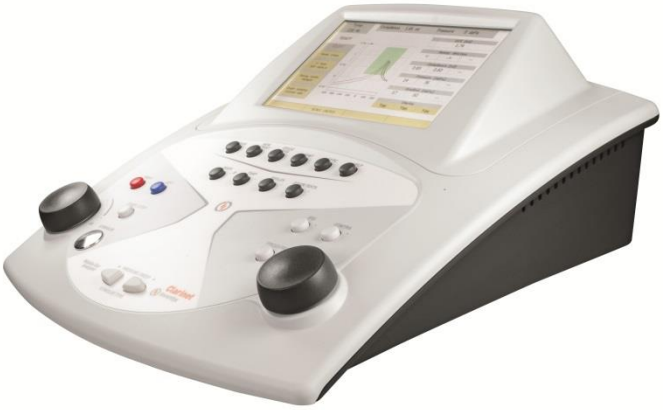

# CLARINET

## MIDDLE EAR ANALYZER

# USER MANUAL

*Read this manual thoroughly before using the device. Pay particular attention to Chapter 1 ("Safety: warnings and information") and Chapter 3 ("Installation and power up").*

*The inspection of internal components must be left to technicians approved by Inventis s.r.l..*

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| Document title: | **IM1C-User Manual En** |
| Revision: | **12** |
| Date: | **2017.07. 01** |

# Summary

# Foreword

Thank you for purchasing an Inventis audiology device.

The Clarinet middle ear analyzer is a clinical instrument offering a set of features and functionalities that place it at the top of its category.

The Inventis company has always considered the use of its devices in conjunction with computers to be a factor of key importance. Maestro software, available with or without proprietary database or as Noah module, can be used to connect any Inventis audiology device to a computer, so that examinations can be archived in a database, and the examination currently in progress can be displayed on the computer screen. We would also remind you that Inventis has developed a complete line of audiology devices: in addition to these middle ear analyzers, the company's product line includes a range of audiometers and a wireless video otoscope.

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
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Tel.: +39 049 8962844 – Fax: 049.8966343
www.inventis.it info@inventis.it

# CHAPTER 1:

# Safety: warnings and information

## OPERATOR MANUAL

Be sure to read this manual through completely, so that all of the features offered by the instrument can be used to their full potential. 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 Clarinet middle ear analyzer 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 of the device 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 Centers approved by Inventis. Inventis s.r.l. and approved Service Centers 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 power supply and ground connections of the system comply with applicable standards for electromedical devices.

## INTENDED USE

The Inventis Clarinet middle ear analyzer is intended for use by trained operators in hospitals, nurseries, ENT clinics and audiology offices in conducting diagnostic hearing evaluations and assisting in diagnosis of possible otologic disorders.

Tympanic membrane of newborns is particularly thin and fragile. Pressure applied on the membrane by the instrument could damage it. Do not use the instrument for children with age under 6 months, in any case perform an otoscopic inspection before executing tympanometry exam.

The Clarinet middle ear analyzer can be used to conduct automatic and manual tympanometry tests, acoustic reflex tests, reflex decay and latency tests, and Eustachian Tube Function tests.
These tests must be conducted in a particularly quiet environment in order to avoid artifacts that could give false measurements.

The Clarinet middle ear analyzer is intended for use by persons who have a detailed knowledge of the procedures associated with the tests supported by these instruments; 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).

## PRECAUTIONS

To ensure correct and safe use of the middle ear analyzer, the following precautions must be observed.

### Installation and general precautions

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

Technical Specifications".

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

Avoid installing and using the middle ear analyzer close to any sources of strong electromagnetic fields: these could interfere with the operation of the instrument.

Use only original accessories supplied by Inventis s.r.l., unless specifically indicated otherwise.

Use only power adapters intended for medical equipment, certified to EN 60601-1. For further information see "Appendix A – Technical Specifications".

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

Clarinet needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in Appendix C.

Use of portable and mobile RF communications equipment can affect the correct operation of Clarinet device. Make reference to the EMC information in the Appendix C.

## Calibration

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

The calibration is valid for transducers supplied with the equipment, if connected directly to the instrument, without any interposition of extension leads and without the passage from connectors to panel. If the transducers are not connected directly to the middle ear analyzer, a new calibration procedure will be required before the instrument is used.

In each test window, when you select a not-calibrated transducer, the background of the 'output' area will be displayed in red color. Moreover, you will not be able to send any stimulus through not-calibrated transducers.

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

## Hygiene

The ear tips of the middle ear analyzer probe are disposable; do not use the same ear tips for different patients. Dispose of ear tips after use.

Disinfect the cushions of audio cups used for contralateral stimulus between one patient and the next, following the procedure described in Chapter 10: Maintenance.

## 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 all electronic devices, the middle ear analyzer contains extremely small quantities of certain hazardous substances. If such substances are allowed to enter the normal waste disposal cycle without suitable preliminary treatment, they can cause damage to the environment and to health. All parts of the middle ear analyzer must therefore be disposed of separately.
At the end of its life, take or send the disused instrument to a public waste collection and recycling facility, or return it to the reseller against the purchase of an equivalent new instrument.
Separate waste collection and the subsequent operations of treatment, recycling and disposal facilitate the manufacture of new appliances from recycled materials, limiting any negative impact on the environment and public health that might otherwise derive from improper disposal.

## CONFORMITY

Clarinet middle ear analyzers are class IIa medical devices, according to Annex IX of Medical Device Directive (MDD) 93/42/EEC, as amended by directive 2007/47/EC.
The Inventis Quality Management System has been certified by TÜV as compliant with ISO 9001 and ISO 13485 standards.

## SYMBOLS ON LABELS

*This symbol means that, for safe use of the device, it is important that the user refers to the warnings contained in this manual.*

*Consult instructions for use.*

*This symbol means this product is covered by the Directive 2012/19/EU on waste electrical and electronic equipment (WEEE). It is required not to dispose this product as unsorted municipal waste, but to collect it separately.*

*Device with Body Floating applied parts (type BF- EN60601-1).*

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*Product conforms to European Community Medical Device Directive (MMD) 93/42/EEC, as amended by 2007/47/EC directive. Class IIa device; number of notified body: 0123 (TÜV SÜD Product Service GmbH).*

Rx only

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

IP20

*IP (Ingress Protection) Code: this device is protected against the ingress of objects sized > 12.5 mm, not protected against liquids.*

REF

*Catalogue number*

*Name and address of the manufacturer*

SN

*Serial number of the device. The number is made up of 13 alphanumeric characters indicating the model, series, year of manufacture and serial number. In particular, the number comprises these segments:*

- *first 5 characters: Inventis product code*
- *characters 6 and 7: year of manufacture ("14" denotes 2014)*
- *character 8: model series*
- *characters 9… 13: serial number*


*UDI code*

# CHAPTER 2:

# Introduction

This chapter describes the main features of the Clarinet middle ear analyzer and in particular, explains the differences between the model Basic and Plus.

## MAIN FEATURES

Even with its notably compact footprint, the Clarinet clinical middle ear analyzer made by Inventis offers the specifications of a device second to none in its class. Given the number of tests it can perform and the accuracy it provides, the Clarinet is the ideal option for clinics and hospitals, and indeed any users who expect the very best from their instruments.

The main strengths of Clarinet middle ear analyzers are:

- fast testing procedures and accurate results;
- large and bright color graphics display, showing the results of examinations graphically;
- compact and intelligent design;
- interaction with computer, usingMaestro software.

Clarinet is available in 2 versions, *Basic* and *Plus*: compared to the Basic version, Clarinet Plus features multi-frequency (with 678, 800 and 1000 Hz probe tones) and multi-component (Y, B and G) tympanometry.

Clarinet models are available with or without built-in thermal printer.

The following table indicate the types of tests that can be performed with each model.

| Exam | Mode |
|---|---|
| TYMPANOMETRY | Automatic |
| | Manual |
| ACOUSTIC REFLEX | Fixed intensity |
| | Automatic threshold |
| | Growing intensity |
| | Manual |
| REFLEX DECAY | Manual |
| REFLEX LATENCY | Manual |
| EUSTACHIAN TUBE FUNCTION | Eardrum intact |
| | Eardrum perforated |
| QUICK A | Tympanometry + acoustic reflex (fixed intensity or automatic threshold mode) |
| QUICK B | Tympanometry + acoustic reflex (fixed intensity or automatic threshold mode) |

## ACCESSORIES

The following table lists the various accessories either supplied with or obtainable to order for the middle ear analyzer.

| | |
|---|---|
| Control box with probe | ● |
| Shoulder strap for probe control box | ● |
| Wrist strap for probe control box | ● |
| Telephonics TDH-39 supra-aural headphones for contralateral stimulation<br>OR<br>IME-100 insert earphone for contralateral stimulation | ● |
| Calibration cavities | ● |

| | |
|---|---|
| Assorted ear tips box | ● |
| Integrated thermal printer | opt. |
| 3pcs heat-sensitive paper rolls | opt. |
| Plastic cover sheet | ● |
| Carrying case | opt. |
| Inventis Software Suite | ● |
| USB cable | ● |
| Medical grade power supply (6V) | ● |
| User manual | ● |

# CHAPTER 3:

# Installation and power-up

Whilst the installation of a Clarinet middle ear analyzer is a relatively simple procedure, it should be entrusted to a person with the requisite skills. If the installation is not performed correctly, the system could be affected by safety problems when in use.
This chapter describes the procedure for installing the system.

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

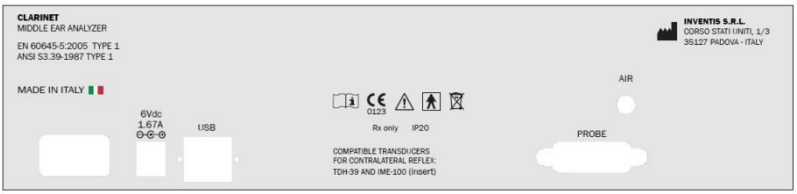
## PRECAUTIONS

Like any other electrical or electronic device, the middle ear analyzer 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 affected device from the middle ear analyzer;
- plug the affected device into a power socket on a circuit other than the circuit to which the middle ear analyzer is connected;
- consult the manufacturer or a service center for assistance.

## CONNECTIONS

All connection points for accessories are located on the rear panel, as also is the power switch.




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

| *Connector* | *Accessory* |
|---|---|
| PROBE | Control box |
| AIR | Air tube |
| USB | USB cable for connection to personal computer |

Connect the power adapter to the 6Vdc 1.3A input and to the relative power cord, which should be plugged into an a.c. mains socket supplying the voltage indicated on the adapter label.

*All connections must be made with the instrument switched off, that is to say with the power switch set to position* **0**.

