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PL

HANDHELD TYMPANOMETER SCREENING AUDIOMETER

TIMPANI

MULTILANGUAGE USER MANUAL

Document title:	**IM1P-User Manual**
Revision:	**09**
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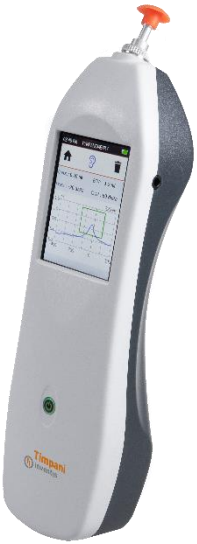
EN



TYMPANOMETER

TIMPANI

USER MANUAL

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

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

CE
0123

Summary

EN

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:

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Corso Stati Uniti, 1/3
35127 Padua, Italy
Tel.: 049.8962844 – Fax: 049.8966343
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Chapter 1
Introduction

1.1 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. 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 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 the repair work has been completed. Defective or faulty parts must only be replaced with original spare parts supplied by Inventis and all repairs must be carried out exclusively by Inventis or by staff authorized 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 or Service Centers approved by Inventis. Inventis 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 Inventis;

- the electrical system and earthing of the installation are in compliance with the specifications of standards for electro-medical appliances.

1.3 INTENDED USE

The Timpani 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.
Timpani is also a pure tone audiometer: by generating and offering the patient sound stimuli of different types and intensities, it helps the operator to assess the patient's auditory sensitivity for the purpose of screening.

1.4 INDICATIONS FOR USE AND END USERS

Timpani 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 – in particular audiometric tests – must be conducted in a silent environment to avoid artifacts and to ensure that no errors are made in determining the auditory threshold.

1.5 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 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 Maestro 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 stimuli:

  - 1000 Hz with *Reflex – Basic (Stimuli @ 1 kHz)* license
  - 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz with *Reflex – Plus (Stimuli @ 0.5, 1, 2, 4 kHz)* license.
- Pure-tone audiometry test (with *Tonal Audiometry* license).

Other accessories available are a dedicated docking station and a portable thermal printer. Refer to chapter 2.2 for more details.

1.6 USE CASES

Timpani 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 (only with *Reflex – Basic* or *Reflex – Plus* license). Moreover, it is also possible to perform the audiometry test using pure tones by activating the *Tonal Audiometry* license.

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

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).

1.7 WARNINGS AND PRECAUTIONS

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

1.7.1 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 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 Inventis, unless specifically indicated otherwise.

Use only medical grade power adapters, certified to IEC 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 IEC 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 IEC 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.

1.7.2 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.

1.7.3 Hygiene

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

1.7.4 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.

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

1.8 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 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.

1.9 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 is a company certified to ISO 13485.

1.10 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.

Follow the instructions for use.

Device serial number:

- *characters 1-5: Inventis 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

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

2.1 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 Inventis service.

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

2.2 BASIC CONFIGURATION, ACCESSORIES, OPTIONAL PARTS

2.2.1 Basic configuration (parts included)

- Tympanometer
- Pack of assorted earpieces and brush thread for cleaning
- USB cable
- Medical-grade USB multi-socket power adapter
- Carry case
- User manual

2.2.2 Accessories

- DD45 headphones[1]
- ER-3C insert earphones[1]

2.2.3 Optional parts

- Docking station

[1] Part applied according to the standard IEC 60601-1

- Calibration cavity
- Bluetooth thermal printer
- Patient response button[1]
- 1 kHz Tone probe license (for Tympanometry)
- Reflex – Basic (Stimuli @ 1 kHz) license
- Reflex – Plus (Stimuli @ 0.5, 1, 2, 4 kHz) license
- Tonal Audiometry Screening License (does not include transducers)

