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PORTABLE AUDIOMETER

PICCOLO

FR

MULTILANGUAGE USER MANUAL

DE

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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 ("Installation").

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

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Summary

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Foreword

Thank you for purchasing an Inventis audiology device.

Advantageously portable and lightweight, the Piccolo audiometer is a powerful and versatile portable device, ideal for professionals on the move.

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

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

For further information, and to report any problems of any kind, contact the company at:

INVENTIS S.r.l.
Corso Stati Uniti, 1/3
35127 Padova, Italia
Tel.: 049.8962844 – Fax: 049.8966343
www.inventis.it info@inventis.it

CHAPTER 1
Safety: warnings and information

OPERATOR MANUAL

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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 Piccolo 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 S.r.l.. All repairs must be performed exclusively by Inventis or by personnel authorised by Inventis.
No parts of the device 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 S.r.l. or an authorised Service Centre. INVENTIS S.r.l. 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 system comply with applicable standards for electromedical devices.

INTENDED PURPOSE

Piccolo medical device is an audiometer. An audiometer is a device that helps the operator in defining the patient's auditory sensitivity by generating and delivering to the patient sound stimuli of different types and intensities for diagnostic purposes.

INDICATION FOR USE AND END USERS

Piccolo is intended for use by healthcare ENT professionals in hospitals, ENT clinics and audiology offices in conducting hearing evaluations and assisting in diagnosis of possible otologic disorders. There is no patient population restriction in the use of the device; always be sure to perform an otoscopy before using the device.
These tests must be conducted in a quiet environment to avoid artifacts.

MEDICAL CONDITIONS

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

PRECAUTIONS

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

To ensure correct and safe use of the 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:

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

The Piccolo audiometer will not be protected if exposed during use 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 detachable parts supplied by INVENTIS S.r.l., unless specifically instructed otherwise.

Only use power adapters intended for medical equipment, certified to IEC 60601-1, with the following specifications:

Main unit: 6V, 1.67A d.c.
External adapter: SL POWER MENB1010A0603F02
100-240Vac 50/60 Hz 0.9-0.34A (included) responding to IEC 60601-1 standard

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 IEC 60601-1) 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 IEC standard 60601-1.

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

Piccolo needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided at the end of this manual.

Use of portable and mobile RF communications equipment can affect the correct operation of Piccolo device. Make reference to the EMC information at the end of this manual.

The power adapter cable and the USB cable are considered the means to disconnect the device from the mains supply.

Do not position the device so that it is difficult to disconnect the device from the mains supply.

Calibration

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

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 transducers supplied with the audiometer, if connected directly to the instrument, without any interposition of extension leads and without the passage from connectors to panel (as habitually occurs in soundproof booth installations). If the transducers are not connected directly to the audiometer, 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 audiometer's specified calibration interval. Use of the instrument beyond its calibration expiry date can lead to unreliable diagnoses.

Hygiene

The eartips of 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 3 "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.

When conducting audiometry using insert earphones, do not insert or in any way try to conduct measurements without proper foam tip in place.

Maintaining the previous intensity of the stimulus when changing frequency, transducer or stimulation side can result in potentially harmful signals being presented to the patient.

To present a stimulus signal stronger than 100 dB HL, the operator must first press the "HIGHER dB" button, which is active only when the intensity of the stimulus reaches 100 dB HL.

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DISPOSAL

Like all electronic devices, your 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, take (or have taken) the disused instrument to 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

Piccolo audiometer is a class IIa medical device according to Annex VIII of Medical Device Regulation (MDR) 2017/745/EU.
The Inventis Quality Management System has been certified by leading assessment body TÜV as compliant with ISO 13485 standard.

SYMBOLS ON LABELS

Name and address of the manufacturer.

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

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.

Refer to instruction manual for use

Device with applied parts of type B (IEC 60601-1).

DC power supply

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

Medical Device

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.

REF

Catalogue number

COMPATIBLE TRANSDUCERS

Section that lists the compatible transducers

Serial number of the device, made up of 13 alphanumeric characters indicating the model, 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)*
- *characters 8… 13: incremental number*

UDI code

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CHAPTER 2
Installation

Whilst the installation of a Piccolo audiometer 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.

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

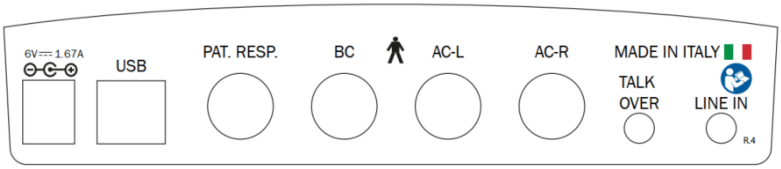
PRECAUTIONS

Like any other electric or electronic device, the Piccolo audiometer will emit electromagnetic waves. Even though its emissions are within the limits of standards, other electronic devices close to the audiometer might be affected, if particularly sensitive to electromagnetic interference.
Should this occur, check just by switching the audiometer OFF and ON and try to eliminate the interference using 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 audiometer;
- plug the affected device into a power socket on a circuit other than the circuit to which the audiometer is connected;
- consult the manufacturer or a service centre for assistance.