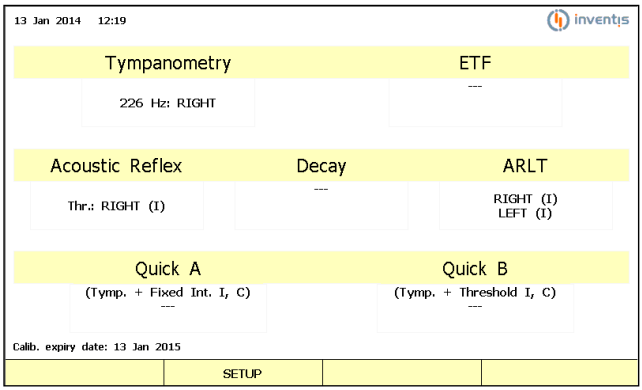
*Use only power adapters intended for medical equipment, certified to EN 60601-1. For further information see "Appendix A – Technical Specifications".*

## POWER-UP AND MAIN SCREEN

Once all cables and leads are connected, the instrument can be switched on at the rear panel.

*At the startup of the instrument, a pressure initialization is performed: in order to complete initialization successfully the probe must be steady and be kept outside of any cavity.*

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




*Main screen of Clarinet middle ear analyzer*

The main screen displays the various tests available, and shows information relating to the examinations already performed on the patient. If no examination has been conducted, the label "---" is displayed.
In the case of Quick exams (a configurable sequential combination of tympanometry and reflex test), the display shows the types of examination that will be (or have been) conducted during the particular test.
To access an examination, simply press the corresponding button on the keyboard, or alternatively, press the area of the touch screen corresponding to the test.

The top part of the display shows the date, the current time and the Inventis logo.
The bottom part of the display indicates the calibration interval expiry date (12 months subsequent to the date of the last calibration).

# CHAPTER 4:

# Controls and probe

This chapter describes the controls incorporated into the keyboards of Clarinet middle ear analyzers.

## THE TOUCH SCREEN

The Clarinet middle ear analyzer has a generously sized touch screen color graphic display. The touch screen is an essential medium for controlling certain functions of the instrument; in particular, touch screen input is used:

- to control certain test parameters;
- to navigate between the various screens of the graphic interface.

The touch-sensitive areas of the screen — which change from window to window — are characterized by a yellow background.
The bottom part of the display is always occupied by four (or more) yellow soft function keys: simply touch any one of the keys to access the relative function.

## CONTROLS FOR DIRECT ACCESS TO EXAMINATIONS

To access the available examinations on Clarinet middle ear analyzers, press the relative button located in the top half of the keyboard, as illustrated below.


The Led associated with the button will also light up to confirm the selection.

The OTHER TESTS button can be used to access those tests for which there is no dedicated button. On pressing OTHER TESTS, the required function can be selected with the left hand knob of the instrument and confirmed by pressing the STIMULUS button.
Quick tests are accessed by way of a single button. Pressing repeatedly, the appliance will toggle between Quick A and Quick B, as indicated by the on/off status of the associated Led.

## CONTROLS FOR CONDUCTING EXAMINATIONS

*Right and Left.* The Right and Left buttons are used to select the side being examined.

*Start/Stop*. Used to initiate and terminate the examination currently selected. As long as the examination is in progress, the associated Led remains alight.

*Stimulus.* Button active during acoustic reflex decay and reflex latency tests. This is used to run (or repeat) the examination relative to the box currently selected (yellow background), without having to repeat the entire test. This is a capacitive type button: to run the test, simply touch the metal cap.

*Left hand knob*. Used to adjust the output strength of the stimulus. In practice, these knobs are used in certain situations for other purposes; for example, with the Settings menu activated, all the various settings of the instrument are selected with the two knobs. When the knobs are used to perform a specific function other than that of attenuating the channel output, the sector-shaped indicator adjacent to the knob will light up.

*Ipsi and Contra*. These buttons can be used to select ipsilateral or contralateral mode for the acoustic reflex test.

*Stimulus Type / Pressure sweep.* These buttons are used to select the type of stimulus presented to the patient when conducting acoustic reflex decay and latency tests. The function of the buttons during tympanometry tests is to select the direction of the pressure sweep.

*Pressure*. Pressing the Pressure button, the tympanometry test can be activated in manual mode or, if pressed internally of the acoustic reflex decay or reflex latency screens, the instrument will show a screen allowing adjustment of the pressure at which the test is conducted. The pressure is changed by turning the right hand knob. The adjustment window shows the current pressure, and the actual compliance value.

## FUNCTION BUTTONS

The six function buttons illustrated below are positioned uppermost in the keyboard area.


*Back.* This is pressed to go back to the previous window. For example, if Back is pressed during a tympanometry test, the main menu will reappear.

*New Patient.* Pressing the New Patient key will clear all examinations conducted in the current session. If these have not been saved to a computer, all the relevant data will be lost.

*Erase data.* Deletes data pertinent to the current graph of the examination. In the case of tympanometry, for example, data relative to the selected side is deleted, whereas in the case of the acoustic reflex test, only those items of data pertinent to the current box and side are deleted.

*Print*. If the middle ear analyzer has a built-in thermal printer, pressing this button will generate a printout of the current examination.

*To PC.* Sends the current examination to a computer, on which Maestro software must be installed (refer to *Maestro – Impedance-Audiometry functionalities – User manual* for more details).

*Help*. This button opens a context-sensitive window, i.e. displaying information pertinent to the type of test being conducted. 'Help' provides general information on the functions of the current window.

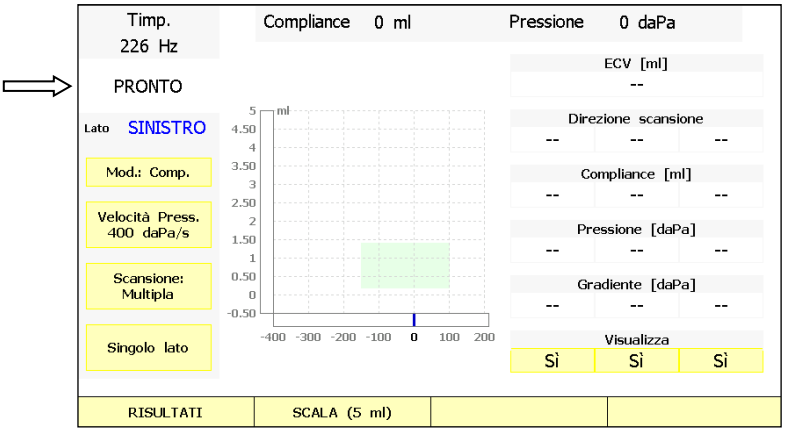
## THE PROBE

Clarinet middle ear analyzers feature a miniature probe, connected by a signal lead and a small-bore air tube to the compact *Control Box* (CB), which in turn is connected to the instrument. Despite being very small and light, the probe is an active type, in other words incorporating speakers for the probe tone and ipsilateral stimulation signals, and a microphone for measuring compliance.

Probe status

The window for each examination presents an area on the left of the screen, below the name of the test (see the figure below), showing information

relative to the current status of the probe (when there is no test in progress) or to the test in progress.




The items that can be displayed are indicated below.

| *Indication in display* | *Explanation* |
|---|---|
| READY | The examination is ready to start |
| OPEN | Probe open: the compliance measured is above the upper limit of the measurement range |
| CLOSED | Probe blocked: the compliance measured is below the lower limit of the measurement range |
| PRESSURIZATION / DEPRESSURIZATION | Pressurization / depressurization of ear canal in progress |
| COMPLIANCE CHECK | Compliance is verified before starting an acoustic reflex test. The stimulus will be presented only when compliance is stable |
| IN PROGRESS | Test in progress |
| PRESSURE LEAKAGE | Lack of airtight seal between probe and ear canal |

It will be noted that you may even start the test in the OPEN and CLOSED situation. The PRESSURE LEAKAGE status is displayed on an orange background and it terminates the examination in progress.

Control Box (CB)

There are two buttons on the CB. The first has the same function as the START/STOP button on the keyboard of the analyzer, described previously, which starts and stops the examination. The second button can be pressed to select the side on which the stimulus is presented.
There are also two LEDs, one of which indicates the ear being tested (red: right ear; blue: left ear), the other indicating the status of the probe.
The colors and the frequency at which this second LED lights up indicate the current status of the probe and of the examination, as indicated on the screen (see description above).
In particular:

| | |
|---|---|
| Green blinking: | examination READY status |
| Green permanently alight: | examination in progress (IN PROGRESS, COMPLIANCE CHECK, PRESSURIZATION, DEPRESSURIZATION) |
| Yellow blinking: | probe blocked (CLOSED) |
| Yellow permanently alight: | probe open, or lack of airtight seal (OPEN, PRESSURE LEAKAGE) |

# CHAPTER 5:

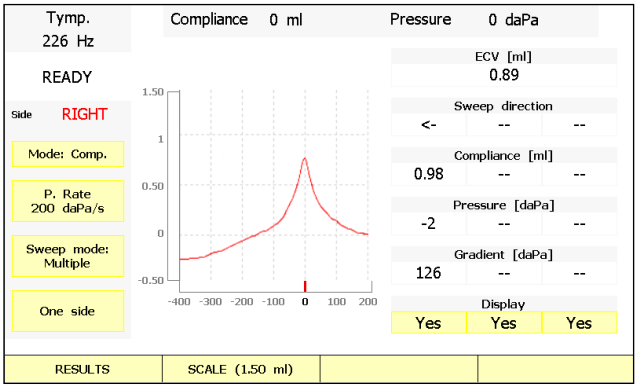
# Tympanometry

This chapter describes the tympanometry test.

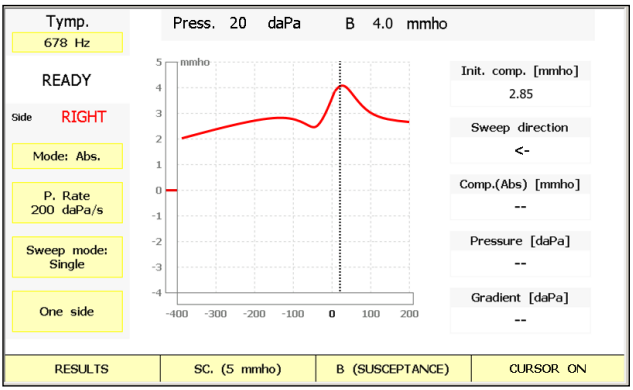
## THE TYMPANOMETRY WINDOW

To conduct the tympanometry test, the operator simply presses the relative button on the keyboard.

The graphic interface of the tympanometry window is illustrated below.




*226 Hz tympanometry test window*




*678 Hz tympanometry test window*

The name of the current test is indicated at the top left of the screen, and immediately below, items of information relating both to the status of the probe and to the progress of the test, as described in the previous chapter.
Lower down, the screen shows information specific to this particular test, namely:

- the stimulation side;
- the mode in which the tympanogram is represented (compensated or absolute);
- the rate at which the pressure sweep occurs during the course of the test;
- selection of single or multiple scan for the side being tested;
- the graph display mode (single or bilateral).

