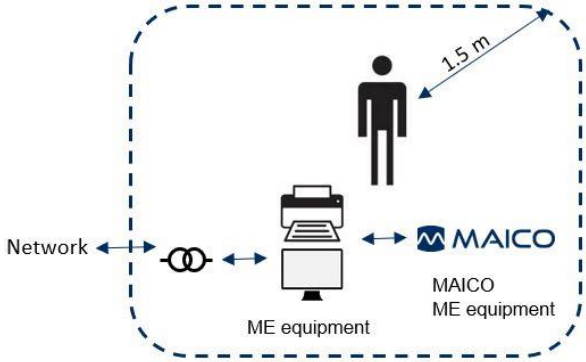
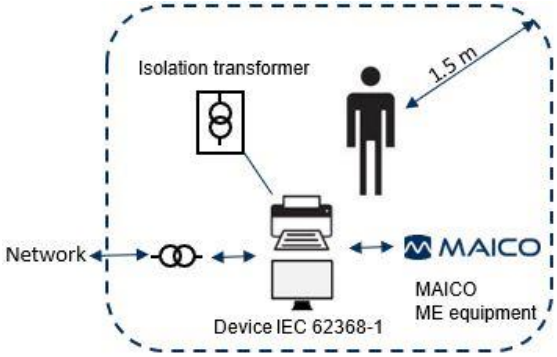
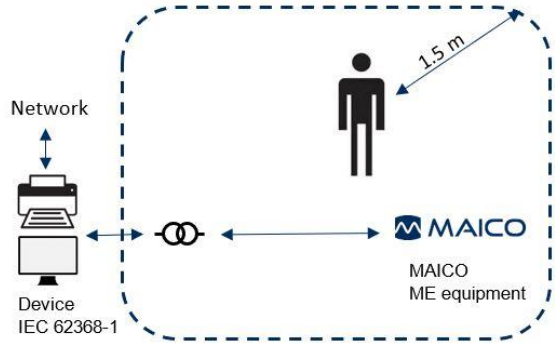
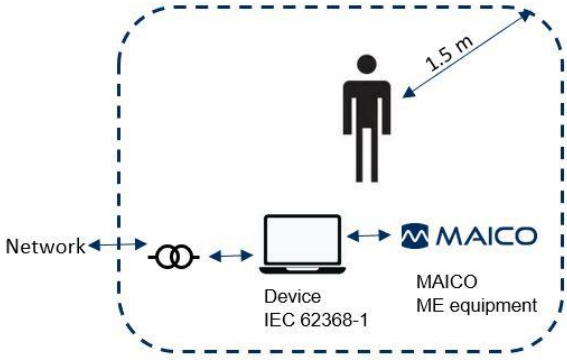
4.2.5 Establishing a PC Connection

To transfer data to a PC, establishing a PC connection via USB is required. If the easyTymp 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 Table 4, 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)
	

4.2.6 Battery

4.2.6.1 Installing the easyTymp Battery

Figure 25

The battery compartment is opened by gently pressing the indentation and pushing the cover downwards (Figure 25).

Figure 26

Place the battery inside the compartment (Figure 26).

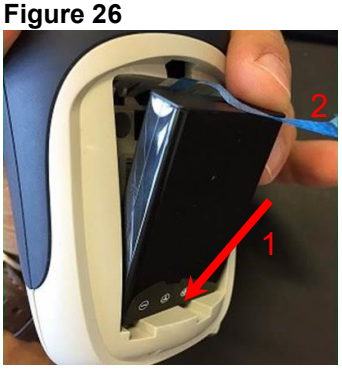


Figure 27

Make sure the battery contacts are aligned before pushing the battery into place (1) and the removal-tab is easy to reach (2) (Figure 27).

Figure 28

The removal-tab, attached to the back of the battery case, should be wrapped around the battery to remove it easily (Figure 28).

Figure 29

Replace the lid on the easyTymp and push it upwards to close the battery compartment (Figure 29).

It is recommended that the battery is removed from the device when it is not in use for extended time periods.

4.2.6.2 Charging the easyTymp Battery

NOTE: The battery needs to be charged for a minimum period of approximately 6 hours prior to first use of the easyTymp.

Charging the Battery in the Device Using the Power Supply Unit

Use power supply unit UES18LCP-050250SPA.

To charge, plug the power supply unit's connector into the micro USB port on the bottom of the device.

Charging the Battery in the Cradle

Figure 30

Use power supply unit UES24LCP-240100SPA to charge the cradle.

Place the device in the cradle for charging (Figure 30).

Charging the Spare Battery in the Cradle

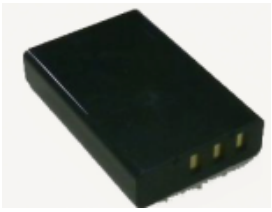


Figure 31

The device comes with a spare battery (Figure 31).

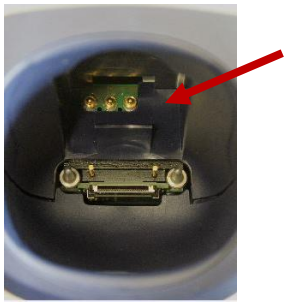


Figure 32

Store and charge the spare battery in the back of the cradle (Figure 32).

Replace the battery according to the instructions in Section 4.2.6.1.

4.2.6.3 Battery Life, Capacity, and Lifespan

Battery Life

- Approximately 200 tests per cycle can be expected, assuming an impedance test on the easyTymp takes about 1 min.
- It is recommended to activate ***Power Save*** and ***Power Off*** to extend battery life and potentially last a full working day on a single charge.

Battery Capacity and Lifespan

- Battery capacity degrades with repeated charging/discharging cycles.
- The battery lifespan depends on usage patterns and is difficult to guarantee.
- Frequent use with a low battery charge level can damage the battery, requiring replacement within 12 months or sooner.

Maintaining Battery Capacity

Avoid fully discharging the battery.

- Charge the device even if the battery is not fully depleted.
- Try to keep the battery charge level above 30 % (1 bar on the indicator).
- Do not operate the device continuously in the red battery zone.

Charging Methods

- Keep the spare battery fully charged; charge in cradle while using the other.
- The device can also be charged via PSU and USB adapter, which is as efficient as charging through the cradle.
- Charging with a USB cable connected to a PC provides only a weak charge and is not recommended.
- Charging in cradle stops after 5 h to prevent battery aging; you may need to reinsert the device into the cradle for full charge.

Charging Time

gives an estimate of the charging time (CT) in hours for the battery. Charging times are the same for the spare battery in the cradle and the battery in the cradled easyTymp.

NOTE: Be aware that negative numbers mean that the battery is discharging.

It is recommended to charge the device only when it is turned off.

Table 5 Charging Time easyTymp

	CT (h) through cradle/PSU up to 80 %	CT (h) through USB (PC) up to 80 %	CT (h) through cradle/PSU up to 100 %	CT (h) through USB (PC) up to 100 %
Off	1.5	3.8	2.3	5.7
On (not testing)	2.8	-32	4.1	-47

4.2.7 Test Cavities

The easyTymp comes with a separate test cavity which can be used to quickly check the probe calibration validity. The test cavity includes 0.2 ml, 0.5 ml, 2.0 ml and 5.0 ml cylinders.

We strongly recommend calibrating each probe at least once a year. If a probe is handled roughly (e.g. has fallen onto a hard surface) it might need to be calibrated again. Calibration values of the probe are stored in the probe itself. Therefore, probes can be always exchanged.

4.2.8 Storage

When the easyTymp is not in use, store it in the optional carry case or in a location where it will be safe from damage to the screen or other sensitive components such as the Acoustic transducers and cables. Store according to the recommended temperature conditions described in Section 6.1.

4.3 Software

You can view and store all measurements with the MAICO Sessions.

NOTE: For installation and functions see the software operation manual. For transferring data to the PC see Section 5.6.

4.4 Using the Thermal Printer (HM-E200)

4.4.1 Connecting the Thermal Printer to the easyTymp

The connection of the easyTymp and the printer is made via wireless pairing. See Section 5.6.5.

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

4.4.2 Powering the HM-E200 Thermal Printer

Figure 33

The thermal printer is powered by a Lithium-ion battery. Use the micro-USB power supply unit delivered by MAICO to power the thermal printer (Figure 33).

4.4.3 Insert Paper Rolls Into the HM-E200 Thermal Printer

The printer indicates that it has run out of paper by displaying the message ***"Out of paper"*** on the screen and the blue LED (ERROR) flashes (Figure 34).

Open the printer by pressing the small latch button (Figure 35).

Insert the paper roll into the printer with the paper end placed towards the open cover. Hold the paper end in place and close the cover. Turn the printer on and press the feed button on the left side so that the printer can properly align the paper with the print head (Figure 36).

