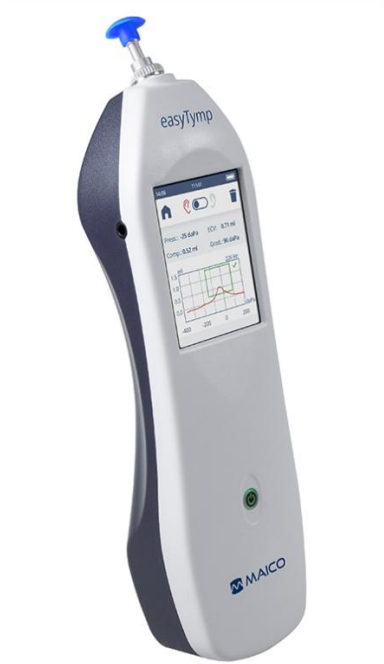

TYMPANOMETER

EASYTYMP

USER MANUAL

Read this manual thoroughly before using the device. Pay particular attention to Chapter 1 ("Safety: warnings and information") and Chapter 2 ("Installation, power-up and power down").

Internal inspections and repairs must only be performed by authorized personnel.

CE
0123

Manufactured for MAICO Diagnostics GmbH.

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Summary

CHAPTER 1
Safety: warnings and information

1.1 OPERATOR MANUAL

Be sure to read this manual through completely, so that all of the features offered by the instrument can be used to their full potential. Pay particular attention to this chapter as it contains warnings that are of fundamental importance in ensuring safe and correct use of the device.

The safety warning symbol illustrated below is used in this manual to draw the attention of the reader to information of particular importance in matters of safety, and to guard against incorrect use.

1.2 OPERATOR RESPONSIBILITIES

The easyTymp tympanometer guarantees consistent and dependable performance only when used in accordance with the instructions and procedures described in this manual.

Should the device need to undergo repair or maintenance work, it must be disconnected from the electrical power supply and not used again until after the repair work has been completed. Defective or faulty parts must only be replaced with original spare parts supplied by MAICO or authorized service companies and all repairs must be carried out exclusively by MAICO or by staff authorized by MAICO. No parts of the device must be modified or replaced without authorization from MAICO.

The user assumes full responsibility for any malfunction resulting from improper use or operation, likewise from maintenance or repair work performed by third parties other than MAICO or Service Centers approved by MAICO. MAICO and approved Service Centers will answer for the performance and reliability of the equipment only if:

- adjustments, modifications or repairs have been entrusted to persons authorized by MAICO;
- the electrical system and earthing of the installation are in compliance with the specifications of standards for electro-medical appliances.

1.3 INTENDED PURPOSE

The easyTymp tympanometer is a medical device intended to measure the biomechanical characteristics of the patient's middle ear, to help the operator assess his or her functional conditions for screening purposes.

1.4 INDICATIONS FOR USE AND END USERS

The easyTymp is intended for use by healthcare ENT professionals in hospitals, ENT clinics and audiology clinics as a tool for hearing screening programs and as an aid to the diagnosis of possible hearing disorders.
There is no limitation of the patient population in using the device. Always be sure to perform an otoscopy before using the device.

These tests must be conducted in a quiet environment to avoid artifacts.

1.5 MEDICAL CONDITIONS

Conditions of impaired sensitivity of the auditory system or any conditions in which the auditory system is thought to play a role in diagnosis.

1.6 MAIN FEATURES

The easyTymp is a portable device that can be used to conduct middle ear screening tests simply, swiftly and accurately. Available with a range of optional licenses, the device is able to meet the needs of private medical practices, clinics and hospitals alike.

The device features:

- backlit color display with touchscreen interface, allowing graphic illustration of test results;
- compact and ergonomic design, lightweight construction;
- long endurance, with built-in rechargeable lithium battery;
- interaction with computer using MAICO Sessions software.

Depending on the licenses activated, the main functionalities available are:

- 226 Hz tympanometry test;
- 1000 Hz tympanometry test (with *1 kHz Probe Tone* license);
    - ipsilateral acoustic reflex test with 226 Hz probe tone and 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz stimuli

Other accessories available are a dedicated docking station and a portable thermal printer.

1.7 USE CASES

The easyTymp can be used to conduct automatic tympanometry tests at low frequency (226 Hz) and at high frequency (1000 Hz, only with *1 kHz Probe Tone* license) and ipsilateral acoustic reflex tests.

These tests must be conducted in a particularly quiet environment in order to avoid artifacts.

The easyTymp tympanometer is intended for use by persons who have a detailed knowledge of the procedures associated with the tests supported by the instrument; the operator must therefore be either an audiometrist (or a technician having the requisite levels of audiological knowledge) or a medical practitioner in possession of specific skills (ENT or audiology specialist).

1.8 PRECAUTIONS

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

To ensure correct and safe use of the device, the following precautions must be observed.

1.8.1 Installation and general precautions

Make certain that the required ambient conditions are met (during transport, storage, and operation):

Operation	*Temperature between +15°C and +35°C* *Relative humidity: between 30% and 90% (no condensation)* *Pressure: between 700 hPa and 1060 hPa*
Transport and storage	*Temperature between -10°C and 50°C* *Relative humidity: 90% max, no condensation* *Pressure: between 500 hPa and 1060 hPa*
Warm-up time	*1 minute*

The device will not be protected if exposed during use to flammable anesthetic gases or similar products. Risk of explosion.

Avoid installing and using the device near sources of strong electromagnetic fields: these could interfere with the operation of the equipment.

Use only original accessories supplied by MAICO, unless specifically indicated otherwise.