The central area of the screen is occupied by the tympanogram relating to the ear currently selected or by the graphs for both ears. Pressure values indicated at the ends of the horizontal scale correspond to the initial positive value and the final negative value of the sweep (selected via the instrument settings, see Chapter 9). When the tympanogram is represented in absolute mode, a dash appears on the right of the graph, indicating the current component (Y, B or G) measurement.
The right hand side of the screen shows the results of the test, which will be described in detail in the relative section.

## TEST PARAMETERS

The default probe tone frequency is always 226 Hz but, on Clarinet Plus only, it can be switched to 678, 800 or 1000 Hz. Values can be changed by pressing on the relative area with yellow background on the top left part of the screen.

Multi-component tympanometry for measuring the Admittance (Y), Susceptance (B) and Conductance (G) values is only available for Clarinet Plus. Press the third soft touch button to decide which one to show. If "single sweep mode" is selected, components B and G can also be displayed together.

The pressure sweep adopted during the course of the examination varies at a rate that can be changed by touching the dedicated area with the yellow background (PRESSURE SWEEP); the values selectable for this parameter are: 15, 50, 100, 200, 300, 400, 600 daPa/sec and 200-600 daPa/sec. In this latter mode, the rate of variation is regulated automatically at 200 daPa/sec or at 600 daPa/sec according to the compliance measurements acquired; the rate is higher when the variation in compliance is low, and lower when the variation is high.

The tympanometry test can be conducted in single scan mode with just one descending pressure sweep, or repeated up to three times in succession with an ascending or descending sweep. This option can be changed by touching the dedicated area of the screen with the yellow background. It is not possible to switch to multiple scan mode when both graphs are displayed on the screen.
Different components can be shown for

In the event of the test being interrupted unexpectedly when in multiple scan mode, the procedure can be resumed maintaining the previous traces simply by pressing the START/STOP control.

To adjust the compliance scale on the graph, simply press function button SCALE. The selectable values of the scale differ according to the current method of representing the tympanogram (compensated or absolute). In either case, it is also possible to select the option "auto", in which case the scale utilized will be selected automatically, so as to represent the acquired data at the highest resolution possible. The indication of the scale currently selected is provided by the relative soft key.

The tympanogram viewing mode can be switched between compensated or absolute by touching the dedicated area of the screen with the yellow background. In absolute mode, the measured values of compliance are displayed directly, whereas in compensated mode, these values are shown minus the equivalent ear canal volume (ECV).

Similarly, the viewing mode for the graphs — one only, or both — can be toggled by touching the dedicated area of the screen.

All the parameters mentioned above are saved automatically by the instrument, and maintained at each successive power-up.

The Clarinet middle ear analyzer can also display the results of the tympanometry test at 226Hz together with those of the acoustic reflex test. The screen is accessible by pressing the RESULTS function key.

## TEST RESULTS

The results of the examination are shown on the right of the window. The following values are calculated:

ECV (Ear Canal Volume)

This is the compliance value measured at the pressure set for the start of the test, or rather the highest pressure of the range selected for the test. This value is also called the “equivalent volume”.

Scan direction

This field indicates the direction of the pressure sweep applied to the ear canal during the test: ascending or descending. The information will not be displayed when bilateral viewing mode is selected.

Compliance / Compliance (Abs)

Amplitude of the tympanogram peak measured against the ECV. In absolute mode, this corresponds to compliance at the tympanogram peak. Compliance value is not shown in case of B and G graphs displayed together.

Pressure

The pressure value registering at the tympanogram peak;

Gradient

This is the gradient of the tympanogram. It can be calculated by two different methods, the selection of which is made from the settings screen (see Chapter 9).

The two calculation criteria are indicated below. Letter *a* indicates the peak amplitude of the tympanogram, and *b* the difference between *a* and ECV:

- width of the tympanogram at 50% of *b* (expressed in daPa);
- letter *c* is the average of compliance values measured at pressures of +50 daPa and -50daPa, relative to the tympanogram peak. The gradient is determined by the following formula: *Gradient* = (*a* - *c*) / *b*

In the event that it is not possible to determine the compliance or the tympanogram pressure peak, the letters "N.F." (NOT FOUND) will be displayed in place of the value.

Cursor

The cursor allows the user to verify every single value assumed by the component displayed. Option for activating the cursor is available from the fourth soft touch button on the right part of the screen. Use the right knob for moving the cursor position and the current component value will be shown on the upper part of the screen.

## HOW THE EXAMINATION IS CONDUCTED

The first step is to select the ear tip best suited to the patient being examined, and introduce the probe together with the ear tip into the patient's ear canal, to the point at which a tight pressure seal is assured.

### Automatic mode

Having selected the ear to test, left or right, and the scan mode, the procedure can be started simply by pressing the START/STOP button, or the corresponding button on the CB.

In the case of a multiple scan, once the first descending scan has been completed, the direction can be maintained or switched, and further scans then activated by pressing the PRESSURE SWEEP or START/STOP buttons on the control box.

Selecting the preferred option from the test settings (see Chapter 9), the examination can be made to start automatically as soon as the instrument detects that the probe has been positioned correctly in the ear canal.

## Manual mode

Having selected Left or Right and set the scan mode, simply press the PRESSURE button to prime the system and start the test. Once maximum pressure has been established as indicated in the settings (see chapter 9), the actual value can be adjusted by turning the right hand knob on the instrument. With each change, the current compliance value will be drawn on the graph.

In the case of a multiple scan, the system will pass on to the next test when the direction of rotation of the knob is reversed.
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, at the selected rate.
The indices described in the previous heading are now calculated and displayed, and pressure in the ear canal is returned to atmospheric, terminating the examination.

The current pressure value is indicated throughout the duration of the test by the vertical dash, below the “x” axis of the tympanogram. The graph is displayed normally in absolute (uncompensated) mode and will appear in compensated mode — if selected — only at the end of the test.

# CHAPTER 6:

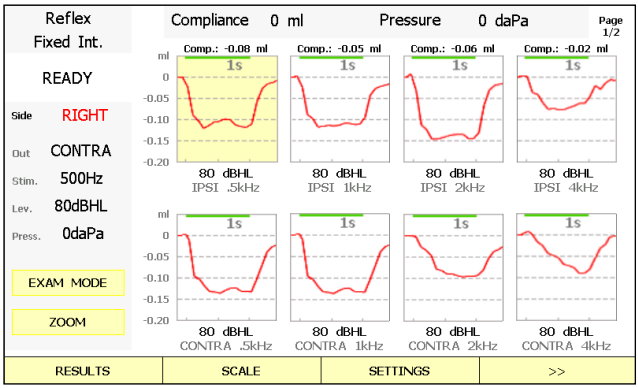
# Acoustic Reflex, Reflex Decay, ARLT and Quick tests

This chapter describes the Acoustic Reflex Test, the Reflex Decay Test and the Reflex Latency Test .

## ACOUSTIC REFLEX TEST WINDOW

To conduct the acoustic reflex test, the operator simply presses the relative button on the keyboard or touches the part of the display dedicated to the main screen.

The graphic interface of the acoustic reflex window is illustrated below.




*Acoustic Reflex Test window*

This test can be conducted in different modes, which will be described in detail further on. The current mode is indicated at the top left of the screen, on a grey background. To change the test mode, simply press function

button 1 (EXAM MODE); the last mode to be selected will be memorized by the instrument.
Independently of the current mode, the bottom-left part of the display will show items of information relating to the ear (side) being examined, to the pressure used during the course of the test (Press.), and to the current stimulus, namely:
- the transducer (Out), Ipsi or Contra;
- the frequency of the stimulus tone or type of noise (Stim.);
- the intensity of the stimulus tone (Lev.).

As concerning pressure, the operator can choose whether to conduct the test entirely at atmospheric pressure (the label "Atm." is displayed) or at the peak pressure of the tympanogram (see Chapter 9). If no tympanometry test has been conducted, the pressure is set in any event to 0 daPa.
When performing the reflex test with the Clarinet model, the pressure at which the test is conducted can be adjusted manually (the caption "Man." appears alongside the pressure value displayed); this functionality is described further on.

Most of the screen is taken up by eight boxes, each one showing the curve of the reflex obtained with a given stimulation signal. Pressing the SCALE function button, the operator can vary the scale of the compliance axis; possible intervals are -0.05 to 0.2 ml and -0.1 to 0.4 ml. It is also possible to change the polarity of the reflex curve, as described in Chapter 9.
The green bar internally of each box represents the stimulus on-time, in other words the duration for which the stimulus is active. The duration of the on-time is configurable (see Chapter 9).
Indicated under each box are details of the stimulus to which the curve relates (side, frequency and intensity).
For greater visual clarity, reflex curves produced with ipsilateral signals are represented in a color darker than that in which contralateral signals are displayed.
The current box is highlighted by a yellow background; to navigate from one box to another, simply turn the right hand knob.
Touching the ZOOM area of the display with the yellow background, the current box can be viewed in full screen mode; this allows the operator to view the curve of the reflex in greater detail. Also in this mode, the amplitude of the reflex is indicated. To exit full screen mode, press "ZOOM" again, or use the BACK button.

Pressing the SETTINGS function button, the operator accesses a window that will allow the selection of settings relative to the method of conducting the reflex tests.

## MODES OF CONDUCTING THE EXAMINATION

As mentioned in the previous section, the acoustic reflex test can be conducted in various ways. Remember that the instrument will always default to the configuration of the last test mode selected, for each ear.
Listed below are the different test modes that can be selected, which vary according to the model and version of the instrument.

### Fixed intensity

In this mode, the patient is presented with a single stimulus signal for each box. All the boxes are preconfigured, and to set the types of stimulus, the operator needs only press function button 4 to access the settings window. The window with settings for the "fixed intensity" mode is illustrated below.

Riflessi (Int. Fissa): Impostazioni

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|---|---|---|---|---|---|---|---|---|
| Abilita | Si | Si | Si | Si | Si | Si | Si | Si |
| Out | I | I | I | I | C | C | C | C |
| Stim. | 500Hz | 1kHz | 2kHz | 4kHz | 500Hz | 1kHz | 2kHz | 4kHz |
| Int. | 80dB | 80dB | 80dB | 80dB | 80dB | 80dB | 80dB | 80dB |

| | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |
|---|---|---|---|---|---|---|---|---|
| Abilita | Si | Si | Si | Si | Si | Si | Si | Si |
| Out | I | I | I | I | C | C | C | C |
| Stim. | 1kHz | 1kHz | 1kHz | 1kHz | 1kHz | 1kHz | 1kHz | 1kHz |
| Int. | 80dB | 80dB | 80dB | 80dB | 80dB | 80dB | 80dB | 80dB |

INDIETRO | | | MODIFICA

*Window with settings for "fixed intensity" mode*

As indicated in the table, which is the same for both stimulation sides, each of the 16 boxes can be configured independently, applying the following parameters:
- *Enable*: indicates the possibility of examining the box (Yes / No);
- *Out*: type of output utilized (IPSI / CONTRA);
- *Stim.*: type of stimulus, i.e. frequency of the tone;
- *Int.*: intensity of the stimulus tone.

