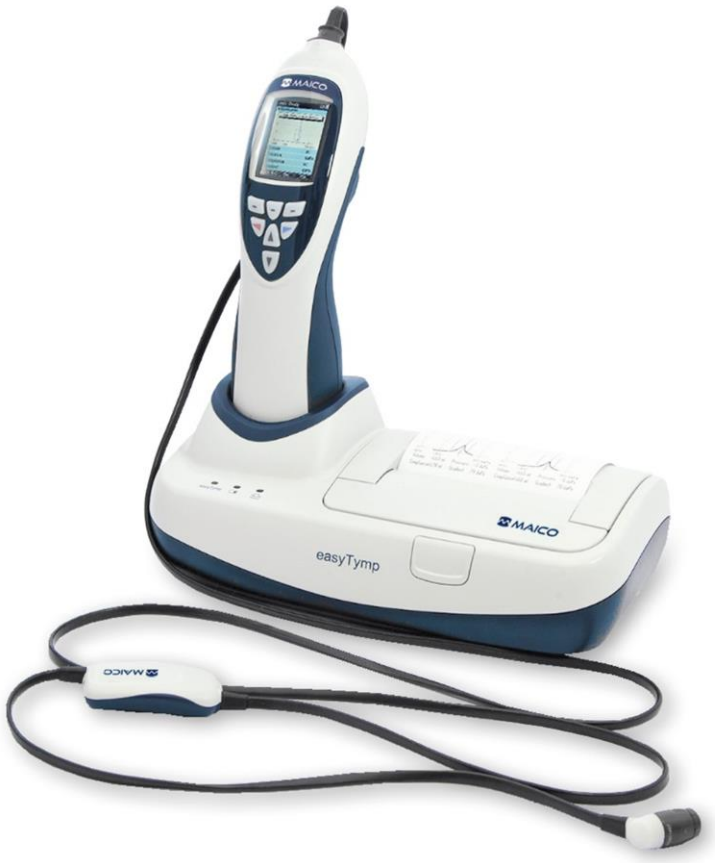
Operation Manual
easyTymp™



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Contents

Title: **easyTymp** – Operation Manual

EC REP

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Compliance

MAICO Diagnostics is an ISO 13485 certified corporation.

Trademark Notice

The easyTymp™ is a registered trademark. For a better readability the TM sign is not repeated throughout this manual.

1 Introduction

Thank you for purchasing a quality product from the MAICO product family. The easyTymp is designed and manufactured to meet all quality and safety requirements. When designing the easyTymp we placed particular importance on making it a user-friendly device. The intent was to make its operation easy to learn, thus making the device simple and easy to operate. This user manual is meant to make it as easy as possible for the operator to become familiar with the operation and functions of the easyTymp when performing tympanometry and acoustic reflex tests. If you have questions or suggestions for further improvements, please do not hesitate to contact us.

Your MAICO Team

NOTE: Although almost attention has been given to ensure the accuracy of the Operation Manual, some minor errors may still exist. We apologize for any inconvenience this may cause.

1.1 Intended Use

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

1.2 Indications for Use

The easyTymp is an electroacoustic test instrument 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.

1.3 Essential Performance

To generate and present stimulus signals in the audio range as specified in the applicable IEC 60645 series in normal conditions.

Absence of these performance features can lead to failure in diagnosis which is considered as an unacceptable risk to the patient. Temporary loss of essential performance is not considered an acceptable risk as long as the loss of performance is detectable. This could be the loss of power, fuse blow of system halt with error message.

1.4 Description

The easyTymp is an automatic middle ear analyzer intended to be used for objective testing the middle ear function and the factors that contribute to the occurrence of the hearing loss in the age range of infants, children and adults It is intended to be used by hearing healthcare professionals (i.e. ENT doctors, audiologists), and other trained personal such as medical technicians, neonatal and school nurses. The instrument is intended for professional use in a hospital, clinic, healthcare facility or other suitable quiet environment as defined in standard ISO 8253-1.

The purpose of the easyTymp test system is to provide a rapid tympanometry and acoustic reflex measurements to measure the middle ear status where a pass or refer notation is identified. easyTymp provides an optional 1 kHz probe tone for testing newborns. 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 physician should be administered if concerns about middle ear function persists.

The easyTymp cradle serves as a docking and recharging station for the handheld device and can include an integrated printer or opening for placement of the eartip box.

Using the included 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. Each version provides specific functionalities dependent upon the user needs.

easyTymp (as Standard Version)

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

easyTymp Plus Version (Contra probe required)

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

easyTymp Pro Version (Contra probe required)

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

2 For your Safety

2.1 How to read this Operation Manual

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

READ THIS ENTIRE MANUAL BEFORE ATTEMPTING TO USE THIS SYSTEM!

Use this device only as described in this manual.

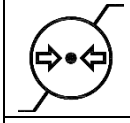
In this manual, the following two labels identify potentially dangerous or destructive conditions and procedures:

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 Regulatory Symbols

Symbol	Description
	Serial number
	Date of manufacture
	Manufacturer
	Caution, consult accompanying documents
	Return to authorized representative, special disposal required
	Reference number
	patient applied part type B according to IEC 60601-1
	Refer to instruction manual (mandatory)
	Read operation instructions
	Keep away from rain
	Transport and storage temperature range
	Transport and storage humidity limitations
	Transport and storage atmospheric pressure limitations
	Electrostatic sensitive sevices
	Do not reuse

Symbol	Description
EC REP	EU authorized representative
CE	Conforms to European Medical Device Directive 93/42/EEC
	Non-ionizing electromagnetic radiation
MAICO	Logo

2.3 General Precautions

Before measurement make sure, that the device works properly.

Do not immerse the unit in any fluids. For cleaning and disinfection see chapter 7 Cleaning and Disinfection Recommendations.

Use and store the instrument indoors only. For operation, storage and transport conditions see table in chapter Technical Data.

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

WARNING

No modification of this equipment is allowed.

Do not drop or otherwise cause undue impact to this device. If the instrument is dropped or otherwise damaged, return it to the manufacturer for repair and/or calibration. Do not use the instrument if any damage is suspected.

Calibration of the instrument: The audiometer and the headphone complement each other and share the same serial number (i.e. 7663252). Therefore, the instrument shall not be used with any other headphone prior to recalibration. Recalibration also needs to be conducted, when a defected headphone is replaced.

WARNING

Uncalibrated instruments may lead to faulty measurements and sometimes even damage the hearing of the examinee.

2.4 Electrical Safety and Measuring Security

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

The protection class of the system depends on the used power supply.

WARNING

In Case of Emergency

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

Do not position the instrument in a way that it is difficult to operate the disconnection device. The supply mains and the power socket shall be accessible at all times.

Do not use the instrument if the mains cable and/or the outlet is damaged.

WARNING

Safety against electrical hazard is guaranteed only when the connected notebook computer is powered by batteries respectively the computer´s power supply accords to the IEC 60601-1 or IEC 60950-1 safety regulations.

External devices such as computer, printer or Ethernet which are connected to the device must meet electrical safety requirements, such as IEC 60601-1 series for medical electrical equipment or IEC 60950 for IT equipment. This is to avoid electrical shock to the user or patient.

This complete system consisting of the MAICO device, computer and isolation transformer, is suitable for use in the patient environment. Equipment not complying with IEC 60601 shall be kept outside the patient environment, as defined in the standard (at least 1.5 m from the patient).