Use only medical grade power adapters, certified to IEC 60601-1, with the following specifications:

Internal battery	*Rechargeable Li-Ion, 18650 standard, 3.7V 2.6Ah*
	Endurance: Minimum 4h continuous use
	Auto-off time: 5 minutes
	Stand-by time: 1 minute
	Recharge time: from PC, standard USB port: 10h max; from dedicated power adapter: 3h max
External power adapter	*Input 100-240Vac 50/60Hz, 0.3-0.15A* *Output 5Vdc 1.4A* *Compliant with the IEC 60601-1 standard.*

The easyTymp is a medical device: if connected to a computer (or any external device) located within the "patient area" (as defined in IEC 60601-1), this likewise must be a medical device, or protected by an isolating transformer, in order to ensure that the combination of computer (external device) + tympanometer is in compliance with IEC 60601-1.

The easyTymp must be installed and operated taking account of the information regarding electromagnetic compatibility (EMC) provided at the end of this manual.

The proximity of portable and mobile appliances used for RF communications can affect the operational efficiency of the instrument box. Refer to the information regarding electromagnetic compatibility (EMC) provided at the end of this manual.

1.8.2 Calibration

The calibration should be performed at least once every 12 months, and whenever a transducer is replaced.

The calibration of the instrument is valid only for the transducers supplied. If a transducer is replaced, the instrument must be recalibrated.

The calibration is valid for transducers supplied with the equipment, if connected directly to the instrument, without

any interposition of extension leads. If the transducers are not connected directly to the device, a new calibration procedure will be required before the instrument is used.

If the transducer selected is not calibrated, an alert will appear in the test screens. It will not be possible to present any stimulus to the patient using transducers that have not been calibrated.

Take note of the calibration interval indicated. Use of the instrument beyond the calibration interval expiry date can lead to unreliable diagnoses.

1.8.3 Hygiene

The earpieces of the tympanometer probes are disposable, likewise that of insert earphones; do not use the same earpiece for different patients. Dispose of earpieces after use.

1.8.4 Use

The instrument can generate tones at an intensity potentially damaging to the patient. Take particular care to set the intensity of the tone correctly before it is presented.

Never insert the probe tip into the ear canal without affixing an ear tip as this may damage the patient's ear canal.

Be sure to insert the probe tip in a way, which will assure an air tight fit without causing any harm to the patient. Using a proper and clean ear tip is mandatory.

Do not perform service or maintenance while using the device on a patient.

1.9 DISPOSAL

Like any other electronic device, the easyTymp tympanometer contains certain extremely hazardous substances, albeit in extremely small proportions. If released into the normal refuse collection system without suitable preliminary treatment, these substances cause serious damage to the environment and to health. At the end of its service life, accordingly, each component of the appliance must go

through a sorted collection process: this means that the user should deliver (or dispatch) waste items to the sorted collection centers set up by local authorities, or alternatively, hand them back to the dealer when purchasing a new appliance of the same or similar type.

Thanks to the sorted collection of waste items and the subsequent processing, recovery and disposal operations they undergo, appliances can be made from recycled materials, and any negative impact of improper waste management on the environment and on health can be suitably limited.

1.10 CONFORMITY

The easyTymp tympanometer is a class IIa medical device, according to Annex VIII of Medical Device Regulation (MDR) 2017/745/EU.

The Inventis Quality Management System has been certified by leading assessment body TÜV as compliant with ISO 13485 standard.

1.11 SYMBOLS ON LABELS

Warning: the use of this device requires certain precautions.
To ensure safe use, consult the accompanying documentation.

Follow the instructions for use.

Device serial number. The number is made up of 13 alphanumeric characters indicating the model, series, year of manufacture and serial number:

- *characters 1-5: product code*
- *characters 6-7: year of manufacture ("20" denotes 2020)*
- *characters 8-13: pro serial number*

Catalog code

Name and address of manufacturer.

Medical Device

Device with applied parts, Type B (IEC 60601-1)

The device emits radio frequency

Product conforms to European Community Medical Device Regulation (MDR) 2017/745/EU. Class IIa device; number of notified body: 0123 (TÜV SÜD Product Service GmbH).

Rx Only

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

The product is subject to the requirements of Directive 2012/19/EU on waste electrical and electronic equipment (WEEE). In the event of this product being sold and/or scrapped, it must not be disposed of as ordinary household or industrial waste, but collected separately.

Do not reuse. Components bearing this mark can be used once only, and must not be reused thereafter.

Consult instructions for use.

(01)08054187381232
(21)IM1PM25000000

UDI code

CHAPTER 2
Installation, power-up and power down

2.1 PRECAUTIONS

Installation of the easyTymp tympanometer is easy but needs to be done carefully: incorrect installation could lead to safety issues while using the system.

Like any other electrical or electronic device, the tympanometer will emit electromagnetic waves. Whilst the level of emissions is guaranteed to be within statutory limits, other electronic devices operating in the immediate vicinity could be affected, if particularly sensitive to electromagnetic interference. If this should occur (interference is verifiable by switching off the instrument and then switching on again) it may be possible to remedy the problem by adopting one or more of the following solutions:

- change the orientation and/or the position of the device affected by interference
- distance the device from the tympanometer
- plug the affected device into a power socket on a circuit other than the circuit to which the tympanometer is connected
- consult MAICO or a service center for assistance

2.2 CONNECTIONS

The easyTymp can be connected either to a PC for recharging and transferring test data, or to the power adapter supplied. Use only the USB cable supplied with the product. Moreover, it is possible to recharge easyTymp and transfer tests through the optional Docking station (see *Chapter 5 Docking station*).

As long as it is connected to a power source, the appliance will remain active in recharge or trickle charge mode.