For reasons of safety, a warning appears whenever the operator selects a stimulus signal of intensity higher than 100 dB HL.
Also, when exiting this screen, if at least one parameter has been changed, the operator will be prompted to save the changes or retain the previous settings (confirming, all data relating to the examination will be deleted).

The reflex test is started in the same way as other examinations, by pressing the START/STOP on the instrument, or the relative button of the control box. Once the pressure reaches the target value, all of the enabled boxes will be examined, starting from the first. The test is terminated automatically once all the boxes have been examined. When the threshold intensities being identified, the "THR." label (THRESHOLD) will be indicated on the box. Importantly, the stimulus is presented after a step in which the stability of the measured compliance value is checked, as described in Chapter 9.
If the examination is interrupted due to lack of pressure or because of "open" / "closed" status of the probe being detected, the sequence can be restarted from the last box examined, simply by pressing the START/STOP button again.
It is also possible to examine a single box. This is done by selecting the box in question and pressing the STIMULUS button.

## Automatic threshold

This mode differs to fixed intensity mode in that the minimum intensity of a given stimulus able to induce the reflex — in short, the Acoustic Reflex Threshold (ART) — can be found automatically.

Likewise in this mode, the boxes are preconfigured and, for each one, the level displayed indicates the intensity at which the test is started, if there is no existing data, or the intensity of the stimulus used to obtain the curve represented.

To configure the boxes, the operator must press the SETTINGS function button to access the settings window. The characteristics of the boxes are selected in the same way as for the fixed intensity mode, except for the inclusion of the "Start" and "Stop" items indicating, respectively, the initial level and the final level of the stimulus in the intensity threshold search.
Also from this window, the operator can select the intensity increment to apply to the stimulus during the threshold search. Possible values are 5 dB and 10 dB.

The procedure for starting the test on a single box, or examining all of the enabled boxes in sequence, is the same as described in the previous section.
Considering the examination of a single box, the method adopted for determining the threshold is described below.
The patient is presented with the stimulus at the set initial intensity and the operator verifies — referring to a check-box alongside the stimulus on-time — whether the measured compliance has varied in relation to the initial value obtained with no stimulus, by at least an amount correlated to the

selected sensitivity (see Chapter 9). If there has been a significant variation, a further check is made on the stability of the measurements in order to limit the identification of false positives (artifacts).
When both these conditions are established, the ART has been found and the test ends automatically. If this is not the case, once the box has been completed, the stimulus is increased by the value of the selected increment, and presented to the patient. This algorithm continues until such time as the reflex is identified, or until the final intensity selected at the outset has been reached.
If the examination should in fact continue to the point that the final intensity value is reached without the threshold intensity being identified, this will be indicated by the "N.F." label (NOT FOUND).
The threshold search algorithm can be accelerated (see Chapter 9): in this mode, the acquisition of the reflex is stopped as soon as the measured value fails to satisfy the identification criterion, and the stimulus of higher intensity is presented to the patient.

## Growing intensity

In this mode, the variation in amplitude of the reflex can be analyzed in relation to the increase in intensity of the stimulus.
Up to two different stimulus signals can be examined on each side (particular combination of output / type of stimulus). There are 4 boxes associated with each signal, which show the reflex measured at progressively increasing intensity.

The operator can select both the value of the increment (selectable values are 1 dB, 2dB and 5 dB) and the maximum possible intensity of the stimulus. The test can also be set up so as to continue the search until the threshold is found, and then display only the three preceding boxes. These parameters are established in the settings window, which is accessed by pressing the SETTINGS function button.
The method of starting the procedure is the same as for the other types of reflex test. During the examination, the patient is presented with four or more stimulus signals generated automatically at increasing intensity. If the intensity exceeds the maximum set value, or the maximum value permitted by the type of stimulus/transducer, the test will be interrupted.

## Manual

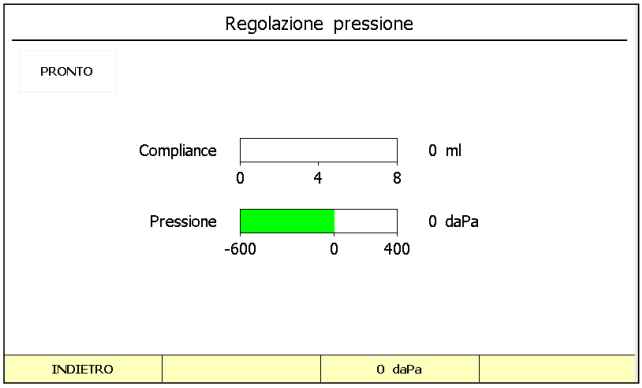
In manual mode, unlike the modes in which the boxes are preconfigured, the details of the stimulus signal to be presented to the patient are selected directly from the screen showing the test, using the dedicated buttons.

In this mode it is possible to perform the exam without sending any stimulus ("NO STIM.").

Pressing the START/STOP button the test will begin, or rather, a pressure equal to that indicated in the display is established in the ear canal. The characteristics of the current stimulus are displayed as captions over the active box. Pressing STIMULUS, the stimulus signal is presented to the patient, and at the same time, data will be acquired and displayed. When the threshold intensity being identified, the "THR." label (THRESHOLD) will be indicated on the box. The pressure will be maintained until the operator ends the examination (by pressing the START/STOP button).
The operator can navigate from box to box during the test, and examine other conditions. Also, if the type of stimulus is changed, then as one box finishes, the test will pass on to the next box automatically.
Parameters associated with this mode are the facility of maintaining the current level unaltered when the type of stimulus is changed and the opportunity to set a default level for the stimulus (access is gained by pressing function button 4).

## MANUAL PRESSURE ADJUSTMENT

To access the window allowing adjustment of the pressure level, illustrated below, the operator must press the PRESSURE button.




*Pressure adjustment window*

The area at the top left of the screen indicates the status of the probe, whilst the central area is occupied by two horizontal bars indicating the measured compliance values and the current target pressure.

If a tympanometry test was conducted beforehand, the peak value of the tympanogram will be indicated above the compliance bar.

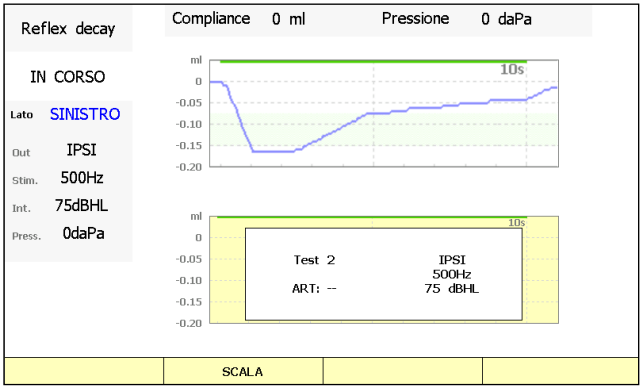
To set the pressure at a desired value, the operator turns the right hand knob. Also, if the operator wishes to set the pressure value swiftly to atmospheric, this can be done by pressing the 0 daPa function button.

Pressing the BACK button, the previous screen reappears and the target pressure of the test is set to the value selected immediately beforehand.

## REFLEX DECAY TEST

To run the acoustic reflex decay test, simply press the OTHER TESTS button and make the selection using the left hand knob.

The decay test window is illustrated below.




*Acoustic reflex decay test window*

The organization of the interface is similar to that of the acoustic reflex test, with the left hand part of the display showing information on the current stimulus, and the remaining area occupied by graphs.

Four graphs are available for each ear, in exactly the same way as for the acoustic reflex test. With two of the four graphs shown in the test screen, the operator can navigate from one to another using the right hand knob.

As regards conducting the examination, the method applied is the same as that used for the acoustic reflex test in manual mode. In addition, the test can also be conducted without any stimulus ("NO STIM.").
Once the test is under way, the following information will be superimposed on the current graph: number of test, threshold intensity (ART) associated with the current stimulus (obtained during the course of reflex test), and the characteristics of the stimulus.
The ART information is useful as the decay test is conducted generally at 10dB above the reflex threshold.
The stimulus on-time can be set at 10 or 20 seconds (see Chapter 9) and is represented in the graph as a green bar.

If the intention is to change the pressure value, simply press the PRESSURE button to access the pressure adjustment screen.
At the end of the examination, the results are shown below the corresponding graph together with the characteristics of the stimulus. The indices shown are:

- *T(50%)*
  The moment (in seconds) at which the reflex registers a decay equivalent to 50% of the maximum amplitude. Also, the region of the graph in which the decay is less than 50% appears in a light shade of green;
- *C (10s) or C(20s)*
  Percentage reduction in reflex amplitude at the end of the stimulus, compared to the maximum value.

The indices will appear with the label "--" if the test has not yet been conducted, or if they cannot be calculated.

## ARLT

To conduct the acoustic reflex latency test (ARLT), press the OTHER TESTS button and proceed to make the selection using the left hand knob..

The organization of the interface is similar to that of the standard acoustic reflex test, with the left hand part of the display showing information on the current stimulus, and the remaining area occupied by graphs.

4 graphs are available for each ear, in exactly the same way as for the acoustic reflex test. Two of the four graphs are displayed in the test screen, and the operator can navigate between them using the right hand knob.

As regards conducting the examination, the method applied is the same as that used for the acoustic reflex test in manual mode.
Once the test is under way, the following information will be superimposed on the current graph: number of test, threshold (ART) intensity associated with the current stimulus (obtained during the course of reflex test), and the characteristics of the stimulus.
The ART information is useful as the decay test will be conducted generally at 10dB above the reflex threshold.
The duration of the stimulus can be set selecting a value of between 300ms and 1700ms (see chapter 9), and is indicated in the graph by a green bar.

If the intention is to change the pressure value, the operator can simply press the PRESSURE button to access the pressure adjustment screen.
At the end of the examination, the results are shown alongside the corresponding graph together with the characteristics of the stimulus utilized, and the test results. The indices shown are:

- *Reflex amplitude*
  Maximum compliance value (absolute) of the acoustic reflex;
- *Latency ON*
  Time taken by the reflex to reach 10% of maximum intensity, measured from the start of the stimulus;
- *Latency OFF*
  Time taken by the reflex to reach 90% of maximum intensity, measured from the end of the stimulus;
- *Rise Time*
  Interval of time, with stimulus ON, during which the reflex registers values between 10% and 90% of the maximum value;
- *Fall Time*
  Interval of time, with stimulus OFF, during which the reflex registers values between 90% and 10% of the maximum value;
- *ON-rate*
  Rate of change of compliance during the rise time, in ml/s. It is calculated considering the straight line joining 30% and 70% of the maximum value during that time;
- *OFF-rate*
  Rate of change of compliance during the fall time, in ml/s. It is calculated considering the straight line joining 30% and 70% of the maximum value during that time;

The indices will appear with the label "--" if the test has not yet been conducted, or if they cannot be calculated.

