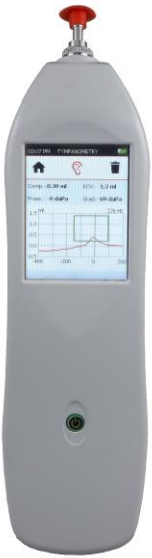


TYMPANOMETER

TIMPANI

USER MANUAL

Read this manual carefully before using the instrument. Pay close attention to the instructions given in the chapter on *Chapter 1* and *Chapter 2*.

Internal inspection of the instrument must be entrusted entirely to approved technicians.

CE
0123

Document title:	**IM1P-User Manual En**
Revision:	**02**
Date:	**18/02/2019**

Summary

Foreword

Thank you for purchasing an Inventis audiology device.

Advantageously compact and lightweight, the Timpani tympanometer is a powerful and versatile screening device, ideal for fast and accurate examinations of the middle ear.

The Inventis company has always considered the use of its devices in conjunction with computers to be a factor of key importance. Installing the Maestro software suite, available with or without proprietary database or as a Noah module, any Inventis audiology device can be connected to a computer, and all examinations conducted then archived in the user's own database.

Bear in mind also that Inventis has developed a complete line of audiology devices: in addition to middle ear analyzers, the company's product line includes a range of audiometers, REM and HIT hearing aid fitting devices, a wireless video otoscope, and much more.

For further information, and to report any problems of whatever description that may be encountered, contact the company at:

Inventis S.r.l.
Corso Stati Uniti, 1/3
35127 Padua Italy
Tel.: 049.8962844 – Fax: 049.8966343
www.inventis.it info@inventis.it

Chapter 1
Introduction

USER 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. In particular, be sure to read this chapter in its entirety, as it contains information and 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.

OPERATOR RESPONSIBILITIES

The Timpani 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 this work has been completed. When defective or failed parts must be renewed, accept only original replacement parts supplied by Inventis s.r.l. Any repairs must be entrusted exclusively to Inventis or to service technicians approved by Inventis.
No parts of the device must be modified or replaced without authorization from Inventis.
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 Inventis s.r.l. or Service Centres

approved by Inventis. Inventis s.r.l. and approved Service Centres will answer for the performance and reliability of the equipment only if:

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

INTENDED USE

The Timpani tympanometer is a device enabling the user to measure hearing impedance and/or conduct pure tone audiometry for screening purposes. It is intended for use by healthcare professionals in hospitals, nurseries, ENT clinics and audiology practices as an instrument for auditory screening programmes, and as an aid to the diagnosis of possible hearing disorders.

MAIN FEATURES

The Timpani 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 main strengths of the device are:

- backlit colour 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 Maestro software.

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

- screening tympanometer able to perform 226 Hz tympanometry test;
- 1000 Hz tympanometry test
- ipsilateral acoustic reflex test (using 226 Hz probe tone) with stimuli enabled at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz if full reflex license is active, and stimulus restricted to 1000 Hz if 1000 Hz-only reflex license is active.

Other accessories available for the Timpani tympanometer are a dedicated charging station and a portable thermal printer.

USE CASES

The Timpani can be used to conduct automatic tympanometry tests at low frequency (226 Hz) and at high frequency (1000 Hz, only with optional 1000 Hz tympanometry license) and ipsilateral acoustic reflex tests (only with full reflex and 1000 Hz-only reflex licences).
These tests must be conducted in a particularly quiet environment in order to avoid artefacts.
The Timpani 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).

WARNINGS AND PRECAUTIONS

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

General precautions

Make certain that the required ambient conditions are met (during transport, storage and operation) as indicated in Appendix A.

The device will not be protected if exposed during use to flammable anaesthetic 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 Inventis s.r.l., unless specifically indicated otherwise.

Use only medical grade power adapters, certified to EN standard 60601-1. For further information see Appendix A.

The Timpani is a medical device: if connected to a computer (or any external device) located within the "patient area" (as defined in EN 60601-1-1), 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 EN standard 60601-1-1.

The Timpani tympanometer can be used in conjunction with a soundproof booth to conduct tests under optimum acoustic conditions. Before connecting the instrument to a soundproof booth, check that the sockets are compatible with the specifications prescribed for each connector.

The Timpani must be installed and operated taking account of the information regarding electromagnetic compatibility (EMC) provided in Appendix C.

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 in Appendix C.

Calibration

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

The calibration is dependable for transducers supplied with the equipment, if connected directly to the instrument, without any interposition of extension leads and without the passage from connectors to panel (as habitually occurs in soundproof booth installations). 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.

Hygiene

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

Use

The instrument is able to 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.