Figure 34

Figure 35

Figure 36

5 Operating the Device

This section offers you information about:

- **how to get started with the easyTymp**
- **the operating panel**
- **preparing the patient for testing**
- **performing impedance testing**
- **settings to be made**
- **managing the test results**

5.1 Getting started with the easyTymp

5.1.1 Use of Equipment After Transport and Storage

Make sure the device is functioning correctly before use. If the device has been stored in a colder environment (even for shorter time) allow the device to become acclimatized. This can take a long time depending on the conditions (like environmental humidity). You can reduce the condensation by storing the device in its original packaging. If the device is stored under warmer conditions than the use conditions no special precaution is 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 test room must be at a normal temperature, usually from 15 °C/59 °F to 35 °C/95 °F, and the device should be turned 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 timed see Section 6.1.

5.1.3 Operating Panel

Figure 37

Function Keys (Figure 37):

Top buttons: Function of the keys is related to the functions indicated in the display above the individual function key (e.g., ***Select Test***, ***Patient***, ***Stop***)

Arrow Keys: Turn on easyTymp by pressing the right or left arrow key.

Turn off easyTymp by pressing both keys at the same time.

Selection of the right or left ear to be tested.

Up and down buttons: Scroll through the different easyTymp settings menu, test protocols or scroll up and down on the display.

5.2 Preparing for Testing

5.2.1 Preparing the Patient

Also, check out our training videos:

easyTymp Tympanometer | MAICO Training | Hearing Screening Diagnostic Tests – Test Environment

https://youtu.be/MEQrEK2YVmQ?si=iSIpdFDFmsuluPis&t=55

Make sure that the patient is comfortable on a chair or on an examination table if necessary. Small children may feel more comfortable sitting on a parent's lap.

WARNING

Keep in mind the indication and contraindications of use given in Sections 1.1 and 1.2.

5.2.2 Visual Inspection of the Ear Canal

Check the external ear canal for wax with an otoscope. Excessive wax should be removed by a qualified professional to prevent the probe opening from clogging which will inhibit testing. Excessive hairs may have to be cut for a seal to be obtained.

5.2.3 Impedance Measurements

Show the probe to the patient and then explain the following:

- An ear tip is placed on the tip of the probe and inserted into the ear canal. A seal must be achieved for the test to progress.
- Coughing, talking and swallowing will disturb test results.
- The aim of Tympanometry is to test the mobility of the tympanic membrane and the condition of the middle ear.
  - A small amount of air will flow through the probe to move the tympanic membrane; it produces a sensation equal to pressing a finger slightly into the ear canal.
  - One or more tones will be heard during the test. No participation is expected from the patient.
- The aim of Acoustic Reflex measurements is to test the condition of the Musculus Stapedius.
  - One or more louder tones will be heard during the test. No participation is expected from the patient.

5.2.4 Handling the Ear Tips

Choose the proper size of ear tips based on your inspection of the size of the patient's ear canals.

WARNING

Do not insert the probe without having an ear tip attached to prevent damage to the patient's ear canals.

Figure 38

Put the ear tip tightly on the probe tip making sure it is pushed all the way down (Figure 38).

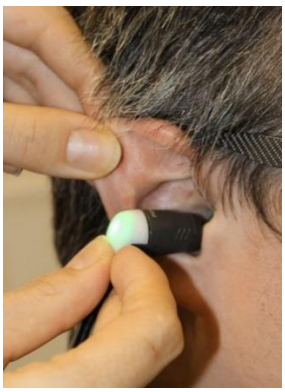


Figure 39

For use with mushroom shaped ear tips:

Insert the probe with ear tip attached into the patient's ear. For children and adults, pull gently up and back on the outer ear (i.e. Pinna) during insertion to straighten the ear canal. Hold the adapter and aim and twist (gently) the ear tip into the ear canal. The fit of the ear tip should be secure; not superficial (Figure 39). Release the earlobe. When testing infants, gently pull the Pinna down and back to straighten the ear canal.

For use with umbrella shaped ear tips:

Gently press the probe against the ear canal to achieve a seal.

WARNING

Each ear tip should only be used once. For more detailed information see Section 3.3.4.

Figure 40

To remove the ear tip, grasp the ear tip at the base using the ***ear tip removal tool*** and pull it smoothly straight off the probe tube (Figure 40). s

NOTE: If the probe tip becomes dirty or clogged, it must be cleaned (see Section 3.3.3) or replaced.

5.2.5 easyTymp Plus and Pro Version (Devices Purchased until 10/2025): Placing and Using the Shoulder Box and Probe

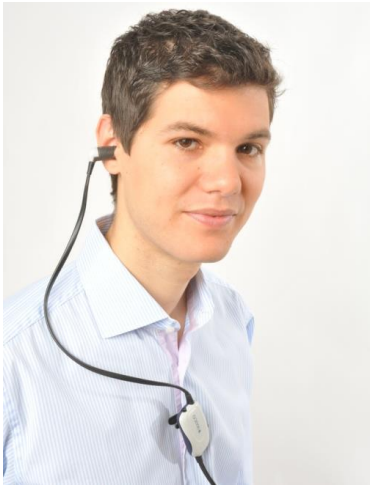


Figure 41

A clip is located on the back of the Shoulder Box which can be attached to the patient's clothing (Figure 41). For most patients it is easiest to clip the Shoulder Box to the patient. When a child is being held by a parent, clip the Shoulder Box to the parent's clothing.

Figure 42

Press the button on the Shoulder Box to start or stop/pause the current measurement or switch between right and left when the probe is not inserted to the ear (Figure 42).

5.2.6 easyTymp Plus and Pro Version (Devices Purchased until 10/2025): Placement of Contralateral Earphones

Multiple transducers are available for purchase to perform ***Contralateral*** measurements.

Figure 43

If the CIR or insert earphone is used, place the proper ear tip on the insert before inserting the phone into the non-test ear (Figure 43).

Figure 44

If the DD45C is used, place the head band over the patient's head. The headphone is placed over the non-test ear (or ***Contralateral Reflex*** ear) (Figure 44).

5.3 Start the Test

To get started, removing the easyTymp from the cradle will turn the device on automatically.

If you don't store the easyTymp in the cradle, press either the red or blue arrow key to switch the device on.

The easyTymp will always start within the test screen, ready to start a measurement. It will always default to the same protocol as previously used.

5.4 Probe Status Indication

If you use the optional probe with the short extension cable the light at the back of the probe indicates the probe status with the following colors (Figure 45):

Figure 45

Red – Right ear is selected. Probe is out of ear.

Blue – Left ear is selected. Probe is out of ear.

Green – Probe is in the ear and is sealing, test is running.

Yellow – Probe is in the ear and blocked or leaking.

White – The probe has just been attached. Probe status is unknown. The probe status stays white for handheld use if the easyTymp is not monitoring the probe status. If the probe light stays white in any other situation easyTymp might need to be switched off and on again to regain proper probe status.

Flashing color – easyTymp is pausing during a protocol and waits for you to press continue. The color in which the probe light is flashing indicates the probe status like above.

Flashing green to red/blue – easyTymp just finished the protocol.

5.5 Testing

5.5.1 General

Operating the easyTymp is very intuitive. After switching the device on, it will usually start in the ***Test*** Screen and is ready to test the same protocol as was used last. After disconnecting easyTymp from a PC it will start in the Select Protocol screen and the desired protocol should be selected.

The battery status bar will show the current battery power status. If the battery is empty, you will be warned, the measurement will be stopped, and all recorded data will be stored. If this occurs, turn off the device and change the battery to continue testing. The measurement data will be recovered when you start up again, so the measurement can continue without restarting the test.

NOTE: If a white screen appears and the easyTymp does not proceed with the next screen, the battery is almost empty. Change the battery to proceed.

The following paragraphs describe the precise operation of the different screens you will observe during the use of easyTymp.

5.5.2 Test

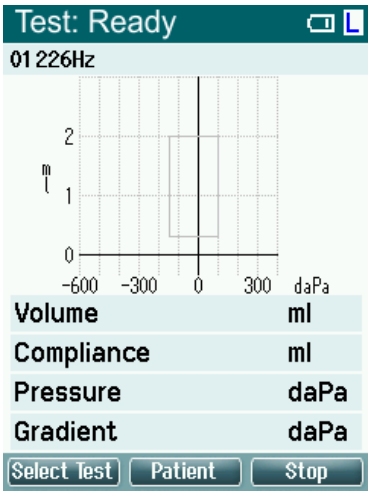


Figure 46

Usually, the easyTymp starts with the ***Test*** screen. When deleting or saving data after a measurement, you will also return to this screen (Figure 46).

The graphics of the ongoing test will also be displayed. The box indicates the normative area where the peak of the tympanogram is expected to fall. The measured curve will be directly shown in the graphic while the measurement is being taken. Below the graphic the measured values (***Volume***, ***Pressure***, ***Compliance*** and ***Gradient***) are shown following the measurement.