2.2.4 Consumables

- Thermal paper for the Bluetooth printer (pack of 5)
- White earpieces (diam. 6 mm) – 30 pcs.
- Pink earpieces (diam. 7 mm) – 30 pcs.
- Purple earpieces (diam. 8 mm) – 30 pcs.
- Green earpieces (diam. 10 mm) – 30 pcs.
- Red earpieces (diam. 12 mm) – 30 pcs.
- Blue earpieces (diam. 14 mm) – 30 pcs.
- Orange earpieces (diam. 16 mm) – 30 pcs.
- Sky blue earpieces (diam. 18 mm) – 30 pcs.
- Yellow earpieces (diam. 21 mm) – 30 pcs.
- Pack with assorted earpieces – 160 pcs.
- Brushes for cleaning the probe

2.3 PRECAUTIONS

Installation of the Timpani 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 the manufacturer or a service center for assistance.

2.4 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 docking station is available, the power adapter only can be connected, or the PC only, or both; the two USB sockets on the underside of the docking station are interchangeable.

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

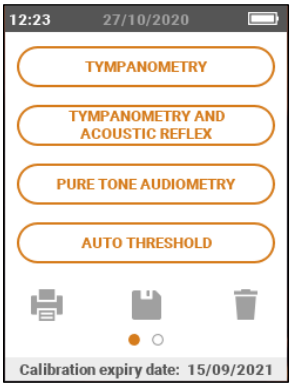
Use only the medical grade power adapter supplied with Timpani, certified according to the IEC 60601-1 standard. For further information see appendix Technical specifications.

2.5 POWER-UP AND MAIN SCREEN

Turn on the instrument 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[2]:



[2] The screen varies depending on the licenses active on the device

Button	Function
TYMPANOMETRY	Perform Tympanometry
TYMPANOMETRY AND ACOUSTIC REFLEX	Perform Tympanometry and then the Acoustic Reflex test
PURE TONE AUDIOMETRY	Perform Audiometry
AUTO THRESHOLD	Perform Automatic Audiometry
	Save the current session to the patient memory (see Chapter 6)
	Delete the current session
	Print the current session to the thermal printer (if configured and available)

Indication	Information
12:23	Current time
27/10/2020	Current date
	Battery status
Calibration expiry date: 15/09/2021	Calibration expiration date

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

Chapter 3
Tympanometry

3.1 THE SCREEN

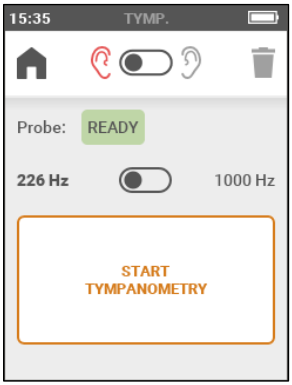
3.1.1 Common commands

The following commands at the top of the touchscreen are common to all types of exams available.

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

3.1.2 Test execution

On pressing the relative button on the main screen, the instrument will be ready to perform the test automatically.



Button	Function
	Probe tone selection
	Force the tympanometry to start.

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

The test's progress is displayed via a progress bar: 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. After a pressurized scan, if a pressure-tight closure is properly ensured, the instrument displays the completed tympanometry.

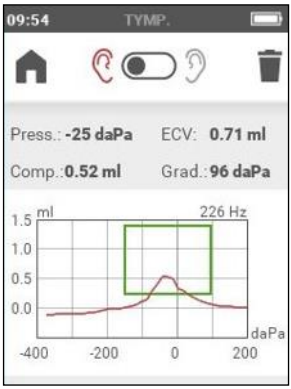
In the event of pressure losses being detected, the instrument will repeat the pressurized scan up to three times before generating an alert to indicate that there is a problem Should it prove impossible to conduct the test as the result of pressure loss, the problem may be overcome by replacing the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

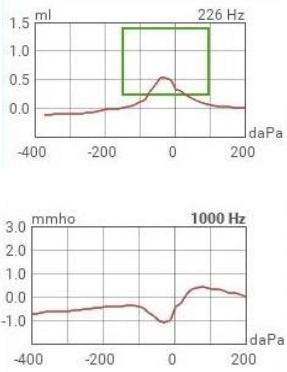
3.2 SETTINGS

For more details on the settings available, see Chapter 7.