Use only the medical grade power adapter supplied with easyTymp, certified according to the IEC 60601-1 standard

Make certain that the electrical power supply and ground connections comply with the applicable standards for electro-medical devices. Risk of electric shock

Plug all transducers and parts into the respective sockets as indicated in the following table:

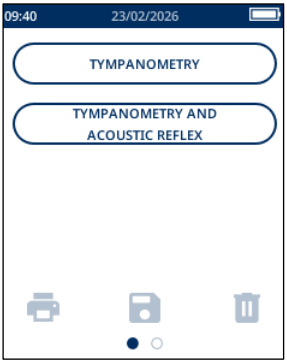
Connector	Detachable part
PHONES	Air conduction headphones
PATIENT RESP.	Patient response button
	USB cable for connection to personal computer

2.3 POWER-UP, POWER DOWN AND MAIN SCREEN

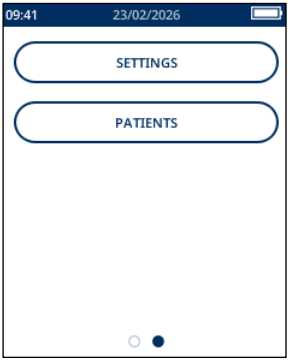
Turn on the instrument by pressing and holding the on/off button; it can be switched off by pressing and holding the same button.

At the startup of the instrument, a pressure initialization is performed: to complete initialization successfully, hold the tympanometer still with the probe positioned in free space.

A few seconds after power-up, the display of the instrument will show the main screen, illustrated below:



Swipe your finger to the left on the display for the settings and to manage the patient memory.



2.4 CONNECTION TO PC

The easyTymp tympanometer can be interfaced with a personal computer after installing the MAICO Sessions software[1]. Connect the easyTymp tympanometer to a USB port of the computer using the cable provided (USB cable with A / mini B connectors) or plug it into the docking station (which in turn is connected to the computer via the USB cable provided).

Use the supplied cable to connect the easyTymp tympanometer to one of the USB ports of the computer

After a few seconds, the connected device will be recognized by the operating system.

Refer to Sessions user manual for more details about the software.

[1] Sessions is manufactured by MAICO Diagnostics GmbH. For software-related issues, please contact MAICO Diagnostics support.

CHAPTER 3
Controls and exams

3.1 Opening the pack and inspecting the contents

Upon receiving the pack, check that the box is not damaged and that the parts contained are neither damaged nor defective.

Having made the various connections, carry out a further visual inspection before switching on, to check for possible damage.

Should the instrument or any of its parts or accessories appear to be damaged or defective, contact the dealer or MAICO service.

Keep the packaging materials, in case the instrument should need to be sent to the dealer or to MAICO for any reason.

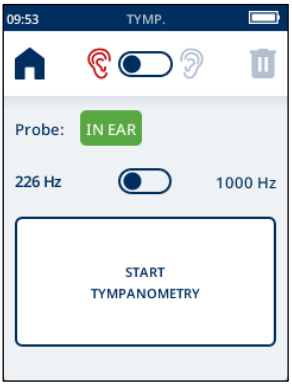
3.2 Controls for direct access to exams

Button	Function
TYMPANOMETRY	Perform Tympanometry
TYMPANOMETRY AND ACOUSTIC REFLEX	Perform Tympanometry and then the Acoustic Reflex test
	Save the current session to the patient memory
	Delete the current session
	Print the current session to the thermal printer (if configured and available)

3.2.1 Function buttons

Button	Function
	Return to the main screen
	Select the ear to test (in the example the right ear was chosen)
	Delete the current test

3.3 TYMPANOMETRY

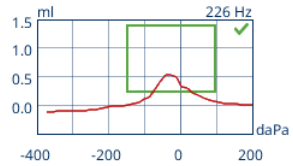
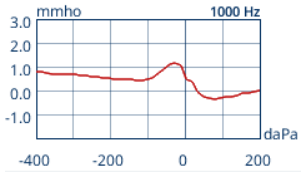


Button	Function
	Probe tone selection
	Force the tympanometry to start.

If the probe is detected as being correctly inserted in the ear of the patient, with a compliance measurement that is stable and within the specified range, the test will begin automatically; alternatively, the start of the test can be forced.

In the event of pressure losses being detected, the instrument will repeat the pressurized scan up to three times before generating an alert to indicate that there is a problem. Should it prove impossible to conduct the test as the result of pressure loss, the problem may be overcome by replacing the earpiece with another of different size and/or adjusting the position and angle of the probe in the auditory canal.

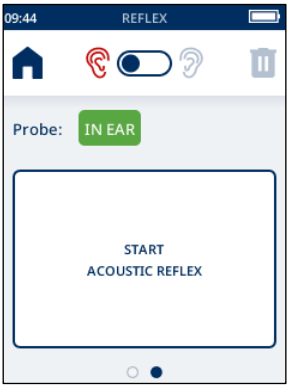
3.3.1 Results

Indication	Information
	Tympanometry. The unit of measurement of the vertical axis (acoustic admittance) is expressed in: - ml (equivalent volume of air), with 226 Hz probe tone - mmho, with 1 kHz probe tone The horizontal axis indicates meatus pressure in relation to ambient pressure, expressed in daPa. Only for 226 Hz probe tone: ✓: the peak falls within the norm. box, ✗: the peak falls outside (or it is not found)
	
Press.: -25 daPa	Pressure at the tympanogram peak.
Vol.: 0.71 ml	Vol.: compliance in ml measured at the maximum value of the pressure range selected for the scan. This value is also called the "equivalent volume".
Comp.: 0.52 ml Comp.: 1.11 mmho	Compliance: Amplitude of the tympanogram peak measured against Vol.. The unit of measurement reflects that of the tympanogram.
Grad.: 96 daPa	Gradient of the tympanogram: width of the tympanogram at 50% of the compliance value (only for the 226 Hz probe tone)

If the test has not been able to determine one or more of the above values, a double dash "--" will appear in place of the number.

3.4 ACOUSTIC REFLEX

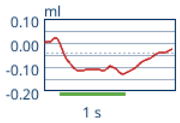
At the end of the Tympanometry test, the instrument automatically performs the reflex test at the peak tympanometry pressure. If the Tympanometry test has not been performed, the Acoustic Reflex test is performed at atmospheric pressure.