Test: Ready The header shows the status of the probe. It might show ***Ready, In Ear, Leaking*** or ***Blocked***. When ***Connected*** is displayed, the device is connected to a cradle or directly to the PC.

- In the upper right corner, the battery status is indicated . When the easyTymp is placed in the cradle, it will charge the battery, and a flashing battery icon will be shown.
- In the upper right corner, an icon indicates if the easyTymp is testing the left ear L or right ear R.
- In the upper right corner, a printer icon indicates the easyTymp is connect to the wireless printer.

NOTE: After turning on the device and the printer it can take up to 30 seconds until the printer icon is shown.

- 03 Tymp 226Hz + Auto Reflex When entering the ***Test*** screen, the second line shows the name of the protocol which is in use. As soon as the easyTymp detects that the probe is in the ear, the second line will show which test of the protocol is running.

Operating from this screen:

Putting the probe in the ear and obtaining a seal will automatically start the test.

- Select Test: The top left button will bring you to the ***Select Test*** screen where you can select a different test protocol.
- Patient**:** The top middle button will bring you to the ***View Patients*** screen where patient data can be viewed, and earlier sessions can be reviewed and/or printed. This function is only displayed if the patient management is activated.
- Stop**:** The top right button, when the measurement is stopped, the top buttons will change to give the option to print, save or delete and ***Done!*** will appear in the upper left hand corner of the screen.
- arrows will select respectively right or left ear for testing.
- If data on one or both ears is still available, the up and down buttons will bring you back to the ***Done!*** screen and allow you scroll through the measurement results.

If a protocol includes an instruction message, pressing the Shoulder Box button results in continuing the protocol, no matter what the probe status indicates.

5.5.3 Select Test Screen

Also, check out our training videos:

easyTymp Tympanometer | MAICO Training | Hearing Screening Diagnostic Tests – Setup

https://youtu.be/MEQrEK2YVmQ?si=yqtx5hCkW_cjGdSo&t=15

Also, check out our training videos:

easyTymp Tympanometer | MAICO Training | Hearing Screening Diagnostic Tests – Tympanometry

https://youtu.be/MEQrEK2YVmQ?si=jQCsszBhh0pLGiRo&t=76

Figure 47

To change the selected protocol, first highlight the protocol and then press Select. The following measurements are available in the easyTymp standard version with international protocols (Figure 47):

01 Tymp 226 Hz

03 Tymp 226 Hz + Auto Reflex

04 Tymp 226 Hz + Reflex 90dB

NOTE: Protocol list is based on version and licensing. Unlicensed protocols are ghosted.

Operating from this screen:

- easyTymp takes you to the ***Setup*** screen.
- Select selects the highlighted protocol and returns to the ***Test*** screen.
- ▲▼ buttons allow scrolling up or down to select one protocol.
- ◤ ◢ buttons will bring you to the top or bottom of the protocol list respectively.

5.5.4 Done!

Also, check out our training videos:

easyTymp Tympanometer | MAICO Training | Hearing Screening Diagnostic Tests – Tympanometry - Results

https://youtu.be/MEQrEK2YVmQ?si=5QR-dzYB8ZeSViQv&t=130

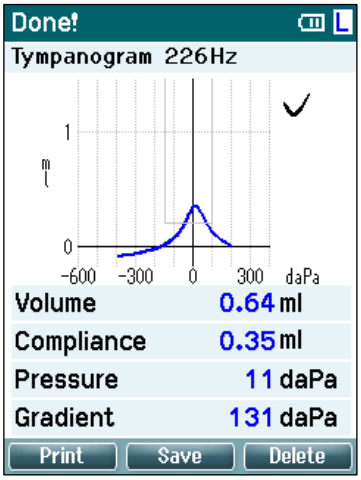


Figure 48

easyTymp will automatically go to the ***Done!*** screen when it has finished testing (Figure 48).

From here, measurements of both ears can be reviewed, printed and/or saved. To start a new measurement in the Test screen, delete the current test ears result or switch ears. Only one result per ear is saved for review, printing or transferring to a PC.

Operating from this screen:

- Print: Top left button will print the test results of the left and right ear. The printer must be on and a connection to the printer prior to starting the test. Printer icon displays in the top right corner of the screen when connected.
- Save: Top middle button will save the measurement of both ears.
- Delete: Top right button will present a dialog saying, “Delete current or both ears?” the top left button will cancel the process. The top middle button will delete the data of the currently selected ear and bring you back to the **Test** screen. The top right button will delete data for both ears and bring you back to the ***Test*** screen.

- buttons will select respectively right or left ear for testing and bring you back to the ***Test*** screen. The existing data of the selected ear will only be deleted after the probe detects that it is in the ear with a proper seal.
- buttons make you scroll through the different test results. When viewing the first or last test of an ear, pressing up or down respectively will bring you to the test results of the other ear.

5.5.5 Advanced Testing: easyTymp Plus and Pro Version (Devices Purchased until 10/2025)

Also, check out our training videos:

easyTymp Tympanometer | MAICO Training | Hearing Screening Diagnostic Tests – Acoustic Reflexes

https://youtu.be/MEQrEK2YVmQ?si=Km62by2cni6GEajt&t=154

Also, check out our training videos:

easyTymp Tympanometer | MAICO Training | Hearing Screening Diagnostic Tests – Acoustic Reflexes - Results

https://youtu.be/MEQrEK2YVmQ?si=NB4u9FrV3e4qp6tG&t=234

Acoustic Reflex Testing (Ipsi and Contra)

Before performing ***Ipsilateral*** (Figure 49) and ***Contralateral reflex*** (Figure 50) testing ***Tympanometry*** will be performed.

NOTE: Deflection of reflexes can be positive or negative and is selected within the setup menu.

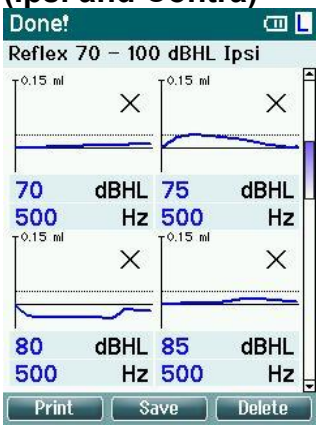


Figure 49

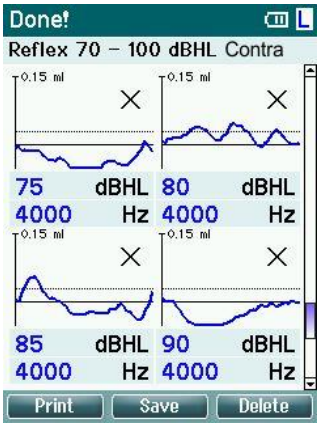


Figure 50

5.5.6 Advanced Testing: easyTymp Pro Version (Devices Purchased until 10/2025)

Also, check out our training videos:

easyTymp Tympanometer | MAICO Training | Hearing Screening Diagnostic Tests – Reflex Decay

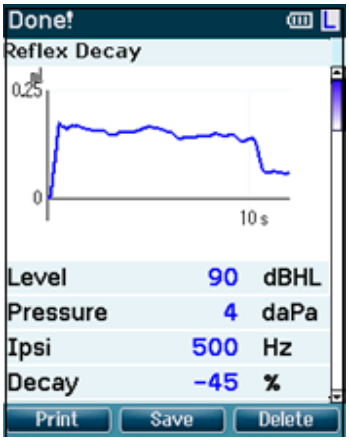
https://youtu.be/MEQrEK2YVmQ?si=mcLg0zXj1JF9bFmJ&t=266

Also, check out our training videos:

easyTymp Tympanometer | MAICO Training | Hearing Screening Diagnostic Tests – Reflex Decay - Results

https://youtu.be/MEQrEK2YVmQ?si=49zAlyWE62xbxSZe&t=323

Acoustic Reflex Decay



Ipsilateral and ***Contralateral Reflex Decay*** testing can be performed (Figure 51).

Figure 51

Also, check out our training videos:

easyTymp Tympanometer | MAICO Training | Hearing Screening Diagnostic Tests – ETF - General

https://youtu.be/MEQrEK2YVmQ?si=ZpDqdYlPNzyKDGXy&t=351

Also, check out our training videos:

easyTymp Tympanometer | MAICO Training | Hearing Screening Diagnostic Tests – ETF - Intact

https://youtu.be/MEQrEK2YVmQ?si=EQ74bxOJh2E6-wOf&t=382

Also, check out our training videos:

easyTymp Tympanometer | MAICO Training | Hearing Screening Diagnostic Tests – ETF – Perforated

https://youtu.be/MEQrEK2YVmQ?si=XN-tpLUQR3IHbClj&t=469

ETF Intact

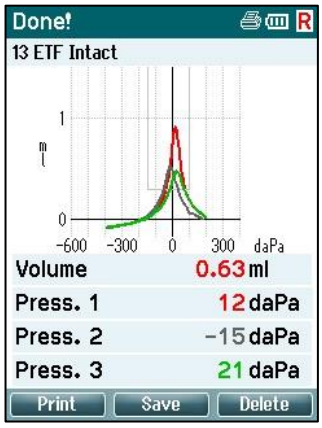


Figure 52

Instructions for testing are displayed at the top of the screen. (Figure 52).