3.3 RESULTS

On completion of the tympanometry test sequence, the relative screen will display the tympanogram obtained and the relative numerical 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.
Press.: **-25 daPa**	Pressure at the tympanogram peak.
ECV: **0.71 ml**	*Ear Canal Volume*: compliance in ml measured at the maximum value of the pressure range selected for the scan. This value is also called the "equivalent volume".

	Compliance: Amplitude of the tympanogram peak measured against ECV. The unit of measurement reflects that of the tympanogram.
	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.

Chapter 4
Tympanometry and acoustic reflex testing

4.1 THE SCREEN

After pressing the relative button on the main screen, the instrument will be ready to perform the Tympanometry test and then the Reflex test in sequence.

4.1.1 Common commands

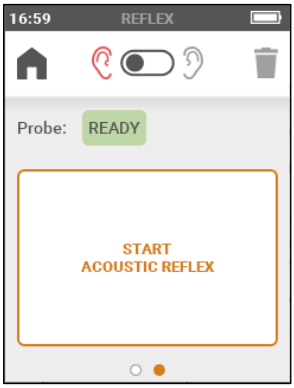
For commands common to all tests, see section 3.1.1.

4.1.2 Execution of the Tympanometry test

For the settings and execution of the tympanometry test see section 4.1.2. To perform acoustic reflexes only, swipe to the left on the display.

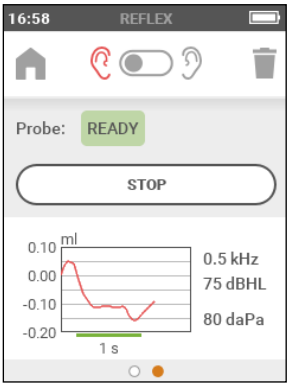
4.1.3 Execution of the Acoustic Reflex test

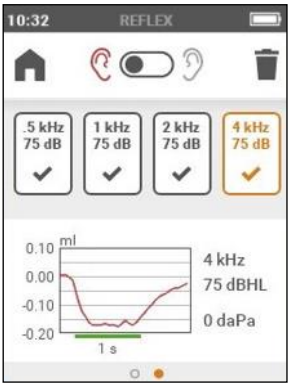
At the end of the Tympanometry test, the instrument automatically performs the reflex test at the peak tympanometry pressure. If the Tympanometry test has not been performed, the Acoustic Reflex test is performed at atmospheric pressure.



Button	Function
START ACOUSTIC REFLEX	Start the Acoustic Reflex test.

During the test, the reflex curve obtained with a given stimulus signal is displayed in real time.





The test finishes when the instrument has analyzed all frequencies at which measurement of the acoustic reflex was programmed.

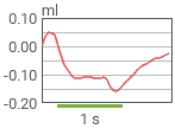
4.2 SETTINGS

For more details on Acoustic Reflex settings see Chapter 7.

4.3 RESULTS

Once the test is completed a screen will appear showing the results.

Button	Function
.5 kHz 75 dB ✓	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.
0.5 kHz 75 dBHL 140 daPa	Reflex frequency, reflex level, pressure at which the reflex search was performed.

Chapter 5
Audiometry

5.1 THE SCREEN

Depending on the selection, the instrument starts the audiometry test manually or automatically.

Before proceeding with the test, have the patient wear the chosen transducers, checking, from the info screen accessible from the setup menu, that the transducers are those duly calibrated.

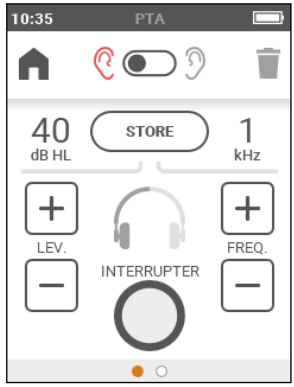
5.1.1 Common indicators

The following indicators are common to both manual and automatic tone audiometry tests.