It is possible to use IEC 60601-1 certified USB and Ethernet insulators which allows the electrically safe use of electrical medical devices in medical electrical systems.

Any person who connects external equipment has created a system and is therefore responsible for the system complying with the requirements of IEC 60601-1-1. If in doubt, contact your service technician or local representative for help.

WARNING

The instrument is not intended for operation in areas with an explosion hazard.

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 instrument.

In order to maintain a high level of safety and to ensure the instrument works properly, it is necessary to have the instrument and its power supply checked according to the medical electrical safety standard IEC 60601-1 by a qualified service technician at least once a year. For more information please see Warranty chapter.

The use of non-calibrated devices can lead to incorrect test results and is not advisable.

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

Remove batteries both in the hand held unit and the cradle if the instrument will not be used for some time.

2.5 Device Control

The user of the instrument should perform an objective instrument check once a week according ISO 8253-1.

See chapter 4.3.1.11 Test cavities for volume check.

2.6 Electromagnetic compatibility (EMC)

The instrument fulfills the relevant EMC requirements. Avoid unnecessary exposure to electromagnetic fields, e.g. from mobile phones etc. If the device is used adjacent to other equipment it must be observed that no mutual disturbance appears.

Please also refer to EMC consideration in section Technical Data.

3 Impedance Measurements

3.1 Tympanometry

Tympanometry is the objective measurement of the tympanic membrane (TM) and middle ear mobility (compliance) and pressure within the middle ear system. During the test, a low-pitched probe tone (226 Hz) is presented to the ear canal by means of the hand-held probe. This tone is used to measure the change in compliance in the middle ear system while the air pressure is varied automatically from a positive value (+200 daPa) to a negative value (-400 daPa max.).

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 “limits” box is available on both the display and printout to aid in diagnosis.

Compliance is measured with respect to an equivalent volume of air, with the scientific quantity milliliter (ml) for 226 Hz and mmho for 1000 Hz. Air is measured in deca-Pascals (daPa).

NOTE: 1.02 mmH_2O = 1.0 daPa.

3.2 Acoustic Reflex

An acoustic reflex, or contraction of the intratympanic muscles, 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 acoustical reflex is referred to as an ipsilateral 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, 1000, 2000 or 4000 Hz are presented as short bursts. If a change in compliance greater than 0.03 ml 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).

3.3 Contralateral Acoustic Reflex

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 Contra Probe.

3.4 Acoustic Reflex Decay

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.

3.5 Eustachian Tube Function Test

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 test 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.

4 Getting Started

4.1 PC System Requirements

Processor:	Intel Dual Core 1,8 GHz
Memory:	2 GB RAM
Graphic display:	1280 x 1024 (optimal), mind. 1024 x 768
Operating system:	Windows 7, Windows 8.1, Professional or Ultimate Version for 32 und 64 Bit Computer
	.NET-Framework 3.5
	free USB port
Connection:	USB 1.1 or higher

4.1.1 Supported Software

Measuring module:	MAICO Impedance Software
Patient Management Software:	MAICO Database, GDT (Germany), NOAH 3, NOAH 4

4.2 Unpacking and Inspection

Check the packaging and content for damage.

Prior to shipping, the easyTymp was carefully packed and inspected. However, it is good practice to thoroughly inspect the outside of the shipping box for signs of damage. If any damage is noted, please notify the carrier immediately.

Please remove the MAICO instrument from the shipping box by lifting the cardboard package on the end flaps. Holding the package securely, fold the side flaps upwards to loosen the tension in the plastic film. The instrument can now be easily removed from the plastic packaging without the use of scissors or other sharp tools.

NOTE: Save all the original packaging material and the shipping container so the instrument can be properly packed if it needs to be returned for service or calibration.

Notify the carrier immediately if any mechanical damage is noted. This will insure that a proper claim is made. Save all packing material so the claim adjuster can inspect it as well. Notify your dealer or MAICO when the adjuster has completed the inspection.

Please check that all accessories listed on the next page have been received in good condition. If any accessories are missing or damaged, immediately notify your dealer or MAICO.

Standard Accessories:

(1) easyTymp Handheld Unit
(1) Probe
(1) Cradle Kit based on configuration
(1) Power supply unit for easyTymp handheld unit based on configuration
(1) DC USB adapter for easyTymp handheld unit based on configuration
(1) Rechargeable Battery
(1) Eartip box (configuration see below)
(1) Test Cavity
(1) Software Kit MAICO Impedance Software
(1) Operation Manual
(1) Quick Guide
(1) Carrying case
(1) Probe cleaning kit

Standard Configuration of Eartip Box:

(10) Eartip flanged 3-5 mm (red)
(10) Eartip mushroom 7 mm (blue)
(10) Eartip mushroom 9 mm (green)
(10) Eartip mushroom 11 mm (blue)
(10) Eartip mushroom 13 mm (green)
(5) Eartip mushroom 15 mm (blue)
(5) Eartip mushroom 19 mm (yellow)
(5) Eartip umbrella 15 mm (red)
(5) Eartip umbrella 19 mm (blue)
(2) Probe Tip (replacement)
(1) MAICO cleaning tool for probe tip
(1) MAICO eartip removal tool
(1) Allen key SW: s = 2 mm (See chapter 4.3.1.5 Adjust the cradle)

Cradle Kit

(1) Cradle with or without printer
(1) USB cable
(1) Power supply
(1) Rechargeable battery
(1) Roll of paper (with printer cradle)

Optional Accessories for easyTymp:

- External Probe (35cm)
- Wall Mount Kit for cradle with integrated eartip box, power supply unit and additional rechargeable battery

Additional Accessories for easyTymp Plus and Pro Version:

- Contra Probe (140 cm)
- CIR55 (Contralateral Earphone)
- EARtone 3A (Contralateral Earphone)
- DD45 (Contralateral Headset)
- Quick Guide (Pro or Plus Version)

Additional Licenses:

- License for high frequency probe tone of 1 kHz
- License for contra reflexes
- License for acoustic reflex decay and ETF

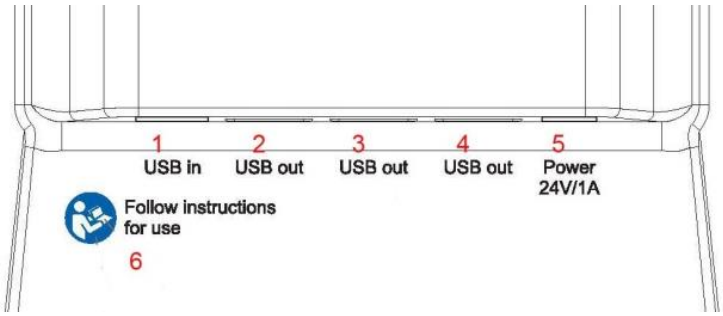
Consumable Material:

- Printer paper
- Replacement eartips
- Probe tip
- Cleaning floss

4.3 System Installation

4.3.1 Hardware Installation

4.3.1.1 Installing the Cradle



1 = USB in;

2 = USB out;

3 = USB out;

4 = USB out

5 = Power;

6 = Follow the instructions for use

Figure 1

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

4.3.1.2 Cradle Indication Lights

Depending on the version (with or without printer) the cradle has up to three indication lights (Figure 2).