(1) Red or Blue: represents test ear.

(2) Grey: represents "***Swallow***".

(3) Green: represents "***Valsalva***".

ETF Perforated

Figure 53

Instruct the patient to swallow.

Measurement of changing pressure indicates status of ***Eustachian tube*** (Figure 53).

5.5.7 easyTymp Plus and Pro Version (Devices Purchased until 10/2025): Shoulder Box Button

The Shoulder Box button will change ears if the probe detects it is not in the ear.

When the probe is in an ear it will interrupt the testing and bring you to the ***Done!*** Screen, and from there also back to the Test screen with a second press of the button. If a protocol includes an instruction message, pressing the Shoulder Box button results in continuing the protocol, no matter what the probe status.

5.5.8 Select Patient & Save

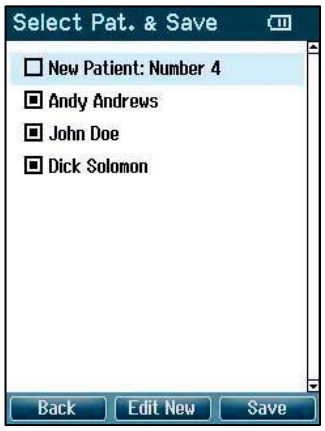


Figure 54

The ***Select Patient & Save*** screen is accessible once a measurement is completed and Save is selected form the test screen. Results can either be saved to an existing patient or to a new patient (Figure 54). New patient will always get the name "New Patient: Number #", where # is always the next available number.

When saving results to a patient, the patient management function must be ***On*** in the settings (see Section 5.6.8).

Operating from this screen:

- Back will bring you back to the ***Done!*** screen without saving and without deleting data.
- Edit New opens a screen for editing new patient details.
- Save will save the data to the selected patient. After saving, all data is deleted and easyTymp returns in the ***Test*** screen, ready for testing.
- buttons will bring you to the top or bottom of the patient list respectively.
- buttons scroll up or down as one patient's information is viewed.

5.5.9 Edit New

Figure 55

With this screen you can input data for a new patient before saving the measurement (Figure 55).

Operating from this screen:

- Save saves the patient details and brings you back to ***Select Patient & Save***.
- Select will select the highlighted field. Backspace is an arrow in the top right corner. Space is a bar underneath the keyboard.
- Next will select the next details for editing.
- arrows buttons will move the selection of the keyboard one character to the left or right.
- buttons will move the selection of the keyboard one character up or down. When editing the birth date the up and down button will change the numerical value.

5.5.10 View Patients

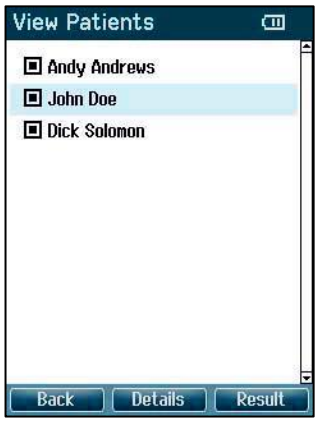


Figure 56

View Patients screen is accessed from the test screen by selecting Patient (Figure 56).

When one or more sessions are stored, the square in front of the patient's name is filled. If a session is not stored yet, this square will be empty.

Operating from this screen:

- Back brings you back to the ***Test*** screen.
- Details brings you to the ***View Details*** screen where the data of the selected patient is shown.
- Result will bring you to the ***View Results*** screen where the available sessions of the selected patient can be reviewed and printed.
- will bring you to the top or bottom of the patient list respectively.
- buttons scroll up or down as one patient's information is viewed.

5.5.11 View Details

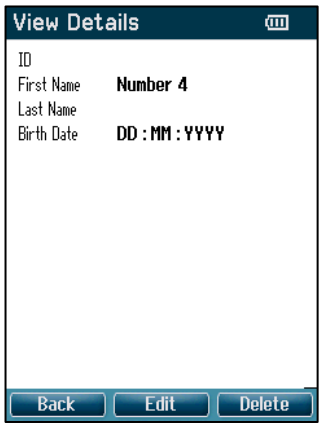


Figure 57

This screen shows demographics of the selected patient (Figure 57).

From here you can either use Back to go back to the ***View Patients*** screen or Edit to edit the patient details in the ***Edit Details*** screen.

Delete button will delete either this patient, or all patients.

5.5.12 Edit Details

Figure 58

This screen shows the patient ***ID***, ***First Name***, ***Last Name,*** and ***Birth Date*** (Figure 58).

Operating from this screen:

- Back brings you back to the ***View Patients*** screen.
- Select selects the highlighted character and put it where the cursor is placed. Backspace is an arrow in the top right corner. Space is a bar underneath the keyboard
- Next selects the next details for editing.
- ◀ ▶ will move the selection of the keyboard one character to the left or right.
- ▲▼ buttons will move the selection of the keyboard one character up or down. When editing the birth date the up and down button will change the numerical value.

5.5.13 View Results

View Results – select session

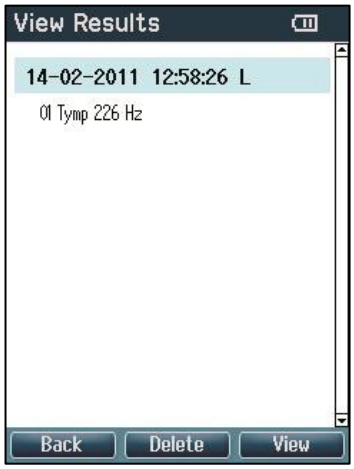


Figure 59

For the selected patient, the screen shows a list of available sessions (Figure 59).

Operating from this screen:

Back brings you back to the ***View Patient*** screen.

Delete prompts you and ask for confirmation before it deletes the selected session or all sessions.

View shows the selected session in the ***View Results*** screen (see Figure 39).

◀ ▶ buttons bring you respectively to the top or bottom of the result list.

▲▼ buttons scroll up or down one session

View Results – show results

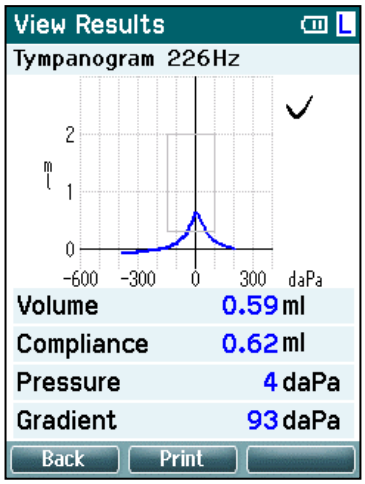


Figure 60

This screen displays the test recordings of the selected session (Figure 60).

Operating from this screen:

- Back brings you back to the ***View Results*** screen.
- Print button will print all results which are stored in the selected session.
- The top right button has no function.
- ◀ ▶ buttons will show the recordings of the right or left ears respectively, if available.
- ▲▼ buttons scroll through the different tests which are included in the selected session.

5.6 Setup Menu

5.6.1 Setup

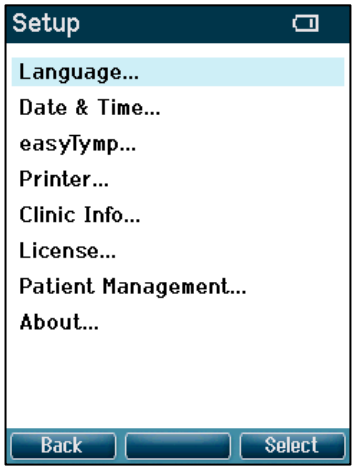


Figure 61

To change the Setup of the easyTymp navigate from ***Test*** screen to ***Select Test*** and then to ***easyTymp*** (Figure 61).

Operating from this screen:

- Back brings you back to the ***Select test*** screen.
- The top middle button has no function.
- Select selects the highlighted setting to be viewed.
- buttons have no function.
- buttons scroll up and down to the next item.

5.6.2 Setup Language

Figure 62

Use right and left arrow keys to adjust language (Figure 62). Available languages are ***English***, ***Deutsch***, ***Español***, ***Français***, ***Italiano***, ***Polski***, ***日本語***, ***中文***, ***русский*** and ***Svenska***.

5.6.3 Setup Time

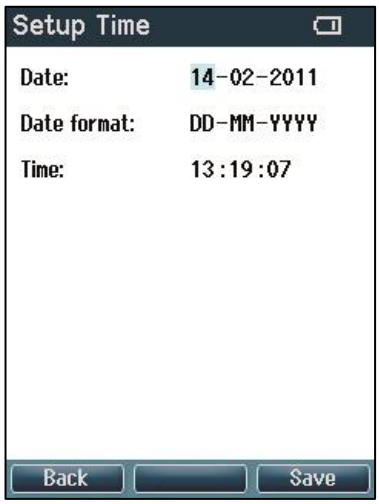


Figure 63

arrow keys will scroll through the options (Figure 63).

buttons adjust ***Date***, ***Date format*** and ***Time***.