Indication	Information
	Patient response button not pressed
	Patient response button pressed
	Headphones
	Active stimulus headphones
	Insert earphones

For commands common to all tests, see section 3.1.1

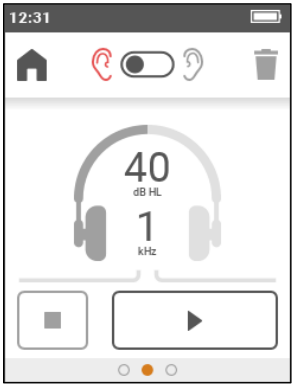
5.1.2 Manual audiometry



Button	Function
STORE	Save the current point
LEV. FREQ.	Increase/decrease Level and Frequency
	Send the stimulus

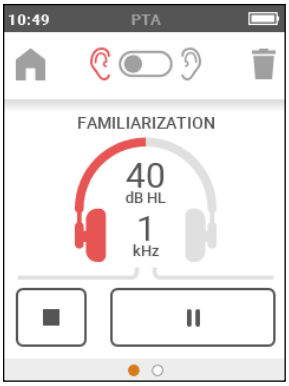
Indication	Information
40 dB HL	Stimulus level
1 kHz	Stimulus frequency. If valid data are associated with the current frequency, this is highlighted in the color representing the side.

5.1.3 Auto threshold (automatic audiometry)



Button	Function
▶	Start the test
⏸	Suspend the test
■	Stop the test

Auto Threshold pure tone audiometry allows the operator to establish the hearing threshold for different frequencies by way of an automatic procedure. The method applied is the Hughson-Westlake technique, modified by Martin, which provides a modified and abbreviated version of the method indicated in the ISO 8253-1 standard for determining the VA threshold without masking.



The automatic test includes an initial familiarization phase, to train the patient on the threshold determination procedure, and this is followed by the actual test at all enabled frequencies. Stimulation takes place for a duration of 1.7 seconds and is then followed by a pause of random duration lasting between 1.7 and 2.5 seconds.

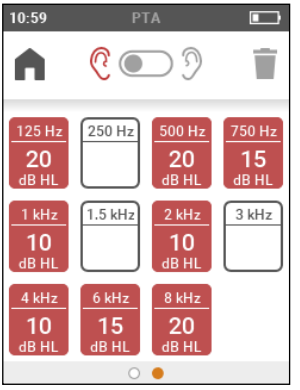
The test finishes automatically once all the enabled frequencies have been analyzed for both ears.

5.2 SETTINGS

For more details on Audiometry settings, see Chapter 7.

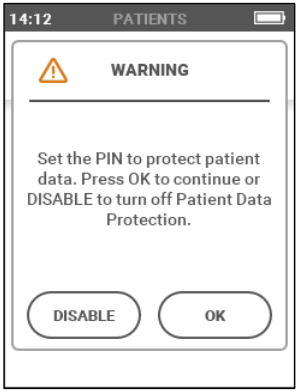
5.3 RESULTS

It is possible to view the hearing thresholds detected for each frequency by scrolling the display to the left. “N.R.” is displayed if the frequency was not heard.

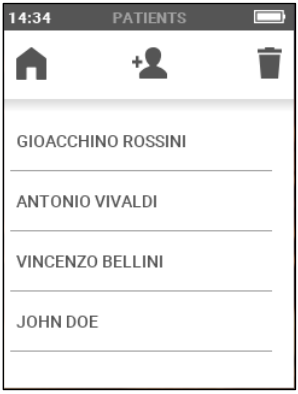


Chapter 6
Patient management

The Patient Management screen allows adding (or editing) patients and updating saved tests. The first time you access the Patient Management screen, Timpani asks you to enter a PIN to prevent unauthorized access. You can choose to enter your PIN or disable data protection.