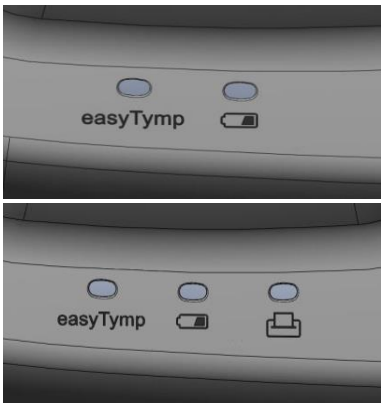


Figure 2

- 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 three 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.
- Printer LED is red when a printer problem occurs.

4.3.1.3 Installing Paper in the Thermal Printer

Figure 3

Step 1 – Push button to open the printer cover (Figure 3).

Figure 4

Step 2 – Pull the blue lever upwards (Figure 4).

Figure 5

Step 3 – Insert paper roll into the compartment with its loose end to the front of the printer. Position the loose end into the printer roll and raise it by rotating the printer roll with your finger (Figure 5).

Figure 6

Step 4 – Push the blue lever down (Figure 6).

Figure 7

Step 5 – Close the printer cover (Figure 7).

4.3.1.4 Mounting the Cradle on the Wall (optional accessory)

Figure 8

In order to mount the cradle on the wall, an optional wall mount kit is available (Figure 8).

4.3.1.5 Adjust the Cradle

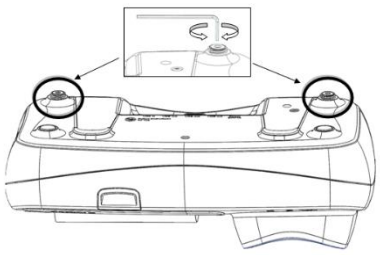


Figure 8.1

Use the allen key to adjust the cradle on the table (Figure 8.1).

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

Please 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.

4.3.1.6 Installing the easyTymp Battery

Figure 9

The battery compartment is opened by gently pressing the indentation and pushing the cover downwards (Figure 9).

Figure 10

Place the battery inside the compartment. Making sure the battery contacts are correctly placed (Figure 10).

The removal-tab, attached to the back of the battery case, should be placed on the top of the battery to remove the battery easily (Figure 11).

Figure 11

Figure 12

Replace the lid on the easyTymp and push it upwards to close the battery compartment (Figure 12).

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

4.3.1.7 Charging the Battery

Figure 13

NOTE: Please note that the battery needs to be charged for a minimum period of approximately 6 hours prior to first use of the easyTymp hand-held Tympanometer (Figure 13). To charge the battery please place the easyTymp into the cradle and connect the cradle to the mains power with the use of the easyTymp power supply provided.

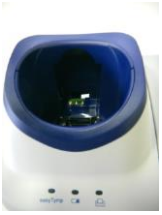


Figure 14

The spare battery is stored and charged in the back of the cradle (Figure 14). Battery LED will show solid blue when the spare battery in the cradle is fully charged. The LED will flash as long as the battery is charging.

Please observe the following precautions:

- 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 charger provided with the easyTymp
- Please see the following section for estimated charging times.

4.3.1.8 Battery Life

The following table gives an estimate of the charging time (CT) in hours for the battery. Be aware that negative numbers mean that the battery is discharging. Charge times are the same for the spare battery in the cradle and the battery in the cradled easyTymp.

	CT through cradle up to 80 %	CT through USB (PC) up to 80 %	CT through cradle up to 100 %	CT through USB (PC) up to 80 %
Off	1.5	3.8	2.3	5.7
On (pump off)	2.8	-32	4.1	-47

4.3.1.9 Changing Probes

Figure 15

To release the probe, press the circular button on the back of the instrument and pull the probe out (Figure 15).

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

Figure 16

Connect the probe to the easyTymp by lining up the red triangles and pushing the probe into the unit (Figure 16).

Figure 17

The probe can be attached to the extension cable by correctly lining up the pins and clicking the probe into the end of the extension cable (Figure 17).

4.3.1.10 easyTymp Plus and Pro Version: Connecting the Contralateral Headphone or Insert Phone

Figure 18

To measure contralateral reflexes it is necessary to connect the Contra Probe to the easyTymp as described previously.

Find the jack labeled “Contra” on the Contra Probe. Insert the contralateral transducer into this jack (Figure 18).

The Contra Probe must be calibrated to the selected contralateral transducer type. This calibration is already completed if the Contra Probe and transducer are purchased at the same time. Otherwise the Contra 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 phones need to be calibrated to the Contra Probe before use. If a new contra phone should be used a recalibration of the Contra Probe is necessary. We strongly advise against using an uncalibrated Contra Phone! Uncalibrated instruments may lead to faulty measurements and possibly damage the patient's hearing.

4.3.1.11 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 exchanged at all times.

4.3.2 Software

You can view and store all your measurements with the MAICO Impedance Software Module through Noah or the MAICO Database.

NOTE: For installation and functions see the software manual.

4.4 Preparing the Test

4.4.1 Patient Instruction

Make sure that the patient is comfortably seated in a chair or on an examination table if necessary. Small children may feel more comfortable sitting on a parent's lap. Show the probe to the patient and then explain the following:

"The aim of the test is to test the mobility of the eardrum. The tip of the probe will be inserted into and seal the ear canal. A small amount of air will flow through the probe to move the eardrum; 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. Please remain as still as possible as coughing, talking and swallowing will interfere with test results."

4.4.2 Visual Inspection of the Ear Canal

Otoscopic examination of the patient's ear canals should be performed prior to testing. Excessive cerumen or vernix in the ear canals may interfere with the test and give invalid or incomplete results. Patients with excessive cerumen, debris, or foreign bodies in the ear canals should be referred to an audiologist or physician for removal of the blockage prior to testing. Excessive hair may need to be trimmed.

4.4.3 Handling the Eartips

Following otoscopy select an eartip of the appropriate size for the patient's canal size and shape from the eartip kit, and press the eartip tightly onto the probe tip.

Selection of the appropriate eartip is necessary for the measurement to be completed. Within the included eartip box, there are multiple sizes for selection as well as 2 distinct shapes, Umbrella and Mushroom. Maico recommends the use of the Umbrella eartip for screening purposes. The Umbrella eartip is never inserted into the ear canal but the examiner holds the probe/eartip in place at the entrance of the ear canal. The eartip must cover the entire ear canal opening for a seal to be maintained during the test. The Tester will select the appropriate size of eartip by gently pulling the ear up and back to straighten the ear canal and an estimation of the correct eartip size can be made.

Umbrella Eartip

Mushroom Eartip

Figure 19

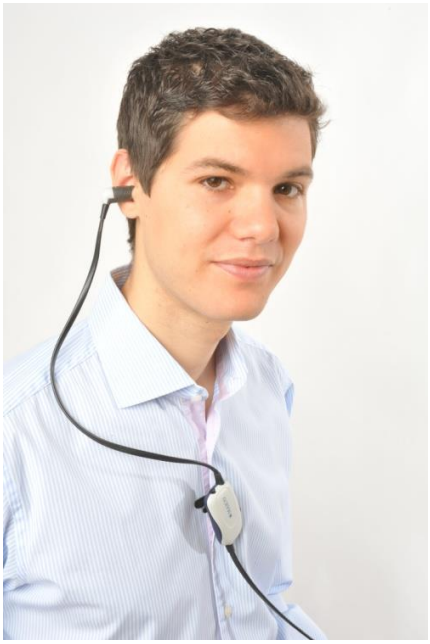
When using the Contra Probe for diagnostic testing, the Mushroom eartip must be used. The Tester will select the appropriate size of eartip by gently pulling the ear up and back to straighten the ear canal and an estimation of the correct eartip size can be made. Hold the probe, aim and twist (gently) the eartip into the ear canal. Release the ear and the probe when testing is to begin. The probe should not be touched until the testing is completed. The Mushroom eartip will provide a seal within the ear canal (Figure 19).

