



PICCOLO

PORTABLE AUDIOMETER

USER MANUAL



Read this manual thoroughly before using the device. Pay particular attention to Chapter 1 (“Safety: warnings and information”) and Chapter 2 (“The first steps”).



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

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CHAPTER 1

Safety: warnings and information

OPERATOR MANUAL

Please read this manual thoroughly to ensure maximum efficiency and safety from your audiometer. It is particularly important that you read this chapter in its entirety. It contains essential warnings and important information on the safe and correct use of the instrument.

In this manual, the safety symbol shown below draws your attention to information that is particularly important for safe and correct use.



OPERATOR RESPONSIBILITIES

The audiometer is guaranteed to work efficiently and reliably only if used according to the instructions and procedures given in this manual.

If the instrument ever develops a malfunction or requires repair, disconnect it from the electrical power supply and do not use it again until the necessary repairs and servicing have been completed. Defective and malfunctioning parts must only be replaced with original spare parts supplied by Inventis srl. All repairs must be performed exclusively by Inventis or by personnel authorised by Inventis.

No part of the instrument may be modified or replaced without the prior written authorisation of Inventis.

Users are entirely responsible for any malfunctions caused by improper use, or by maintenance or repairs performed by any party other than Inventis srl or an authorised Service Centre. Inventis srl and its Service Centres accept responsibility for the performance and reliability of the instrument only if:

1. all connections, adjustments, modifications and repairs are performed exclusively by personnel authorised by Inventis;
2. the electrical power supply and ground connections of the installation comply with applicable standards for electro-medical devices.

INTENDED USE

The Piccolo audiometer is designed for use by audiology specialists conducting pure tone and speech audiometry examinations.

Audiometric exams must be conducted in a particularly quiet environment, and preferably in a soundproof booth. If these conditions cannot be provided, the patient should be given sound-isolating headphones to wear so that ambient and background noise can be blocked out as far as possible.

The Piccolo audiometer is intended for use by persons who have a detailed knowledge of the procedures involved in audiometric examinations; the operator must therefore be either an audiologist (or a technician with knowledge and experience of audiometry) or a doctor in possession of specific skills (an audiology specialist or occupational physician).

PRECAUTIONS

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

Installation and general precautions



Make sure that the required ambient conditions are met during transport, storage and operation. See “APPENDIX A: Technical Specifications”.



The Piccolo audiometer is not protected against exposure to flammable anaesthetic gases or similar products during use. Risk of explosion!



Avoid installing and using the Piccolo audiometer close to sources of strong electromagnetic fields, since this could interfere with the operation of the device.



Use only original accessories supplied by Inventis srl, unless specifically instructed otherwise.



Only use power adapters intended for medical equipment, certified to EN 60601-1. For further information see “APPENDIX A: Technical Specifications”.



The Piccolo audiometer is a medical device. Any other external device to which it is connected (such as a computer or CD player) within the “patient area” (as defined in EN 60601-1-1) must also be a medical device, or must be protected by an isolating transformer in order to ensure that the complete combination (computer or external device + audiometer) complies with EN standard 60601-1-1.

Calibration



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



The calibration of the audiometer is valid for the transducers supplied with the audiometer only if these are connected directly to the instrument without extension leads or other devices between their connectors and the instrument (as habitually occurs in soundproofed booth installations). If transducers are not connected directly to the audiometer, the instrument must be recalibrated before use.



Take note of the audiometer’s specified calibration interval. Use of the instrument beyond its calibration expiry date can lead to unreliable diagnoses.

Hygiene



The eartips of ER-3A and ER-5A insert earphones are disposable. Do not use the same eartip for different patients. Dispose of eartips after use.



Disinfect the cushions of headphones between one patient and the next, following the procedure described in *CHAPTER 6 "Maintenance"*.

Use



The audiometer can generate tones at an intensity potentially damaging to the patient. Take particular care to adjust the intensity of the tone correctly before examinations.

DISPOSAL

Like all electronic devices, the Piccolo audiometer contains extremely small quantities of certain hazardous substances such as cadmium or mercury. 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 audiometer must therefore be disposed of separately.

At the end of its life, dispose of the disused instrument through a civic waste disposal 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 devices from recycled materials, limiting any negative impact on the environment and public health that might otherwise derive from improper disposal.

CONFORMITY

The Piccolo audiometer is a class IIa medical device according to Annex IX of the Medical Device Directive (MDD) 93/42/EEC as amended by directive 2007/47/EC.

The Inventis Quality Management System is certified compliant to ISO 9001 and ISO 13485 standards by the prestigious TÜV organisation.

SYMBOLS ON LABELS



Name and address of the manufacturer.



Caution: specific warnings or precautions are associated with this device; consult the accompanying documentation for safe use.



The instrument is marked with this symbol to indicate that it is electronic equipment covered by Directive 2002/96/EC on waste electrical and electronic equipment (WEEE).



Device with applied parts of type BF (EN60601-1).



Product conforms to European Community Medical Device Directive (MMD) 93/42/EEC, as amended by directive 2007/47/EC. 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; it is not protected against liquids.

MODEL

Device model.

REF

Catalogue number.



Serial number of the device. This 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 (e.g. "12" stands for 2012)*
- *character 8: model series*
- *characters 9... 13: serial number*

CHAPTER 2

First steps

MAIN FEATURES OF THE AUDIOMETER

The Piccolo audiometer is a portable unit that can be controlled from a computer or iPad. If connected to a computer, it can be controlled using Daisy, the Inventis application for medical record management, or using the dedicated module of Noah. If connected to an iPad, a dedicated App, available from the Apple App store, must be installed.

The Piccolo audiometer is available in 3 different versions:

- *Basic*: for pure tone audiometry via air conduction
- *Plus*: for pure tone audiometry via air conduction and bone conduction
- *Speech*: for speech audiometry and pure tone audiometry

All models are available with the Aero option, which allows the audiometer to be controlled from an iPad.

ACCESSORIES

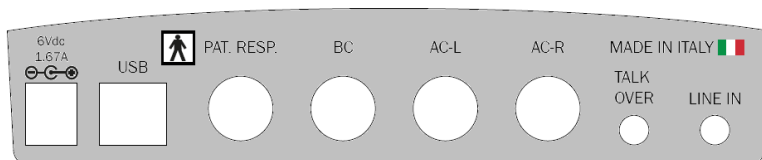
The following table lists the various accessories either supplied with or obtainable on order for the Piccolo Basic, Plus and Speech audiometers.

Part	Piccolo Basic	Piccolo Plus	Piccolo Speech
Telephonics TDH-39 supra-aural headphones	•	•	•
ER-5A insert earphones	opt.	opt.	opt.


ER-3A insert earphones	opt.	opt.	opt.
Amplivox Audiocups noise excluding enclosures	opt.	opt.	opt.
B71 bone vibrator	-	●	●
Patient response switch	●	●	●
Clip-on microphone for patient-to-operator communication	●	●	●
Jack / jack cable (diam. 3.5 mm)	-	-	●
Inventis Daisy Patient Record Manager, with Daisy Maestro module	●	●	●
Noah Maestro module	●	●	●
USB cable	●	●	●
Medical grade power supply (6V)	●	●	●
User manual	●	●	●

CONNECTIONS

All power and accessory connections are located on the rear panel. This section refers to the Piccolo Speech audiometer. The Piccolo Plus does not have a LINE IN connector (for an external sound source). The Basic model also lacks a BC connector (for a bone vibrator).



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


Connector	Accessory
6Vdc 1.67A 	Power supply. When the Piccolo is connected to a computer USB port, the power supply is not needed.
USB	USB port for connection to a PC
PAT. RESP.	Patient response switch
BC	Bone vibrator
AC-L	Left headphone
AC-R	Right headphone
TALK OVER	Microphone for operator to patient communications
LINE IN	External line for connecting a sound source for speech audiometry




Only use power adapters intended for medical equipment, certified to EN 60601-1. For further information see “Appendix A – Technical Specifications”.



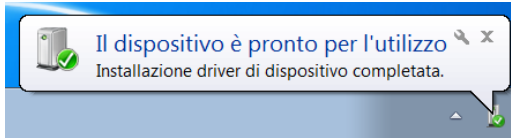
If the Piccolo audiometer is powered via a USB cable, maximum values (in AC and BC) are 10 dB lower than nominal values.

The green LED near the  symbol indicates that the audiometer is powered either from the mains power adapter or via the computer’s USB cable.

The LED near the  symbol indicates the status of communications between the audiometer and computer or iPad. This LED lights if the audiometer is communicating with its control device. The LED can assume two different colours: green for communications with a PC (via a USB cable), blue for communications with an iPad (over a Bluetooth connection).

CONNECTION TO A PC

To permit control from a computer, the Piccolo audiometer must be connected to one of the computer's USB ports using the cable provided (a standard USB A/B cable). The connection is plug-and-play, and no special drivers are required for the installation. A few seconds after plugging in, the operating system will recognize the device and install the drivers automatically. The installation is complete when the following message appears at the bottom right of the screen:



The Piccolo audiometer is compatible with computers running a Microsoft Windows 32 or 64 bit operating system, XP SP3 or later. The Piccolo audiometer can be controlled from a computer using Inventis Daisy software or the dedicated module of Noah. It can also be controlled from an iPad. The following chapters describe how to install the audiometer software.

INSTALLATION CD

To control the Piccolo audiometer from a computer, you need to install Daisy software or the Noah Maestro module.

Insert the Inventis CD that came with the audiometer in your computer's CD drive. After a few seconds the following window (*Inventis Installer*) should appear. From this window you can choose to install either Daisy software or the Noah Maestro module, as described in the following sections. If the installation software fails to run automatically, you can run it manually from the CD ("InventisInst.exe" file).



When the CD is inserted in the computer's CD drive, a request to install other software may appear in place of this window. When the CD is inserted, the installation utility verifies the presence on the computer of the Microsoft.NET 4.0 libraries needed for the correct functioning of Daisy and Noah Maestro. If these libraries are not present, they are installed automatically. Simply click on "Run" and wait. The Inventis Installer window will open after the necessary libraries have been installed.