Notification on first access to the Patient Management screen



Patient Management screen

6.1 COMMANDS

The following touchscreen commands are available on the interface:

Icon	Function
	Return to the main screen
	Create new patient
	Delete all saved patients

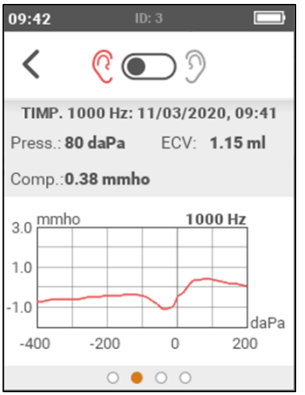
6.2 CREATE NEW PATIENT

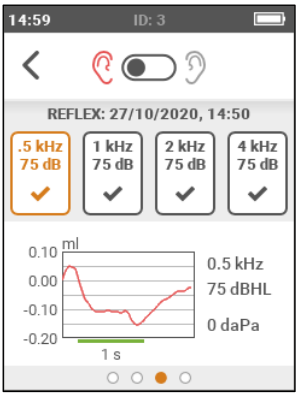
To enter the patient's personal details, press the relevant item and fill in the fields using the keypad. The ID field contains a unique code that is assigned automatically by the system at the time of creation and cannot be changed.

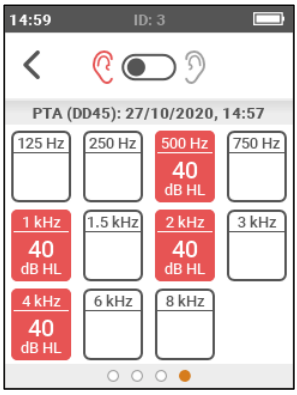
6.3 VIEW PATIENT DATA

To access the stored details, touch the name or code of the desired patient. Scrolling left and right, you can see:

- the patient's personal details
- 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)
- audiometry test associated with the patient (if stored)





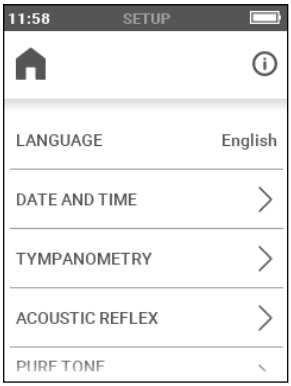


Button	Function
	Return to the list of patients
	Side of the test saved
	Delete the current patient
	Print the tests of the current patient

Chapter 7
Settings

7.1 SETUP MENU

The Settings screen allows the user to change the Timpani parameters.



Icon	Function
	Return to the main screen
	Access the info screen with device serial number, calibrated transducers, firmware version and other useful information for support

7.2 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.

7.2.1 Language

Selection of the interface language used by the instrument. Default value: English (could change based on destination)

7.2.2 Date and time menu

Access the menu used to set the date, time and format.

7.2.3 Data security

Access the menu used to change the PIN and enable/disable it.

7.2.4 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.

7.2.5 Tympanometry

Access the menu for tympanometry settings. Allows selecting the pressure range used to conduct the test: Standard [-400; +200] daPa or Reduced [-300; +100] daPa. Default value: Standard.

7.2.6 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.

7.2.7 Pure Tone Audiometry

Access the menu for the Audiometric test settings:

- Frequency selection: selection of stimulus frequencies in the range 125 Hz – 8 kHz. The value 1kHz cannot be unselected. Default value: all frequencies enabled.
- Stimulus mode: sets the stimulation mode, allowing the user to choose between continuous stimulation or pulsed 1 Hz stimulation. Default value: continuous.
- Default intensity: sets the intensity of the stimulus from which to start the frequency change for the manual examination. Default value: 40 dB HL.
- Automatic frequency skip function: enables / disables automatic switching to the next frequency after a value is saved. Default value: disabled.
- Switch mode: allows the interrupter button to be used as a button (stimulation active as long as the key is pressed) or switch (stimulation is activated when the key is pressed and deactivated when it is pressed again). Default value: pulsating.
- VA transducer: sets the type of transducer for air conduction, allowing the user to choose between supra-aural and insert earphones. Default value: supra-aural headphones.