WARNING

Discard single-use equipment after use! In case of re-use of the single-use equipment you enhance the risk of cross contamination!

Always use eartips from MAICO or Sanibel.

4.4.4 easyTymp Plus and Pro Version: Placing and Using the Contra Probe



A clip is located on the back of the Contra Probe which can be attached to the patient's clothing (Figure 20). For most patients it is easiest to clip the Contra Probe to the patient. When a child is being held by a parent, clip the Contra Probe to the parent's clothing.

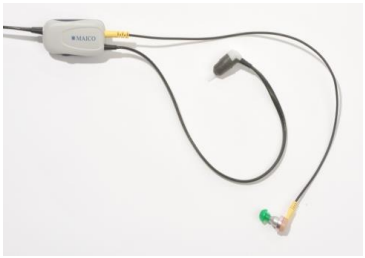
Figure 20

Press the button on the Contra Probe to start or stop/pause the current measurement or switch between right and left when the probe is not inserted to the ear (Figure 21).

Figure 21

4.4.5 easyTymp Plus and Pro Version: Placement of the Contralateral Phones

Multiple transducers are available for purchase to perform contralateral measurements.



If the CIR55 insert phone is used, place the proper eartip on the insert before inserting the phone into the non test-ear (Figure 22).

Figure 22

If the DD45 is used, place the head band over the patient's head. The audiometric headphone is placed over the non test-ear (or contralateral reflex ear).

Figure 23

4.5 Operating Panel

Figure 24

Function Keys:

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.

4.6 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.

To switch easyTymp off, press both red and blue arrow keys together and hold for one second.

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.

4.7 Probe Status Indication

If you use the optional external probe the light at the back of the probe indicates the probe status with the following colors (Figure 25):

Figure 25

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 in hand held 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 Operating easyTymp

Operating the easyTymp is very intuitive. After switching the instrument 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 shut down the instrument 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. Please change the battery to proceed.

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

5.1 Test

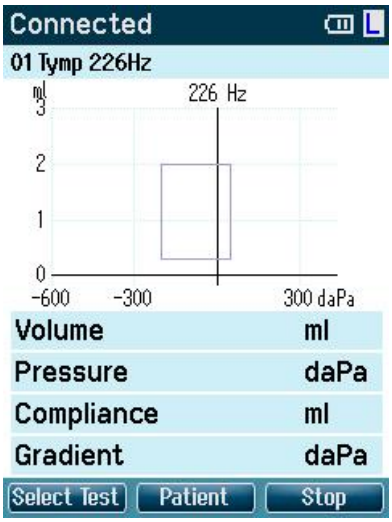


Figure 26

Usually the easyTymp starts with the Test Screen. When deleting or saving data after a measurement, you will also return to this screen (Figure 26).

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.

The header shows the status of the probe. It might show **Ready, In Ear, Leaking** or **Blocked**.

- 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  or right ear  .

- 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 **Patient** screen where patient data can be viewed or changed and earlier sessions can be reviewed and/or printed. This function is only displayed if the patient management is activated.
- Stop**:** Top right button will interrupt the test and **Done!** will appear in the upper left hand corner of the screen. When the measurement is stopped the top buttons will change to give the option to print or delete.
- 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.

When the probe is in an ear the button will interrupt the testing and bring you to the **Done!** screen. To return to the **Test** screen, press print, save or delete results.

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

5.2 Select Test Screen

Figure 27

To change the selected protocol press “**Select**” (Right Top Button). The following measurements are available in the standard easyTymp (Figure 27):

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. Not active protocols are ghosted.

Operating from this screen:

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

5.3 Done

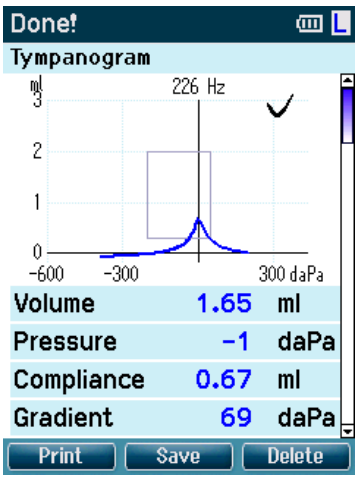


Figure 28

easyTymp will automatically go to the **Done!** screen when it has finished testing (Figure 28).

From here, measurements of both ears can be reviewed, printed and/or saved. Of course, you can also directly start a new measurement in the Test screen from here.

Operating from this screen:

- Print **:** Top left button will print the test results of the left and right ear. Note that there should be a connection to the printer by placing the easyTymp in the cradle.
- Save **:** Top middle button will save the measurement of both ears.
- Delete **:** Top right button will present a popup message 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.

5.3.1 Advanced Testing: easyTymp Plus and Pro Version

Acoustic Reflex Testing (Ipsi and Contra)

Figure 29

Before performing ipsilateral and contralateral reflex testing tympanometry will be performed (Figure 29).

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

5.3.2 Advanced Testing: easyTymp Pro Version

Acoustic Reflex Decay

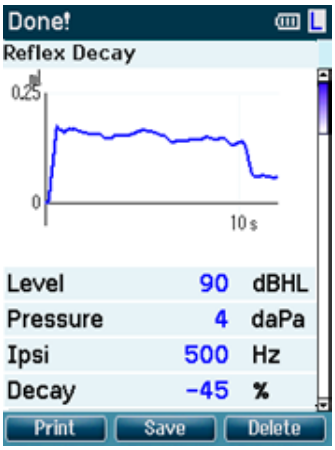


Figure 30

Ipsilateral and Contralateral Reflex Decay Testing can be performed (Figure 30).

ETF Testing

- Intact

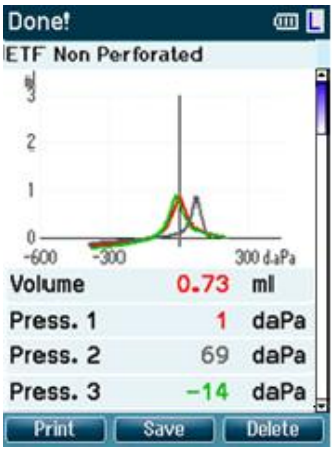


Figure 31

Instructions for testing will be displayed at the top of the screen (Figure 31).

(1) Red or Blue: represents test ear

(2) Grey: represents “Valsalvation”

(3) Green: represents “Swallow”

- Perforated

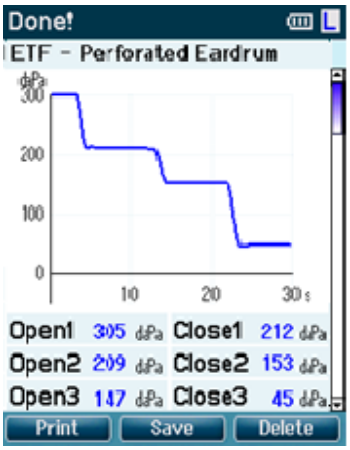


Figure 32

Instruct patient to swallow.

Measurement of changing pressure indicates status of Eustachian tube (Figure 32).