If the Microsoft.NET 4.0 libraries have not been installed automatically, you will need to do so manually. Open My Computer and open "Daisy" (the CD drive) to view CD content. Double-click on the "Start.bat" file.

INSTALLING DAISY SOFTWARE

Daisy is an application developed by Inventis for the computerised management of medical records. Daisy can be used to store patients' clinical details together with a variety of instrumental examinations, acquired by connecting to the necessary instruments.

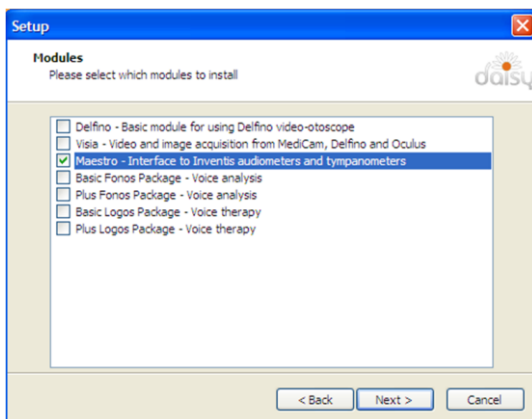
The Piccolo audiometer is controlled by Daisy's Maestro module, which is installed along with Daisy.

For further details of the features and capabilities of Daisy software, and for minimum system requirements, refer to the Daisy operator manual.

To launch the installation of Daisy software and the Maestro module, click on "Daisy software" and then on "Install Daisy".



Follow the installation procedure, taking care to select "Maestro" in the Modules window.



INSTALLING THE NOAH MAESTRO MODULE

If you wish to control your Piccolo audiometer using Noah software, you need to install the Noah Maestro module.

Click on “Noah Modules”, then on “Noah Maestro” and follow the installation procedure.



MAESTRO APP

The Piccolo audiometer can be controlled from an iPad using the Maestro app, which is available free of charge from the Apple App Store.

To install the Maestro app, simply download it from the App Store. Follow the standard procedure. Launch the “App Store” app, search for the keywords “Inventis Maestro” and download the App. Once installed, the *Maestro* icon appears on your iPad screen.

If you want to uninstall the application, simply touch the *Maestro* icon until all icons start to oscillate, then select “X”



Uninstalling the Maestro App entails the loss of all data from your archive.

CHAPTER 3

The audiometric testing

This chapter describes the pure-tone and speech audiometry tests and the procedures to correctly perform these examinations.

PURE TONE AUDIOMETRY

Pure tone audiometry is the standard hearing test used in audiology clinical practice: it allows to determine type and extent of the hearing loss at different frequencies and, therefore, provides the basis for patient diagnosis and management.

Hearing threshold

The *hearing threshold* is a basic concept in the field of audiology. Related to a stimulus, the hearing threshold is the minimum intensity that will elicit an auditory response.

In clinical hearing assessment, more exactly, this is referred to as the *audiometric threshold*, that is, the weakest level of a stimulus signal that the patient is able to hear at least 50% of the time.

In practice, pure tone audiometry is the test that determines the audiometric threshold of the patient at different frequencies.

The tone signals generated by the audiometer, and the level of the audiometric threshold, are measured in decibels (dB). In reality, the unit of measure is the dB HL (Hearing Level); in contrast to the dB SPL (Sound Pressure Level), which represents the actual intensity of the sound, the dB HL includes a compensating factor whereby a person with normal hearing tested under ideal conditions will have a hearing threshold of 0 dB HL at every frequency. These compensating factors, which are different for each frequency and each type of transducer, have been calculated from studies

conducted on a large number of patients and are published in international standards (EN ISO 389-1, 389-2, 389-3, 389-4, 389-5 and 389-7).

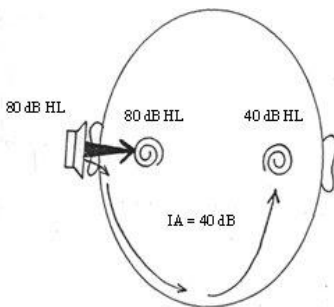
Masking

When a signal is presented to one ear, the cochlea of the other ear can also be stimulated, in dissimilar measure, as a result of the sound being transmitted through the bones of the skull. The mechanism whereby a signal presented to one ear stimulates the cochlea of the opposite ear is known as *cross-hearing*. In situations where cross-hearing could occur, a masking signal must be used.

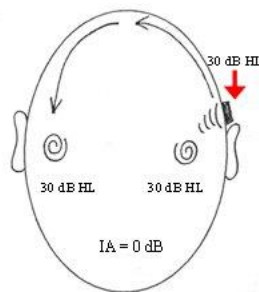
Masking consists in raising the threshold of the contralateral ear by presenting an appropriate masking signal (generally a narrow band noise, NBN, centred on the current stimulation frequency) at a predetermined level. This prevents the contralateral ear from sensing the stimulus presented to the ear being tested, which could lead to the responses of the patient registering false positives and affecting the measured threshold.

The unit of measure for narrow band masking noise (NBN) is dB EM (*Effective Masking*). In contrast to dB HL, the correction factor introduced into dB EM is such that when using a given stimulation frequency (e.g. 1 kHz), a narrow band noise of predetermined intensity (e.g. 20 dB EM) will render inaudible any signal of intensity less than or equal to the noise in question (or in the case of the example, any tone of 1 kHz frequency generated at an intensity of up to 20 dB HL).

A fundamental concept applied in the selection of a suitable masking strategy is that of *interaural attenuation* (IA): the reduction of energy in a sound signal presented to one ear and transmitted by bone conduction to the contralateral ear.



Interaural attenuation with AC



Interaural attenuation with BC

For air-conducted signals, the level of IA varies according to the frequency and the transducer adopted (supra-aural headphones or insert earphones) and, to an extent, from one individual to another.

In the case of headphones, reference can be made to the following table, taken from Goldstein BA, Newmann CW (1994) “Clinical masking: a decision making process”, in the Handbook of Clinical Audiology by J Katz (ed).

<i>Frequency (Hz)</i>	<i>125</i>	<i>250</i>	<i>500</i>	<i>1000</i>	<i>2000</i>	<i>4000</i>	<i>8000</i>
IA (dB)	35	40	40	40	45	50	50

In the case of insert type earphones (EARTone models 3A and 5A), IA is much higher (above 70 dB).

For bone-conducted signals, conversely, IA is near to 0 dB: consequently, one can never be certain which cochlea has been stimulated by a BC tone, irrespective of where the vibrator is positioned, which means that cross-hearing can always be a factor in bone conduction.

Having introduced the concept of interaural attenuation, instances of cross-hearing can be identified with the following formula, in which case a masking signal becomes necessary:

$$\mathbf{AC_{TE} - IA \geq BC_{NTE}}$$

where: $\mathbf{AC_{TE}}$ = the air conduction threshold for the Test Ear

\mathbf{IA} = interaural attenuation

$\mathbf{BC_{NTE}}$ = bone conduction threshold for the Non-Test (contralateral) Ear

In the same way as for a test tone, if the masking noise is of sufficiently powerful intensity, it can be transmitted by bone conduction to the test ear. If the intensity of the masking noise is sufficient to mask not only the non-tested ear but the test ear as well, the effect is referred to as *overmasking*. The maximum intensity of masking noise above which overmasking occurs ($\mathbf{M_{max}}$) is given by this formula:

$$\mathbf{M_{max} = IA + BC_{TE}}$$

Accordingly, overmasking occurs when the level of the masking signal ($\mathbf{EML_{NTE}}$) is as determined by this formula:

$$\mathbf{EML_{NTE} \geq IA + BC_{TE} + 5}$$

Air conduction audiometry

The general rule when performing an audiometric test with air-conducted signals is to use a pure tone input, which can be either continuous or pulsed. Referring to the considerations of the previous section, the operator must decide whether or not a masking signal is needed, and determine its level.

To ensure a dependable outcome, the test should be conducted in suitably quiet surroundings, and preferably in a soundproof booth. If there is no such enclosure available, the use of special sound-isolating headphones is recommended, in particular Audiocups, which can be supplied as an optional accessory with Piccolo audiometer. Standard EN ISO 8253-1 specifies the maximum permissible ambient noise level compatible with dependable results.

Having invited the patient to put on the headphones, conduct the test in accordance with the following procedure — taken from EN ISO 8253-1.

Instructions to the patient

Tell the patient to press the button (or raise a hand) when a sound is heard, and release the button (or lower the hand) only when the sound is no longer heard.

Presentation and interruption of test tones

The test tone should be presented for a duration of 1 or 2 seconds. When there is a response from the patient, the interval between successive test tones must be varied, although never reduced to a duration less than that of the actual tone.

Initial familiarization

Before determining the hearing threshold, the patient must be familiarized with the task by presenting a signal of intensity sufficient to elicit a precise response. After this familiarization step, the operator can be confident that the patient understands the procedure and is able to respond correctly.

The following method of familiarization can be used:

1. present a 1000 Hz tone at a clearly perceptible level, say, 40 dB HL for a person with normal hearing;
2. reduce the level of the tone by steps of 20 dB until there is no longer any response;
3. increase the level of the tone by steps of 10 dB until a response is elicited;

4. present the tone again at the same level.

If the responses are consistent with the presentation of the tones, the familiarization process is complete. If not, the procedure should be repeated. Following a second failure, repeat the instructions.

In cases of profound deafness, these procedures may not be applicable.

Estimation of hearing threshold (ascending method)

Conduct the test initially on the ear that the patient considers to be the better ear. The different frequencies should be tested in the following sequence: 1000, 2000, 4000, 8000, 500, 250 Hz, including half octaves if appropriate. Perform the following sequence of steps.

1. Present the first tone of the test at a level 10 dB less than the lowest level of the response given by the patient during the familiarization session. Following each tone that fails to elicit a response, increase the level of the test tone by steps of 5 dB until a response is forthcoming.