7.2.8 Display brightness

The brightness of the display can be set between 20% and 100%. Default value: 80%.

7.2.9 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.

7.3 LICENSE MENU

Access the menu to enable additional licenses.

Chapter 8
Docking station

The docking station, available upon request, allows the user to store away the Timpani after use, recharging the device and transferring the data to the computer.[1]

Plug the docking station into a power socket using the power adapter supplied by Inventis 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.

Place the Timpani stably on the docking station so as to ensure correct communication.

[1] Requires Maestro Summer 2020 version (1.10.0) or later

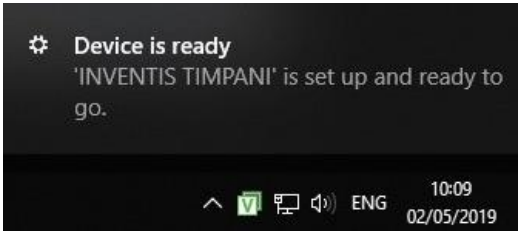
Chapter 9
Interface with PC

The Timpani tympanometer can be interfaced with a personal computer after installing the Inventis Maestro software.[1] Refer to the User Manual *Maestro – General Functionalities* for a detailed description of the procedures involved when installing Maestro on the computer, and to the User Manual *Maestro – Functionalities for audiometry and impedance testing* for more information on using the Timpani tympanometer in conjunction with a computer.

9.1 CONNECTION TO PC

Connect the Timpani 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).

After a few seconds, the connected device will be recognized by the operating system. Installation is complete when the following message appears:



[1] Maestro Spring 2019 version (1.09.0) or later

Chapter 10
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 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 Inventis.

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

10.1 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 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, see appendix Troubleshooting.

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

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

10.2 MAINTENANCE OF TRANSDUCERS

Do not use liquids or sprays to clean the tympanometer.

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

- The cushions of the headphones are made of biocompatible material but are not sterile. To prevent the spread of infections and to ensure their biocompatibility, they must be sanitized before being used on a new patient using wipes dampened with denatured alcohol or a microfiber cloth dampened with denatured alcohol.

- The earpieces of the probe and the insert earphones are made of biocompatible material and must be used once only, then discarded in compliance with current waste disposal regulations.

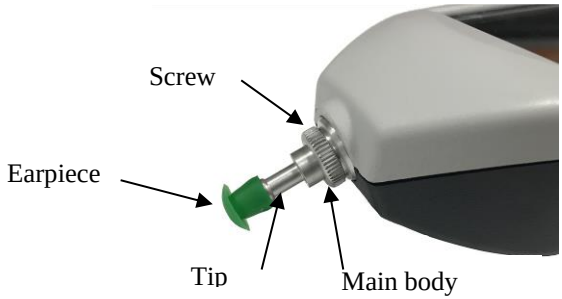
Earpieces are not sterile. Reusing unsterilized earpieces can cause ear infections.

To avoid damaging the DD45 headphones, do not press them against a flat surface. This can create a vacuum and damage the transducer (suction cup effect).

10.3 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.

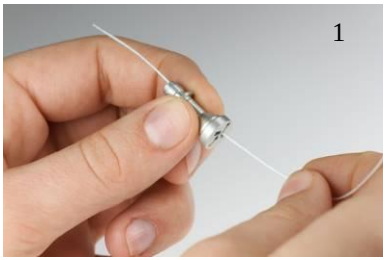
As illustrated below, the probe comprises a main body rigidly attached to the instrument, a tip (to which the earpiece is fitted) and a screw collar, which keeps the tip of the probe firmly secured to the body.



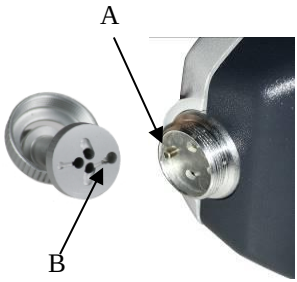
The procedure for cleaning the probe will now be described.