5.4 Select Patient & Save

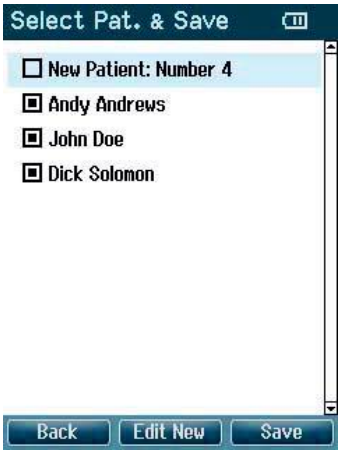


Figure 33

Patient From this screen you can either save data to an existing patient or save data to a new client (Figure 33). New patient will always get the name “New Patient: Number #”, where # is always the next available number.

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 client. 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 client list respectively.
- buttons scroll up or down as one client's information is viewed.

5.5 Edit New

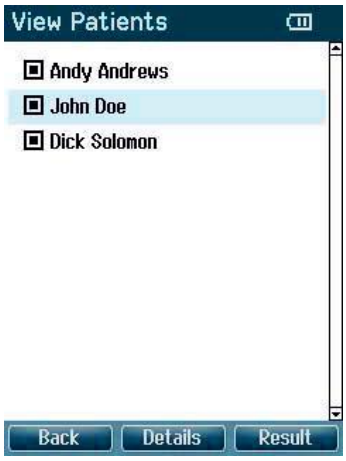
With this screen you can input data for a new client before saving the measurement (Figure 34).

Figure 34

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.

5.6 View Patients



This screen shows a list of clients (Figure 35).

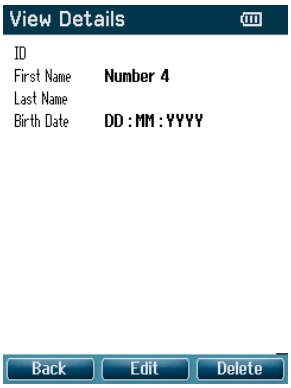
When one or more sessions are stored, the square in front of the patient's name is filled. If a session is not stored yet, this square will be empty.

Figure 35

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 client is shown.
- Result will bring you to the **View Sessions** screen where the available sessions of the selected client can be reviewed and printed.
- will bring you to the top or bottom of the client list respectively.
- buttons scroll up or down as one client's information is viewed.

5.7 View Details



This screen shows demographics of the selected client (Figure 36).

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

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

Figure 36

5.8 Edit Details

Figure 37

This screen shows the client ID, First Name, Last Name and Birth Date (Figure 37).

Operating from this screen:

- Back brings you back to the **View Details** screen.
- Select will select 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 will select 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.

5.9 View Results

View Results – select session

Figure 38

For the selected client, the screen shows a list of available sessions (Figure 38).

Operating from this screen:

- Back button brings you back to the **View Patient** screen.
- Delete will prompt you and ask for confirmation before it deletes the selected session or all sessions.
- View will show the selected session in the **View Results** screen (see Figure 39).
- ◀ ▶ buttons will bring you respectively to the top or bottom of the result list.
- ▲▼ buttons scroll up or down one session

View Results – show results

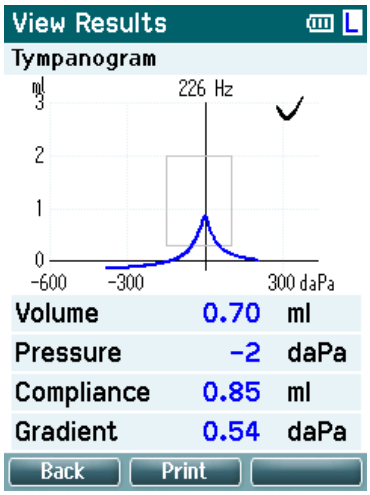


Figure 39

In this screen the test recordings of the selected session are shown (Figure 39).

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.

5.10 Setup

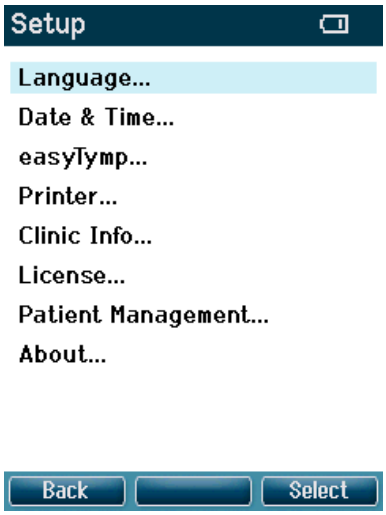


Figure 40

To change the Setup of the easyTymp navigate from Test screen to Select test and then to easyTymp (Figure 40).

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.

5.10.1 Setup Language

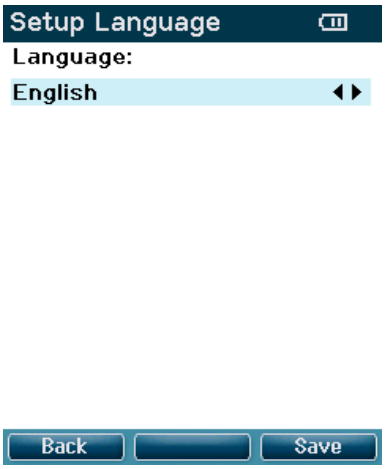


Figure 41

Use right and left arrow keys to adjust language (Figure 41). Available languages are English, German, Spanish, French, Italian, Chinese, Japanese and Polish.

5.10.2 Setup Date & Time

Figure 42

arrow keys will scroll through the options (Figure 42).

buttons adjust Date, Date format and Time.

5.10.3 Setup easyTymp

will scroll through the options. buttons to adjust selection (Figure 43).

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

The **Power Off** can be set to “Never” or from 1 to 10 minutes.

Show Pass/Fail: If “On” the test result will display with a Pass / Fail symbol depending on Normative Values defined internally

Show Calibration Warning: When “On”, calibration reminder will display on device, when turned on

Figure 43

Reflex Presentation: Negative or Positive deflection in the graphs

5.10.4 Setup Printer

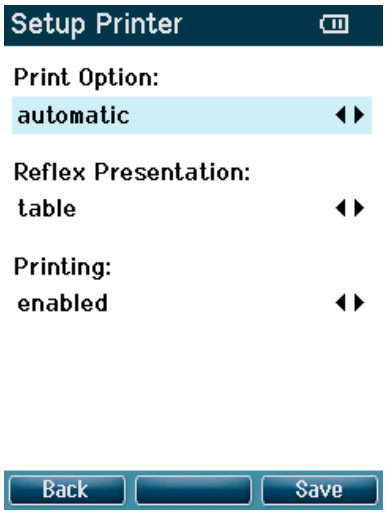


Figure 44

buttons will scroll through the options (Figure 44). buttons to adjust selection.

Print Options: automatic or manual.

Reflex Presentation: table or graph.

Printing: enabled or disabled.

5.10.5 Setup Clinic Info

Figure 45

Use Up, Down, Right and Left arrow keys to move the cursor over the keyboard (Figure 45).

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

Next to select the next details for editing.

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

5.10.6 Setup License

Figure 46

Option to buy licenses to unlock further measurements (Figure 46):

Select**:** By pressing the Top right button you can select the module to view, add or change the license key.

NOTE: License should be modified by the licensed distributor only.

Figure 47

Use Left, Right, Up and Down arrow keys to move the cursor over the keyboard (Figure 47).

Select**:** The top middle button will select the highlighted character. Backspace is an arrow in the top right corner. Space is a bar underneath the keyboard.