Button	Function
START ACOUSTIC REFLEX	Start the Acoustic Reflex test.

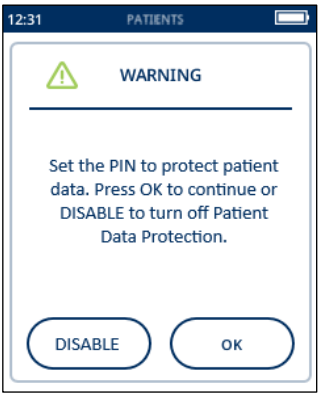
3.4.1 Results

Button	Function
	Display the reflex plot at the specific frequency. Button information: ✓: reflex threshold detected, ✗: reflex threshold not detected

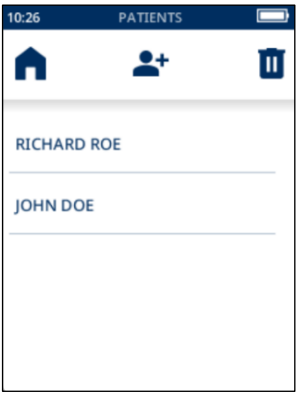
Indication	Information
	Reflex performance. The green segment indicates the duration of the stimulus. The dotted line represents the recognition sensitivity level set.
0.5 kHz 75 dBHL -25 daPa	Reflex frequency, reflex level, pressure at which the reflex search was performed.

3.5 PATIENT MANAGEMENT

The Patient management screen allows adding (or modifying) patients and reviewing stored exams. The first time the Patient Management screen is accessed, easyTymp asks for a PIN to prevent data access from unwanted accesses. You can choose either to enter the PIN or disable data protection.



Message prompt at the first Patient Management screen access

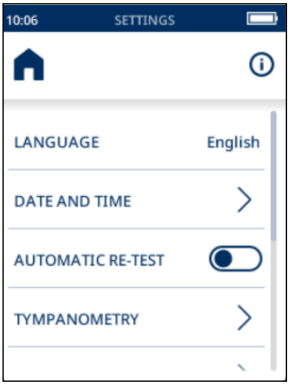


Patient Management screen

It is recommended to enable the PIN for patient data protection

Button	Function
	Return to the main screen
	Create new patient
	Delete all saved patients
	Return to the list of patients
	Side of the test saved
	Delete the current patient
	Print the tests of the current patient

3.6 SETTINGS



Button	Function
	Go back to the main screen
	Access the info screen, with serial number of the device, calibrated transducers, firmware version and other information for service

3.6.1 User-settable parameters

General configuration parameters for the device are listed below. The availability of some configuration parameters depends on the licenses active on the device.

- **Language**: Interface language. Default value: English (may vary based on destination)
- **Date and time**: Access the menu to adjust date and time and its format.
- **Automatic test repetition**: Enables/disables the possibility of repeating the test, re-inserting the probe in the ear (without having to manually delete the previous test). Default value: disabled.

- **Tympanometry**: Access the menu for tympanometry settings:
    - Pressure range: Standard [-400; +200] daPa or Reduced [-300; +100] daPa. Default value: Standard.
    - Norm. box 226Hz: sets the normal range, allowing the user to choose between:
      - None
      - 0.2 to 1.4 ml; -150 to 100 daPa
      - 0.3 to 2.0 ml; -150 to 100 daPa
      - 0.2 to 2.0 ml; -150 to 100 daPa

      Default value: 0.2 to 1.4 ml; -150 to 100 daPa.
    - Result display: allows to display or not the exam result on the 226Hz tympanogram graph (tick or cross): if the norm. box 226Hz is set to none, this option is disabled and off. Default value: enabled.
- **Acoustic reflex**: Access the menu for the Acoustic Reflex test settings:
    - Frequency selection: the available stimulus frequencies can be selected individually: 0.5 kHz, 1 kHz, 2 kHz, 4 kHz. Default value: all frequencies enabled.
    - Test mode: sets the mode in which the test is conducted, namely fixed intensity or threshold search. Default value: threshold search.
    - Test configuration:
        - Select the level of the stimulus in dB HL (in fixed intensity mode). Default value: 90 dB HL
        - Selection of the initial and final level, selection of the variation rate in steps of 5 or 10 dB. Default value: 75-95 dB, 5 dB steps.
    - Reflex sensitivity: sensitivity with which identification of the reflex (variation of compliance) occurs, normal (0.04 ml) or strong (0.06 ml). Default value: normal (0.04 ml).
    - Data polarity: sets the method for representing data in the chart: negative polarity (decrease in compliance caused by the reflex is represented with a deflection of the reflex curve), positive polarity (decrease in compliance caused by the reflex is represented with an increase in the curve). Default value: negative.

- **Data security**: Access the menu to modify the PIN and enable/disable it
- **Display brightness**: Set the display brightness between 20% and 100%. Default: 80%.
- **Printer**: Access to the print options menu:
  - Print patient details: allows enabling the printing of the patient's personal details. Default value: enabled.
  - Print reflex graphs: allows printing the acoustic reflexes in graph form. Default value: disabled.

3.6.2 License menu

Access the menu to enable additional licenses.

CHAPTER 4
Printer

It is possible to print the exam results directly from the device thanks to the thermal portable mini printer, available upon request: the communication with the device is wireless.

To print the results, switch on the printer and then press the PRINT icon on the device. The printing process will start automatically, and pop-up messages will inform you of the printing status.

Ensure that the device is within the printer's wireless communication range

CHAPTER 5
Docking station

The docking station, available upon request, allows the user to store away the easyTymp after use, recharging the device and transferring the data to the computer.

Place the easyTymp stably on the docking station to ensure correct communication.