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 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.

10.4 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.

10.5 REPLACING THE BATTERY

Should the instrument appear to be giving much shorter endurance than described in appendix *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 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 accessories mentioned in the manual are designed especially for use with this instrument. Only accessories supplied by Inventis should be connected to the tympanometer.

10.6 REPAIRS AND TECHNICAL ASSISTANCE

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

AVAILABLE TESTS
Tympanometry (226Hz and optional 1000Hz), Acoustic Reflexes (optional), Manual tonal audiometry (optional), Automatic tonal audiometry.

CALIBRATION
12 months

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 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 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

AUDIOMETRY – audiometry license required		
Stimulus	Pure tone	
Attenuator step	5 dB	
Method of presentation	Continuous, Pulsed (cadence: 1Hz)	
Frequency accuracy	0.1%	
Intensity accuracy	±3 dB between 125Hz and 4kHz; ±5 dB over 4kHz	
Total harmonic distortion (THD)	VA: less than 2.5%	
Compatible transducers		
Type	*Manufacturer*	*Model*
Supra-aural headphones	Radioear Corp.	DD45
Insert earphones	Etymotic Research Inc.	ER-3C

Available frequencies and maximum intensities

Freq. [Hz]	**DD45 [dB HL]**	**ER-3C [dB HL]**
125	60	70
250	80	90
500	90	95
750	100	100
1000	100	100
1500	100	100
2000	100	100
3000	100	100
4000	100	100
6000	90	80
8000	85	70

EQUIVALENT THRESHOLD LEVELS OF REFERENCE FOR PURE TONE

	DD45	**ER-3C**	**IPSI**
Ref. standard	**ISO 389-1 (ANSI S3.6)**	**ISO 389-2 (ANSI S3.6)**	**ISO 389-2 (ANSI S3.6)**
Coupler	IEC 60318-3	IEC 60318-5	IEC 60318-5
Freq. [Hz]	**dB [re 20 µPa]**	**dB [re 20 µPa]**	**dB [re 20 µPa]**
125	47.5	26.0	-
250	27.0	14.0	-
500	13.0	5.5	11
750	6.5	2.0	-
1000	6.0	0.0	5.5
1500	8.0	2.0	-
2000	8.0	3.0	7
3000	8.0	3.5	-
4000	9.0	5.5	2
6000	20.5	2.0	-
8000	12.0	0.0	-

SOUND ATTENUATION VALUES

Freq. [Hz]	DD45(*) [dB]	ER-3C [dB]
125	3.0	33.5
250	5.0	34.5
500	7.0	34.5
750	-	-
1000	15.0	35.0
1500	-	-
2000	26.0	33.0
3000	-	-
4000	32.0	39.5
6000	-	-
8000	24.0	43.5

(*) With MX41\AR or PN 51 cushions

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

POWER SUPPLY	
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.

COMPUTER INTERFACE	
Connection:	USB (no driver needed)
Compatible software products	Inventis Maestro suite

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

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 IEC 60645-5 type 2, ANSI S3.39 type 3 Audiometer IEC 60645-1 type 4, ANSI S3.6 type 4
Electrical safety:	IEC 60601-1 Class II, Type B
EMC	IEC 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

Upon request, Inventis 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 Inventis has deemed repairable by staff.

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 properly	Check that the transducer is connected properly
	Transducer damaged	Contact Inventis service department or dealer
Unable to establish a direct connection between the PC and the Timpani 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 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 the docking station	Check the positioning of the instrument Check that the contacts are clean Check connections
	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 device
message: “Hardware error”	Non-fatal internal error	Press OK to continue; if the problem persists, contact the Inventis service department

Problem	Possible cause	Solution
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 center 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:

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

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.

The instrument has no ESSENTIAL PERFORMANCE risks as envisaged in IEC 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 affecting voltage on incoming electrical power supply 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.	The quality of electrical power supplied by the grid must correspond to that of 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 From 80 MHz to 2.7 GHz	3 V/m From 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 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