2. Following the response, reduce the level by degrees of 10 dB until there is no response, then begin the ascending sequence again. Continue until the patient produces three responses at the same level on a maximum of five ascending sequences.

Using the ascending method, if less than three responses at the same level are elicited on five ascending sequences (or less than two responses on three ascending sequences, using the short method), present a tone at a level 10 dB higher than the level of the last response. Repeat the test procedure.

It has been shown that a shortened version of the ascending method gives comparable results, and in certain instances can be considered suitable for the purpose in question. Using the short method, continue with the test until the patient gives at least two responses at the same level on a set of three ascending sequences.

3. Move on to the next frequency, starting at a level that ought to be audible on the basis of the previous responses, and repeat step 2). Complete the test on one ear, at all the frequencies, in the sequence indicated.

Repeat the measurement at 1000 Hz. If the results of the repeat test at 1000 Hz on the same ear are comparable with the first, registering a difference of less than 5 dB from the previous level, then proceed with the other ear. If there is an improvement of the order of 10 dB in liminal hearing, repeat the test at other frequencies in the same order until the values reflect a deviation equal to or less than 5 dB.

4. Continue until the test has been completed on both ears.

Bone conduction audiometry

Given that bone-conduction IA is near to 0 dB, the exact determination of the hearing threshold for an ear using bone-conduction audiometry requires masking of the non-test contralateral ear at all levels.

Follow the steps indicated below to establish the threshold level.

1. Position the bone vibrator on the patient's mastoid, behind and as near as possible to the conch, without touching, and place the masking headphone over the non-test ear (the unused headphone should be positioned forward of the test ear, leaving the cavity exposed). Make certain that the head bands of the two transducers do not interfere with one another.
2. Begin the test with the ear the patient considers to be the better ear, at a frequency of 1000 Hz.
3. Establish the threshold level without the masking signal, using the shortened ascending method described in the previous section. Bear in mind that the result of this operation cannot serve as a true estimate of the bone-conduction threshold, given the possibility that the non-test ear could be affected by occlusion (see next section).
4. Activate the masking noise and establish the correct intensity of the masking component — hence the hearing threshold — using the Plateau method described in the next section.
5. Move on to the other frequencies, following the same sequence as indicated for air-conduction testing. Continue until the test has been completed on both ears.

How masking is applied

As mentioned previously, whenever cross-hearing could be an issue, a masking noise must be applied to the non-test ear, delivered by way of the headphones or a dedicated insert earphone.

The method described here for determining the level of the masking tone is the so-called “plateau technique” described by J.D. Hood in 1960. This involves gradually increasing the masking noise applied to the non-test ear in such a way as to arrive at a plateau — that is to say, a range of masking values across which there is no increase in the hearing threshold of the test ear. The presence of the plateau suggests that, within the range of masking intensity values in question, there is no undermasking (i.e. a level not sufficient to prevent cross-hearing) and no overmasking.

The plateau technique involves the following three steps.

1. Find the threshold for the ear being tested, without masking.
2. Activate the masking noise at an initial level of 10 dB higher than the air conduction threshold for the non-tested ear (in the case of bone conduction, see the following note); except in certain particular cases, this level will not produce overmasking.
3. Check the threshold of the test ear again. If the threshold of the test ear has not changed, increase the intensity of the noise by steps of 5 (or 10) dB, checking the value after each increment; if there is no change in the threshold over three successive increases in the intensity of the noise (or two increases, for steps of 10 dB), this means that the plateau has been found, and the value can be considered as the threshold. Conversely, if there is a change in the threshold value, this indicates that it was influenced by undermasking, and the procedure must be repeated with the new threshold level.

If bone-conduction is being used for the test, the initial level of the masking signal should be increased to compensate for the *occlusion effect* (OE). OE — due to the headphone being placed over the non-test ear — causes an increase of the bone-conduction tone threshold in the frequency range between 250 and 1000 Hz; in particular, the threshold in question increases by 15 dB at 250 Hz and 500 Hz, and by 10 dB at 1000 Hz. The initial value of the masking noise therefore needs to be higher than the AC threshold of the non-tested ear, by 25 dB at 250 Hz and 500 Hz, and by 20 dB at 1000 Hz.

AUTO THRESHOLD

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

The Auto Threshold test comprises an initial familiarization step serving to train the patient in the threshold identification procedure. The patient must press the response button every time the stimulus is heard, and release the button thereafter. In particular, the stimulus is presented for a duration of 1.7 seconds, followed by a pause of random duration between 1.7 seconds and 2.5 seconds.

The adopted method of determining the threshold envisages an increase of 5 dB in the level of the stimulus, and a reduction of 10 dB. The threshold is established as the level for which at least 2 positive responses are elicited from the patient over 3 sequences.

During the familiarization phase, the stimulus presented to the patient is generated at a frequency of 1 kHz and an initial intensity of 40 dB HL (which cannot be changed). Once the threshold has been identified, the familiarization step ends, and the test begins automatically.

The first frequency examined in the Auto Threshold sequence is 1 kHz. Once the hearing threshold has been identified for this frequency, the test passes on to the next frequency. The order in which the selected frequencies are analysed is as follows: first, frequencies higher than 1 kHz, in ascending order, then frequencies lower than 1 kHz, in descending order, and finally, the 1 kHz frequency again.

Once all these frequencies have been analysed for one ear, the test is repeated automatically on the other ear.

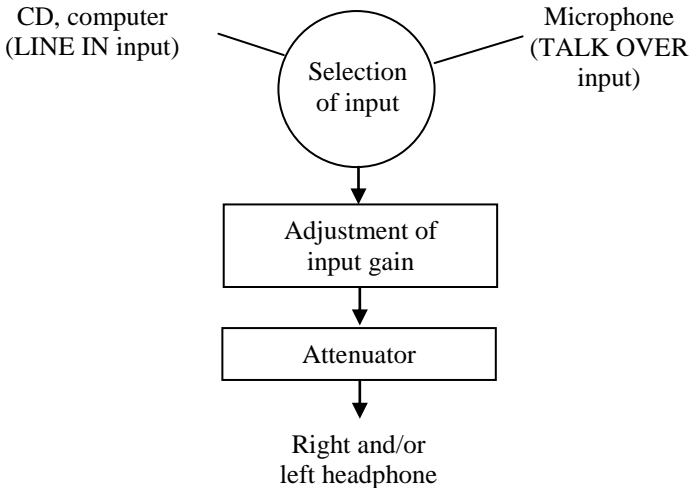
In practice, if the patient is unable to hear a stimulus signal even at the maximum permissible level for a given frequency and after it has been presented 10 times, the signal in question will be identified as "not heard".

The audiogram will be updated in real time during the course of the test, to show the results obtained.

SPEECH AUDIOMETRY

Pure tone audiometry provides only partial information on the abilities of the patient to hear and understand the spoken voice, which is the most important of audible signals. About this, further information can be obtained by the speech audiometry, in which the patient is presented with a succession of standardized speech stimuli, typically single syllables, words or phrases. The goal is the assessment of certain aspects of the patient's hearing ability, like verbal intelligibility, i.e. the faculty to recognize these inputs as sound stimuli with meaning. The speech material can be presented directly by the operator, talking into a microphone (connected to the "TALK OVER" input of the audiometer), or recorded on a CD or a tape cassette and reproduced by a player connected to the LINE IN input of the audiometer.

The following diagram illustrates how the speech material is presented to the patient from the audiometer.



Selection of input

The input signal for speech audiometry can be the microphone (connected to the TALK OVER input on the rear panel) or an external audio source (PC, CD or cassette player) connected to the LINE IN input.

Adjustment of input gain

Before starting a speech audiometry test, the level of gain on the selected input must be adjusted. The purpose of this operation is to ensure that recorded speech material utilized for the test or the operator voice, in case of live speech test, will be played back at the correct volume.

In case of recorded speech material, the input gain will be correct if, playing the calibration tone supplied with the speech material, the loudness measured on the VU-meters of the two channels — displayed on the pc or iPad screen — touches 0 dB, that is to say, the point at which the meter changes from green to red.

In case of live speech test, the gain will be correct if the mean value measured by the VU-meter of channel 1 is 0 dB while you speak test words and the distance between yourself and the microphone is the usual kept during the test.

If the level is incorrect, press the GAIN button and make the necessary adjustment on the window that will appear. The gain level for each input is saved and will be set again at the same level even afterwards.

Attenuator

The speech signal is adjusted to the level set by the operator (level of channel 1) and sent to the connected VA transducer (headphones or insert earphones).

Masking and competing signal

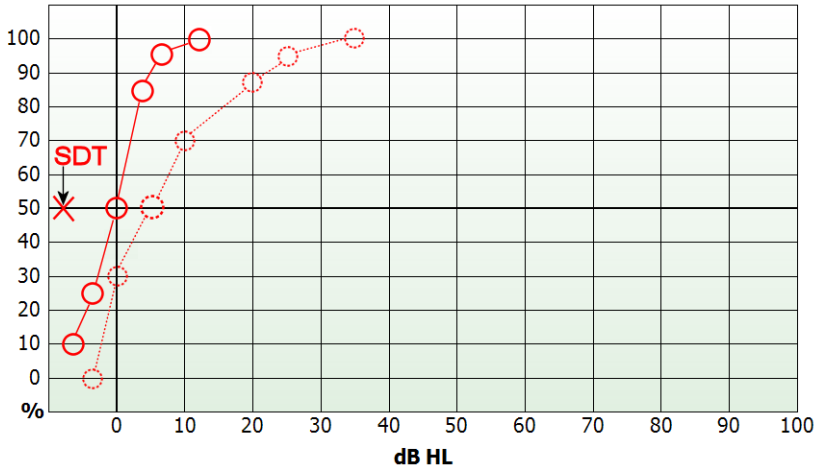
As in pure tone audiometry, a masking signal can be used in speech audiometry to avoid the eventuality of measurement errors being induced as a result of cross-hearing. The masking signal is generated through channel 2 of the audiometer; the recommended signal for speech audiometry is *speech noise* (SN), which produces an energy output concentrated in the frequency band typical of the human voice. The Piccolo audiometer also features a white noise (WN) as the masking signal.