5.6.4 Setup easyTymp

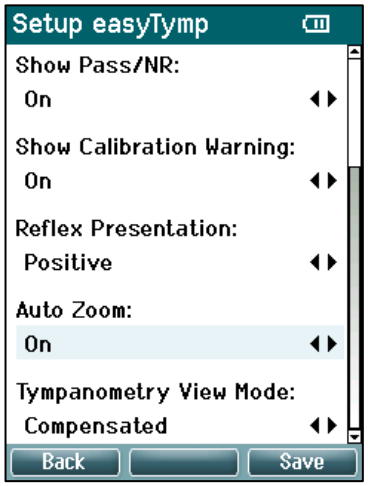


Figure 64

will scroll through the options. buttons to adjust selection (Figure 64).

The ***Power Save*** can be set to ***Never*** or ***1***, ***2***, ***3***, ***4*** or ***5 min***.

The ***Power Off*** can be set to **Never** or from **1** to **10 min**.

Show Pass/NR**:** If ***On*** the test result will display with a ***Pass*** ✓ / ***NR*** (No Response) ✕ symbol depending on Normative Values defined internally.

Show Calibration Warning**:** When ***On***, calibration reminder will display on device, when turned on.

Reflex Presentation**: *Negative*** or ***Positive*** deflection in the graphs.

Auto zoom**:** Auto zoom allows the best possible display of the results in the Tympanogram. Otherwise, the scale is fixed to the default display range of the ***Tympanometry View Mode***.

Tympanometry View mode*:* Set the for viewing the Tympanogram:

- ***Compensated:*** compensates the Tympanogram according to the measured ear canal volume (default display range: 3 ml/mmho).
- ***Uncompensated:*** shows absolute values (default display range: 6 ml/mmho).

5.6.5 Setup Printer

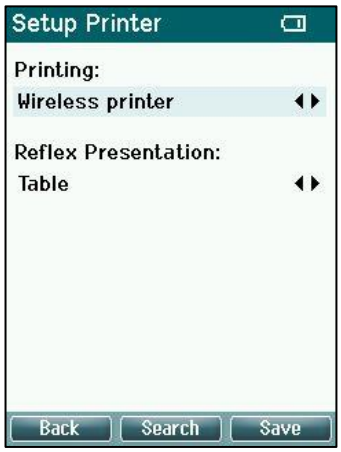


Figure 65

Figure 66

buttons will scroll through the options. Press the buttons to adjust selection (Figure 65).

Printing: Can be set to ***Wireless printer, Cradle printer*** or ***Disabled***. Selection of the printing type will hide not applicable printing options.

NOTE: ***Cradle printer*** is selectable for a discontinued configuration where a cradle printer was provided.

Reflex Presentation: Choose between ***Table*** or ***Graph*** by pressing the buttons (Figure 65).

Pairing Wireless printer: Press Search to start searching for the wireless printer. This process takes about 1 minute.

Select the printer using the buttons and press Select to configure the device to the wireless printer provided by MAICO (Figure 66). Select Save or Back to exit the Setup Printer screen.

NOTE: The printer must be turned on by pressing the ***power button*** before starting the pairing process.

5.6.6 Setup Clinic Info

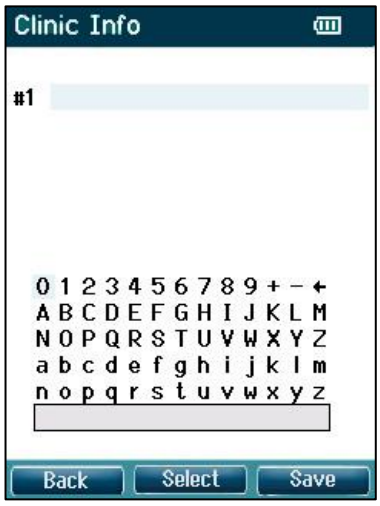


Figure 67

To enter the clinic information to display on the printout, enter the ***Setup*** Menu and select ***Clinic Info*** from the list. Once within the ***Clinic Info*** screen, select Edit.

Use ***Up***, ***Down***, ***Right*** and ***Left*** arrow keys to move the cursor over the keyboard (Figure 67).

Select to select the highlighted character. Backspace is an arrow in the top right corner. Space is a bar underneath the keyboard.

Save to save and return to the ***Setup*** screen.

5.6.7 Setup License

Figure 68

Option to buy licenses to unlock further measurements (Figure 68):

Edit: The middle button starts the edit mode to insert the License Key.

NOTE: License should be modified by a licensed distributor only. If you accidently enter the edit mode, press the Back button to return.

5.6.8 Setup Patient Management

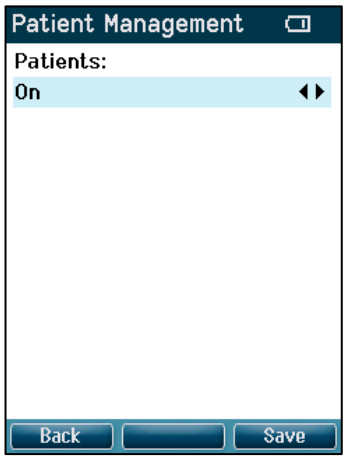


Figure 69

Turns the internal patient data management ***On*** or ***Off*** (Figure 69).

NOTE: When changing from ***On*** to ***Off***, all measured and/or stored data will be deleted.

5.6.9 About

Figure 70

About displays the firmware version and calibration dates (Figure 70).

5.7 Managing Test Results

5.7.1 General

Also, check out our training videos:

easyTymp Tympanometer | MAICO Training | Hearing Screening Diagnostic Tests – Managing Test Results

https://youtu.be/MEQrEK2YVmQ?si=rBRObFIQwHc3uYB-&t=564

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

5.7.2 Deleting Test Results

The procedure of deleting test results depends on whether patient management is active or not.

Deleting Test Results Directly After Testing

Deleting a measurement is possible by pressing the Delete button directly after having finished a measurement and the ***Done!*** screen is shown. It is possible to delete measurements of one or both ears. See Section 5.5.4 for more information.

NOTE: Making a measurement on the same ear without having saved the previous measurement will overwrite the previous test result.

Deleting Test Results in the Patient Management

Using the patient management, it is possible to delete either single or all results of a patient or one or all patients including test results. See Section 5.5.13 on how to delete single or all test results of a patient. See Section 5.5.11 on how to delete a single or all patients including test results.

NOTE: When the management system is activated or deactivated, a dialog warns that all measurement data will be deleted. Press Yes to change the setting and delete the data or Back to keep the settings. See also Section 5.6.8.

5.7.3 Printing Test Results with the Thermal Printer

Print directly from the ***Done!*** screen (see Section 5.5.4) or after viewing results via patient management (see Section 5.5.13).

5.7.4 Data Transfer Between easyTymp and MAICO Sessions

NOTE: For transfer data between easyTymp and MAICO Sessions it is necessary to activate the license for PC connection which can be additionally purchased.

With easyTymp Patient Management Enabled (Only with OtoAccess® Database or Noah)

To transfer data, do the following:

- Complete the measurement and save it on the device.
- Connect the easyTymp to the computer using the USB cable.
- Upload patients or download sessions (see MAICO Sessions Software Operation Manual for more information).

With easyTymp Patient Management Disabled

Disable patient management in easyTymp. See section 5.6.8 for more information.

Proceed as follows to transfer data:

- Complete the measurement.
- Connect the easyTymp to the computer using the USB cable.
- The data transfer starts automatically (see MAICO Sessions Software Operation Manual for more information).

NOTE: The easyTymp cannot make a measurement if it is connected to the running Sessions software.