5.1 INSTALLATION AND GENERAL PRECAUTIONS

For a complete list of applicable precautions, please refer to the *Installation and general precautions* paragraph in Chapter 1. In addition to the listed warnings, please be aware that the following applies for docking station:

The easyTymp Docking station is an accessory of a medical device: if connected to a computer (or any external device) located within the "patient area" (as defined in IEC 60601-1), this likewise must be a medical device, or protected by an isolating transformer, in order to ensure that the combination of computer (external device) + tympanometer is in compliance with IEC 60601-1.

The easyTymp Docking station must be installed and operated taking account of the information regarding electromagnetic compatibility (EMC) provided at the end of this manual.

5.2 CONFORMITY

The easyTymp Docking station is a class I accessory, according to Annex VIII of Medical Device Regulation (MDR) 2017/745/EU.

5.3 SYMBOLS ON LABELS

Warning: the use of this device requires certain precautions.
To ensure safe use, consult the accompanying documentation.

Follow the instructions for use.

Device serial number. The number is made up of 13 alphanumeric characters indicating the model, series, year of manufacture and serial number:

- *characters 1-5: product code*
- *characters 6-7: year of manufacture ("20" denotes 2020)*
- *characters 8-13: pro serial number*

Catalog code

Name and address of manufacturer.

Product conforms to European Community Medical Device Regulation (MDR) 2017/745/EU. Class I accessory.

Rx Only

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

The product is subject to the requirements of Directive 2012/19/EU on waste electrical and electronic equipment (WEEE). In the event of this product being sold and/or scrapped, it must not be disposed of as ordinary household or industrial waste, but collected separately.

(01)08054187381249
(21)IM1PN25000000

UDI code

5.4 CONNECTIONS

Plug the docking station into a power socket using the power adapter supplied and to the computer using the cable supplied (USB cable with A / mini B connectors). The two USB ports on the back of the instrument are interchangeable; both can communicate with the computer and also power the device. It is not necessary for both ports to be connected.

Use only the medical grade power adapter supplied by MAICO, certified according to the IEC 60601-1 standard

Make certain that the electrical power supply and ground connections comply with the applicable standards for electro-medical devices. Risk of electric shock

CHAPTER 6
Maintenance

The easyTymp tympanometer does not require any special periodic maintenance other than calibration and normal cleaning, both of which are described in this chapter. The instrument must be switched off before commencing any kind of cleaning operation.

The performance and safety of the instrument will be assured as long as the recommendations for care and maintenance indicated here are correctly observed.

Apart from replacing the battery, the inspection and servicing of internal components must be left entirely to technicians approved by MAICO.

Transducers are manufactured utilizing ultra-fragile diaphragms that could be damaged in the event of impact. Handle with care during maintenance operations.

6.1 PERIODIC CHECKS

The procedure described under this heading must be carried out when the instrument is used for the first time each day.

The tests must be conducted with the instrument positioned for normal use.

Before switching on the instrument, make certain that there is no sign of damage visible on the equipment, including the accessories and the external power adapter; make a visual inspection of the power cable and connectors to verify the integrity of the insulation, and ensure that they are not subject to any kind of mechanical loading or stress that could cause damage; check that all parts and cables are properly connected.

Verify correct operation of the probe and check the pressure. To this end, carry out the following sequence of steps:

- Fit a new earpiece to the probe;
- Select the tympanometry test;
- Check that the probe is identified as being ready;
- Start the test in manual mode and check that the internal pump carries out pressurization cycles until the point, after a few seconds, that a pressure loss alert is generated, then press OK;
- Occlude the probe by placing a finger over it;
- Check that the probe is identified as being blocked;
- Start the test manually and make certain it is carried out in a few seconds, showing a tympanometry graph that appears blank, with Vol. < 0.2 ml;
- If calibration cavities of 0.5 ml, 2.0 ml and 5.0 ml capacity are available, run a tympanometry test on each one and check that the ECV value obtained is compatible in each case;
- Select the reflex test, holding the probe open;
- Check that the probe is identified as being ready;
- Start the test manually and check that the cycle is performed as expected, given the reflex configuration selected; bringing the tip of the probe closer to the ear, in noiseless conditions, the stimuli should be audible.

If any part or transducer has any malfunction, consult Chapter7 “Troubleshooting”.

Also, check that the calibration interval has not expired: the date is shown on the info screen accessible from the settings menu.

Calibration must be entrusted to technicians approved by MAICO. The operation should be performed at least once every 12 months, and whenever a transducer is replaced.

6.2 MAINTENANCE OF TRANSDUCERS

Do not use liquids or sprays to clean the tympanometer.

Do not allow dust to collect on the transducers. Also:

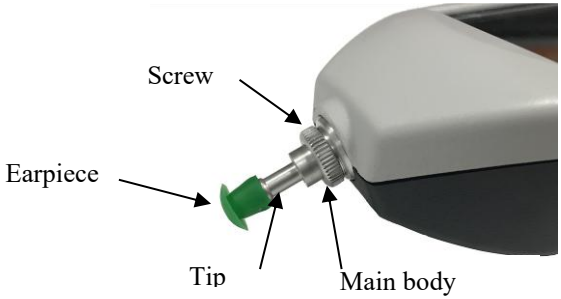
- The ear tips of the probe are intended to be inserted in the patient's ear canal. They are made of biocompatible material and disposable: use once only and dispose of in accordance with current health and safety regulations.

Earpieces are not sterile. Reusing unsterilized earpieces can cause ear infections.

6.3 CLEANING THE PROBE

To guarantee accurate compliance measurements, the three channels incorporated into the probe must be kept properly clean. In effect, these three channels carry the compliance measurement system, the stimulus speaker, and the pressurization system.