DISPOSAL

Like any other electronic device, the Timpani 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 despatch) waste items to the sorted collection centres 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.

CONFORMITY

The Timpani tympanometer is a class II device, in accordance with Annex IX of the medical devices directive 93/42/EEC as amended and supplemented by directive 2007/47/EC.

Inventis s.r.l. is a company certified to ISO 13485.

SYMBOLS ON LABELS

Warning: the use of this instrument calls for certain precautions; to ensure safe use, consult the accompanying documentation.

Refer to the instructions for use.

Refer to the manual for information.

SN

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

- *first 5 characters: Inventis product code*
- *characters 6 and 7: year of manufacture ("12" denotes 2012)*
- *character 8: model series*
- *characters 9-13: pro serial number*

REF *Catalogue code*

Name and address of manufacturer.

Device with applied parts, Type B (EN60601-1)

The device emits radio frequency

CE
0123

Mark indicating conformity with Council Directive 93/42/EEC concerning medical devices (as amended and expanded by Directive 2007/47/EC) – Class IIa device, notified body 0123 (TÜV SÜD Product Service GmbH).

Rx only *Under United States federal law, the device can be sold only to authorized healthcare professionals.*

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.

(01)80541873807472
(21)IM1PA18200595

UDI code

Chapter 2
Installation and use

The procedure for installing the Timpani tympanometer is simple, but requires careful attention. If the installation is not performed correctly, the system could be affected by safety problems when in use.
This chapter describes the parts supplied, and the procedure for installing the system.

OPENING THE PACK AND INSPECTING THE CONTENTS

On taking receipt of the pack, make certain that the box is not damaged. Check that all parts contained in the box are free of damage or defects.

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 Inventis service.

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

PARTS AND ACCESSORIES

Parts and accessories supplied with the product or available to order are listed in the following tables.

Tympanometer pack
Tympanometer
Pack of assorted earpieces and brush thread for cleaning
Inventis Software Suite
USB cable
Medical grade USB multi socket power adapter
Carry case
Tympanometer user manual
Conformity and calibration certificates

Optional accessories
Calibration cavity
Charging station
Thermal printer

PRECAUTIONS

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 the manufacturer or a service centre for assistance.

CONNECTIONS

The Timpani 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.

If the optional charging base is available, the power adapter only can be connected, or the PC only, or both; the two USB sockets on the underside of the charging base are interchangeable.

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

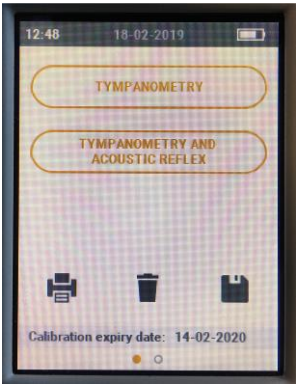
Use only the medical grade power adapter supplied by Inventis and certified to EN standard 60601-1. For more information, see the Technical Specifications appendix

POWER-UP AND MAIN SCREEN

Once all the cables are connected, the instrument can be switched on by pressing and holding the on/off button; it can be switched off at any time by pressing and holding the same button.

When the instrument is powered up, a pressure initialization procedure will commence: to ensure the initialization routine is brought about correctly, 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.



The main screen shows the buttons for selection of the main tests supported by the Timpani, depending on the specific licenses that are activated.

The lower part of the main screen shows the icons that can be selected to print, delete and save tests conducted during the current session.

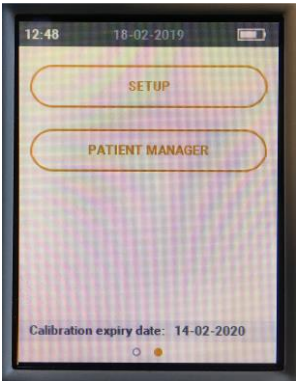
To access the screen for acquisition of the required test, simply select the relative button.

When at least one test has been conducted, the delete and save icons will be enabled, allowing the user to clear the items of data collected or save them

to the patient database. In addition, if the thermal printer is available and correctly configured, the print icon allows the user to access the print menu.

All screens of the software utility show the time at the top left, and the charge status of the battery at the top right.

Scrolling to the left, the display will show the second page of the main menu, from which the user can access the setup menu or the patient management menu, by selecting the relative button in either case.



Chapter 3
Tympanometry

HOW THE TEST IS CONDUCTED

The first step is to select the most suitable earpiece for the patient being examined. The probe, with the selected earpiece attached, is introduced into the auditory canal of the patient and inserted deep enough to ensure a pressure-tight fit.