To assess the ability of a patient to recognize speech in an environment with background noise, in other words under conditions typical of everyday life, speech audiometry can be conducted by presenting a *competing sound* either to the tested ear or to the contralateral, non-tested ear. The competing sound, which is generated through channel 2 of the audiometer, can be the speech noise or white noise mentioned above, or a signal incorporated into the audio track of the selected speech material, recorded on the channel opposite to that containing the word lists.

Articulation function, Speech Recognition and Speech Detection Thresholds

The articulation function (or performance-intensity function) is the curve that describes the speech recognition score (average percentage of correct answers) as a function of speech intensity level. The articulation function provides information on how speech material of different types (monosyllabic words, spondaic words, etc). is identified correctly by the patient in relation to the intensity of presentation.

The following illustration provides an example of articulation functions.



The two curves in the graph relate to two different types of speech material, and more exactly, lists of spondaic words (continuous line) and of monosyllabic, phonetically balanced words (dotted line). The level of intensity at which 50% of correct responses are obtained with lists of spondaic words is known as the *Speech Recognition Threshold* (SRT). The average SRT for adults with normal hearing is 20 dB SPL; standard EN 60645-2 defines this level as equivalent to 0 dB HL. In the case of speech audiometry, accordingly, to convert a value of intensity expressed in dB SPL to the corresponding value in dB HL, simply subtract 20 dB from the value.

The articulation function in persons with normal hearing presents a steep curve: on average, 100% of correct responses will be registered at a value as low as 27.5 dB SPL (or 7.5 dB HL).

Also indicated in the foregoing graph is the *Speech Detection Threshold* (SDT), that is, the intensity at which the patient detects the speech signal (without comprehending it) 50% of the times it is presented. The SDT value for a person with normal hearing is around 13 dB SPL (or -7 dB HL).

CHAPTER 4

Using the Piccolo audiometer from a computer

This chapter describes how to use the Piccolo audiometer through a computer. It also describes the functions of the various buttons and explains how to save examinations.



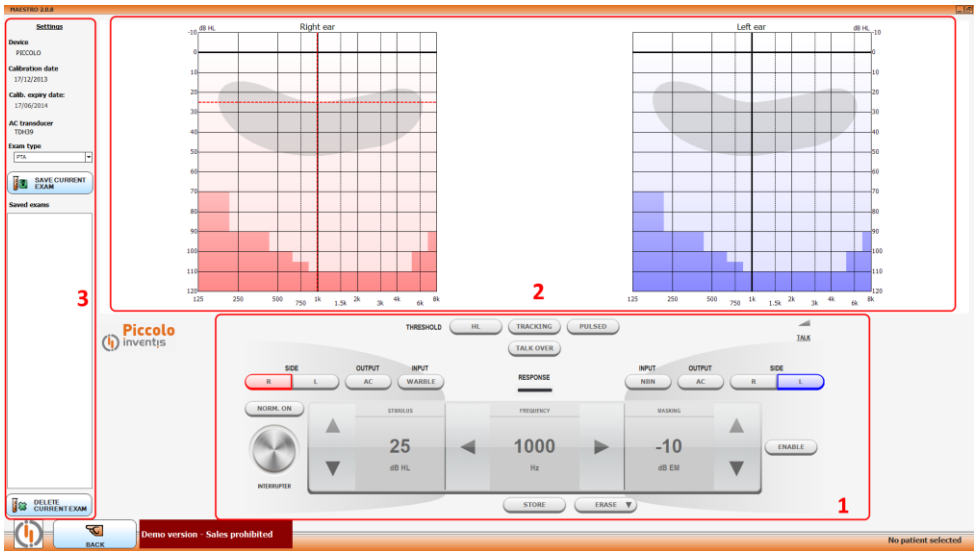
To avoid possible malfunctions, check that the USB cable, transducers and other accessories are properly plugged in to their respective connectors before you run the Maestro module.

MAESTRO MODULES FOR DAISY AND NOAH

If used with a computer, the Piccolo audiometer can be controlled using Daisy, the Inventis application for medical record management, or Noah software. In either case, the audiometer is controlled by the Maestro module, which is available for both Daisy and Noah. The two modules are similar, and this chapter makes no distinction between them.

Daisy software and Maestro modules for Daisy and Noah are supplied with the Piccolo audiometer. See Chapter 2 for a description of the installation procedure.

When you open the Maestro module, the following screen appears.



This screen is made up of three areas:

1. the audiometer control panel
2. the audiogram (pure tone and speech)
3. device specifications and parameter settings

The control panel differs depending on the type of exam selected: pure tone or speech audiometry (WRS or SRT-MCL-UCL).

THE PURE TONE AUDIOMETRY CONTROL PANEL

The following figure illustrates the Piccolo audiometer's control panel for pure tone audiometry.



Output. Lets you select what type of transducer to use (AC or BC). The masking signal is delivered by air-conduction.

Side. Lets you select the stimulation side: right (R) or left (L). Stimulation side can also be changed by clicking directly on the audiograms or by pressing the “Tab” key.

Response. Displays the status of the response switch. An orange light comes on whenever the patient presses the button.

Interrupter. Lets you send a tone. The stimulus can be sent by placing the mouse cursor on the screen button, thus avoiding unwanted noise, or by clicking the right button on the mouse with the cursor inside the audiogram area. You can also send the stimulus from the keyboard, by pressing the pre-configured key (see *Device specifications and parameter settings*).

Norm On. Selecting “Normally On” reverses the operating logic of the interrupter. Output is permanently active and pressing the interrupter turns it off.

Input. You can select the type of stimulus (TONE or WARBLE), by clicking on the corresponding area. You can also select stimulus presentation mode: CONTINUOUS, PULSED 0.5 Hz, PULSED 1 Hz or PULSED 2 Hz.

Stimulus intensity can be modified in five ways:

- by clicking on the corresponding arrows
- by using the mouse scroll wheel with the cursor inside the stimulus area
- by using the mouse scroll wheel with the cursor over the currently active audiogram
- by clicking on the target intensity on the audiogram (only if the stimulus is not active)
- by pressing the pre-configured keys on the keyboard (see *Device specifications and parameter settings*)

For reasons of safety, if the intensity of 100 dB is reached, a “HIGHER dB” label is displayed. You must click on it before you can increase the dB value further. Stimulus intensity changes in fixed steps of 5 dB.

Frequency. You can modify frequency in four ways:

- by clicking on the corresponding arrows
- by using the mouse scroll wheel with the cursor inside the frequency area
- by clicking on the target frequency on the audiogram (only if the stimulus is not active)

- by pressing the pre-configured keys on the keyboard (see *Device specifications and parameter settings*)

Masking. The masking signal is narrow band noise (NBN), centred on the stimulus frequency. You can modify the intensity of the masking signal:

- by clicking on the corresponding arrows
- by using the mouse scroll wheel with the cursor inside the masking area

Enable. Lets you enable or disable the masking signal.

Tracking. If this function is active, the difference in current intensity between stimulus and masking signal remains fixed when stimulus intensity is changed.

Pulsed. Lets you switch to pulsed stimuli. Pulsation rates may be chose between 0.5, 1, 2 Hz values.

Talk over. Permits patient-to-operator communications. Click and hold the corresponding button or press and hold the “T” key on the keyboard. While the communication channel is open, transmission of all other signals is blocked. Releasing the TALK OVER button re-enables signal transmission. You can adjust communication volume by clicking on the speaker icon to the right of the button. Gain for the talk over microphone may be set by pressing on ‘Talk’ label.

Store (No Resp). Lets you store the measured threshold level in the audiogram. You can also do this by pressing the pre-configured key on the keyboard (see *Device specifications and parameter settings*).

If the patient does not respond even when maximum stimulus intensity is reached, you can mark the threshold level with a different symbol by clicking on the NO RESP button.

Erase. Lets you delete a saved point or trace from the audiogram. Move to the frequency of the point to be deleted and press the button. Full traces may be deleted by clicking on the little arrow on the button and select ‘Erase Trace’.

Test type. Lets you select the type of pure tone audiometry: HL or UCL. In UCL tests, the BC and Masking options are disabled.

THE SPEECH AUDIOMETRY CONTROL PANEL

The Piccolo speech audiometer lets you perform different types of speech examination: Word Recognition Score (WRS), Speech Reception Threshold (SRT), Most Comfortable Level (MCL) and Uncomfortable Level (UCL).

Speech audiometry exams can be performed using speech material from a CD, from a computer, or spoken by the examiner (*live* speech).

For *live* speech, a microphone must be connected to the Piccolo audiometer's TALK OVER input. If recorded material is used, the sound source (computer or CD player) must be connected to the Piccolo audiometer's LINE IN input.

Material stored on a computer can be *indexed*. A table can be associated with each sound track so that the examiner can see the word being pronounced in the exam window without having to monitor the audio signal.

To index your tracks, use the Inventis ATIT software on the CD supplied with the Piccolo audiometer. The CD also contains the ATIT user manual.



If speech material is saved on a computer, all computer sound effects (e.g. Dolby effect) must be disabled, and computer output volume on the Volume Control panel must be set to maximum.





The following figure illustrates the Piccolo control panel for speech exams.



If your speech material is saved on your computer, the top part of the Control Panel will contain a material type and list selection box and playback controls. If you are using Daisy Maestro, speech material must be saved in the *c:\Daisy\Application\OMMaestro\Material* folder. If you are using Noah Maestro, speech material must be saved in *C:\Program Files (x86)\Inventis\NoahMaestro\Material*. This folder contains a number of subfolders corresponding to different types of speech material (e.g. *Monosyllabic words* or *Disyllabic words*). Each subfolder contains tracks and word lists (*.wav* files).

If speech material is indexed, the last pronounced word (or sentence) appears to the right of the playback buttons.

The following table describes the functioning of the playback buttons.