Certain settings for the reflex latency test can be accessed directly from the interface using the relative function button. The operator can set the number of acquisitions on which to calculate the average used to process results, and choose whether or not to display the percentage indicators measured. Each of the parameters in question can be selected with the right hand knob and adjusted by turning the left hand knob.
Other parameters can be accessed from the instrument settings menu (see Chapter 9).

## QUICK TEST A AND QUICK TEST B

Quick A and Quick B are sequential tests in which the tympanometry test and then the acoustic reflex test are run automatically in sequence. From the settings window (see Chapter 9), the operator can configure the mode of conducting the acoustic reflex test (choice between fixed intensity and automatic threshold modes) and the type of stimulus to be presented to the patient for each of the 8 boxes.

Access to the Quick tests will differ according to the instrument model, as described in previous chapters.

The graphic interface of the test reflects that of the tympanometry and acoustic reflex tests described under previous headings. To change the type of test displayed, simply press the relative function button.

To start a Quick test, the operator must press the START/STOP button (or the relative button on the CB) from one of the two screens of the test; the tympanometry test and the acoustic reflex test will then be run in sequence. The sequence terminates automatically on completion of the last test.

*The execution of QUICK A/B tests may cause the loss of tympanometry and acoustic reflex data stored on the machine. A warning message shall appear.*

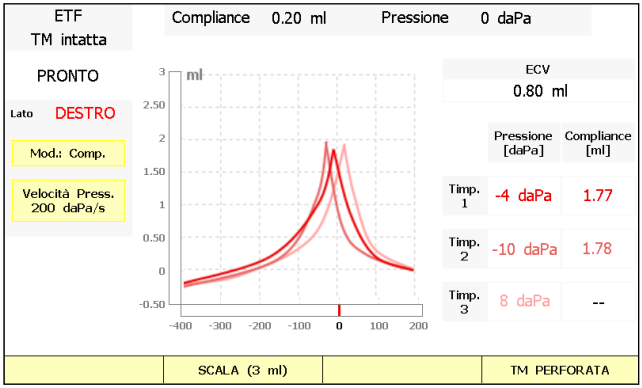
# CHAPTER 7:

# Eustachian Tube Function test (ETF)

This chapter describes the Eustachian Tube Function (ETF) tests. The test can be conducted both on patients whose eardrums are intact, and on patients having a perforated eardrum.

## ETF TEST WITH INTACT EARDRUM

To access the ETF test, simply press OTHER TESTS on the keyboard of the instrument, then select the option with the left hand knob. Function button 4 is used to select the type of test, i.e. with intact eardrum (ETF- TM intact) or with perforated eardrum (ETF – TM perforated).
The graphic interface of the ETF intact eardrum window is illustrated below.




*Window for ETF test with intact eardrum*

The graphic interface is very similar to that of the tympanometry test; the only differences are in the right hand side of the screen, showing the results of the examination, which are described in detail on the following pages.

The central area of the screen is occupied by the graph relating to the ear currently selected. Pressure values indicated at the ends of the horizontal scale correspond to the initial positive value and the final negative value of the sweep (selected via the instrument settings, see Chapter 9).
As in the case of the tympanometry test, when the tympanogram is represented in absolute mode, a dash appears on the right of the graph, indicating the current compliance measurement.

## Test parameters

The parameters that can be set directly from the ETF screen are the same as those described for the tympanometry test In particular, the user can:

- change the rate of the pressure sweep adopted during the course of the examination, by touching the *Pressure Sweep* button;
- adjust the compliance scale on the graph, pressing the SCALE function button. Remember that the selectable values of the scale differ according to the current method of representing the tympanogram (compensated or absolute);
- toggle the tympanogram representation mode between compensated or absolute, touching the area with the yellow background in which it is indicated. In absolute mode, the measured values of compliance are displayed directly, whereas in compensated mode, these values are shown minus the equivalent ear canal volume (ECV).

All the parameters mentioned above are saved automatically by the instrument, and retained at each successive power-up.

## How the examination is conducted

The first step is to select the ear tip best suited to the patient being examined, and introduce the probe together with the ear tip into the patient's ear canal, to the point at which a tight pressure seal is assured.
Having selected the ear to test, left or right, the procedure can be started simply by pressing the START/STOP button, or the corresponding button on the control box.

The test is based on the automatic acquisition of three tympanograms under different patient conditions, as follows:

First tympanogram

For the acquisition of this first tympanogram, the patient is allowed to remain entirely passive. Both the initial positive pressure and the final negative pressure can be configured from the settings window (see Chapter 9).

Second tympanogram

On completion of the first tympanometry test, the pressure in the ear canal is raised automatically to +400 daPa. Once the higher pressure has been established, the patient is asked to swallow several times, thereby forcing open the Eustachian tube. Once the patient has complied with the instruction, simply press and hold the CONTINUE function button to record the second tympanogram.

Third tympanogram

As soon as the second tympanogram has been recorded, the pressure in the ear canal is lowered automatically to –400 daPa. In the same way as for the previous step, the patient is asked to swallow several times so that the Eustachian tube will be forced open. To record the third tympanogram, simply press and hold the CONTINUE function button as before.

It will be noted that the three tympanograms are represented in varying shades of red (if the stimulus is presented to the right ear) or blue (if the stimulus is presented to the left ear).

## Test results

The results of the examination are shown on the right of the window. The following values are calculated:

ECV (Ear Canal Volume)

This is the compliance value measured at the pressure set for the start of the test, or rather the highest pressure of the range selected for the test. This value is also called the “equivalent volume”.

Pressure

The pressure values registering at the tympanogram peak. The pressure indicated in the box named *Pressure 1* is the level recorded during the first acquisition; *Pressure 2* indicates the peak pressure measured during the second recording (the patient is asked to swallow when pressure in the middle ear registers at +400 daPa); *Pressure 3* indicates the peak pressure measured during the third recording (the patient is asked to swallow when pressure in the middle ear registers at -400 daPa).

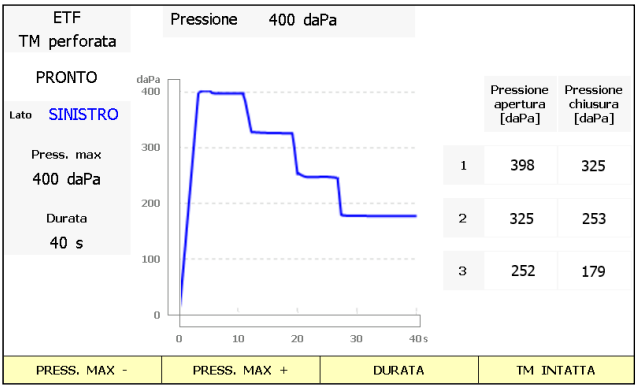
Compliance

Amplitude of the tympanogram peak measured against the ECV. In absolute mode, this corresponds to compliance at the tympanogram peak.

In the event that it is not possible to determine one of the tympanogram pressure peaks, the letters “N.F.” (NOT FOUND) will be displayed in place of the value.

## ETF TEST WITH PERFORATED EARDRUM

The graphic interface of the ETF perforated eardrum window is illustrated below.




*Window for ETF test with perforated eardrum*

The organization of the interface is the same as for all other tests. The left hand part of the window shows information relative both to the status of the probe and to the examination: progress, maximum pressure value and duration.

The central area of the screen is occupied by the graph relating to the ear currently selected. The graph shows a curve representing the pressure level in the ear canal during the course of the test

### Test parameters

All the parameters of this test can be set directly from the ETF screen, whereupon they will be saved automatically by the instrument and maintained at each successive power-up. In particular, the user can select the maximum pressure (function button PRESS. MAX) or rather, the pressure that must be established in the middle ear of the patient to allow an assessment of Eustachian tube function. Pressure values between –600 daPa and +400 daPa can be selected, in 50 daPa increments (it is not possible to select atmospheric pressure).

To adjust the duration of the test, simply press the DURATION function button . Selectable values are 20, 30, 40 or 50 seconds.

As indicated previously, the user can switch to the window for ETF testing with intact eardrum by pressing the TM INTACT function button.

## How the examination is conducted

Having selected the ear tip best suited to the patient being examined, and introduced the probe together with the ear tip into the patient's ear canal, simply select the side, left or right, and press the START/STOP button (or the relative button on the control box) to start the test.

Once the test has been started, the patient’s ear canal is pressurized to the selected value, whereupon the pressure pump shuts off automatically. Thereafter, the patient will be asked to swallow repeatedly so that the Eustachian tube can be forced open. If this occurs, the user will see a drop in the pressure level measured by the instrument.

## Test results

Results are calculated automatically and displayed in the right hand side of the window. The screen shows a table with three pairs of values, each pair consisting in two pressures of which the first indicates the measurement of a significant variation in pressure, and the second is the same value when stabilized. Accordingly, these pairs of values can identify the pressures at which the Eustachian tube opens and closes.

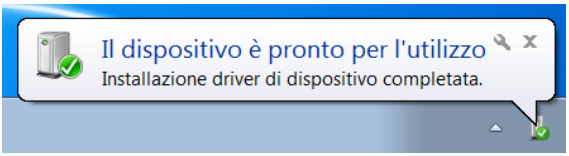
# CHAPTER 8:

# Interface with the computer

The Clarinet middle ear analyzer can be interfaced with a computer by way of a USB connection. Maestro software must be installed on the computer *with or without proprietary* database or as *Noah module*.
Refer to *Maestro – General Functionalities – User Manual* for a detailed description of how to install Maestro on your computer and to *Maestro – Impedance-Audiometry functionalities – User manual* for more information about how to follow a test currently in progress, on the computer screen rather than on the graphic display of Clarinet.

## CONNECTION TO PC

The Clarinet middle ear analyzer is connected to one of the USB ports on the computer using the cable supplied (standard USB A/B cable). The connection is plug-and-play, with no special drivers required for installation purposes: a few seconds after plugging in, the operating system will recognize the devices and install the drivers automatically. The installation is complete when the following message appears at the bottom right of the screen:




Clarinet middle ear analyzers are compatible with computers using a Microsoft Windows 32 or 64 bit operating system, XP SP3 or later.

# CHAPTER 9:

# Settings

Clarinet middle ear analyzers have a number of configuration parameters that can be changed in the settings window. This chapter describes the parameters available, and how to change them.

## SETTINGS WINDOW

To access the settings window, simply press the SETTINGS function button shown on the main screen of the instrument.
Once the settings window appears, the left hand knob can be used to scroll through the available items, whereas to change the value of the selected item, either rotate the right hand knob or press the CHANGE button.
Certain items, such as specific test settings and adjustment of the date and time, require access to a particular window if changes are to be made; in these cases, press the SELECT button to access the changes window.
The settings window also includes an INFO function button, which opens a window containing certain items of information on the instrument, such as the serial number and the version of the internal software.
When exiting the settings window, if at least one parameter has been changed, the instrument will prompt whether to save the new settings or maintain the previous settings.