The ear icon can now be used to select the side on which the test will be conducted: the red ear icon represents the right hand side, and the blue ear icon represents the left.

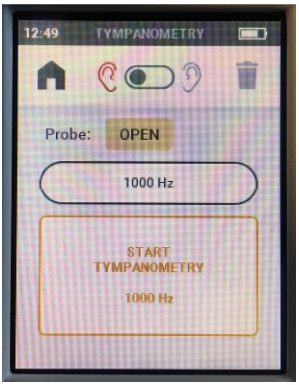
The tympanometry setup menu allows customization of the pressure range used to conduct the test. More exactly, the user can choose between two pressure ranges: Standard [-400; +200] daPa or Low [-200; +100] daPa. The default range setting is Standard.

For more details on the setup menu, refer to Chapter 6.

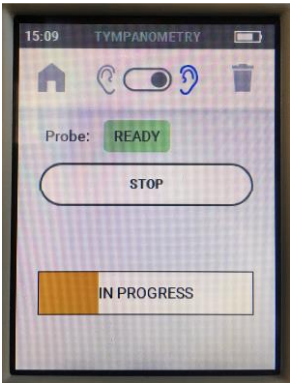
THE TYMPANOMETRY WINDOW

On pressing the *Tympanometry* button, the instrument will be ready to perform the test automatically.

The screen indicates the status of the probe: 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 by pressing the *start tympanometry* button.



Once the tympanometry function is under way, besides indicating the status of the probe, the screen will also display a progress bar showing how far the test has advanced. The instrument carries out a pressurized scan, and if a pressure-tight closure is properly ensured, displays the completed tympanometry: 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.

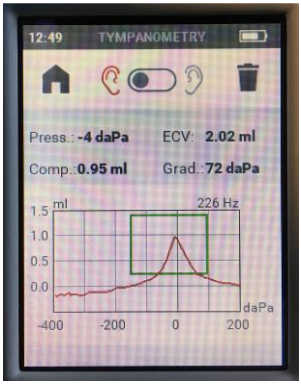


Should it prove impossible to conduct the test as the result of pressure loss, the problem may be overcome by replacing the earpiece with another of different size and/or adjusting the position and angle of the probe in the auditory canal.

TEST RESULTS

On completion of the tympanometry test sequence, the relative screen will display the data acquired by the instrument and the relative numerical results.

The results of the test consist in a graph — the tympanogram — and, shown above the graph, measurements of the typical parameters.



Tympanogram

The tympanometry graph shows the variation in acoustic admittance in response to pressure. If a 226 Hz probe tone is being used, the vertical axis indicates the acoustic admittance of an equivalent volume of air, expressed in ml. If a 1 kHz probe tone is being used (see section on *1000 Hz tympanometry*), the vertical axis indicates acoustic admittance expressed in mmho. The horizontal axis indicates meatus pressure in relation to ambient pressure, expressed in daPa.

Comp.

Amplitude of the tympanogram peak measured against ECV, expressed in ml (millilitres).

ECV (Ear Canal Volume)

Compliance value in ml measured at the maximum value of the pressure range selected for the scan. This value is also called the "equivalent volume".

Press.

The pressure value in daPa registering at the tympanogram peak;

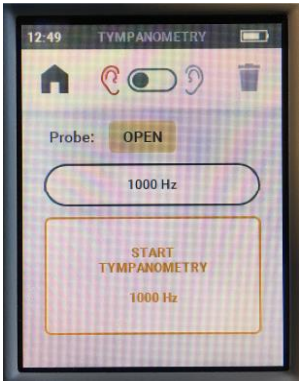
Grad.
The gradient of the tympanogram, specified in daPa, represents the width of the tympanogram curve at 50% of the compliance value.

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.

Once the test is under way, the instrument raises the pressure in the ear canal to the established maximum positive value, whereupon the recording of the tympanogram will commence and continue until the pressure drops to the minimum value.

1000 HZ TYMPANOMETRY

To conduct a test with 1000 Hz probe tone, in the case of Timpani appliances with a *1000 Hz tympanometry* license, the user must select the relative button on the tympanometry screen.



The graphic interface is almost identical to that of the 226 Hz tympanometry test window. The only difference is in the unit of measure used to indicate compliance, namely mmho.

The parameters and test results are the same as for low frequency tympanometry.

Chapter 4
Tympanometry and acoustic reflex testing

This chapter describes the possibility of performing tympanometry tests and acoustic reflex tests in sequence, given activation of the reflex license (full reflex license or 1000 Hz-only reflex license).

To run the tympanometry and acoustic reflex test sequence, simply press the relative button on the main screen: first, a tympanometry test will be conducted as described in the previous chapter, and when this has been completed, the acoustic reflex test will start automatically.