	<p><i>Rewind.</i> If indexed speech material is being played back, this button repeats the last pronounced word. If speech material is not being played back, it moves to the previous track.</p>
	<p><i>Play/Pause.</i> Begins or pauses speech material playback.</p>
	<p><i>Forward.</i> If indexed speech material is being played back, this button moves on to the following word. If speech material is not being played back, it moves to the next track.</p>
	<p><i>Stop.</i> Ends playback.</p>

VU-meter and Gain. The VU-meters over the channel controls show the level of the selected sound source. These must be set in an appropriate way to ensure correct results from the exam. (See the “Speech audiometry” section in the previous chapter for a more exhaustive description of this issue). Input signal level can be adjusted by clicking on GAIN.

Input. The stimulus signal controls are located in the left part of the Control Panel. You can select input signals from EXT1, EXT2 or MIC, by clicking on the corresponding areas. Stimulus intensity can be adjusted in four ways:

- by clicking on the corresponding arrows
- by using the mouse scroll wheel with the cursor inside the stimulus area
- by clicking on the target intensity in the audiogram
- by pressing the pre-configured keys on the keyboard (see *Device specifications and parameter settings*)

Score. This keeps count of the correct/incorrect answers given by the patient. The way in which responses are scored depends on the “Speech score mode” chosen in “Settings” (see *Device specifications and parameter settings*).

MODE 1. If the answer is correct, click on the right arrow; otherwise, click on the left arrow. You can also mark answers as correct/incorrect from the keyboard, by pressing the pre-configured keys (see *Device specifications and parameter settings*).

MODE 2. The number of words in each list is fixed and only correct answers are counted. Answers are marked in the same way as for *MODE 1*, but clicking the button for an incorrect answer decreases the final score by one.

Masking. The masking signal controls are located in the right part of Control Panel. You can select masking signals from:

- EXT1 if the stimulus signal comes from EXT2
- EXT2 if the stimulus signal comes from EXT1
- MIC, if the stimulus signal comes from the microphone
- WN, *white noise*
- SN, *speech noise*

Masking signal intensity can be adjusted:

- by clicking on the corresponding arrows
- by using the mouse scroll wheel with the cursor inside the masking signal area

Store. Lets you store the current score. You can also store the current score by pressing the pre-configured key on the keyboard (see *Device specifications and parameter settings*).

Erase. Lets you delete a saved score for the current intensity level. Press the “Del” key on the keyboard or click the “Erase” button. Full traces may be deleted by clicking on the little arrow on the button and select ‘Erase Trace’.

The score is reset automatically when a new point is saved on the graph.

Reset Score. Lets you reset the score (only if “Speech mode score” is set to “MODE 1” in the “Settings”).

Test type. Lets you select the type of speech audiometry: SRT, MCL or UCL.

THE AUTO THRESHOLD CONTROL PANEL

The following figure illustrates the Piccolo control panel for WRS speech exams.



To begin the test, simply press the *START* button. The test finishes automatically once all the enabled frequencies have been analysed for both ears. The procedure can be interrupted if necessary, by pressing the *STOP* button (which replaces *START* once the test is in progress).

After pressing *START*, a message will appear warning the operator that any air-conduction-related threshold data saved previously will be erased.

During the exam, it is possible to activate the TALK OVER function for the operator to talk to the patient.

Before starting the exam, the initial side to be tested can be selected.

THE AUDIOGRAM

In pure tone audiometry examinations, you can select whether to display the left and right audiograms overlapping or separate. (in Daisy: open the Settings window from the main screen. In Noah: click on “Tools” and “Preferences” in the Maestro module).

Some areas of the audiogram are highlighted. These correspond to frequency/intensity values not obtainable with the selected transducer. Important! if Piccolo is powered from a PC via a USB cable, maximum values are 10 dB lower than theoretical ones.

By clicking on the pure tone audiogram with the left mouse button, frequency and intensity are set to the corresponding values for the specific point. In speech audiometry, stimulus intensity is modified instead.

You can overlap a previous exam over the current audiogram. This option is only available if the patient has been selected before the Maestro module was opened. The option is enabled from the left section of module panel, as described in the following section.

DEVICE SPECIFICATIONS AND PARAMETER SETTINGS

This section of the screen contains, from top to bottom:

- the model of the connected device
- the date of last calibration
- the calibration expiry date
- the current air-conduction transducer
- the type of exam selected
- the label for opening the audiometer parameter settings window
- (only for Daisy Maestro) the option for overlapping audiograms of previous exams (see the next section)
- the button for saving/ deleting the current exam

- a list of saved exams

Clicking on “Settings” opens a window in which you can modify a number of parameters. These are described below.

The following figures illustrate the Piccolo control panel for pure tone and speech exams.

The screenshot shows the 'PURE TONE AUDIOMETRY SETTINGS' window. It includes a 'GENERAL SETTINGS' section with 'AC transducer' set to 'Headphones', 'Default intensity (dB)' set to '0', and 'Maintain intensity' set to 'YES'. Below this are four tabs: 'PURE TONE AUDIOMETRY SETTINGS' (selected), 'SPEECH AUDIOMETRY SETTINGS', 'KEYBOARD SHORTCUTS', and 'SERVICE INFO'. The main settings area includes 'Automatic frequency jump' (YES/NO), 'Frequency jump mode' (0k > 1k, 0k > 125), and a 'Frequency selection' grid with buttons for 125, 250, 500, 750, 1500, 2000, 3000, 4000, 6000, and 8000 Hz.

Pure tone audiometry settings

The screenshot shows the 'SPEECH AUDIOMETRY SETTINGS' window. It includes a 'PURE TONE AUDIOMETRY SETTINGS' section with 'Speech score mode' (Mode 1/Mode 2), 'Speech words number' (10), 'Pause after each word' (YES/NO), and 'Enables WRS single point' (YES/NO). Below this are two sections for 'Standard curve 1' and 'Standard curve 2', each with 'Show standard curves' (YES/NO) and 'Points' (dB and %) input fields. At the bottom are two 'Associated material' dropdown menus with options like BORNE ORD, KALIBRERINGS, SMABORNE ORD, and TAL ORD.

Speech audiometry settings

GENERAL SETTINGS

AC transducer. The user can choose the headphones or insert-phones used for exams via air conduction.

Default intensity (dB). Lets you set default intensity for the audiometer (between 0 and 60 dB).

Maintain intensity. If this setting is enabled (YES), intensity is maintained after switching to the next frequency. If it is disabled (NO), the default intensity is automatically selected.



Take great care to ensure that the type of transducer selected corresponds to the one actually used. Mismatches invalidate the results of the audiometry exam.

PURE TONE AUDIOMETRY SETTINGS

Automatic frequency jump. Lets you enable or disable automatic switching to the next frequency after saving the threshold level on the audiogram (*Store* function).

Frequency jump mode. Lets you choose the next frequency value after maximum frequency (8 kHz) is reached. Selecting 8k→1k returns you to 1kHz, whereas selecting 8k→125 returns you to 125 Hz.

Frequency selection. Lets you choose the set of frequencies to test.

SPEECH AUDIOMETRY SETTINGS (only for piccolo Speech)

Speech score mode. Lets you choose between two different modes of scoring the patient's answers.

- MODE1: the examiner records both correct and incorrect answers; the current score therefore refers to the number of words already presented.
- MODE2: the examiner only records correct answers; the current score therefore refers to the total number of the words in the list.

Speech words number. If "Speech score mode" is set to "MODE2", this setting lets you select the number of words for each list (from 1 to 99).

Pause after each word. If the speech material is indexed, select YES to pause playback automatically after each word or select NO to enable non-stop playback of words.

Enable WRS single point. Option for measuring a single score on WRS speech mode.

Standard curves. Standard traces may be displayed on the speech graph as references for normal response to such material. Up to 2 curves can be shown and associated to a particular material.

KEYBOARD SHORTCUTS

Touch screen mode. (Only for Windows 7). Enable this function only if the audiometer is controlled by a touch screen device.

Choose up or down arrow to increase intensity. Allows to select the direction for increasing the intensity of stimulus, through the arrows on the panel control or with the mouse scroll wheel.

The other items let you select what keyboard buttons to use for custom keyboard shortcuts.

SERVICE INFO

Only for service purposes.

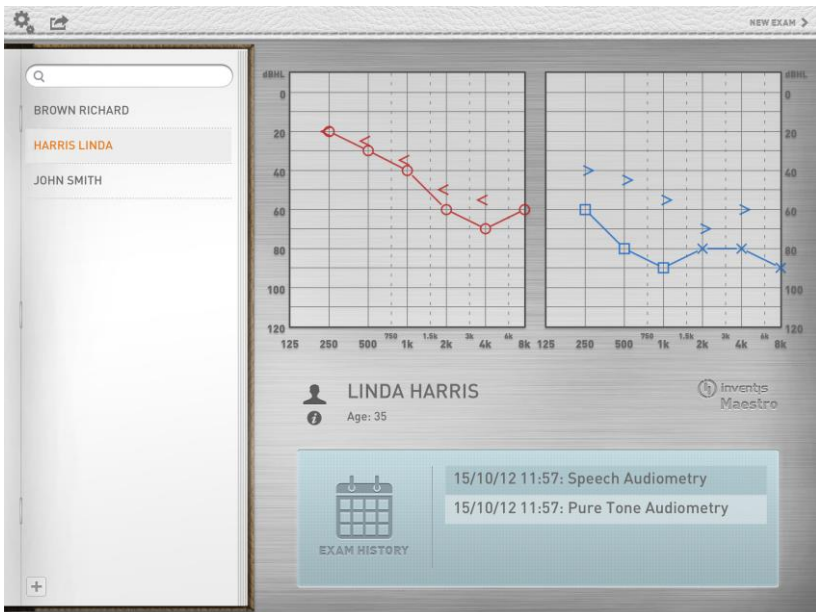
CHAPTER 5


Using the Piccolo audiometer from an iPad

This chapter describes the Maestro app for using the Piccolo audiometer from an iPad. The Maestro app is available free of charge from the Apple App Store.

ARCHIVE



The following image illustrates the archive window of the Inventis Maestro app.