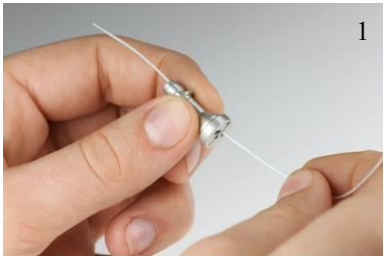
As illustrated below, the probe comprises a main body rigidly attached to the instrument, a tip (to which the earpiece is fitted) and a screw collar, which keeps the tip of the probe firmly secured to the body.

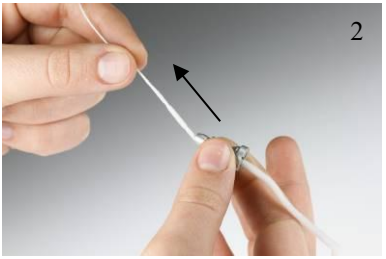


The procedure for cleaning the probe will now be described.

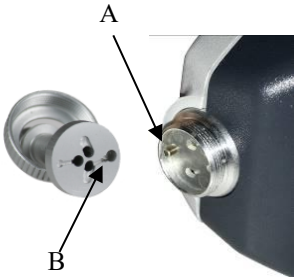
Remove the earpiece then loosen the screw collar so that the tip of the probe can be separated from the main body.

Use thin nylon threads to clean the three channels in the tip of the probe. Insert the thread into each of the channels in turn, from the base, and push through until it can be pulled out from the top.





Having cleaned the channels thoroughly, the tip of the probe must be refitted. Offer the tip of the probe to the main body, being careful to align the guide pin *A* presented by the body with the hole *B* located in the tip, as illustrated in the figure below. Retighten the screw collar.



Clean the outer surface of the probe using a lint-free soft cloth moistened with water and mild detergent; if the probe is to be sanitized, moisten the cloth with a 3% solution of hydrogen peroxide.

Do not immerse the probe or part of it in any kind of liquid

In the event of the probe being broken or malfunctioning, contact an MAICO service technician or an authorized Service Centers. The replacement of the probe must be entrusted exclusively to MAICO or to a service technician authorized by MAICO. If the probe is replaced, it must be calibrated before being used with the instrument.

6.4 CLEANING THE INSTRUMENT

Clean the instrument using a lint-free soft cloth moistened with water and mild detergent; if it is to be sanitized, moisten the cloth with a 3% solution of hydrogen peroxide.

6.5 REPLACING THE BATTERY

If the device fails to operate as long as expected despite a full charge, the battery may be damaged or dead.

The incorrect battery replacement can potentially be dangerous. Take particular care to replace it.

Purchase a new battery from an MAICO-approved dealer; proceed to replace the existing battery from the instrument as described below:

- Switch off the instrument and disconnect it from the USB cable;
- Position it face down (display directed downwards) on a soft surface;
- Undo the screw retaining the flap of the battery compartment;
- Remove the battery. Separate the connectors without tugging; ease apart using tweezers;
- Fit the connector of the new battery;
- Position the lead inside the compartment below the screw and locate the new battery in its housing, then close the flap and secure with the retaining screw.

Recharge the instrument completely before use.

All parts mentioned in the manual are designed especially for use with this instrument. Only parts supplied by MAICO should be connected to the device.

6.6 REPAIRS AND TECHNICAL ASSISTANCE

Before contacting the service department, make certain that all the possible solutions in *Chapter 7* "*Troubleshooting"* have been tried.

Parts that are to be returned for service must be cleaned and sanitized, following the directions in this manual. Transducers must be shipped in a closed and sealed transparent bag.

Should the instrument need to be sent to the service department or returned to the dealer, it is important that the original packing be used, and that all accessories and transducers are enclosed.

CHAPTER 7
Troubleshooting

Problem	Possible cause	Solution
No probe tone	Holes of probe tip blocked	Unscrew the probe tip and clean inside
No pressurization *message*: “Pressure loss”	Probe not correctly positioned and tightened	Check that the tip of the probe is properly tightened
	Probe not inserted tightly in ear / unsuitable earpiece	Change the earpiece and reinsert the probe Change the angle of the probe in the ear
Compliance measurements affected by noise	Probe not properly positioned	Reposition the probe so as to minimize vibrations
	Holes of probe tip blocked	Unscrew the probe tip and clean inside
No signal from a transducer	Transducer not connected properly	Check that the transducer is connected properly
	Transducer damaged	Contact service department or dealer
Unable to establish a direct connection between the PC and the easyTymp or docking station	Problems with USB connection	Check the USB connection between instrument and computer
	USB cable damaged	Change the USB cable (USB A – mini B standard)

Problem	Possible cause	Solution
Unable to transfer the data to the PC via the docking station	Instrument not positioned correctly in the docking station	Check the positioning of the instrument Check that the contacts are clean Check connections
The instrument does not switch on	Battery flat	Connect the instrument to a power source and switch on the device
The display remains blank (LED on)	Instrument in stand-by	Touch the screen or press the power button
	Display damaged	Contact service department or dealer
Battery does not recharge	USB cable damaged	Change the USB cable (USB A – mini B standard)
	Adapter damaged	Contact service department or dealer
	Instrument not positioned correctly in the docking station	Check the positioning of the instrument Check that the contacts are clean Check connections
	Battery damaged	Replace the battery - Contact service department or dealer
A test cannot be accessed	Optional test not activated	Contact the service department to obtain the license, supplying the serial number of the device
message: “Hardware error”	Non-fatal internal error	Press OK to continue; if the problem persists, contact the service department
message: “Serious error”	Fatal internal error	Restart the instrument; if the problem persists, contact the service department

Annex A

Technical Specifications

APPLICABLE STANDARDS	
Performance	Middle ear analyzer IEC 60645-5 type 2 ANSI S3.39 type 3
Calibration	IPSI: ISO 389-2
Electrical safety	IEC 60601-1 Class II, Type B
Electromagnetic compatibility	IEC 60601-1-2
Enclosures	IEC 60601-1 IP20
Operation mode	Continuous