The acoustic reflex test setup menu allows customization of various parameters relating to the test, in particular:

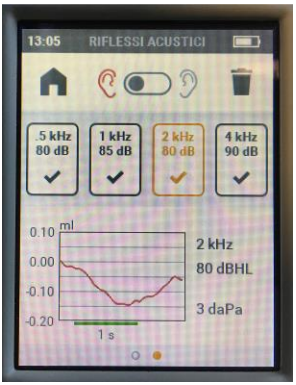
- Frequency selection: the available stimulus frequencies can be selected individually: 0.5 kHz, 1 kHz, 2 kHz, 4 kHz. Default value: all frequencies enabled.
- Test mode: sets the mode in which the test is conducted, namely fixed intensity or threshold search; Default value: threshold search.
- Test configuration: in fixed intensity mode, the level of the stimulus can be selected in dB HL. In threshold search mode, the initial and final level can be selected, also the rate of variation, in steps of 5 or 10 dB. Default value: fixed intensity, 90 dB HL, threshold search 75-95 dB, variation step 5 dB.
- Reflex sensitivity: sets the sensitivity with which identification of the reflex (variation of compliance) occurs, options normal (0.04 ml) and strong (0.06 ml). Default value: normal (0.04 ml).
- Data polarity:determines the method of representing data in the graph. Selecting negative polarity, the reduction in compliance caused by the reflex is represented as a downward movement of the reflex curve; selecting positive, the reduction is represented as an upward movement of the curve. Default value: negative.

For more details on the setup menu, refer to Chapter 6.

ACOUSTIC REFLEX TEST WINDOW

As in the case of the tympanometry test, if the requisite conditions are detected, the test will begin automatically; alternatively, the start of the test can be forced by pressing the *Start acoustic reflex* button.
The instrument will run the test according to the procedures and parameters configured by way of the setup menu (see *Settings*).

The central part of the screen is occupied by a graph that provides a real time indication of the reflex curve obtained with a given stimulus signal. The frequency and intensity of the stimulus associated with the reflex curve are indicated to the right of the graph, along with the target pressure. The green bar below the graph represents the stimulus on-time, in other words, the duration for which the stimulus remains active.
The test finishes when the instrument has analyzed all frequencies at which measurement of the acoustic reflex was programmed.
On completion of the test, a screen will appear showing the results and the icons of the stimuli presented. A symbol in each of the icons will indicate whether or not the acoustic reflex has been detected: in particular, a green tick ✓ indicates that the reflex threshold has been found, whereas a grey cross indicates that it has not been possible to identify the reflex threshold.
Pressing the relative buttons, the user can display the curve of the reflex analyzed previously. The frequency and intensity of the stimulus associated with the reflex curve are indicated to the right of the graph, along with the target pressure.



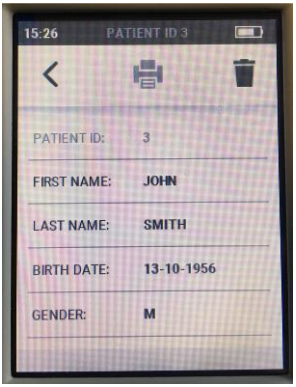
Chapter 5
Patient management

This chapter describes the functionality of saving acquired test data to the non-volatile memory of the Timpani instrument, and associating the information with a specific patient.

To access the patient management window, all the user needs to do is scroll the display toward the left and then press the *Patient management* button.

CREATE NEW PATIENT

To create new patients and save them in the memory of the instrument, simply access the patient management screen and select the *New patient* icon. A window will open, in which the user can specify the details of the patient to be saved, including first name, last name, date of birth and gender.

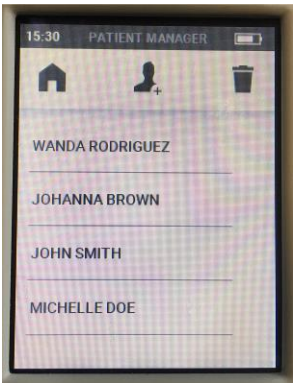


Patient details are entered simply by selecting the relative item and typing the information by way of the keypad.
A new patient can also be created without specifying any personal details: in this instance the individual is identified by way of a unique code that will

be attributed automatically by the system at the moment of creation and cannot be changed.

VIEW PATIENT LIST

To display the list of patients stored in the Timpani memory, simply go to the patient management page. Scrolling the display up and down, the user can view the entire list, which shows the essential information associated with each patient: unique ID code and first/last names (if specified at the moment when the patient identity was created).