## USER-SETTABLE PARAMETERS

All 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.
Not all of the items listed are available on every model.

## Language

Selection of the interface language used by the instrument.

Default value: English

## Contralateral transducer

Selection of the transducer used to present the stimulus via the contralateral output. The operator can choose between the TDH 39 supra-aural headphone and the IME-100 insert earphone.

Default value: TDH 39 headphone

## Enable *live view* feature

If enabled, allows the operator to follow the progress of the test on the computer screen as well as on the instrument display.

Default value: Yes

## Tympanometry setup menu

This window shows the parameters relating to the tympanometry test, namely:

Auto start:

Enables / disables automatic start of the tympanometry test as soon as the probe is inserted correctly in the ear canal.

Default value: No

Start pressure

Initial positive test pressure, expressed in daPa. Values between 50 and 400 daPa can be selected, in 50 daPa increments.

Default value: 200

Stop pressure

Final negative test pressure, expressed in daPa. Values between -50 and -600 daPa can be selected, in 50 daPa increments.

Default value: -400

Gradient

Method of calculating the tympanogram gradient. This can be calculated as the width of the peak (in daPa) or as a ratio between compliance values, as described in detail in the chapter on tympanometry.

Default value: Peak width

Show normal range

Enables / disables display of the tympanometry normality range (ASHA, 32, Suppl. 2, 1990, 17-24) in the tympanogram.

Default value: Yes

## Reflex setup menu

This screen presents the parameters for the acoustic reflex test, namely:

dB attenuator step

Sets the attenuation step used during all reflex tests, including Decay and ARLT

Data polarity

This parameter 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

Pressure

Selects the pressure utilized during the test. The operator can elect to conduct the test at atmospheric pressure, or at the peak pressure of the tympanogram.

Default value: Tymp peak

Stimulus On-Time

The length of time for which the stimulus is presented during each test, expressed in ms. The setting can be selected between 500 and 2500 ms, with a resolution of 500 ms.

Default value: 500

Stimulus Off-Time

The interval of time, after the end of the stimulus on-time, during which data acquisition continues, expressed in ms. The setting can be selected between 500 and 2500 ms, with a resolution of 500 ms.

Default value: 500

Recognition sensitivity

Sets the level of sensitivity when identifying the reflex, used in threshold mode. Possible values are: sensitive, normal, robust.
Selecting “sensitive”, the reflex is classified as being identified if, during the stimulus on-time, there is a reduction in compliance of at least 0.025 ml; selecting “normal” the reduction must exceed 0.05 ml; and selecting “robust” there must be a reduction of 0.08 ml.

Default value: Normal

Compliance check

Enables / disables a check — run at the start of data acquisition — on the stability of compliance measurements. The examination can start as long as compliance values remain stable for a duration of one second. If enabled, and compliance measurements are found not to be stable, the start of the test can be forced by pressing the STIMULUS button.

Default value: No

## Decay setup menu

This screen shows the parameters relating to the acoustic reflex decay test, namely:

Stimulus On-Time

The length of time for which the stimulus is presented during each test, expressed in seconds. Possible values are 10 and 20 seconds.

Default value: 10

Stimulus Off-Time

The interval of time, after the end of the stimulus on-time, during which data acquisition continues, expressed in seconds. The interval can be set between 1 and 5 seconds.

Default value: 1

## ARLT settings

This screen presents the parameters for the acoustic reflex latency test, namely:

Stimulus On-Time

The length of time for which the stimulus is presented during each test, expressed in ms. Values can be selected in the range 300ms … 1700ms.

Default value: 500

Stimulus Off-Time

The interval of time, after the end of the stimulus on-time, during which data acquisition continues, expressed in ms. The interval can be set between 300 and 1700 seconds.

Default value: 500

## ETF-TM intact setup menu

This window shows the parameters relating to the ETF test used when the eardrum of the patient is intact, namely:

Start pressure

Initial positive test pressure, expressed in daPa. Values between 50 and 400 daPa can be selected, in 50 daPa increments.

Default value: 200

Stop pressure

Final negative test pressure, expressed in daPa. Values between -50 and -600 daPa can be selected, in 50 daPa increments.

Default value: -400

## Quick test settings

Accesses the window for the configuration of acoustic reflex tests associated with Quick Test A and Quick Test B. For each of these, the operator can select the mode of inducing the reflexes and the types of stimulus to present to the patient (8 boxes).

## Printer menu

This window shows the settings for the print function, namely:

Print patient data header

Enables / disables printout of the heading with details of the patient.

Default value: Yes

Clinic data menu

Access to a window in which the user can enter details of the clinic, for inclusion in the header of the printed document. The user can also enable or disable printout of the window.

Extended printout

If enabled, printout of the examinations is generated in greater detail, which means in turn that more paper will be used.

Default value: No

Reflexes (threshold): print data only

If enabled, the printout of the acoustic reflex tests conducted in automatic threshold mode will show only numerical results (graphs will not be printed).

Default value: No

## Settings protected by password

If enabled, access to settings screen is protected by the password “010113”.

Default value: No

## Calibration menu

Access to the menu for calibration of the instrument. The operator may elect to calibrate the probe tone, compliance measurement, stimulus signals and pressure sensors.

## Date and time menu

Access to the window in which the date and the time are set. The time is written, by default, in the 24-hour notation: by accessing this window it is possible to switch to the 12-hour time format.

## Service tests

Access to the window from which service tests are run on the instrument. For maintenance purposes only.

# CHAPTER 10:

# Maintenance

Clarinet middle ear analyzers do 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 inspection and servicing of internal components must be left entirely to technicians approved by Inventis s.r.l.*

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

## MAINTENANCE OF TRANSDUCERS

*Do not use liquids or sprays to clean the middle ear analyzer.*

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

- The headphone cushions are made of biocompatible material, but are not sterile: whenever the headphones are to be worn by a new patient, the cushions must be wiped with a hypoallergenic proprietary disinfectant, following the maker's instructions. This will prevent the spread of infection and guarantee the biocompatibility of the material.
- The ear tips of the probe, the insert earphones (ER-3A, ER-5A) and the masking insert earphones (IME-100) are made of biocompatible material and disposable: use once only and dispose of in accordance with current health and safety regulations.

*The ear tips are not sterile. The use of unsterilized ear tips can cause ear infections.*

## PERIODIC CHECKS

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

Before switching on the instrument, check that all accessories and transducers are connected correctly.

To ensure the maximum reliability of results given by the instrument, it is good policy to check daily that the probe measuring compliance is correctly calibrated. To this end, carry out the following sequence of steps:

- Insert the probed (without ear tip) into the 2.0 ml test cavity;
- Launch the tympanometry test screen;
- Make certain that the current compliance value shown by the relative indicator is equal to the size of the cavity in question, i.e. 2 ml; the indicator, located on the right of the graph, is of triangular shape and can be seen only in absolute viewing mode. In the event that the measured value does not correspond to the volume of the cavity, proceed with calibration of the probe as described under the next heading.

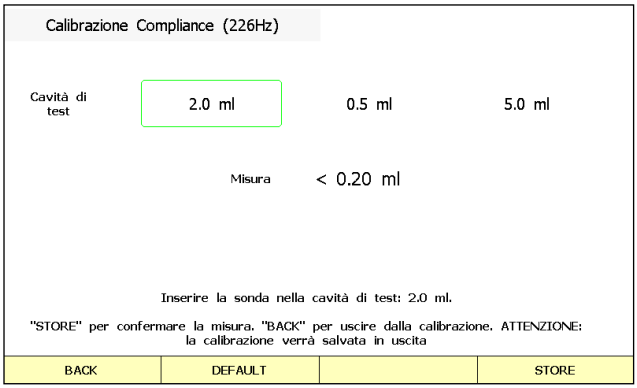
## TOUCH SCREEN CALIBRATION

If the device touch screen does not respond accurately to your commands, it will most likely require a recalibration; this operation is very simple and fast.
You must first enter the touch screen calibration window through the device settings window. Once entered, you will see four crosses in sequence on the screen: touch each cross in its center, trying to this as accurately as possible. At the end of this operation, the touch screen is calibrated.
If the touch screen is so much out of calibration (e.g. as a result of a collision) that it does not allow you to access to the calibration window, you can open it even by pressing simultaneously the BACK and HELP function keys during the ignition phase, before the Inventis logo is displayed on the screen.

## CALIBRATION OF COMPLIANCE MEASURED BY THE PROBE

The procedure described below is carried out whenever the needs arises to recalibrate the measurement of compliance by the probe.

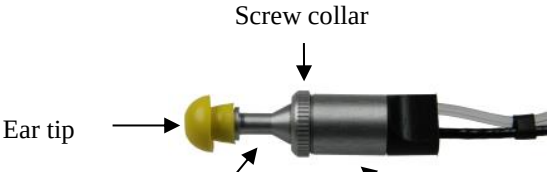
Access the main “Settings” menu by pressing the relative function button. Now select the item "Calibration Menu", and thereafter “Compliance calibration”. The following screen appears:




As indicated, locate the probe (without ear tip) in the 2.0 ml tet cavity and press “STORE” to save the reading. Check that on pressing the button, the new value measured is consistent with the amplitude of the cavity in question. Repeat the operation for all cavities, following the order indicated by the procedure.

## CLEANING THE PROBE

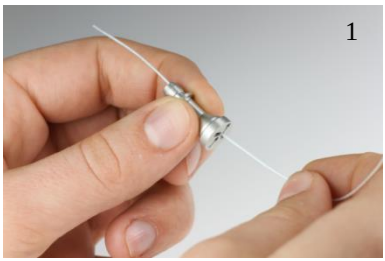
To guarantee accurate compliance measurements, the three channels incorporated into the probe must be kept properly clean. In effect, these three channels accommodate the compliance measurement system (microphone), the speaker carrying the stimulus signals, and the pressurization system.
As illustrated below, the probe consists in a main body, a tip (to which the ear tip is attached) and a screw collar, which keeps the tip firmly associated with the body.

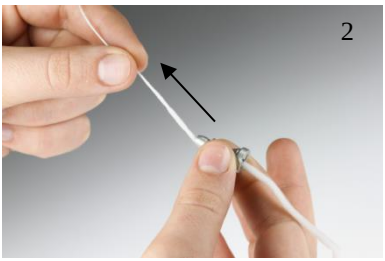


The procedure for cleaning the probe will now be described.

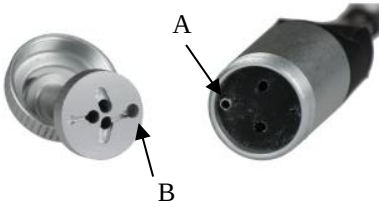
First of all, remove the ear tip, loosen the screw collar and separate the tip of the probe from the main body.

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 element *A*, in the body, with the hole *B* provided in the tip, as illustrated in the figure below. Retighten the screw collar.




For external cleaning use a lint-free soft cloth moistened with a solution of water and mild detergent; in case of sanitization wipe the cloth with hydrogen peroxide at a 3% concentration.