The patient list is displayed on the left of the screen. To add a new patient, touch the  icon and enter the necessary patient information in the PATIENT EDITOR window. Press *Done* when you have finished. First name, last name, gender and birth date fields are mandatory. To delete a patient from the archive, swipe the finger over the patient's name then select the *Delete* button when it appears.

The rest of the screen is divided into the following areas:


- The bottom of the screen contains a list of examinations performed on the current patient, sorted by date. To delete an exam, swipe the finger over the exam to delete then select the *Delete* button when it appears.
- The top of the screen displays the currently selected test. In case of pure tone exams you can view the right and left graphs separately or overlapped. To switch from two to one graph, touch the two graphs simultaneously and drag them up to the centre. Drag a single graph in the opposite direction to separate it into two overlapping graphs.
- The middle of the screen displays the current patient details (name and age). To view and edit patient data, touch the patient's name or the "i" icon.

The upper part of this window also contains three function buttons. The  button on the left lets you open the settings menu (see the "*The Settings*" section). The  button lets you access the exam export menu (see the "*The Export menu*" section). The *New Exam* button on the right lets you open the Exam Window (pure tone or speech, as available).

BLUETOOTH CONNECTION

The Bluetooth connection must be enabled before your iPad can communicate with the Piccolo audiometer. Bluetooth connectivity is normally enabled by default, but if it is not, open the *Settings* menu (see the "*Settings*" section), select *Bluetooth*, then *Bluetooth* and enable the connection.

The iPad identifies the audiometer by means of its serial number (SN), which is printed on a label underneath the device. Enter the SN in the relevant field of the *Bluetooth Communication* screen.

Enter the complete number, i.e. the 13-digit alphanumeric code that appears after the  symbol on the device label. Once entered, the serial number is saved in the app, and does not need to be re-entered (unless you need to connect to a different device).



If Bluetooth Communication is enabled but the SN has not been entered, when you press the “New exam” button, you will be asked to enter the serial number for your audiometer.

The message *Looking for device* indicates that the iPad is searching for the audiometer. If the device is found, a connection is established and the connection LED on the Piccolo audiometer lights in blue. If the device has not been detected after 20 seconds, the *No Device Found* message appears. Select *Cancel* to interrupt the operation or *Retry* to try to connect again.

Connection failures (*Connection Lost*) may have several causes, but are generally easy to rectify.

- iPad and audiometer too far apart. → Move the iPad and device closer together.
- Obstacles interfering with communication. → Remove any objects between the iPad and audiometer.
- The audiometer power supply has been disconnected while the audiometer is connected to the iPad. → Re-connect the audiometer power supply and select the *Retry* option in the *Connection Lost* message box.

PURE TONE EXAM

The figure hereafter illustrates the exam window for pure tone audiometry.



The *Archive* button in the upper left corner of the screen lets you return to the archive window. If you press this button, the “Save Exam” menu appears. This lets you select the patient to whom you want to associate the exam you have just performed, or delete the exam.

Output. Lets you select what type of transducer to use: headphones / earphones (AC) or bone vibrator (BC). The masking signal is always sent through AC.

Side. Lets you select the stimulation side: right (R) or left (L). Stimulation side can also be changed by touching the audiograms. The masking signal is automatically set as contralateral.

Off-line/Connected. Shows the status of the connection between the iPad and the Piccolo audiometer: connected (light on) or disconnected (light off).

Interrupter. Delivers the stimulus.

Norm On. Selecting “Normally On” reverses the operating logic of the interrupter. Output is permanently active and pressing the interrupter turns it off.

Stimulus. You can change the type of stimulus (TONE or WARBLE) and the presentation mode (PULSED or CONTINUOUS) by touching the corresponding labels. The arrows let you adjust stimulus intensity in steps of 5 dB.

For reasons of safety, if the stimulus intensity of 100 dB is reached, a “HIGHER dB” warning is displayed. You must click on this warning before you can increase the dB value further. (The intensity value becomes red in colour.)

Frequency. You can increase/decrease frequency by touching the corresponding arrows.

Masking. The masking signal is narrow band noise (NBN) centred on the stimulus frequency. You can modify the intensity of the masking signal by touching the corresponding arrows. Masking is always contralateral.

Enable. Lets you enable or disable the masking signal.

Tracking. If this function is active, the difference in current intensity between stimulus and masking signal remains fixed when stimulus intensity is changed.

Talk over. Press and hold this button to enable operator-to-patient communications. While the communication channel is open, transmission of all other signals is blocked. You can adjust communication volume by touching the speaker icon to the left of the button.

Exam Mode. Lets you select the exam mode: UCL or HL

Response. Displays the status of the patient’s response switch: the light is on when the patient presses the button.

Store / No Resp. Lets you store the measured threshold level in the audiogram. If the patient does not respond even when maximum intensity is reached, you can mark the threshold level with a different symbol by touching the NO RESP button.

Delete. Deletes the threshold stored for the current frequency.

The ***i*** icon in the lower right corner only appears if audiometer and iPad are connected. Touching this symbol displays the *Device Info* menu. This menu contains the following information.

Device Name. The name of the connected device.

Calibration date. The date of the last calibration.

Calibration Exp. Date. Calibration expiry date (12 months after the last calibration).

AC Transducer. The type of AC transducer currently used, selectable between TDH-39 headphone and ER-3A / ER-5A insert earphone.



Take great care to ensure that the type of transducer selected corresponds to the one actually used. Mismatches invalidate the results of the audiometry exam.

Fw. Rev. Firmware revision.

Hw. Rev. Hardware revision.

BT. Rev. Bluetooth module revision.

Service info. Only for service purposes.

SPEECH EXAM

The Piccolo speech audiometer lets you perform different types of speech exam: Word Recognition Score (WRS), Speech Recognition Threshold (SRT), Most Comfortable Level (MCL) and Uncomfortable Level (UCL).

SPEECH MATERIAL

Speech audiometry exams can be performed using material spoken by the examiner (*live* speech) or recorded speech material, which can be stored on the iPad or a different audio source (e.g. a CD player).

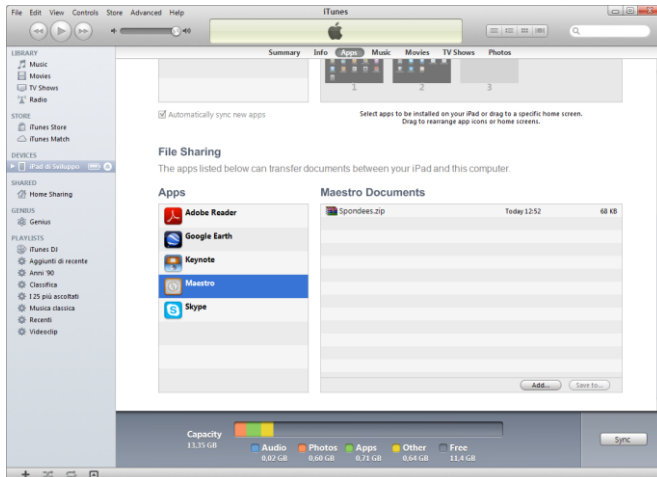
For *live* speech, a microphone must be connected to the Piccolo audiometer's TALK OVER input. If recorded material is used, the sound source (iPad or CD player) must be connected to the Piccolo audiometer's LINE IN input

Speech material can be uploaded to your iPad from a PC. Speech material must be in the form of *wav* or *mp3* files, and your iPad must be able to connect to your computer.

Proceed as follows to upload non indexed speech material:

- On your computer, create a new folder and name it according to the type of material you want to place in it (e.g. *Spondees*).
- Copy all the tracks of this type of material (e.g. *spondees*) to this folder.

- Zip this folder. You should obtain a zip file with a relevant name (e.g. *Spondees.zip*).
- Repeat these three steps for all types of material you want to upload (e.g., logotomes, complete phrases, etc)..
- Copy all the zip files just created into the “Maestro Documents” folder on your iPad. To locate this folder, open iTunes and look for Maestro in the list of apps installed in your iPad, as shown in the picture below



- Disconnect the iPad from the computer. Open the Maestro app and access the “Edit Speech Material” menu from the Main window (see *The Settings/Speech* section). You should now be able to play your speech material through your iPad.



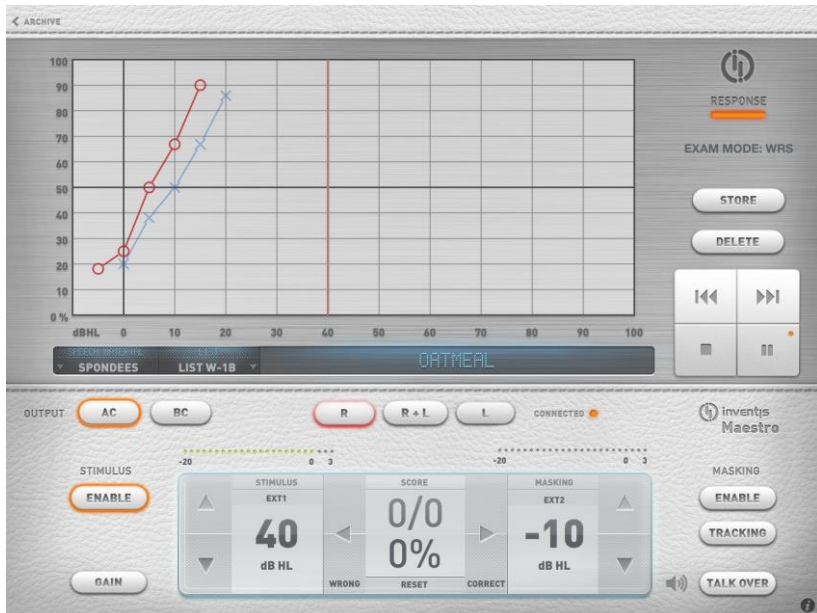
The audio tracks import could take several seconds depending on the number and size of the audio files. Do not turn off the iPad or the app in the meantime.

Speech material can be *indexed*. A table can be associated with each sound track so that the examiner can see the word being pronounced in the exam window without having to monitor the audio signal.