6 Technical Data

This section offers you important information about

- **the easyTymp hardware specifications**
- **connections**
- **the pin assignment**
- **impedance calibration values**
- **electromagnetic compatibility (EMC)**
- **electrical safety, EMC and associated Standards**

6.1 easyTymp Hardware

CE 0123

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

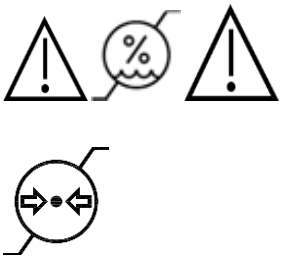
General Information About Specifications

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

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

STANDARDS	
Medical CE-mark	Yes
Safety Standards	IEC 60601-1:2005+A1:2012/ ANSI/AAMI ES60601-1:2005/ A2:2010/ CAN/CSA-C22.2 No. 60601-1:14 Class II, Type B Applied Parts
EMC Standards	IEC 60601-1-2:2014
Tympanometer Standards	IEC 60645-5:2004, Type 2 ASA/ANSI S3.39-1987, Type 2
	Normative Box: Appendix

DEVICE SPECIFICATIONS

Environmental Conditions 	Operation	+15 °C to +35 °C / +59 °F to +95 °F Humidity: 30 % to 90 %, non-condensing Ambient pressure 98 kPa to 104 kPa[1] 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 +50 °C / -4 °F to +122 °F Humidity: 10 % to 95 %, non-condensing
Power supply, UES18LCP-050250SPA	Consumption	12.5 W
	Input	100 - 240 VAC ± 10 %, 50/60 Hz, 500 mA
	Output	5 VDC/2.5 A
	Dimensions	Max. 88 mm x 30 mm x 57 mm 3.46” x 1.18” x 2.24”
Battery Type	NP120 Li-Ion	3.7 V 1700 mAh
Dimension and weight	Dimension	80 mm x 300 mm x 70 mm 3.15” x 11.81” x 2.76”
	Weight	427 g / 1 lb
Display	Display size	2.2” diagonal
	Resolution	240 x 320
PC connection	USB	Input/output for computer communication.
Memory		Stores test results for up to 499 patients. The easyTymp handheld device is delivered with an 8 GB memory card
Mode of operation	Continuous	
Data Interfaces	PC connection	USB
	Wireless printing (version dependent)	Transmit frequency: 2400 MHz to 2483.5 MHz Modulation: GFSK, π/4-DQPSK and 8DPSK Radiated power: 2.5 mW (Class 2) OR Frequency Range 2402 MHz to 2480 MHz Effective radiated power up to +12 dBm Modulation: GFSK, π/4-DQPSK or 8-DPSK
Dimensions Probe	34 mm	
Dimensions Probe Short Extension Cable	350 mm	
Shoulder Box Cable	1400 mm	
Warm-up time	approx. 1 minute	

[1] Environmental conditions during operating according to IEC 60645-1

NOTE: Reference equivalent threshold sound pressure levels may differ significantly with ambient pressures outside the above range. Therefore, recalibration around the normal ambient pressure at the site of the user should be undertaken in those circumstances where the calibration site and the user site do not share similar ambient conditions.

IMPEDANCE MEASURING SYSTEM

Probe tone	Frequency	226 Hz, 1000 Hz
	Level	85 dB SPL at 226 Hz, 69 dB SPL at 1000 Hz with AGC, assuring constant level at different ear canal volumes.
Air pressure	Control	Automatic.
	Indicator	Measured value is displayed on the graphical display.
	Pressure change rate (international protocols)	Speed at compliance peak: **Automatic**: 600/200 daPa/s
	Pressure change rate (Swedish protocols)	See Section 6.6.
	Range	-400 daPa to +200 daPa.
	Pressure limitation	-750 daPa and +550 daPa.
Compliance	Range	0.1 ml to 8.0 ml at 226 Hz probe tone (Ear volume: 0.1 ml to 8.0 ml) and 0.1 mmho to 15 mmho at 1000 Hz probe tone.
Test types	Tympanometry	Automatic.
Accuracy	Compliance	±5 % or ±10 daPa, whichever is greater
	Pressure	±5 % or ±0.1 ml, whichever is greater
Precision	Pressure	1 daPa
	Compliance	0.01 ml
Indicators	Graphical display	Compliance is indicated as ml for 226 Hz and as mmho for 1000 Hz and pressure as daPa. Stimulus level is indicated as dB HL. View modes: Compensated/Uncompensated ETF Intact: Compensated view mode only
Memory	Tympanometry	1 curve per ear, per Tympanometry test. And theoretically an infinite number of tests per protocol.

ACOUSTIC REFLEX FUNCTIONS

Stimulus	Type	Ipsilateral and Contralateral: • Pure tone (500, 1000, 2000, 4000 Hz) • Broadband noise (BB
	Level	Automatic pure tone: International: 70-100 dB HL in 5 dB steps Swedish: 70-95 dB HL in 5 dB steps
		Fixed pure tone: International: 90 dB HL Swedish: 85 dB HL
		International: Fixed BB: 80 dB HL
Outputs	Ipsi earphone	Probe earphone incorporated in the probe system for reflex measurements.
	Contra earphone	CIR insert earphones, DD45C, IP30 for reflex measurements.
	Air	Connection of the air system to the probe.
Transducers – Headband tension	DD45 C	Headband Static Force 4.5 N ± 0.5 N
Test types	Ipsi- and contralateral	• Single intensities • Reflex auto search

REFLEX DECAY FUNCTIONS

Test method	Ipsi- and contralateral	
Test signals	Pure Tones	500 Hz, 1000 Hz, 2000 Hz, 4000 Hz each with ± 3 %
	Noise	Broadband
Test level	Ipsi- and contralateral	10 dB above reflex threshold 80 dB HL to maximum level of transducer
Control Acoustic Reflexes	Automatic	Automatic reflexes: Single reflex auto search
Tone presentation	10 s	
Compliance Range	-0.05 ml to 0.25 ml	
Graphical display	y-axis: Compliance in ml x-axis: Time in s Level in dB HL	
Ipsi earphone	Earphone integrated in probe	

ETF – INTACT

Same specification as Tympanometry, 226 Hz probe tone only.

ETF – PERFORATED

Test signals	Pure tone: 226 Hz with ± 1 %
Test level	85 dB SPL ±1.5 dB measured in an IEC 60318-5 Acoustic coupler. The level is constant for all volumes in the measurement range.
Control Tympanometry	Automatic
Time range	0 s to 30 s (settings)
Pressure range	0 daPa to 400 daPa
Accuracy	Pressure ±5 % or ±0.1 ml, whichever is greater
Precision	Pressure 1 daPa
Graphical display	x-axis: Time in s y-axis: Pressure in daPa

CALIBRATION PROPERTIES

Calibrated transducers	Probe system	Ipsilateral and Contralateral Earphone: is integrated in the probe system.
		Probe frequency transmitter and receiver and pressure transducer is integrated in the probe system.
Accuracy	General	Generally, the device is made and calibrated to be within and better than the tolerances required in the specified standards:
	Reflex frequencies	±3 %
	Ipsilateral reflex tone levels	±3 dB for 500 Hz to 4000 Hz
	Contralateral Reflex Tone Levels	±3 dB for 500 Hz to 4000 Hz
	Pressure measurement	±5 % or ±10 daPa, whichever is greater
	Compliance measurement	±5 % or ±0.1 ml, whichever is greater

IMPEDANCE CALIBRATION PROPERTIES

Probe tone	Frequencies	226 Hz ± 1 %, 1000 Hz ± 1 %
	Level	85 dB SPL ±1.5 dB measured in an IEC 60318-5 Acoustic coupler. The level is constant for all volumes in the measurement range.
	On-Off ratio SNR A-Weighted noise in off condition Rise/fall times	> 70 dB > 70 dB < 25 dB > 5 ms
	Distortion	Max. 1 % THD
Compliance	Range	0.1 ml to 8.0 ml
	Temperature dependence	-0.003 ml/°C
	Pressure dependence	-0.00020 ml/daPa
	Reflex sensitivity	0.001 ml is the lowest detectable volume change
	Temporal reflex characteristics	Initial latency = 35 ms (±5 ms) Rise time = 45 ms (±5 ms) Terminal latency = 35 ms (±5 ms) Fall time = 45 ms (±5 ms) Overshoot = max. 1 % Undershoot = max. 1 % ON and OFF time = 750 ms
Pressure	Range	-400 daPa to +200 daPa
	Safety limits	-750 daPa and +550 daPa, ±50 daPa

REFLEX CALIBRATION STANDARDS AND SPECTRAL PROPERTIES

General	Specifications for stimulus signals are made to follow IEC 60645-5/ ANSI S3.39.	
Ipsi- and Contra-lateral Earphone	Pure tone	±3 dB for 500 Hz to 4000 Hz
	Broadband noise (BB)	MAICO Standard Values
	Spectral properties	As “Broadband noise” specified in IEC 60645-5, but with 500 Hz as lower cut-off frequency.
	General about levels	The actual sound pressure level at the tympanic membrane will depend on the volume of the ear.

The risk of artifacts at higher stimulus levels in reflex measurements are minor and will not activate the reflex detection system.