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

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

## CLEANING THE INSTRUMENT

To prevent the accumulation of dust on the instrument, always fit the protective cover when the analyzer is not in use. Also, ensure that dust collecting underneath the instrument is cleaned away regularly.
All parts not mentioned specifically in the previous section can be cleaned using a soft cloth moistened with a solution of water and mild detergent; in case of sanitization wipe the cloth with hydrogen peroxide at a 3% concentration.

## REPLACEABLE PARTS

The probe, transducers and accessories can be disconnected from the instrument. Should a fault develop in any one of these devices, the middle ear analyzer must be switched off and isolated from the power supply, and the defective item then disconnected from the instrument.

*All accessories of the middle ear analyzer are designed specifically for use with the instrument. Only accessories supplied by Inventis*

*should be connected to the analyzer.*

## LOADING THE PRINTER PAPER

To load a new roll of paper in the printer, the rear cover must first be opened and the empty spool removed.

*The heat-sensitive side of the paper is located externally of the winding mechanism: the paper must be positioned so that the heat-sensitive face does not come into contact with the rubber pinch roller.*

Raise the lever and offer the paper to the bottom part of the roller. Feed the paper through until it emerges from the top part at the required height. Lower the lever.

*Make certain that the paper is correctly aligned. If this is not the case, follow the manual loading instructions to correct the alignment.*

Slip the paper through the slot in the cover, and close the cover.

## REPAIRS AND TECHNICAL ASSISTANCE

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

All the parts being returned to the manufacturer for repair and service shall be cleaned and sanitized. Transducers should be sealed in a transparent bag.

Important: should the instrument need to be sent to the Inventis service department or returned to the dealer, make certain that the original packing is used, and that all accessories and transducers are enclosed.

# APPENDIX A:

# Technical specifications

***Classification***

Clarinet

Type 1 middle ear analyzer (EN 60645-5 / ANSI S3.39)

<table>
<tr><th colspan="6">ADMITTANCE MEASUREMENT SYSTEM</th></tr>
<tr><td colspan="6">Probe Tone</td></tr>
<tr><td>Frequency</td><td>226 Hz ± 1%</td><td>678 Hz ± 1%</td><td>800 Hz ± 1%</td><td colspan="2">1000 Hz ± 1%</td></tr>
<tr><td>Level</td><td>85 ± 1.5<br>dB SPL</td><td>80 ± 1.5<br>dB SPL</td><td>75 ± 1.5<br>dB SPL</td><td colspan="2">75± 1.5<br>dB SPL</td></tr>
<tr><td colspan="6">Admittance</td></tr>
<tr><td rowspan="5">Maximum represented range</td><td colspan="4">Tympanometry</td><td></td></tr>
<tr><td>226 Hz</td><td>678 Hz</td><td>800 Hz</td><td colspan="2">1000 Hz</td></tr>
<tr><td>Absolute (Y):<br>0.2 ÷ 8 ml<br><br>Compensated (Y):<br>-0.5 ÷ 5 ml</td><td>Absolute (Y):<br>0.6 ÷ 16 mmho<br><br>Compensated (Y):<br>-2 ÷ 6 mmho</td><td>Absolute (Y):<br>0.7 ÷ 16 mmho<br><br>Compensated (Y):<br>-2 ÷ 6 mmho</td><td colspan="2">Absolute (Y):<br>0.9 ÷ 16 mmho<br><br>Compensated (Y):<br>-2 ÷ 6 mmho</td></tr>
<tr><td>Absolute (B-G):<br>-2 ÷ 8 mmho<br><br>Compensated (B-G):<br>-2 ÷ 5 mmho</td><td>Absolute (B-G):<br>-4 ÷ 16 mmho<br><br>Compensated (B-G):<br>-7 ÷ 7 mmho</td><td>Absolute (B-G):<br>-4 ÷ 16 mmho<br><br>Compensated (B-G):<br>-7 ÷ 7 mmho</td><td colspan="2">Absolute (B-G):<br>-4 ÷ 16 mmho<br><br>Compensated (B-G):<br>-7 ÷ 7 mmho</td></tr>
<tr><td colspan="4">Acoustic Reflex<br>226 Hz</td><td></td></tr>
<tr><td colspan="4">-0.2 ÷ 0.05 ml<br>-0.4 ÷ 0.1 ml</td><td></td></tr>
<tr><td>Scale</td><td colspan="4">Manual and Automatic</td><td>Manual</td></tr>
<tr><td>Accuracy</td><td colspan="5">± 0.1 ml or ± 5%, whichever is greater</td></tr>
<tr><td>Influence of ambient temperature</td><td colspan="5">-0.003 ml/°C</td></tr>
</table>

| | |
|---|---|
| Influence of atmospheric pressure | -0.0002 ml/daPa |

Note: Under standard reference conditions using a probe tone of 226 Hz, the volume of trapped air in a hard-walled cavity is equal to the acoustic volume of that same cavity. In other words, 1 cubic centimeter (cc) or milliliter (ml) of trapped air equals the acoustic admittance of 1 mmho in a hard-walled cavity.
This equivalency is the reason for representing admittance in cc or ml.

| **PRESSURE MEASUREMENT SYSTEM** | |
|---|---|
| Maximum range | -600 daPa ÷ +400 daPa |
| Safety limits | -800 daPa and +600 daPa |
| Accuracy | ±10 daPa or ±5 %, whichever is greater |
| Test range | -600 daPa ÷ +400 daPa<br>selectable by 50 daPa increments |
| Change rates | 15, 50, 100, 200, 300, 400, 600 daPa/s,<br>AUTO (test starts and stops at 600 daPa/s, slows to 200 daPa/s at the tympanogram peak) |
| Control | Automatic and Manual |

| IMPEDANCE – AVAILABLE SIGNALS | | |
|---|---|---|
| Stimuli | Pure tones and noises | |
| Pure tone frequencies | *Ipsilateral* | 500, 1000, 2000, 3000, 4000, 6000 Hz |
| | *Contralateral* | 250, 500, 1000, 2000, 3000, 4000, 6000, 8000 Hz |
| Types of noise | Broadband Noise (BBN), Low Pass Noise (LPN), High Pass Noise (HPN) | |

| IMPEDANCE - SIGNAL SPECIFICATIONS | |
|---|---|
| Attenuators step | 1, 2, 5 dB |
| Presentation mode | Continuous |
| Frequency accuracy | 0.1 % |
| Intensity accuracy | ±3 dB |
| Total Harmonic Distortion (THD) | Less than 2.5 % |
| Broadband Noise (BBN) | As specified in EN 60645-5 / ANSI S3.39 |
| Low Pass Noise (LPN) | Same as BBN with 1600 Hz, 6° order Low Pass Filter |
| High Pass Noise (HPN) | Same as BBN with 1600 Hz, 6° order High Pass Filter |
| Acoustic Reflex | |
| Automatic threshold | increment: 1, 5, 10 dB selectable |
| Growing intensity | increment: 1, 2, 5 dB selectable |
| ON – Time | from 0.5 to 2.5 s selectable by 0.5s increments |
| OFF – Time | from 0.5 to 2.5 s selectable by 0.5s increments |
| Reflex sensitivity | lowest detectable volume change: 0.001 ml |
| Reflex tests: the risk of artifacts at higher stimulus levels in compliance measurements are negligible and will not activate the reflex detection system. | |
| Reflex Decay | |

| | |
|---|---|
| ON – Time | 10 or 20 s selectable |
| OFF – Time | 1, 2, 3, 4, 5 s selectable |
| ARLT | |
| ON – Time | from 0.3 to 1.7 s programmable with 0.1 s step |
| OFF – Time | from 0.3 to 1.7 s programmable with 0.1 s step |
| ETF – TM perforated | |
| Maximum pressure | -600 daPa ÷ +400 daPa selectable by 100daPa increments |
| Duration of test. | 20, 30, 40, 50 s selectable |

| **IMPEDANCE – AVAILABLE OUTPUTS** | |
|---|---|
| *Output* | *Clarinet* |
| Ipsilateral | ● |
| Contralateral<br>(TDH 39 headphone or IME-100 insert earphone) | ● |

| **IMPEDANCE<br>STIMULUS: AVAILABLE FREQUENCIES AND MAXIMUM LEVELS** | | | |
|---|---|---|---|
| **Freq. (Hz)** | **IPSI (dB HL)** | **CONTRA TDH 39 (dB HL)** | **CONTRA IME-100 (dB HL)** |
| 250 | - | 100 | 100 |
| 500 | 100 | 120 | 110 |
| 1.000 | 110 | 120 | 115 |
| 2.000 | 105 | 120 | 110 |
| 3.000 | 105 | 120 | 110 |
| 4.000 | 100 | 120 | 110 |
| 6.000 | 100 | 105 | 100 |
| 8.000 | - | 100 | - |
| BBN | 95 | 115 | 105 |
| LPN | 95 | 115 | 105 |
| HPN | 95 | 115 | 105 |

| ACOUSTIC SAFETY OF INSTRUMENT | |
|---|---|
| Alert condition | Tone intensity higher than 100 dB HL (EN 60645-1, §5.2) |
| Safety measures in alert condition | 1) Intensity cannot be set higher than 100 dB HL without operator confirmation<br>2) Warning on the display |

| COMPATIBLE TRANSDUCERS | | | |
|---|---|---|---|
| *Type* | *Manufacturer* | *Model* | *Impedance* |
| Supra-aural headphone for contralateral stimulation | Telephonics Corp. | TDH39 | 10 ohm (1 kHz) |
| Insert earphone for contralateral stimulation | Inventis s.r.l. | IME-100 | 100 ohm (1 kHz) |

| AVAILABLE TESTS | | |
|---|---|---|
| | *Clarinet Basic* | *Clarinet Plus* |
| Tympanometry | | |
| *226 Hz* | ● | ● |
| *678 Hz* | - | ● |
| *800 Hz* | - | ● |
| *1000 Hz* | - | ● |
| *Two Components* | - | ● |
| Acoustic reflex | | |
| *Fixed intensity* | ● | ● |
| *Growing intensity* | ● | ● |
| *Automatic threshold* | ● | ● |
| *Manual* | ● | ● |
| Reflex Decay | ● | ● |
| ARLT | ● | ● |
| ETF | | |
| *TM intact* | ● | ● |
| *TM perforated* | ● | ● |
| Quick A | ● | ● |
| Quick B | ● | ● |

| DATA MANAGEMENT | |
|---|---|
| Integrated thermal printer (paper size: 112 mm) | Optional |
| Communication to the computer | USB |
| Management software | Maestro installed with or without proprietary database or as Noah module |

| DISPLAY | |
|---|---|
| Type | TFT LCD color graphics |
| Touch screen type | Resistive |
| Size | diagonal 7”, 150 mm x 90 mm |
| Resolution | 800 x 480 |