Save**:** The top left button will save and return to the **Setup** screen

5.10.7 Setup Patient Management

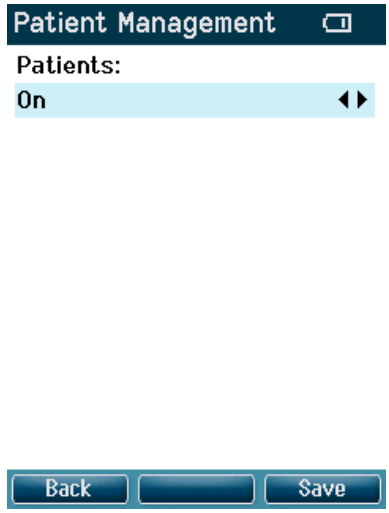


Figure 48

Turns the internal patient data management “on” or “off” (Figure 48).

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

5.10.8 About

About displays the firmware version and calibration dates (Figure 49).

Figure 49

5.11 easyTymp Plus and Pro Version: Contra Probe Button

The Contra Probe button will change ears as long as 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 Contra Probe button results in continuing the protocol, no matter what the probe status.

6 Connecting to a PC

1. Choose which database you will be using for storing patient data.
    a. If using NOAH, make sure this is installed on your computer.
    b. If using Maico Database, install the program titled “MAICO Database” included on the disc.
2. Next, make sure all programs are closed.
3. Insert disc and choose appropriate module to install according to the database you are using:
    a. If using NOAH, install the “easyTymp module for NOAH.”
    b. If using the Maico Database, install “easyTymp module for Maico Database.”
4. Follow on-screen directions for installation.
5. Next, open the database you are using (either NOAH or Maico Database).
6. Open the easyTymp module from the database.
7. Select “Extras→Settings” from the menu bar.
8. Select “USB: easyTymp communicator,” then press “OK”. Keep the easyTymp module open.
9. In easyTymp handheld device, select “select test”→”easyTymp”→”Patient Management”→”select.” Make sure this setting is “Off” then press “Save.”
10. In easyTymp handheld device, select “select test”→”easyTymp”→”Printer”→”select.” Make sure this setting is on “Manual” then press “Save.”
11. Connect USB cord to easyTymp cradle and connect the other end of USB to the computer.
12. Follow any prompts on the screen to load drivers.
13. Perform a tymp test and press “Save”
14. Place in cradle.
15. Test should download to module and display on computer screen.

7 Cleaning and Disinfection Recommendations

7.1 General Recommendations

It is recommended that parts (device and accessories like extended probe or contraphones) which come in direct contact with the patient be subjected to standard cleaning and disinfecting procedure between patients. Please disinfect the instrument and its accessories in dependence on the specific existing infection potential.

Recommendations for cleaning and disinfection of MAICO device presented in this document are not intended to replace or contradict policies in effect or procedures required for infection control at the facility.

If there is not a high infection potential, MAICO recommends:

- Before cleaning always switch off and disconnect the device from power supply
- For cleaning use a lightly dampened cloth with soap water solution
- Disinfect the instrument and its accessories by wiping the surfaces with wet Sani-Cloth® Active wipes or a comparable product and allow them to take effect for the duration related to the specific disinfection aim listed in product data sheet of the disinfection product. Please follow also its instructions for cleaning.
    - Wipe before and after each patient
    - After contamination
    - After infectious patients
- Disinfect computer, keyboard, transport trolley etc. with Sani-Cloth® Active wipes:
    - once a wee
    - after contamination
    - when polluted

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

- Do not autoclave or sterilize
- Do not use the device in the presence of fluid that can come into contact with any of the electronic components or wiring.

Should the user suspect fluids have contacted the system components or accessories, the unit should not be used until deemed safe by a MAICO certified service technician.

- Do not use hard or pointed objects on the device or its accessories
- Use 70% isopropyl alcohol only on hard cover surfaces

WARNING

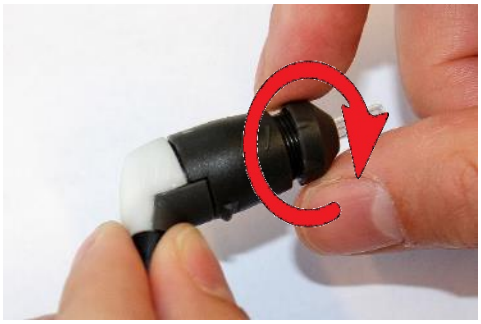
Discard single-use equipment after use! In case of re-use of the single-use equipment you enhance the risk of cross contamination!

7.2 Cleaning the probe tip

In order to secure correct impedance measurements it is important to make sure that the probe system is kept clean at all times. Therefore please 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 please follow the illustrated instructions below.

Never clean the probe tip while the tip is still attached to the probe (Figure 50).

Figure 50



1. Unscrew the probe cap by turning it in a counter clockwise direction (Figure 51).

Figure 51

2. Take the plastic probe tip out of the probe (Figure 52).

Figure 52

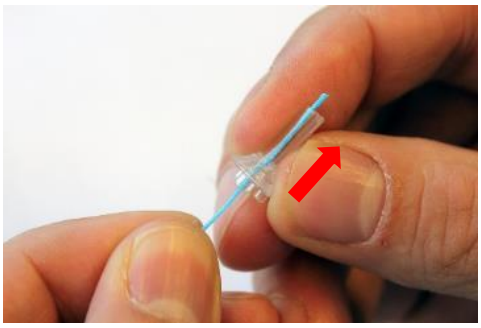


Figure 53

3. 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 53).

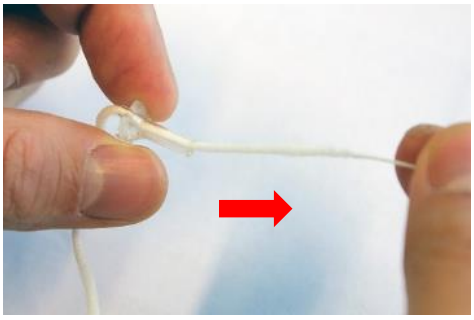


Figure 54

4. Proceed in the same way with all 4 probe channels. Use the floss only once (Figure 54).

Figure 55

5. Place the probe tip back onto the probe. Make sure that the plastic pegs are inserted into the appropriate corresponding cavities (Figure 55).

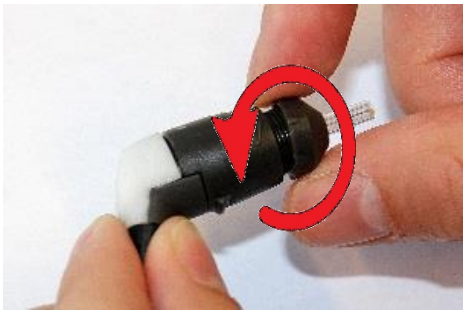


Figure 56

6. Screw the probe cap back on the probe (Figure 56). 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:

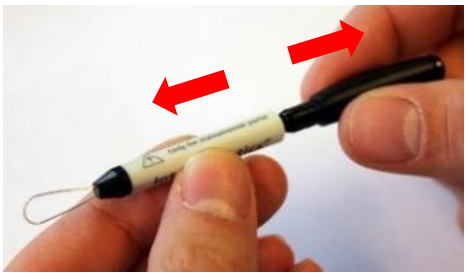


Figure 57

Use the cleaning set from the eartip box (Figure 57): Take the cleaning tool apart to find the thin brush and thin rigid plastic cord (Figure 58).