CRADLE

Power supply, UES24LCP-240100SPA	Consumption	24 W
	Input	100 - 240 VAC ± 10 %, 50/60 Hz, 500 mA
	Output	24 VDC/1 A
	Dimensions	Max. 88 mm x 30 mm x 57 mm 3.46” x 1.18” x 2.24”

PRINTER HM-E200

Thermal printer	Type	HM-E200
	Connection	Wireless
	Battery	7.4 V rechargeable Li-polymer battery, 1300 mAh
	Weight	234 g / 8.3 oz
	Paper	Thermal paper
	Paper size	57.5 mm ± 0.5 mm (width)
	Printing time	<5 seconds per test result
Power supply	Type	UES12LCP-050160SPA
	Input	100 to 240 V AC, 50/60 Hz, 0.5 A
	Output	5.0V DC, 1.6A MAX
	Safety	IEC 60601-1, Class II

6.2 Connections and Pin Assignment

easyTymp Device

Table 6 Pin Assignment easyTymp

OUTPUTS	CONNECTOR TYPE	PIN ASSIGNMENT	
USB mini 	USB Type B	USB port for communication	
Probe connector 	Probe connector, 12-pole	CH1 out CH1 GND DGND GND Microphone Microphone – input / Analog balanced in Microphone + input / Analog balanced in Power supply +3/+5V CH2 out CH2 GND I2C CLK I2C DATA I2C Interrupt	
Data connector 	Data connector, 30-pole	STAT2_HH Cradle+5V Cradle+5V Cradle+5V DGND DGND DGND USB+5V USBDP USBDN Temp.bat PRT_BUSY IC33-NO2 PRT_ACK/U2RX TP116 IC33-NO1	TRIGGER-OUT2 RESET# TRIGGER-IN2 KEY_DOWN / POWER ON Vbat PRT_ACK/U2RX Strobe# DATA0 DATA1 DATA2 DATA3 DATA4 DATA5 DATA6 DATA7
Contra headphone jack socket 	3.5 mm Mono	Ground	Signal

Cradle

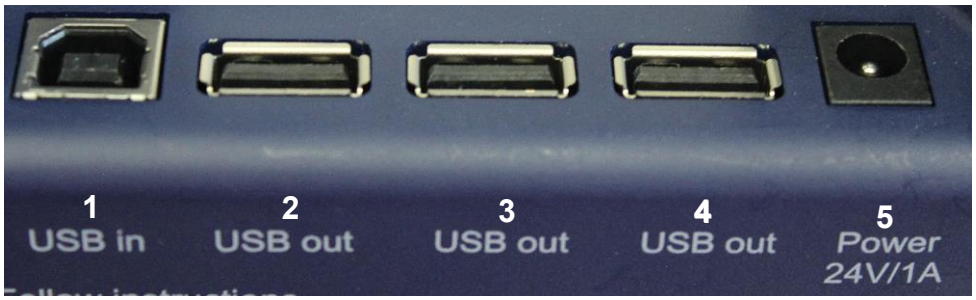
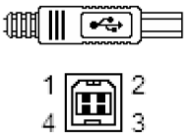
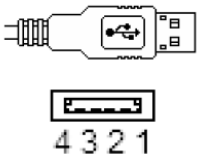
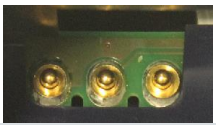


Figure 71

Table 7 Pin Assigment Cradle

NO.	CONNECTOR TYPE	PIN ASSIGNMENT		
1	USB in	USB 2.0  1 2 4 3	1. +5 VDC 2. Data - 3. Data + 4. Ground	
2 to 4	USB out	USB 2.0  4 3 2 1	1. +5 VDC 2. Data - 3. Data + 4. Ground	
5	Power supply	 DC socket 24 V/3 A		
-	Data connector 	Data connector, 30-pole	STAT2_HH Cradle+5V Cradle+5V Cradle+5V DGND DGND DGND USB+5V USBDP USBDN Temp.bat PRT_BUSY IC33-NO2 PRT_ACK/U2RX TP116 IC33-NO1	TRIGGER-OUT2 RESET# TRIGGER-IN2 KEY_DOWN / POWER ON Vbat PRT_ACK/U2RX Strobe# DATA0 DATA1 DATA2 DATA3 DATA4 DATA5 DATA6 DATA7
-	Charging connector 	⊖ ⏚ ⊕	- pole ground + pole	

6.3 Reference Values for Stimulus Calibration

Table 8 Coupler Types used by Calibration

COUPLER TYPES USED BY CALIBRATION	
IOW Probe (probe system):	Calibrated using a IEC 60380-5 (2cc) Acoustic coupler made in accordance to MAICO Standard Values
CIR:	Calibrated using a IEC 60380-5 (2cc) Acoustic coupler made in accordance to ISO 389-2:1994
DD45C:	Calibrated using a IEC 60318-3 (6cc) Acoustic coupler made in accordance to MAICO Standard Values

Table 9 Reference Values for Stimulus Calibration

REFERENCE VALUES FOR STIMULUS CALIBRATION				
Frequency [Hz]	**Reference equivalent threshold sound pressure level [RETSPL, dB re. 20 µPa]**			
	CIR ISO 389-2	**DD45 C MAICO Standard Values**	**IOW Probe MAICO Standard Values**	**IP30 ISO 389-2**
500	5.5	13.0*	9.5*	5.5
1000	0.0	6.0*	6.5*	0.0
2000	3.0	8.0*	12.0*	3.0
4000	5.5	9.0*	3.5*	5.5
BB	**-5.0**	**-8.0***	**-5.0***	**0.0**

*All values marked with at star are MAICO Standard Values.

Table 10 Frequencies and Intensity Ranges for Impedance

FREQUENCIES AND MAXIMUM VALUES FOR IMPEDANCE				
Center Frequency [Hz]	**Intensities [dB HL]**			
	CIR	**DD45 C**	**IOW Probe**	**IP30**
	Tone	**Tone**	**Tone**	**Tone**
500	110	115	100	115
1000	115	120	105	120
2000	115	115	105	120
4000	110	115	100	120
BB	120	120	105	120

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.

NOTICE: If Non-Medical Electronic Equipment (typical information technology equipment) is attached, it is the responsibility of the operator to ensure that this equipment comply to applicable standards and the system as whole complies to the EMC requirements. Commonly used standards for EMC testing information technology equipment and similar equipment[3] are:

Emissions testing	
EN 55032 (CISPR 32)	Electromagnetic compatibility of multimedia equipment - Emission requirements
EN 61000-3-2	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤16 A per phase)
EN 61000-3-3	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection)
Immunity testing	
EN 55035 (CISPR 35)	Electromagnetic compatibility of multimedia equipment — Immunity requirements

[3] Products include personal computer, PC, tablet, laptop, notebook, mobile device, PDA, Ethernet hub, router, WiFi, computer peripheral, keyboard, mouse, printer, plotter, USB storage, Hard drive storage, solid-state storage and many more.

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

Item	Manufacturer	Model	s	
			Length [meter]	Screened [Y/N]
Handheld test setup (Wireless active) :				
Probe	MAICO	Clinical Extension Cable	0.4	Combined
Probe with Extension Cable			1.7	Combined
Contra Headphone	RadioEar	IP30	0.35	Y
Printer	Sanibel	MPT II	-	-
Printer	Xiamen PRT technology	HM-E200	-	-
PSU	Fuhua	UES18LCP-050250SPA	1.5	N
Cradle test setup (Wireless off) :				
Probe	MAICO	Clinical Extension Cable	0.4	Combined
Probe with Extension Cable			1.7	Combined
Contra Headphone	RadioEar	IP30	0.35	Y
Cradle	MAICO	Cradle ear tip box	-	-
PSU	Fuhua	UES24LCP-240100SPA	1.5	N
USB cable A-B	Sanibel	8011241	1.8	Y

Portable and mobile RF communications equipment can affect the easyTymp. 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 *easyTymp* is intended for use in the electromagnetic environment specified below. The customer or the user of the *easyTymp* should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The *easyTymp* 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 *easyTymp* 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 *easyTymp*.			
The *easyTymp* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *easyTymp* can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *easyTymp* 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 *easyTymp* is intended for use in the electromagnetic environment specified below. The customer or the user of the *easyTymp* 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%.
Immunity to proximity fields from RF wireless communications equipment IEC 61000-4-3	Spot freq. 385-5.785 MHz Levels and modulation defined in table 9	As defined in table 9	RF wireless communications equipment should not be used close to any parts of the *easyTymp*.
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 Line to line +2 kV Line to earth	Not applicable	Mains power quality should be that of a typical commercial or residential environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	0% *UT* (100% dip in *UT*) for 0.5 cycle, @ 0, 45, 90, 135, 180, 225, 270 and 315° 0% *UT* (100% dip in *UT*) for 1 cycle 40% *UT* (60% dip in *UT*) for 5 cycles 70% *UT* (30% dip in *UT*) for 25 cycles 0% *UT* (100% dip in *UT*) for 250 cycles	Not applicable	Mains power quality should be that of a typical commercial or residential environment. If the user of the *easyTymp* requires continued operation during power mains interruptions, it is recommended that the *easyTymp* 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.
Radiated fields in close proximity — Immunity test IEC 61000-4-39	9 kHz to 13.56 MHz. Frequency, level and modulation defined in AMD 1: 2020, table 11	As defined in table 11 of AMD 1: 2020	If the *easyTymp* contains magnetically sensitive components or circuits, the proximity magnetic fields should be no higher than the test levels specified in Table 11
Note: *UT* is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity			
The *easyTymp* is intended for use in the electromagnetic environment specified below. The customer or the user of the *easyTymp* should assure that it is used in such an environment,			
Immunity test	**IEC / EN 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any parts of the *easyTymp,* including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC / EN 61000-4-6	3 Vrms 150kHz to 80 MHz 6 Vrms In ISM bands (and amateur radio bands for Home Healthcare environment.)	3 Vrms 6 Vrms	$d = \frac{3,5}{Vrms}\sqrt{P}$
Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,7 GHz 10 V/m 80 MHz to 2,7 GHz Only for Home Healthcare environment	3 V/m 10 V/m (If Home Healthcare)	$d = \frac{3,5}{V/m}\sqrt{P}$ 80 MHz to 800 MHz $d = \frac{7}{V/m}\sqrt{P}$ 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 *easyTymp* is used exceeds the applicable RF compliance level above, the *easyTymp* should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *easyTymp.* [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/EN 60601-1:2012: Medical Electrical Equipment, Part 1 General Requirements for Safety
- JIS T0601-1:2017: Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
- CAN/CSA-C22.2 No. 60601-1:14: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ANSI/AAMI ES 60601-1: 2005 / A2:2010: Medical Electrical Equipment, Part 1 General Requirements for Safety
- IEC 62368-1:2018: Audio/video, information and communication technology equipment - Part 1: Safety requirements Information
- IEC 60601-1-1:2000: General requirements for safety; Collateral standard: Safety requirements for medical electrical systems
- IEC 60601-1-2:2014: Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and tests
- General Safety and Performance Requirements of the current REGULATION (EU) 2017/745
- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2)
- DIRECTIVE 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE)