| POWER SUPPLY | |
|---|---|
| *Model without printer* | |
| Power supply | Main unit: 6V, 1.67A d.c.<br>External adapter: SL POWER MENB1010A0603F02<br>100-240Vac 50/60 Hz 0.9-0.34A (included) responding to EN 60601-1 standard |
| *Model with printer* | |
| Power supply | Main unit: 6V, 3.6A d.c.<br>External adapter: SINPRO MPU31-103<br>100-240Vac 50/60 Hz 0.9-0.34A (included) responding to EN 60601-1 standard |

| CALIBRATION | |
|---|---|
| Calibration validity | 12 months |

| ENVIRONMENTAL CONDITIONS | |
|---|---|
| Operation | Temperature: between 15°C (59°F) and 35°C (95°F)<br>Relative humidity: between 30% and 90% (non-condensing)<br>Pressure: between 700 hPa and 1060 hPa |
| Transport and storage | Temperature: between -10°C (14°F) and 50°C (122°F)<br>Relative humidity: max. 90% non-condensing<br>Pressure: between 500 hPa and 1060 hPa |
| Warm-up time | 1 minute |

| MECHANICAL SPECIFICATIONS | |
|---|---|
| *Model without printer* | |
| Size (LxDxH) | 32 x 32 x 15 cm |
| Weight (instrument only) | 2.0 Kg |
| Weight (including transducers and package) | 4.4 Kg |
| *Model with printer* | |
| Size (LxDxH) | 32 x 39 x 15 cm |
| Weight (instrument only) | 2.5 Kg |
| Weight (including transducers and packaging) | 4.9 Kg |

| SOCKETS ON REAR PANEL | | |
|---|---|---|
| *Description* | *Type* | *Connector* |
| Power supply | In | DC plug, 2.5 mm |
| Probe control box (CB) | Out | DB-15F |
| Air tube | Out | - |
| Headphone for contralateral stimulation (on CB) | Out | Audio jack, 3.5 mm mono |
| USB | In - Out | USB type B |

| INPUT SPECIFICATIONS | | |
|---|---|---|
| *Input* | *Connector* | *Electrical property* |
| Power supply | DC plug, 2.5 mm | Internal pin +6V, external pin 0V |

| OUTPUT SPECIFICATIONS | | | |
|---|---|---|---|
| *Output* | *Connector* | *Available Voltage* | *Nominal Impedance* |
| Control box (CB) | DB-15F | 8Vpp | 10 Ω |
| Contra TDH39 | Jack, 3.5mm mono | 8Vpp | 10 Ω |
| Contra IME-100 | Jack, 3.5mm mono | 8Vpp | 32 Ω |

| REFERENCE EQUIVALENT THRESHOLD LEVELS | | | |
|---|---|---|---|
| *Frequency* | **IPSI** | **IME-100** | **TDH 39** |
| | *ISO 389-2* | *ISO 389-2 (ANSI S3.6)* | *ISO 389-1 (ANSI S3.6)* |
| *[Hz]* | *[dB re 20µPa]* | *[dB re 20µPa]* | *[dB re 20µPa]* |
| 250 | - | 14 | 25.5 |
| 500 | 11 | 5.5 | 11.5 |
| 1000 | 5.5 | 0 | 7 |
| 2000 | 7 | 3 | 9 |
| 3000 | 4 | 3.5 | 10 |
| 4000 | 2 | 5.5 | 9.5 |
| 6000 | 1 | 2 | 15.5 |
| 8000 | - | - | 13.0 |
| BBN | 6 | 6 | 2 |
| LPN | 9 | 9 | 6 |
| HPN | 6 | 6 | 2 |

| APPLICABLE STANDARDS | |
|---|---|
| | *Clarinet Basic/Plus* |
| EN 60645-5 / ANSI S3.39 | Type 1 |
| Calibration | IPSI: EN ISO 389-2,<br>CONTRA: EN ISO 389-1 (TDH 39), EN ISO 389-2 (IME-100) |
| Electrical safety | EN 60601-1, Class I, Type BF |
| EMC | EN 60601-1-2 |

| CE CERTIFICATE | |
|---|---|
| 93/42/EEC MDD classification | Class IIa |
| Classification rule (Annex IX, 93/42/EEC) | 10 |
| Notified body | TÜV SÜD Product Service GmbH<br>Ridlerstrasse 65<br>D-80339 Műnchen |
| Number of notified body | 0123 |

## APPENDIX B:

# Troubleshooting

| Problem | Possible cause | Solution |
|---|---|---|
| No probe tone | Probe lead not properly connected | Attach the probe lead to the designated connector |
| | Holes of the probe tip blocked | Unscrew the probe tip and clean internally |
| No pressurization | Pressure air line not properly connected | Attach the pressure air line to the designated connector |
| | Probe not inserted hermetically into the ear channel | Change the tip and reinsert the probe into the ear |
| Compliance measurements affected by noise | Probe not accurately positioned | Reposition the probe so as to minimize vibrations |
| | Holes of the probe tip blocked | Unscrew the probe tip and clean internally |
| Connection between PC and middle ear analyzer cannot be established | Problems with USB connection | Check the USB connection between instrument and computer |
| | USB cable damaged | Change the USB cable (standard USB A/B cable) |
| Date and time prompt appears when instrument is powered up | Internal battery failure | Contact Inventis service department or dealer to have the battery replaced |

| | | |
|---|---|---|
| Display remains blank | Instrument not powered up correctly | Check the connection to the power supply and make certain the switch is in position “I” |
| | Adapter damaged | Contact Inventis service department or dealer |

## APPENDIX C:

# Electromagnetic emissions

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

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

*Clarinet should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, Clarinet should be observed to verify normal operation in the configuration in which it will be used.*

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

- change the orientation and/or position of the affected device;
- move the two devices further away from each other;
- contact the manufacturer or authorised service organisation for further assistance.

**List of cables, transducers and accessories**

Cables, transducers and accessories with which Inventis claims the compliance with the IEC 60601-1-2 standard are those ones supplied with the device, in particular the followings:

1) Control Box with Probe (Manufactured by Inventis)
2) 6Vdc Medical grade Power Supply
3) Power supply cable (maximum length: 1.8 m)
4) Single Telephonics TDH-39 contralateral headset with 60cm shielded cable
5) IME-100 contralateral insert earphone with 50cm shielded cable
6) USB cable, shielded, maximum length: 2 m

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

Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard.

| **Guidance and manufacturer's declaration – electromagnetic emissions** | | |
|---|---|---|
| Clarinet is intended for use in the electromagnetic environment specified below. The customer or the user of Clarinet should assure that it is used in such an environment. | | |
| **Emissions test** | **Compliance** | **Electromagnetic environment-guidance** |
| RF emissions CISPR11 | Group 1 | Clarinet uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR11 | Class B | Clarinet is suitable for use in all establishments including domestic establishment and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations / flickers emissions IEC 61000-3-3 | Complies | |

| **Guidance and manufacturer's declaration – electromagnetic immunity** | | | |
|---|---|---|---|
| Clarinet is intended for use in the electromagnetic environment specified below. The customer or the user of Clarinet should assure that it is used in such an environment. | | | |
| **Immunity Test** | **IEC 60601 test level** | **Compliance Level** | **Electromagnetic Environment - Guidance** |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | ± 6kV contact<br>± 8 kV air | ± 6kV contact<br>± 8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30% |
| Electrical fast transient / burst<br>IEC 61000-4-4 | ± 2 kV for power supply lines<br>± 1 kV for input / output lines | ± 2 kV for power supply lines<br>± 1 kV for input / output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge | ± 1 kV differential | ± 1 kV differential | Mains power quality should be that of a |

| | | | |
|---|---|---|---|
| IEC 61000-4-5 | mode<br><br>±2 kV common mode | mode<br><br>±2 kV common mode | typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br><br>IEC 61000-4-11 | < 5% $U_T$<br>(> 95% dip in $U_T$)<br>for 0,5 cycle.<br><br>40% $U_T$<br>(60% dip in $U_T$)<br>for 5 cycles.<br><br>70% $U_T$<br>(30% dip in $U_T$)<br>for 25 cycles.<br><br><5% $U_T$<br>(> 95% dip in $U_T$)<br>for 5 s. | < 5% $U_T$<br>(> 95% dip in $U_T$)<br>for 0,5 cycle.<br><br>40% $U_T$<br>(60% dip in $U_T$)<br>for 5 cycles.<br><br>70% $U_T$<br>(30% dip in $U_T$)<br>for 25 cycles.<br><br><5% $U_T$<br>(> 95% dip in $U_T$)<br>for 5 s. | Mains power quality should be that of a typical commercial or hospital environment. If the user of Clarinet requires continued operation during power mains interruptions, it is recommended that Clarinet be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field<br><br>IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| *Note:* $U_T$ is the a.c. main voltage prior to application of the test level. | | | |

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| Clarinet is intended for use in the electromagnetic environment specified below. The customer or the user of Clarinet should assure that it is used in such an environment. | | | |
| **Immunity Test** | **IEC 60601 Test Level** | **Compl. Level** | **Electromagnetic environment – Guidance** |
| Conducted RF<br>IEC 61000-4-6<br><br>Radieted RF<br>IEC 61000-4-3 | 3 Vrms<br>150 kHz to 80 Mhz<br>3 V/m<br>80 Mhz to 2,5 Ghz | 3 Vrms<br><br>3 V/m | Portable and mobile RF communications equipment should be used no closer to any part of Clarinet, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>**Recommended separation distance**<br>$d = 1,2\sqrt{P}$<br>$d = 1,2\sqrt{P}$ 80 MHz to 800MHz<br>$d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz<br>where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range. [b]<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |
| *Note 1:* At 80 MHz and 800 MHz, the higher frequency range applies.<br>*Note 2:* These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |
| [a] Field strengths from fixed transmitters, such as base stations for radio (cellular / Cordless) telephones and land mobile, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If measured field strength in the location in which Clarinet is used exceeds the applicable RF compliance level above, Clarinet should be observed to verify normal operation. If abnormal performance | | | |

is observed, additional measures may be necessary, such as re-orienting or relocating Clarinet.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Recommended separation distances between portable and mobile RF communications equipment and Clarinet**

Clarinet is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Clarinet can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Clarinet as recommended below, according to the maximum output power of the communications equipment.

| **Rated maximum output power of transmitter (W)** | **Separation distance according to frequency of transmitter (m)** | | |
|---|---|---|---|
| | 150 kHz to 80 MHz<br>$d = 1{,}2\sqrt{P}$ | 80 MHz to 800 MHz<br>$d = 1{,}2\sqrt{P}$ | 800 MHz to 2,5 GHz<br>$d = 2{,}3\sqrt{P}$ |
| 0,01 | 0,12 | 0,12 | 0,23 |
| 0,1 | 0,38 | 0,38 | 0,73 |
| 1 | 1,2 | 1,2 | 2,3 |
| 10 | 3,8 | 3,8 | 7,3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) cam be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer.

*Note 1:* At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

*Note 2:* These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## APPENDIX D:

# Bibliography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