CE CERTIFICATE	
MDR 2017/745/EU Classification	Class IIa
Classification rule (Annex VIII, 2017/745)	10
Notified body	TÜV SÜD Product Service GmbH Ridlerstrasse 65 D-80339 Műnchen, Germany
Notified body number	0123

AVAILABLE TESTS
Tympanometry (226Hz and optional 1000Hz), Acoustic Reflexes

TYMPANOMETRY 226HZ	
Probe tone	With AGC
Frequency and intensity	226 Hz ± 1%; 85 ± 1.5 dB SPL
Measurement range and accuracy	0.2 to 8.0 ml ± 0.1 ml or ± 5% (whichever is greater)
Representation	Meatus-compensated
Influence of ambient temperature	-0.003 ml/°C
Influence of atmospheric pressure	-0.0002 ml/daPa
Scan range	Standard +200 to -400 daPa Low +100 to -300 daPa ± 10 daPa or ± 10 % (whichever is greater)
Scan rate	400 daPa/s
Pressure control	automatic
Pressure safety limits	Upper limit 550 daPa Lower limit -750 daPa
TYMPANOMETRY 1000HZ – Tympanometry 1000Hz license required	
Frequency and intensity	1000 Hz ± 1%; 75 ± 1.5 dB SPL
Measurement range and accuracy	0.9 to 16 mmho ± 0.5 mmho or ± 5% (whichever is greater)
Representation	Meatus-compensated
ACOUSTIC REFLEXES – Reflex and Reflex 1000Hz	
Type of stimulation	Ipsilateral, pulsed (50ms ON, 70ms OFF)
Stimulus frequencies and accuracy	1kHz ± 1% (with 1000Hz-only reflex license) 500Hz, 1kHz, 2kHz, 4kHz ± 1% (with full reflex license)
Harmonic distortion	THD 2.5% maximum
Intensity and accuracy	70 to 100dB HL ± 3 dB HL
Duration of stimulus	1s
Type of test	- Fixed intensity, adjustable intensity, 5dB steps - Threshold search, attenuator steps 5dB or 10dB, initial value and final value adjustable through 5dB steps
Recognition threshold	Adjustable 0.04 or 0.06 ml ± 0.01ml There is a negligible risk of artifacts in measurements at high stimulus levels, and they do not influence the reflex identification system
Test pressure	Automatic - Tympanogram peak pressure - Peak pressure less gradient (width of pressure curve at half peak height) - Atmospheric pressure

	IPSI
Ref. standard	**ISO 389-2 (ANSI S3.6)**
Coupler	IEC 60318-5
Freq. [Hz]	**dB [re 20 µPa]**
125	-
250	-
500	11
750	-
1000	5.5
1500	-
2000	7
3000	-
4000	2
6000	-
8000	-

PATIENT MANAGEMENT	
Maximum number of patients	50
Details memorized	Patient details (first name, last name, date of birth, gender), test date and time, Tympanogram (RH + LH), reflex tracing (RH + LH), audiometric thresholds (RH + LH)

PHYSICAL SPECIFICATIONS	
Display	TFT LCD 2.8” RGB, 240x320 pixels Viewing area 43.2 mm x 57.6 mm
Touchscreen	Capacitive
Dimensions of Tympanometer instrument	(W x D x H) 65 x 44 x 240 mm / 2.6 x 1.8 x 9.5 in
Weight of instrument	340 g / 12 oz
Dimensions of docking station	(W x D x H) 109 x 83 x 131 mm / 4.3 x 3.3 x 5.2 in
Weight of base only	280 g / 9.9 oz

TYMPANOMETER CONNECTORS	
AC headphone	Output, 3.5mm 4-pole audio jack, 8Vpp max with 10Ω load
Patient response button	Input, 2.5 mm mono audio jack, 4Vpp max
USB	I/O, mini B type, 5.5Vdc max
Docking station contacts	I/O, target type for spring-loaded contact, +/-10Vpp

DOCKING STATION CONNECTORS	
USB	I/O, 2x mini B type, 5.5Vdc max
Docking station contacts	I/O, spring-loaded contact, +/-10Vpp

INTERFACE WITH COMPUTER	
Connection:	USB (no driver needed)
Minimum pc requirements	USB 2.0 port
Compatible software products	MAICO Sessions

BLUETOOTH PRINTER INTERFACE	
Module type	Bluetooth v4.2 – dual mode
Frequency	2402 - 2480 GHz
Maximum power in transmission	Class 1 +8 dBm from antenna
Sensitivity	94 dBm
Coverage	100m maximum
Conformity	EC: Essential requirements as in article 3 of EU directive 2014/53/EU; Radio Equipment Directive (RED); FCC ID: SQGBT850; Industry Canada IC: 3147A-BT850

Upon request, it will make available circuit diagrams, parts lists, descriptions, calibration instructions or other information that may assist service personnel in repairing parts of the device that the manufacturer has deemed repairable by staff.

Annex B

Electromagnetic compatibility

The instrument has been tested and respects the limits for electro-medical devices specified by IEC 60601-1-2 standards. These limits ensure reasonable protection against hazardous interference in typical medical installations.

The device generates, uses and radiates radio frequency energy. If not installed and used according to the instructions in this manual, it may interfere with other nearby devices. No guarantee is given that interference will not occur under certain conditions.

This device is suitable for use in professional healthcare facility environments, i.e. in hospitals, 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 instrument should not be used adjacent to or stacked on other equipment. If such use is necessary, this instrument and the other equipment should be observed to verify that they are operating normally.

The existence of electromagnetic interference can be verified easily by turning the device off and back on again. If it is found that the device is indeed interfering with other equipment, try to solve the problem by adopting one of the following solutions:

- Change the orientation and/or position of the affected device.
- Move the two devices further away from each other.
- Contact the manufacturer or authorised service center for further assistance.