To index your tracks, use the Inventis ATIT software on the CD supplied with the Piccolo audiometer. Once completed, copy the zipped folder obtained with ATIT into the Maestro Documents Folder, as described above. See the ATIT user manual for further information.




THE SPEECH EXAM SCREEN

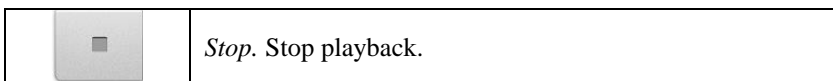
The figure below illustrates the speech exam screen.



The upper part of the screen contains a graph of the articulation function. If the speech material is stored on your iPad, the current speech material, list and word (only for indexed tracks) are displayed underneath.

The right section of the window contains the *Response* light, the current exam type (WRS, SRT, MCL and UCL audiometry exams are available by touching the exam name), *Store* and *Delete* keys and buttons for playback control.

	<p><i>Play/Pause.</i> Begins or pauses speech material playback.</p>
	<p><i>Rewind.</i> During playback, in case of indexed speech material it jumps to the previous word, otherwise it jumps 5 seconds before. If speech material is not being played back, it moves to the previous track.</p>
	<p><i>Forward.</i> During playback, in case of indexed speech material it jumps to the next word, otherwise it jumps 5 seconds ahead. If speech material is not being played back, it moves to the next track.</p>



The lower section of the screen contains the control panel, as illustrated below.



Side. Side of stimulation.

Stimulus: Enable. Turns on the stimulus channel. The channel must be turned on during examinations.

VU-meter and Gain. The VU-meters over the channel controls show the level of the selected sound source. These must be set in an appropriate way to ensure correct results from the exam. (See the “Speech audiometry” section in the previous chapter for a more exhaustive description of this issue). Input signal level can be adjusted by clicking on GAIN.

Stimulus. The stimulus signal controls are located in the left part of the Control Panel. You can select input signals from EXT1, EXT2 or MIC, by touching the corresponding areas. Stimulus intensity can be adjusted by means of the arrows on the left.

Score. This keeps count of the correct/incorrect answers given by the patient. The way in which responses are scored depends on the “Speech score mode” chosen in “Settings” (see the *Settings* section).

- *MODE 1.* The score is the percentage of correct answers versus the total answers count.
- *MODE 2.* The score is the percentage of correct answers versus the number of items selected in settings. Answers are marked in the same way as for *MODE 1*, but clicking the button for an incorrect answer decreases the final score by one.

Press the *Reset* button to reset the current score.

Masking. You can select masking signals from:

- EXT1 if the stimulus signal is EXT2

- EXT2 if the stimulus signal is EXT1
- MIC if the stimulus signal is MIC
- WN, *white noise*
- SN, *speech noise*

Masking signal intensity can be adjusted using the corresponding arrows.

Store. Lets you store the current score. The score is reset automatically when a new point is saved on the graph.

Delete. Lets you delete a stored score from the current intensity level.

THE SETTINGS MENU

The top-left of the archive window contains two icons. The former opens the Settings menu described here while the latter opens the Print / Export menu described in the next section.

PURE TONE

Maintain intensity. If this setting is enabled (ON), intensity is maintained after switching to the next frequency. If it is disabled (OFF), the default intensity is automatically selected.

Default intensity (dB). Lets you set default intensity for the audiometer (between 0 and 60 dB).

Automatic frequency jump. Lets you enable or disable automatic switching to the next frequency after saving the threshold level.

Frequency jump mode. Lets you choose the next frequency value after maximum frequency (8 kHz) is reached. Selecting 8k→1k returns you to 1kHz, whereas selecting 8k→125 returns you to 125 Hz.

Frequency selection. Lets you choose the set of frequencies to test.

Up-arrow increases dB. If enabled, the channel intensity level may be increased by pressing the up-arrow, otherwise the down-arrow.

SPEECH

Speech Score

Lets you choose between two different modes of scoring the patient's answers.

- MODE1: the examiner records both correct and incorrect answers; the current score therefore refers to the number of words already presented.

- **MODE2:** the examiner only records correct answers; the current score therefore refers to the total number of the words in the list. The total number of words may be changed by varying the items number value.

Speech Words Number

Words Number. If “Speech score mode” is set to “MODE2”, this setting lets you select the number of words for each list.

Pause after each word. If the speech material source is indexed, select ON to pause playback automatically after each word or select OFF to enable non-stop playback of words.

Speech Material. Lets you organise speech material on your iPad. Press a heading to view the corresponding track list. You can delete a single list or the whole folder by swiping the finger over the title and press the delete button that appears.

Standard curves. Standard traces may be displayed on the speech graph as references for normal response to such material. Up to 2 curves can be shown and associated to a particular material.

BLUETOOTH COMMUNICATION

Bluetooth communication. You can enable (ON) or disable (OFF) Bluetooth connection between your iPad and the Piccolo audiometer. Disable Bluetooth communication only if you want to use the Maestro app offline.

Piccolo SN. This is the serial number of the Piccolo audiometer paired with the iPad. To connect the iPad to another Piccolo audiometer, delete this SN and enter that of the new audiometer instead.

EXAM DISPLAY OPTIONS

Different Symbols for AC Masked/Unmasked. AC masked and unmasked points are represented with different symbols.

Different Symbols for BC Right/Left. BC right and left points are represented with different symbols.

Link BC Symbols. Link BC symbols on audiograms.

BC symbol. Lets you select the BC symbol.

Symbol for Masked BC. Lets you select the symbol identifying the right BC threshold with masking signal enabled.

PASSWORD

Password Protection. Lets you set a password to protect access to the app.

Password. Enter your chosen access password here.

PRINT/EXPORT

Export options.

Export To. Lets you select how to export exams using the “Documents Folder” or “Email”. In the first case, exported files are stores in the Maestro Documents folder and are accessible through iTunes. In the second case, files are sent via e-mail, as attachments.

Default Recipient. Use this field to enter the default e-mail address to which exported exams are to be sent.

Print Options.

Paper Size. Lets you choose the paper size for printing exam reports (A4 or Letter).

Header Line 1. Header Line 2. Lets you edit the first and second lines of report headers.

Backup.

New Backup. Creates a backup of the app, saving all patient data.

Restore Backup. Lets you restore the app from an old backup.

ABOUT

Information about the Maestro app.

THE PRINT/EXPORT MENU

EXPORT TO NOAH / DAISY

This function lets you export exams to a *.nha* / *.dsy* file that can be imported into Noah / Daisy. You can choose whether to export exams only for the current patient or for the whole archive. The file is sent via email to the default recipient or stored in the Maestro documents folder, depending on the export options setting (see previous section).

PDF REPORT

This function lets you generate a pdf report containing selected exams. The document is automatically saved in the documents folder of the Maestro app. Once the file has been generated, you can open it or send it via e-mail.

PRINT

This function lets you print a report containing one or more exams on an AirPrint compatible printer.

CHAPTER 6

Maintenance



For any cleaning operation, the device must be firstly switched off.



The inspection and servicing of internal components must be left entirely to technicians approved by Inventis srl.



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

DAILY CHECKS

To ensure the audiometer correct functioning, it's suggested to daily do the following quick checks, before performing the first exam.

- Before switching on the instrument, check that all the contacts are perfectly connected and that the cables and/or connectors as well as all other elements do not appear to be broken or damaged externally
- Check subjectively that the air conduction and bone conduction output is equal on both channels and all frequencies, In order to do this 10 or 15 dB, just enough to hear is applied. The person who carries out this check should have good hearing
- Check at a level of 60dB in AC and 40dB in BC that there is no distortion, noise or parasitic signals in any of the frequencies

- Check that the patient response switch, the control panel and the indicators function correctly
- Check the inputs of speech audiometry (MIC and EXT).
- Check the headband strain of headset and of bone vibrator
- Check the communication with the patient



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

CLEANING

For cleaning the device, use a soft cloth moistened with ethyl alcohol. The cushion of the headphones and the bone vibrator are made of biocompatible material, but are not sterile. To avoid the infections spread, it is necessary to disinfect them, before using these for another patient. For whipping, use a commercial non-allergic disinfectant, following the instruction given by the manufacturer.

The eartips of insert earphones and masking insert earphones are made of biocompatible material and disposable: use once only and dispose of in accordance with current health and safety regulations.



The eartips of insert earphones are not sterile.

REPLACEABLE PARTS

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



All accessories of the audiometer are designed specifically for use with the device. Only accessories supplied by Inventis should be connected to the audiometer.

REPAIRS AND TECHNICAL ASSISTANCE

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

There are no requirements for the sterilization or disinfection of parts being returned to the manufacturer for repair and servicing (ISO 10940 §6 b).

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

APPENDIX A

Technical specifications

Classification

Piccolo Basic

Type 4 pure tone audiometer (EN 60645-1 / ANSI S3.6)

Piccolo Plus and Speech

Type 3 pure tone audiometer (EN 60645-1 / ANSI S3.6)

AVAILABLE SIGNALS			
<i>Type</i>	<i>Basic</i>	<i>Plus</i>	<i>Speech</i>
Pure tone	●	●	●
Warble tone	●	●	●
2 external inputs for speech audiometry	-	-	●
MIC input for live speech audiometry	-	-	●
Narrow-band noise (NBN)	●	●	●
White noise (WN)	-	-	●
Speech noise (SN)	-	-	●

SIGNALS SPECIFICATIONS	
Attenuators step	5 dB
Presentation mode	Continuous Pulsed, with rate of 0.5, 1 or 2 Hz
Frequency accuracy	0,1 %
Intensity accuracy	±3 dB between 125 Hz and 4 kHz ±5 dB above 4 kHz
Total Harmonic Distortion (THD)	AC: less than 2,5 % BC: less than 5,5 %
Warble tone	Frequency of the modulating signal: 5 Hz Modulation waveform: sine wave Modulation range: ±12%
NBN	Band: ½ octave, i.e.: - lower cut-off frequency $f_l = f / 1.1892$ - upper cut-off frequency $f_u = f \cdot 1.1892$ where f is the centre frequency
WN	Lower cut-off frequency: 100 Hz Upper cut-off frequency: 24 kHz
SN	As specified in EN 60645-2 §13
External signals	EXT1 and EXT2 input: max 3 Vrms

AVAILABLE OUTPUTS			
<i>Output</i>	<i>Basic</i>	<i>Plus</i>	<i>Speech</i>
Air conduction (TDH-39 or EARTone 3A / 5A insert earphones)	●	●	●
Bone conduction (B-71 bone vibrator)	-	●	●

PURE AND WARBLE TONE AVAILABLE FREQUENCIES AND MAXIMUM INTENSITIES				
Freq. (Hz)	AC TDH39 (dB HL)	AC EARTone 3A (dB HL)	AC EARTone 5A (dB HL)	BC (dB HL)
125	80	90	90	-
250	100	105	100	45
500	110	110	110	65
750	115	115	120	70
1.000	120	120	120	75
1.500	120	120	120	80
2.000	120	120	115	80
3.000	120	120	115	75
4.000	120	110	110	75
6.000	105	95	100	55
8.000	95	90	90	50

(*) Levels refer to devices powered by electricity network. In case they are powered by USB, maximum levels decrease by 10 dB.