Selecting a specific patient name or code, the user can access the details associated with the person in question: scrolling the display right and left, the following information will appear:

- personal details associated with the patient, if specified at the moment of creation
- tympanometry test on right ear and left ear associated with the patient (if stored)
- acoustic reflex test on right ear and left ear associated with the patient (if stored)

Pressing the trash icon on the page of the patient currently selected, the user can delete this same patient from the list.

SAVE CURRENT SESSION

To save data acquired during the current session to the memory of the instrument, in association with a particular patient, simply press the *Save*

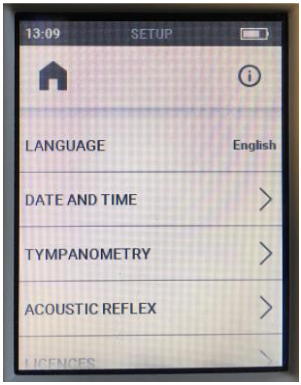
icon on the main screen and select the patient in question from the list, or alternatively, create a new patient and associate the data with the new name or ID code.

Chapter 6
Settings

The Timpani tympanometer has a number of configuration parameters that can be changed in the settings window. This chapter describes the general parameters available, and how to change them.

SETTINGS WINDOW

To access the settings window, all the user needs to do is scroll the display toward the left and then press the *Settings* button. To go back to the previous page, press the *home* icon.



Once the settings window is active, the display can be scrolled up and down to view the items available for selection. Having selected and edited the item as desired, press the *back* icon to return to the settings menu.
To enable changes to certain items, such as specific settings for hearing tests, and the current date and time, access to a particular window is required.
For a detailed description of the settings associated with each test, refer to the chapter describing the test of interest.

Also displayed in the settings window is an *info* icon, which can be selected to view the serial number of the instrument, together with the firmware version and the relative date.

GENERAL USER-SETTABLE PARAMETERS

General configuration parameters that can be set by the user are listed below. A default value is indicated for each parameter. This represents the factory setting.
Certain items may not be available, as they become active only when the respective license is installed,

Language

Selection of the interface language used by the instrument.

Default value: English

Date and time menu

Access to the menu used to set the date and time. The default setting for the time display is 24 hour format: this menu can be used to change the display to 12 hour am/pm format.

Display brightness

The brightness of the display can be set between 20% and 100%.

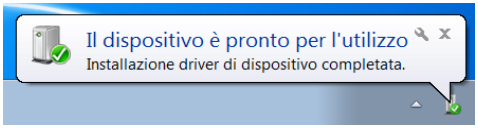
Default value: 80%.

Chapter 7
Interface with PC

The Timpani tympanometer can be interfaced with a personal computer.
The Maestro software suite must be installed on the computer (with or without proprietary database, or as a Noah module). Refer to *Maestro User Manual – General Functionalities* for a detailed description of the procedures involved when installing Maestro on the computer, and to *Maestro User Manual – Impedance Audiometry functionalities* for more information on using the Timpani tympanometer in conjunction with a computer.

CONNECTION TO PC

The Timpani tympanometer is connected to a USB port of the computer using the cable provided (conventional USB cable with A / mini B connectors) or plugged into the charging base (which in turn is connected to the computer via USB).
No special drivers are required for installation purposes: a few seconds after plugging in, the tympanometer or the charging base will be recognized by the operating system, which installs the requisite drivers automatically. The installation is complete when the following message appears at the bottom right of the screen:



The Timpani tympanometer and the charging base are compatible with computers using a Microsoft Windows 32 or 64 bit operating system, version Windows 7 or later.

Chapter 8
Maintenance

The Timpani tympanometer does not require any special periodic maintenance other than calibration and normal cleaning, both of which are described in this chapter.
The performance and safety of the instrument will be assured as long as the recommendations for care and maintenance indicated here are correctly observed.
The instrument must be switched off before commencing any kind of cleaning operation.

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

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

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 any part of 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 open;
    - 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 closed;
    - Start the test manually and make certain it is carried out in a few seconds, showing a tympanometry graph that appears blank, with ECV < 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.
- If the optional acoustic reflex license is installed:
    - Select the reflex test, holding the probe open;
    - Check that the probe is identified as being open;
    - 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.

Should any accessory not function correctly, consult Appendix - "Troubleshooting".

It is essential to make certain that the calibration interval has not expired: an alert will be generated by the device to indicate when calibration is due.

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

MAINTENANCE OF TRANSDUCERS

Do not use liquids or sprays to clean the tympanometer.