6.6 Test Protocols

NOTE: Test protocols are configuration dependent.

International Protocols

01 226Hz	Tympanometry, Frequency: 226 Hz Ear side: Ipsilateral
02 1kHz	Tympanometry, Frequency: 1 kHz Ear side: Ipsilateral
03 226Hz + Ipsi Reflex Auto	Tympanometry, Frequency: 226 Hz Number of Reflexes tested = 4, Frequencies: 0.5, 1.0, 2.0, 4.0 kHz Intensity Reflex Min (Intensity in dB HL) = 70 Intensity Reflex Max (Intensity in dB HL) = 100 Probe frequency during reflexes: 226 Hz Ear side: Ipsilateral
04 226Hz + Ipsi Reflex 90 dB	Tympanometry, Frequency: 226 Hz Number of Reflexes tested = 4, Frequencies: 0.5, 1.0, 2.0, 4.0 kHz Intensity Reflex (Intensity in dB HL) = 90 Probe frequency during reflexes: 226 Hz Ear side: Ipsilateral
05 1kHz + Ipsi Reflex Auto	Tympanometry, Frequency: 1 kHz Number of Reflexes tested = 4, Frequencies: 0.5, 1.0, 2.0, 4.0 kHz Intensity Reflex Min (Intensity in dB HL) = 70 Intensity Reflex Max (Intensity in dB HL) = 100 Probe frequency during reflexes: 226 Hz Ear side: Ipsilateral
06 1kHz + Ipsi Reflex 80 dB BB	Tympanometry, Frequency: 1 kHz Number of Reflexes tested = 1, Test signal: Broadband noise Intensity Reflex (Intensity in dB HL) = 80 dB Probe frequency during reflexes: 226 Hz Ear side: Ipsilateral
07 226Hz + Ipsi-Contra Auto	Tympanometry, Frequency: 226 Hz Number of Reflexes tested = 8, Frequencies: 0.5, 1.0, 2.0, 4.0 kHz Intensity Reflex Min (Intensity in dB HL) = 70 Intensity Reflex Max (Intensity in dB HL) = 100 Probe frequency during reflexes: 226 Hz Ear side: Ipsi- and Contralateral

08 226Hz + Ipsi-Contra 90 dB	Tympanometry, Frequency: 226 Hz Number of Reflexes tested = 8, Frequencies: 0.5, 1.0, 2.0, 4.0 kHz Intensity Reflex (Intensity in dB HL) = 90 Probe frequency during reflexes: 226 Hz Ear side: Ipsi- and Contralateral
09 1kHz + Ipsi-Contra Auto	Tympanometry, Frequency: 1 kHz Number of Reflexes tested = 8, Frequencies: 0.5, 1.0, 2.0, 4.0 kHz Intensity Reflex Min (Intensity in dB HL) = 70 Intensity Reflex Max (Intensity in dB HL) = 100 Probe frequency during reflexes: 226 Hz Ear side: Ipsi- and Contralateral
10 1kHz + Ipsi-Contra 80 dB BB	Tympanometry, Frequency: 1 kHz Number of Reflexes tested = 2, Test signal: 80 Broadband noise Intensity Reflex (Intensity in dB HL) = 80 Probe frequency during reflexes: 226 Hz Ear side: Ipsi- and Contralateral
11 Decay Ipsi	Number of Reflexes tested = 4, Frequencies: 0.5, 1.0, 2.0, 4.0 kHz Intensity Reflex Min (Intensity in dB HL) = 70 Intensity Reflex Max (Intensity in dB HL) = 110 Probe frequency during reflexes: 226 Hz Duration of Signal: 10 s Ear side: Ipsilateral
12 Decay Contra	Number of Reflexes tested = 4, Frequencies: 0.5, 1.0, 2.0, 4.0 kHz Intensity Reflex Min (Intensity in dB HL) = 70 Intensity Reflex Max (Intensity in dB HL) = 120 Probe frequency during reflexes: 226 Hz Duration of Signal: 10 s Ear side: Contralateral
13 ETF Intact	Tympanometry, Frequency: 226 Hz Number of Measurements = 3 Ear side: Ipsilateral
14 ETF Perforated	Frequency during Testing: 226 Hz Duration of Signal: 30 s Ear side: Ipsilateral

Swedish Protocols

01 Tymp slow	Tympanometry, frequency: 226 Hz Ear side: ipsilateral Pressure change rate: 150 daPa/s
02 Tymp medium	Tympanometry, frequency: 226 Hz Ear side: ipsilateral Pressure change rate: 250 daPa/s
03 Tymp fast	Tympanometry, frequency: 226 Hz Ear side: ipsilateral Pressure change rate: 400 daPa/s
04 Tymp slow + Reflex Auto	Tympanometry, frequency: 226 Hz Pressure change rate: 150 daPa/s Number of reflexes tested = 4, frequencies: 0.5, 1.0, 2.0, 4.0 kHz Intensity Reflex Min (intensity in dB HL) = 70 Intensity Reflex Max (intensity in dB HL) = 95 Test frequency during reflexes: 226 Hz Ear side: Ipsilateral
05 Tymp medium + Reflex Auto	Tympanometry, frequency: 226 Hz Pressure change rate: 250 daPa/s Number of reflexes tested = 4, frequencies: 0.5, 1.0, 2.0, 4.0 kHz Intensity Reflex Min (intensity in dB HL) = 70 Intensity Reflex Max (intensity in dB HL) = 95 Test frequency during reflexes: 226 Hz Ear side: Ipsilateral
06 Tymp fast + Reflex Auto	Tympanometry, frequency: 226 Hz Pressure change rate: 400 daPa/s Number of reflexes tested = 4, frequencies: 0.5, 1.0, 2.0, 4.0 kHz Intensity Reflex Min (intensity in dB HL) = 70 Intensity Reflex Max (intensity in dB HL) = 95 Test frequency during reflexes: 226 Hz Ear side: Ipsilateral
07 Tymp slow + Reflex 85dB	Tympanometry, frequency: 226 Hz Pressure change rate: 150 daPa/s Number of reflexes tested = 4, frequencies: 0.5, 1.0, 2.0, 4.0 kHz Intensity reflex (intensity in dB HL) = 85 Test frequency during reflexes: 226 Hz Ear side: Ipsilateral

08 Tymp medium + Reflex 85dB	Tympanometry, frequency: 226 Hz Pressure change rate: 250 daPa/s Number of reflexes tested = 4, frequencies: 0.5, 1.0, 2.0, 4.0 kHz Intensity reflex (intensity in dB HL) = 85 Test frequency during reflexes: 226 Hz Ear side: Ipsilateral
09 Tymp fast + Reflex 85dB	Tympanometry, frequency: 226 Hz Pressure change rate: 400 daPa/s Number of reflexes tested = 4, frequencies: 0.5, 1.0, 2.0, 4.0 kHz Intensity reflex (intensity in dB HL) = 85 Test frequency during reflexes: 226 Hz Ear side: Ipsilateral
10 Reflex Screening 1 kHz 85dB	Number of reflexes tested = 1, frequency: 1.0 kHz. Intensity reflex (intensity in dB HL) = 85 Test frequency during reflexes: 226 Hz Ear side: Ipsilateral

7 Appendix

Literature

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