SPEECH AUDIOMETRY MAXIMUM INTENSITIES			
AC TDH39 (dB HL)	AC EARTone 3A (dB HL)	AC EARTone 5A (dB HL)	BC (dB HL)
100	100	100	55

(*) Levels refer to devices powered by electricity network. In case they are powered by USB, maximum levels decrease by 10 dB.

EXTERNAL SIGNALS LEVEL INDICATOR (only for Speech model)	
Type of indicator	VU-meter
Dynamic range	+3..-20dB
Input Voltage at 0 dB	1.5 Vrms

MASKING AVAILABLE FREQUENCIES AND MAXIMUM INTENSITIES			
Freq. (Hz)	AC TDH39 (dB EM)	AC EARTone 3A (dB EM)	AC EARTone 5A (dB EM)
125	60	70	65
250	80	85	85
500	95	95	95
750	100	100	100
1.000	105	105	100
1.500	105	105	100
2.000	105	105	100
3.000	105	105	100
4.000	105	100	100
6.000	100	90	95
8.000	90	80	80
WN	90	80	80
SN	90	80	80

(*) Levels refer to devices powered by electricity network. In case they are powered by USB, maximum levels decrease by 10 dB.

ACOUSTICAL SAFETY OF THE DEVICE	
Alert condition	Tone intensity higher than 100 dB HL (EN 60645-1, §5.2)
Safety measures in alert condition	<ol style="list-style-type: none"> 1) The operator has to press “Higher dB” button to increase the intensity over 100 dB HL 2) Warning on the display 3) “Normally on” function disabled

COMPATIBLE TRANSDUCERS		
<i>Type</i>	<i>Manufacturer</i>	<i>Model</i>
Supra-aural headphones	Telephonics Corp.	TDH39
Insert earphones	Etymotic Research Inc.	ER-3A
Insert earphones	Etymotic Research Inc.	ER-5A
Bone vibrator	Radioear Corp.	B71

PATIENT – OPERATOR COMMUNICATION			
	<i>Basic</i>	<i>Plus</i>	<i>Speech</i>
Talk-over through external microphone (not included)	●	●	●
Patient response trigger	●	●	●

AVAILABLE TESTS			
	<i>Basic</i>	<i>Plus</i>	<i>Speech</i>
Pure tone audiometry	●	●	●
Auto-threshold	●	●	●
Speech audiometry	-	-	●

AUDIOMETER CONTROL		
	<i>Without AERO option</i>	<i>With AERO option</i>
Through computer with Inventis Daisy software and Maestro module.	●	●
Through computer with Noah software and Noah Maestro module.	●	●
Through iPad with Piccolo app	-	●

COMMUNICATION WITH THE AUDIOMETER		
	<i>Computer control</i>	<i>iPad control</i>
USB 1.1	●	-
Bluetooth 4	-	●

MINIMUM REQUIREMENTS FOR THE CONTROL DEVICE	
<i>Computer</i>	
Operating system	Microsoft Windows XP SP3 or sup., 32 o 64 bit
Processor	Intel Core 2 Duo 1.6 GHz or sup.
RAM	1 GB (suggested 2 GB)
Minimum resolution	1024 x 600
<i>iPad</i>	
Model	iPad 3 or following

POWER SUPPLY	
Consumption	8 Watt
Power supply	6V, 1.67A cont., through an external 100-240 Vac 50/60 Hz power supply (included), compliant to EN 60601-1 standard

CALIBRATION	
Calibration validity	12 months

ENVIRONMENTAL CONDITIONS	
Use	Temperature: between 15°C (59°F) and 35°C (95°F) Relative humidity: between 30% and 90% (non-condensing)
Transport and storage	Temperature: between -10°C (14°F) and 50°C (122°F) Relative humidity: max. 90% non-condensing
Warm-up time	1 minute

MECHANICS	
Size (LxDxH)	160 x 160 x 35 mm / 6.3 x 6.3 x 1.2 in
Weight (device only)	300 g / 10.6 oz

SOCKETS ON THE REAR PANEL		
<i>Description</i>	<i>Type</i>	<i>Connector</i>
Power supply	In	DC plug 2.5 mm
L and R headphones	Out	2 audio jack, 1/4" mono

Bone vibrator (not in Piccolo Basic)	Out	Audio jack, 1/4" mono
Patient response trigger	In	Audio jack, 1/4" mono
External microphone for talk-over	In	Audio jack, 3.5 mm mono
USB	In - Out	USB type B
<i>Only on Piccolo Speech</i>		
LINE IN 1 and LINE IN 2	In	Audio jack, 3.5 mm stereo

SPECS OF INPUT FACILITIES	
<i>Input</i>	<i>Electrical property</i>
Power supply	Internal pin +6V, external pin 0V
Patient response	Switches 3V to logical input (switch current: 10mA)
LINE IN 1 and LINE IN 2.	Sensitivity: 3mV at max volume and 0Vu Impedance: 10K Ω Freq. response: 75-12000Hz +/- 3dB
Microphone	Electret or 200 Ω dynamic microphone Impedance: 47K Ω Freq. response: 100-12KHz +/- 3dB Electret Bias: 2.2V trough 2.2K Ω

SPECS OF OUTPUT FACILITIES		
<i>Output</i>	<i>Available Voltage</i>	<i>Nominal Impedance</i>
L and R phones	8Vpp	10 Ω
Bone vibrator	8Vpp	10 Ω

SOUND ATTENUATION VALUES		
<i>Frequency [Hz]</i>	<i>TDH 39 with MX41\AR or PN 51 cushion [dB]</i>	<i>ER 3A ER 5A [dB]</i>
125	3	33.5
250	5	34.5
500	7	34.5
750	-	-
1000	15	35
1500	-	-
2000	26	33
3000	-	-
4000	32	39.5

6000	-	-
8000	24	43.5

REFERENCE EQUIVALENT THRESHOLD LEVELS				
Freq	TDH 39	ER 3A	ER 5A	B71*
	<i>ISO 389-1 (ANSI S3.6)</i>	<i>ISO 389-2 (ANSI S3.6)</i>	<i>ISO 389-2</i>	<i>ISO 389-3 (ANSI S3.6)</i>
<i>[Hz]</i>	<i>[dB re 20µPa]</i>	<i>[dB re 20µPa]</i>	<i>[dB re 20µPa]</i>	<i>[dB re 1µN]</i>
125	45	26	26	-
250	25.5	14	14	67
500	11.5	5.5	5.5	58
750	7.5 (8)	2	2	48.5
1000	7	0	0	42.5
1500	6.5	2	2	36.5
2000	9	3	3	31
3000	10	3.5	3.5	30
4000	9.5	5.5	5.5	35.5
6000	15.5	2	2	40
8000	13	0	0	40

(*) Calibration of bone vibrator (B71) refers to the placement on the mastoid.

APPLICABLE STANDARDS			
	<i>Basic</i>	<i>Plus</i>	<i>Speech</i>
EN 60645-1 / ANSI S3.6	Type 4	Type 3	Type 3
Calibration	<u>AC</u> : EN ISO 389-1 (TDH 39), EN ISO 389-2 (ER-3A e 5A), <u>BC</u> : EN ISO 389-3		
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 Ridlerstrasse 65 D-80339 München
Number of the notified body	0123
Number of the Inventis CE certificate	G1 12 09 65346 006

APPENDIX B

Troubleshooting

Problem	Possible cause	Solution
No signal from a transducer	Transducer not connected to the correct output	Connect the transducer to the correct output
	Transducer damaged	Contact your dealer or service provider
No signal from patient response button when pressed	Wrong connection	Connect the patient response button to the correct socket
	Patient response button damaged	Contact your dealer or service provider
Connection between PC and audiometer 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)
Connection between iPad and audiometer cannot be established	Wrong Serial Number	Check the serial number in the Maestro app settings
	iPad version not compatible with the audiometer	Substitute the iPad (it must be the version 3 or successive)

	The audiometer does not feature the Aero option	Substitute the audiometer
	Faulty Bluetooth module of audiometer	Contact your dealer or service provider
Unlikely exam results	Expired calibration	Perform audiometer calibration
	Wrong kind of selected AC transducer (headphones or earphones)	Modify the selection of current AC transducer, from Maestro module or app



When the audiometer is used in conjunction with a soundproof booth, check that the connections both inside the booth and between the booth and the instrument are correct and secure.

APPENDIX C

Electromagnetic emissions

The Piccolo audiometer is a Class B instrument according to IEC 60601-1-2.

The Piccolo audiometer 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 operated 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.

The existence of electromagnetic interference can be verified easily by switching the instrument off and back on again. If it is proven that the audiometer 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.



*This device contains transmission module FCC ID: QOQBLE112
This device contains transmission module IC: 5123A-BGTBLE112*

APPENDIX D

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