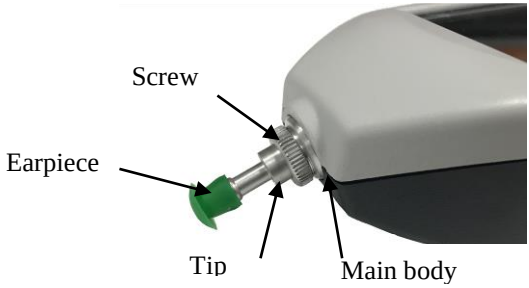
Do not allow dust to collect on the transducers. Also:

- The cushions of headphones are made of biocompatible material but are not sterile: before being used on a new patient, these items must be sanitized by wiping the surfaces with a proprietary hypoallergenic disinfectant, following the maker's instructions. This will prevent the spread of infection.
- The earpieces of the probe are made of biocompatible material and must be used once only, then discarded in compliance with current waste disposal regulations.

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

CLEANING THE PROBE

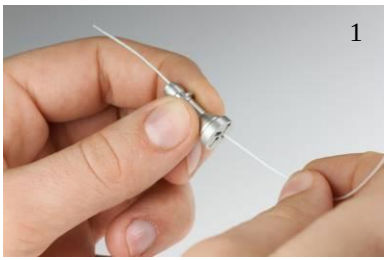
To guarantee accurate compliance measurements, the three channels incorporated into the probe must be kept properly clean. In effect, these three channels carry the compliance measurement system, the stimulus speaker, and the pressurization system.
As illustrated below, the probe comprises a main body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

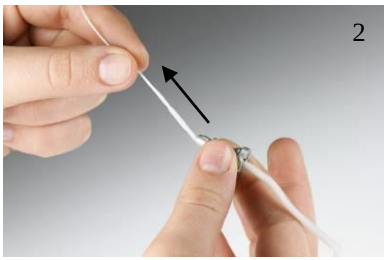


The procedure for cleaning the probe will now be described.

First, the screw collar must be loosened and removed so that the tip of the probe can be separated from the main body.

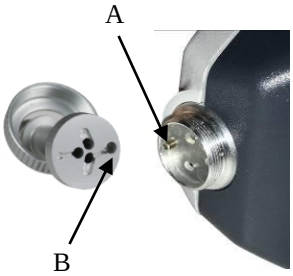
The three channels in the tip of the probe can be cleaned using thin nylon threads. Insert the thread into each of the channels in turn, from the base, and push through until it can be pulled out from the top.





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 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 dip the probe or any part of the probe in liquids of whatever nature

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

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.

REPLACING THE BATTERY

Should the instrument appear to be giving much shorter endurance than expected (see *Technical Specifications*) even when fully recharged, it may be that the battery is damaged or spent.

Purchase a new battery from an Inventis-approved dealer; proceed to remove 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.

Run a full recharge cycle before using the instrument.

All accessories mentioned in the manual are designed especially for use with this instrument. Only accessories supplied by Inventis should be connected to the tympanometer.

REPAIRS AND TECHNICAL ASSISTANCE

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

Parts that are to be returned to the manufacturer 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.

Appendix A
Technical Specifications

226Hz tympanometry specifications	
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 -200 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

1000Hz tympanometry specifications - 1000Hz tympanometry 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

Reflex measurement specifications – Full reflex or 1000Hz-only reflex license required	
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 artefacts 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

Calibration		
Duration of calibration:	12 months	
Calibration reference:	IPSI: EN ISO 389-2	
Acoustic couplers	For probe: IEC 60318-5	
Reference equivalent threshold levels	Frequency [Hz]	IPSI RetSPL [dB SPL]
	125	-
	250	-
	500	11
	750	-
	1000	5.5
	1500	-
	2000	7
	3000	-
	4000	2
	6000	-
	8000	-

Patient management	
Number of patients storable	50
Details memorized	Patient details (first name, last name, date of birth, gender) Date and time of test Tympanogram (Rx + Lx) Reflex curve (Rx + Lx)

Physical specifications	
Display	LCD TFT 2.8” Viewing area 43.2 mm x 57.6 mm Resolution 240x320xRGB
Touchscreen	Capacitive
Dimensions of Tympanometer instrument	(WxDxH) 65 x 44 x 240 mm / 2.6 x 1.8 x 9.5 in
Weight of instrument	340g / 12 oz
Dimensions of charging base	(WxDxH) 109 x 83 x 131 mm / 4.3 x 3.3 x 5.2 in
Weight of base only	280g / 9.9 oz
Tympanometer connectors	
AC headphone	For future use
Patient response button	Input, 2.5 mm mono audio jack, 4Vpp max (for future use)
USB	I/O, mini B type, 5.5Vdc max
Charging base contacts	I/O, target type for spring-loaded contact, +/-10Vpp