Figure 58

Figure 59

Use the plastic cord or brush to push debris out of the probe tip (Figure 59). Always enter the probe tip from the rear to avoid accumulation of debris inside the vents (Figure 60).

Figure 60

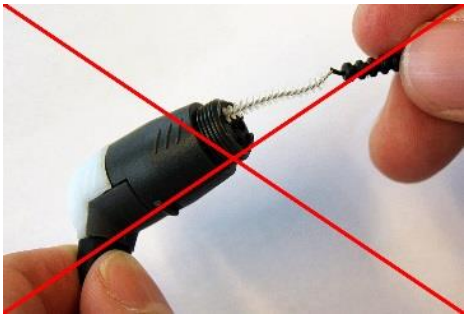


Figure 61

CAUTION

This procedure destroys the probe (Figure 61).

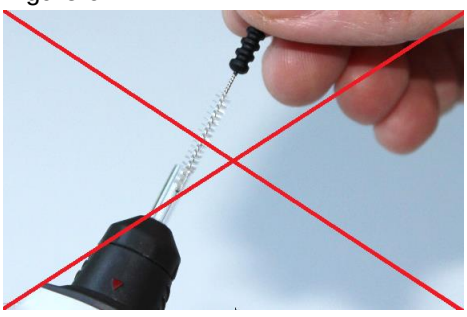


Figure 62

CAUTION

This procedure destroys the probe (Figure 62).

8 Warranty, Maintenance and After-Sales Service

8.1 Warranty

The MAICO device is guaranteed for 2 years.

This warranty is extended to the original purchaser of the instrument by MAICO through the distributor from whom it was purchased and covers defects in material and workmanship for a period of two years from date of delivery of the instrument to the original purchaser.

The device shall only be repaired and serviced by your distributor or by an authorized service center. Opening the instrument case will void the warranty.

No modification of this equipment is allowed.

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

In order to ensure that the instrument works properly, it has to be checked and calibrated at least once a year.

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

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

8.2 Recycling and Disposal

Within the European Union it is illegal to dispose of electric and electronic waste as unsorted municipal waste. According to this, all MAICO products sold after August 13, 2005, are marked with a crossed-out wheeled bin. Within the limits of Article (9) of DIRECTIVE 2002/96/EC on waste electrical and electronic equipment (WEEE), MAICO has changed their sales policy. To avoid additional distribution costs we assign the responsibility for the proper collection and treatment according to legal regulations to our customers.

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

9 Technical Specifications

9.1 Classification according EEC

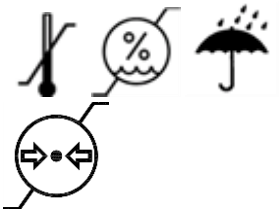
CE 0123

The device is graded as active diagnostic medical product in class IIa, see also rule 10 of the 93/42/EEC (Appendix IX).

9.2 Technical Data

The easyTymp is an active, diagnostic medical product according to the class IIa of the EU medical directive 93/42/EEC.

Approval of the quality system is made by TÜV – identification no 0123.

Standards:	Safety:	IEC 60601-1, Class II, Type B
	EMC:	IEC 60601-1-2
	Impedance:	IEC 60645-5/ANSI S3.39, Type 2
	Normative Box:	e.g. Appendix A
Power, UE24WCP-240100SPA	Consumption:	0.6 A
	Mains voltages and fuses:	100 – 240 VAC, 50 – 60 Hz
Power, easyTymp	Fuses:	3 A (5 V)
Power, Cradle	Fuses:	3 A (24V)
Environment Conditions: 	Operation	+15 °C … +35 °C / +59 °F … +95 °F Humidity: 30 % … 90 %, non-condensing Air pressure 98 kPa … 104 kPa[1] Maximum altitude: 2000 m / 6561 ft above sea level
	Storage	0 °C … +50 °C / +32 °F … +122 °F Humidity: 10 % … 95 %, non-condensing
	Transport	-20 °C … +50 °C / -4 °F … +122 °F Humidity: 10 % … 95 %, non-condensing

[1] Environment conditions during operating according 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.

Dimension and weight	Dimension	W x D x H: 80 x 300 x 70 mm / 3.15” x 11.81” x 2.76”
	Weight	427 g / 1 lb
Warm-up time		less than 10 minutes

Impedance Measuring System

Probe tone:	Frequency:	226 Hz, 1000 Hz
	Level:	69 dB HL with AGC, assuring constant level at different ear canal volumes.
Air pressure:	Control:	Automatic.
	Indicator:	Measured value is displayed on the graphical display.
	Range:	-400 to +200 daPa.
	Pressure limitation:	-750 daPa and +550 daPa.
Compliance:	Range:	0.1 to 8.0 ml at 226 Hz probe tone (Ear volume: 0.1 to 8.0 ml) and 0.1 to 15 mmho at 1000 Hz probe tone.
Test types:	Tympanometry	Automatic.
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 Hearing Level.
Memory:	Tympanometry:	1 curve per ear, per tympanometry test. And theoretically an infinite number of tests per protocol.

Reflex Functions

Signal sources:	Tone - Ipsi, Reflex:	500, 1000, 2000, 4000 Hz, max. 100 dB $_{HL}$.
	Noise - Ipsi, Reflex:	Broad-band noise (BBN)
	Tone - Contra, Reflex:	500, 1000, 2000, 4000 Hz, max. 100 dB $_{HL}$.
	Noise - Contra, Reflex:	Broad-band noise (BBN)
Outputs:	Ipsi Earphone:	Probe earphone incorporated in the probe system for Reflex measurements.
	Contra Earphone:	Probe earphone incorporated in the probe system for Reflex measurements.
	Air:	Connection of the air system to the probe.
Test types:	Automated Reflex	Automatic reflexes: Single intensities Single 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 ± 2%
Test level:	Ipsilateral:	70 to 110 dB HL
	Contralateral:	70 to 120 dB HL
Control acoustic reflexes:	Automatic	Single intensities Reflex growth
Time range:	0 to 12 s	
Volume Range:	-0.05 to 0.25 ml	
Graphical display:	y-axis: Volume in ml x-axis:Time in s Level in dB HL	
Ipsi earphone:	Earphone integreted in probe	

ETF – Intact

Same specification as tympanometry, expect only one test signal (226 Hz).

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.	
Distortion:	Max 5 % THD	
Control tympanometry:	Automatic	
Time range:	0 to 30 sec. (settings)	
Pressure range:	0 to 400 daPa	
Accuracy:	Compliance:	±5% or ±10 daPa, whichever is greater
	Pressure:	±5% or ±0.1 ml, whichever is greater
Graphical display:	x-axis: Time in sec. y-axis: Pressure in daPa	

General		
PC connection	USB:	Input/output for computer communication.
Memory:		Theoretically an infinite amount of test results can be stored on the PC. The easyTymp hand held unit is delivered with a 2 GB memory card, enough for storing more than a quarter of a million tests.