List of cables, transducers and accessories

Cables, transducers and accessories for which manufacturer declares compliance with IEC 60601-1-2 standard are those supplied with the device, in particular:

- Medical grade USB power adapter
- USB cable: 2m length, screened.
- Docking station
- Transducers: 2m length, screened.
- Patient button: 2m length, screened.

The use of accessories, transducers and cables other than those specified, except for transducers and cables sold by the manufacturer as spare parts for internal components, may result in increased emissions or decreased electromagnetic immunity of the device and result in improper operation.

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 device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Anyone connecting other items of equipment must ensure that the overall system complies with IEC 60601-1-2.

The instrument does not have any ESSENTIAL PERFORMANCE as per the IEC 60601 1 standard.

Note: All instructions necessary for maintaining compliance with regard to electromagnetic compatibility can be found in the maintenance section in this manual. No further steps are required.

<table>
<tr><th colspan="3">Manufacturer's indications and declaration - electromagnetic emissions</th></tr>
<tr><td colspan="3">easyTymp is intended for use in an electromagnetic environment as specified below. The customer or the user of easyTymp should assure that it is used in such an environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment Guidance</th></tr>
<tr><td>RF emissions
CISPR11</td><td>Group 1</td><td>easyTymp uses RF energy for its internal functions, and contains a Bluetooth radio module that responds to pertinent regulations. Consequently, the RF emissions generated are minimal and unlikely to interfere with other equipment operating nearby.</td></tr>
<tr><td>RF emissions
CISPR11</td><td>Class B</td><td rowspan="3">easyTymp is suitable for use in professional healthcare facilities and for connection direct to the low voltage public electricity grid.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Fluctuations in voltage/emissions (flicker)
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Manufacturer's indications and declaration - electromagnetic immunity			
easyTymp is intended for use in the electromagnetic environment as specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity tests	**Test level to IEC 60601**	**Level of Compliance**	**Electromagnetic environment – guidelines**
Electrostatic discharges (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transients / bursts 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 professional healthcare 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 professional healthcare environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T[(1)] (dip >95% in U_T) for half cycle. 40% U_T (dip >60% in U_T) for 5 cycles. 70% U_T (dip >30% in U_T) for 25 cycles. <5% U_T (dip >95% in U_T) for 5 s.	< 5% U_T[(1)] (dip >95% in U_T) for half cycle. 40% U_T (dip >60% in U_T) for 5 cycles. 70% U_T (dip >30% in U_T) for 25 cycles. <5% U_T (dip >95% in U_T) for 5 s.	Mains power quality should be that of a professional healthcare environment. If the user of easyTymp requires continued operation during power mains interruptions, it is recommended that the instrument be powered from an uninterruptable power supply or its battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a professional healthcare environment.
Note: (1) U_T is the A.C. mains voltage prior to application of the test level.			

Manufacturer's indications and declaration - electromagnetic immunity			
easyTymp is intended for use in an electromagnetic environment as specified below. The customer or the user of easyTymp should assure that it is used in such an environment.			
Immunity tests	**Test level to IEC 60601**	**Level of Compliance**	**Electromagnetic environment – guidelines**
Conducted RF IEC 61000-4-6	3 Vrms 0.15 – 80 MHz 6 Vrms in ISM bands between 0.15 - 80 MHz	3 Vrms 0.15 – 80 MHz 6 Vrms in ISM bands between 0.15 - 80 MHz	Portable and mobile RF communications equipment should be used no closer than 30 cm (12 inches) to any part of easyTymp, including cables specified by the manufacturer. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey(1), should be less than the compliance level in each frequency range.(2) Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz - 2.7 GHz	3 V/m 80 MHz - 2.7 GHz	
Radiated RF (from RF Wireless communication equipment) IEC 61000-4-3	9 V/m 704-787 MHz 5100 – 5800 MHz	9 V/m 704-787 MHz 5100 – 5800 MHz	
	27 V/m 380 - 390 Mhz	27 V/m 380 - 390 Mhz	
	28 V/m 430 - 470 Mhz 800 - 960 Mhz 1700 - 1990 Mhz 2400 - 2570 Mhz	28 V/m 430 - 470 Mhz 800 - 960 Mhz 1700 - 1990 Mhz 2400 - 2570 Mhz	
Proximity Fields IEC 61000-4-39	8A/m 30KHz CW 65 A/m 134.2KHz Pulse Mod 2.1KHz 7.5 A/m 13.56MHz Pulse Mod 50KHz	8A/m 30KHz CW 65 A/m 134.2KHz Pulse Mod 2.1KHz 7.5 A/m 13.56MHz Pulse Mod 50KHz	

Note: At 80 MHz and at 800 MHz, the higher frequency range is applied.

Note: These guidelines may not be valid in all situations. Electromagnetic propagation is affected by absorption and reflection on encountering structures, objects and persons.

Note:

(1) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile, 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 measured field strength in the location easyTymp is used in exceeds the applicable RF compliance level

above, easyTymp should be observed to verify its normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating easyTymp.

(2) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Manufacturer's indications and declaration - electromagnetic immunity	
Function requiring verification to exclude unacceptable risks	**Pass/fail acceptance criteria**
Sound generator operating correctly	No unwanted sound from transducers exceeding 80 dB; lockup or restart of the device is acceptable
Tympanometry on test cavity, conducted correctly in normal operating conditions	Flat tympanometry curve, ECV indication equivalent to nominal value of cavity +/- 0.1ml ESD: presence of artifacts in tympanometry recognizable by skilled professional, HW error, lockup or restart of device — all these are acceptable

Contains transmitter module in compliance with ETSI EN 301 489-1 and ETSI EN 300 328 standards

The device emits radio frequencies in the 2.4 GHz band, class 1
Contains transmitter module in compliance with ETSI EN 301 489-1 and ETSI EN 300 328 standards