Charging base connectors	
USB	I/O, 2 x mini B type, 5.5Vdc max
Charging base contacts	I/O, spring-loaded contact, +/-10Vpp

Power supply	
Battery	Rechargeable lithium ion type, standard 18650, 3.7V 2600mAh

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
Maximum power consumption	From USB 7W
External power adapter	Medical USB type, responding to EN 60601-1 standard output 5Vdc min 1.4A input 100-240Vac 50/60Hz, 0.3-0.15A

Interface with computer	
Connection:	USB (no driver needed)
Compatible software products	Inventis Maestro suite

Bluetooth interface for printer	
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	CE: Essential requirements as in article 3 of EU directive 2014/53/EU; Radio Equipment Directive (RED); FCC ID: SQGBT850; Industry Canada IC: 3147A-BT850

Ambient conditions	
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

Applicable standards	
Performance:	Middle ear analyzer EN 60645-5 type 2, ANSI S3.39 type 3
Electrical safety:	IEC 60601-1, ANSI/AAMI ES60601-1, CAN-CSA C22.2 No 60601-1 Class II, Type B
EMC	EN 60601-1-2

CE certificate	
93/42 classification (DDM)	Class IIa
Classification rules (Annex IX of 93/42)	10
Notified body	TÜV SÜD Product Service GmbH Ridlerstrasse 65 D-80339 Műnchen

Notified body number	0123

Appendix B
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 to correct output	Connect the transducer to the correct output
	Transducer damaged	Contact Inventis service department or dealer
Connection between PC and instrument cannot be established	Problems with USB connection	Check the USB connection between instrument and computer
	USB cable damaged	Change the USB cable (USB A – mini B standard)
Date and time prompt appears when instrument is powered up	Internal battery failure	Contact Inventis service department or dealer to have the battery replaced

Problem	Possible cause	Solution
Display remains blank	Battery flat	Check the connection to the power supply and make certain the switch is in position 'I'
	Adapter damaged	Contact Inventis service department or dealer
Battery does not recharge	USB cable damaged	Change the USB cable (USB A – mini B standard)
	Adapter damaged	Contact Inventis service department or dealer
	Instrument not positioned correctly in charging base	Check the positioning of the instrument Check that the contacts are clean
	Battery damaged	Replace the battery - Contact Inventis service department or dealer
A test cannot be accessed	Optional test not activated	Contact the Inventis technical service department to obtain the license, supplying the serial number of the instrument
message: “Hardware error”	Non-fatal internal error	Press OK to continue; if the problem persists, contact the Inventis service department
message: “Serious error”	Fatal internal error	Restart the instrument; if the problem persists, contact the Inventis service department

Appendix C
Electromagnetic compatibility

The instrument has been tested and been found to comply with the limits for electromedical devices imposed by IEC 60601-1-2 standard. These limits guarantee a reasonable level of protection against harmful interference in a typical medical installation.

The instrument generates, utilizes and radiates energy at radio frequency, and if not correctly installed and used as indicated in the instructions, can cause harmful interference to other devices located in the immediate vicinity. At all events, there can be no guarantee that interference will not occur in certain situations.

This instrument is suitable for use in professional healthcare facilities, for example in hospital buildings, although not in close proximity to high frequency surgical equipment and RF shielded rooms housing MRI systems, where the intensity of electromagnetic disturbance is typically high.

The instrument must not be used in close proximity to other equipment or stacked together with other equipment. If this cannot be avoided, check the operation of the instrument carefully to ensure that it is able to deliver normal levels of performance in the configuration adopted.

Should the instrument appear to interfere with other devices — this can be verified 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 devices one from another;
- consult the manufacturer or a service centre for assistance.

Cables, transducers and accessories

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

1) Medical grade USB power adapter
2) Shielded USB cable, maximum length: 2 m
3) Charging base

The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by Inventis as replacement parts for internal components, can have the effect of increasing emissions from the device and reducing its immunity.

Portable items of RF communication equipment (including peripherals such as antenna cables and external antennas) must be used at a distance no closer than 30 cm (12 inches) to any part of the Timpani, including cables specified by the maker. If this advice is ignored, the performance of the instrument may suffer.

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

The instrument has no ESSENTIAL PERFORMANCE risks as envisaged in IEC standard 60601-1

Note: all instructions necessary for the purposes of maintaining conformity with regard to electromagnetic compatibility are provided in the maintenance section of this manual. No further procedures are required.