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 instrument is made and calibrated to be within and better than the tolerances required in the specified standards:
	Reflex Frequencies:	±3%
	Ipsilateral Reflex Tone Levels:	±5 dB for 500 to 2000Hz and +5/-10 dB for 3000 to 4000Hz
	Contralateral Reflex Tone Levels:	±5 dB for 500 to 2000Hz and +5/-10 dB for 3000 to 4000Hz
	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.
	Distortion:	Max 5% THD
Compliance	Range:	0.1 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%
Pressure	Range:	- 400 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	
Ipsi- and Contra-	Pure tone:	±3 dB
lateral Earphone	Broad-band noise (BBN):	MAICO Standard
	Spectral properties:	As “Broad-band 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 eardrum 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

9.3 Connections and Pin Assignment

Inputs	Connector Type	Pin Assignment	
USB	USB Type „B“	USB port for communication	
power	Mains cable	DC socket 24 V/1 A	
Outputs	**Connector Type**	**Pin Assignment**	
USB	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

9.4 Reference values for stimulus calibration

Table 1

Reference equivalent threshold sound pressure level [dB re. 20 μPa]			
Hz	CIR55	DD45	IOW Probe
125	26	47.5	41.0
250	14	27.0	24.5
500	5.5	13.0	9.5
1000	0.0	6.0	6.5
1500	2.0	8.0	5.0
2000	3.0	8.0	12
3000	3.5	8.0	11
4000	5.5	9.0	8.0
6000	2.0	20.5	5.5
8000	0.0	12.0	-0.5
WB	-5.0	-8.0	-5.0
LP	-7.0	-6.0	-7.0
HP	-7.0	-10.0	-8.0

Coupler types used by calibration

IOW Probe (easyTymp) and CIR55 are calibrated using an IEC 60380-5 (2cc) acoustic coupler made in accordance to IEC 60318-5.

DD45 are calibrated using a 6cc acoustic coupler made in accordance to IEC60318-3.

9.5 Electromagnetic Compatibility

The device fulfils the relevant EMC requirements. Precautions should be taken to avoid unnecessary exposure to electromagnetic fields, e.g. from mobile phones etc. If the device is used adjacent to other equipment it must be observed that no mutual disturbance appears.

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.

<table>
<tr><td colspan="3">Guidance and manufacturer’s declaration - electromagnetic emissions</td></tr>
<tr><td colspan="3">The easyTymp is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions Test</td><td>Compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The device 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The device is suitable for use in all commercial, industrial, business, and residential environments.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Complies
Class A Category</td></tr>
<tr><td>Voltage fluctuations /flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Recommended separation distances between portable and mobile RF communications equipment and the easyTymp.

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device 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 2.5 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 device is 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	+6 kV contact +8 kV air	+6 kV contact +8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.
Electrical fast transient/burst IEC 61000-4-4	+2 kV for power supply lines +1 kV for input/output lines	+2 kV for power supply lines +1 kV for input/output lines	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	+1 kV differential mode +2 kV common mode	+1 kV differential mode +2 kV common mode	Mains power quality should be that of a typical commercial or residential environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	< 5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70% UT (30 % dip in UT) for 25 cycles <5 % UT	Mains power quality should be that of a typical commercial or residential environment. In case of a power failure the device will automatically shut down within 10 s. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptable power supply or its battery.
Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.
Note: UT is the A.C. mains voltage prior to application of the test level.			

<table>
<tr><td colspan="4">Guidance and manufacturer’s declaration — electromagnetic immunity</td></tr>
<tr><td colspan="4">The easyTymp is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC 60601
test level</td><td>Compliance level</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td></td><td></td><td></td><td>Portable and mobile RF communications equipment should be used no closer to any parts of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance:</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz</td><td>3 Vrms</td><td>$d = 1{,}2\sqrt{P}$</td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2,5 GHz</td><td>3 V/m</td><td>$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz
$d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz</td></tr>
<tr><td></td><td></td><td></td><td>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:
  </td></tr>
<tr><td colspan="4">NOTE 1 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.</td></tr>
<tr><td colspan="4">[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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

10 Test Protocols

01 226Hz	Tympanometry, Frequency: 226 Hz Earside: Ipsilateral
02 1kHz	Tympanometry, Frequency: 1 kHz Earside: 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 Earside: Ipsilateral
04 226Hz + Ipsi Reflex 90dB	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 Earside: 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 Earside: Ipsilateral
06 1kHz + Ipsi Reflex 80dB BB	Tympanometry, Frequency: 1 kHz Number of Reflexes tested = 1, Test signal: Broad-band noise Intensity Reflex (Intensity in dB HL) = 80 dB Earside: 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 Frequency during Reflexes: 226 Hz Earside: 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 Earside: 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 Earside: Ipsi- and Contralateral
10 1kHz + Ipsi-Contra 80dB BB	Tympanometry, Frequency: 1 kHz Number of Reflexes tested = 2, Test signal: 80 Broad-band noise Intensity Reflex (Intensity in dB HL) = 80 dB Earside: 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) = 100 Duration of Signal: 10 s Earside: 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) = 100 Duration of Signal: 10 s Earside: Contralateral
13 ETF Intact	Tympanometry, Frequency: 226 Hz Number of Measurements = 3 Earside: Ipsilateral
14 ETF Perforated	Frequency during Testing: 226 Hz Duration of Signal: 30 s Earside: Ipsilateral

11 Troubleshooting

Issue	Solution
White Screen	If the device shows white screen after turning on, make sure battery is fully charged.
Frozen Display	If the display freezes try ○ to restart the unit ○ to shut off the system and change the battery
	NOTE: Please do not take out the battery before turn off. Always turn off the device and then take out the battery.
Battery cavity	- Please check that the battery is properly inserted into the compartment. - Please check that the battery connector (spring contacts) inside the compartment is clean and working properly.
Probe	Make sure the probe tip is inserted correctly into the probe. Otherwise, follow the suggestions in Probe tip.
Probe tip	1. Please clean the probe tip as described in the manual. 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. Change the complete probe and check if the system is running.
Extension cable	If the device shows leaking, please 1. Follow the suggestions for probe tip/ Probe. 2. If step 1 is not helpful, please change the extension cable. If the problem persists follow the suggestions for Probe tip/Probe.
Battery slot	1. If the spare battery is not charging, please, check if the battery is properly inserted and the terminals are in contact (springs in cradle). 2. Please make sure the battery contacts are clean in the case.
Connection in cradle	1. Make sure the handheld is properly inserted after the test. Improper docking may lead to no connection between device and the cradle. 2. Please make sure battery contacts are clean in the case.
Printer problem	1. Please check if the cradle is connected with power supply. 2. Please check if the printer function is activated in the device. 3. Please check if the printer paper is properly inserted. 4. Properly place the handheld on the cradle.

5. When during printing process the 2nd battery is charged also, take the 2nd battery out of cradle and try again.

PC Connections

1. Make sure the Patient database and the printer is deactivated from handheld.
2. Handheld:
    a. Please check the USB connection in the PC and the system.
    b. Use another USB cable.
3. Cradle:
    a. Make sure the device is properly placed into the Cradle.
    b. Make sure the Cradle is powered while transferring the result to PC.
4. Make sure the easyTymp option is selected in the PC software (for detail contact your distributor).
5. 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 using the installation CD.

12 Appendix

1 kHz

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Electrical Safety, EMC and Associated Standards

(1) UL 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety

(2) IEC 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety

(3) CAN/CSA-C22.2 No. 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety Electrical Equipment for Laboratory Use

(4) IEC 60601-1-2: Medical Electrical Equipment, Part 1 - Electromagnetic Compatibility - Requirements and Tests

(5) Essential Requirements of the current European Union Medical Device Directive 93/42/EEC

(6) RoHS (Restriction of the use of certain Hazardous Substance)

(7) WEEE (Waste Electrical & Electronic Equipment) Legislation

Specifications are subject to change without notice.

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