CONNECTIONS

All connection points for detachable parts 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 detachable parts into their respective sockets as indicated in the following table:

Connector	Detachable part
6V ⎓ 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 the PC
PAT. RESP.	Patient response button
BC	Bone vibrator
AC-L	Left headphone/insert earphone
AC-R	Right headphone/insert earphone
TALK OVER	Operator microphone
LINE IN	External line for speech audiometry with external audio source

Only use power adapters intended for medical equipment, certified to IEC 60601-1.

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

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.

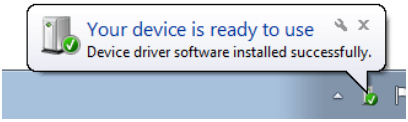
The LED near the symbol indicates the status of communications between the audiometer and computer: this LED lights in green if the audiometer is communicating with a PC.

CONNECTION TO COMPUTER

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).

Use the supplied cable to connect the Piccolo audiometer to one of the USB ports of the computer

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 the following message appears:



Piccolo audiometer can be controlled from a computer using Inventis Maestro software: for further details about the use and the features of Maestro software, and for minimum system requirements, refer to the *Maestro User Manual*.

CHAPTER 3
Maintenance

Piccolo audiometer does not require any special periodic maintenance other than calibration, checks, and normal cleaning, all of which are described in this chapter.
The performance and safety of the instrument will be maintained if the recommendations for care and maintenance given in this chapter are observed.
The instrument must be switched off and disconnected from the power supply before commencing any kind of cleaning operation.

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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.

PERIODIC CHECKS

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

The tests must be done with the audiometer in its installation position.

- Before switching on the instrument, check that no sign of damage is visible in any part of the device, including detachable parts and the external power supply; double check visual integrity of insulation of the mains cable and the connectors, and verify that they are not exposed to any kind of mechanical load that could involve damage; verify that all the parts and cables are properly connected
- 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 60 dB in AC and 40 dB in BC that there is no distortion, noise or parasitic signals in any of the frequencies
- Check that the patient response switch and the indicators function correctly
- Check the speech audiometry inputs by doing a speech test with every speech input
- Check the headband strain of headset and of bone vibrator
- Check the communication with the patient

If any part or transducer has any malfunction, consult the "Troubleshooting" Chapter.

Always check that the calibration interval has not elapsed: the expiry of the interval is indicated at the top left of Maestro software.

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

MAINTENANCE OF TRANSDUCERS

Do not use liquids or sprays to clean the audiometer.

Do not allow dust to collect on the transducers. In addition:

- The headphone cushions are made of biocompatible material but are not sterile: to prevent the spread of infection and guarantee the biocompatibility of the material, whenever the headphones are to be worn by a new patient, the cushions must be wiped with
    - for DD45/TDH-39 cushions, denatured alcohol wipe or denatured alcohol with a microfiber cloth;
    - for all other cushions: Hypoallergenic disinfectant, following the maker's instructions.
- The ear tips of insert earphones are intended to be inserted in the patient's ear canal. They are made of biocompatible material and disposable: use once only and dispose of in accordance with current health and safety regulations

The eartips of insert earphones are not sterile. The use of unsterilized earpieces can cause ear infections.

The bone vibrator and the headphone cushions can be repeatedly cleaned as described in the "Maintenance of Transducers" paragraph. In the event of any malfunctioning after any cleaning operation, contact an Inventis service technician.

Though the bone vibrator and headphone cushions can be repeatedly cleaned, always check that their characteristics and integrity are maintained. To do so, it is sufficient to perform the tests described in the "Periodic checks" paragraph. As soon as any failure is encountered, contact an Inventis service technician to verify whether your transducer needs to be replaced.

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To avoid damaging the DD45/TDH39 headphones, do not push it against a flat straight surface as this can create vacuum and cause a damage to the transducer (suction cup effect).

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 lint-free soft cloth moistened with a solution of water and mild detergent; in case of sanitization, moisten the cloth with hydrogen peroxide at a 3% concentration. The device allows multiple cleanings without degradation of basic safety or performances; always check that the device characteristics and integrity are maintained. To do so, it is sufficient to perform the tests described in the "Periodic checks" paragraph. As soon as any failure is encountered, contact an Inventis service technician to verify whether any parts need to be replaced.

REPLACEABLE PARTS

The transducers and detachable parts 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 detachable parts of the audiometer are designed specifically for use with the device. Only parts 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"* Chapter 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 detachable parts and transducers are enclosed.

CHAPTER 4
Troubleshooting

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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)
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 software or app
You cannot access to a test	Optional test not enabled	Contact your reference technical service to obtain the licence, communicating the device serial number

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.