Manufacturer's indications and declaration - electromagnetic emissions		
The Timpani is designed for use in an electromagnetic environment as specified below. The user of the Timpani must ensure that the instrument is operated in ambient conditions as close as possible to these.		
Emission tests	**Conformity**	**Electromagnetic environment - guidelines**
RF emissions CISPR11	Group 1	The Timpani utilizes 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.
RF emissions CISPR11	Class B	The Timpani is suitable for use in professional healthcare facilities and for connection direct to the low voltage public electricity grid.
Harmonic emissions IEC 61000-3-2	Class A	
Fluctuations in voltage/emissions (flicker) IEC 61000-3-3	Compliant	

Manufacturer's indications and declaration - electromagnetic immunity			
The Timpani is designed for use in an electromagnetic environment as specified below. The user of the Timpani must ensure that the instrument is operated in ambient conditions as close as possible to these.			
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	The floor must be wood, concrete or ceramic tile. If floors are covered with materials that present synthetic coatings, relative humidity must be at least 30%.
Electrical fast transients / bursts IEC 61000-4-4	± 2 kV for electrical power supply lines ± 1 kV for input/output lines	± 2 kV for electrical power supply lines ± 1 kV for input/output lines	The quality of electrical power supplied by the grid must correspond to that of professional healthcare facilities.
Overcurrent IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	The quality of electrical power supplied by the grid must correspond to that of professional healthcare facilities.
Voltage dips, short interruptions and fluctuations	< 5% U_T[(1)] (dip >95% in U_T)	< 5% U_T[(1)] (dip >95% in U_T)	The quality of electrical power supplied by the grid must correspond to that of

affecting voltage on incoming electrical power supply lines IEC 61000-4-11	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.	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.	professional healthcare facilities. If the user of the Timpani needs to rely on uninterrupted operation of the unit even in the absence of mains power, the instrument must be connected either to a UPS or to a battery.
Magnetic field at power frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields at power frequencies must correspond to the levels typical of professional healthcare facilities.
Note: (1) U_T is the a.c. supply voltage prior to application of the test level.			

Manufacturer's indications and declaration - electromagnetic immunity			
The Timpani is designed for use in an electromagnetic environment as specified below. The user of the Timpani must ensure that the instrument is operated in ambient conditions as close as possible to these.			
Immunity tests	**Test level to IEC 60601**	**Level of Compliance**	**Electromagnetic environment - guidelines**
Conducted RF IEC 61000-4-6	3 Vrms 0.15MHz to 80Mhz 6 Vrms ISM bands between 0.15 MHz and 80 MHz	3 Vrms 0.15MHz to 80Mhz 6 Vrms ISM bands between 0.15 MHz and 80 MHz	Portable items of RF communication equipment (including peripherals such as antenna cables and external antennas) must be used at a distance no closer than 30 cm (12 inches) to any part of the Timpani, including cables specified by the maker The field strengths of fixed RF transmitters, established by way of an electromagnetic survey on site, *a)* must be lower than the level of compliance within each range of frequencies, *b)* may be associated with instances of interference near appliances bearing the symbol indicated below 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 Mhz to 2.7 GHz	
Note 1: At 80 MHz and at 800 MHz, the higher frequency range is applied. *Note 2:* These indications may not be valid in all situations. Electromagnetic propagation is affected by absorption and reflection on encountering structures, objects and persons.			
a) It is not possible to make a theoretical prediction with absolute certainty as to the field strengths of fixed transmitters, such as base radio stations (cell/cordless), terrestrial mobile			

telephones and radio, ham radio, AM and FM radio or TV transmissions. To evaluate the electromagnetic environment created by fixed RF transmitters, it may be necessary to conduct an electromagnetic survey on site. If the field strength measured at the point where the Timpani is in use exceeds the applicable RF level of compliance indicated above, check the operation of the instrument closely, to ensure that its performance levels meet the required standards. If abnormalities are observed, then additional measures may be necessary, such as changing the directional position or the location of the Timpani.

b) In the frequency range from 150 kHz to 80 MHz, field strengths must be lower 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 artefacts in tympanometry recognizable by skilled professional, HW error, lockup or restart of device — all these are acceptable

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

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

Appendix D
Bibliography

- Cynthia G. Flower and Janet E. Shank, Tympanometry, Handbook of Clinical Audiology, 175-202, Katz J. Editor, Williams & Wilkins (2002).

- Stanley A. Gelfand, The Acoustic Reflex, Handbook of Clinical Audiology, 205-229, Katz J. Editor, Williams & Wilkins (2002).

- Jackie L. Clark, Ross J. Roeser, Marissa Mendrygal, Middle Ear Measures, Audiology Diagnosis, 380-398, Ross J. Roeser, Michael Valente, Holly Holly Hosford-Dunn Editors, Thieme (2007).