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 3 ("Installation").

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

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Document title: **AU1P-User Manual En**

Revision: **15**

Date: **2022.07.08**

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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.

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:

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CHAPTER 1

Safety: warnings and information

OPERATOR MANUAL

We recommend that you read this manual thoroughly to obtain 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 installation's electrical power supply and ground connections comply with the applicable standards for electro-medical devices.

INTENDED USE

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 and to ensure that errors are not committed when determining the hearing threshold.

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 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 accessories supplied by Inventis srl, unless specifically instructed otherwise.

Only use power adapters intended for medical equipment, certified to IEC 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 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 needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in Appendix C.

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

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.

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.

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 4 "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.
Inventis Quality Management System is ISO 13485 certified.

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.

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).

The Aero version of the device emits radiofrequency signals.

DC power supply

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).

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

Serial number of the device. This number is 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

CHAPTER 2

Introduction

This chapter describes the main features of the Inventis Piccolo audiometer, and in particular, explains the differences between the model Basic, Plus and Speech.

MAIN FEATURES

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 from Maestro, the medical record manager software application developed by Inventis able to interface also with Noah database. 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 pure tone audiometry, speech audiometry, Master Hearing Aid test and, optionally, the QuickSIN™ test

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
RadioEar DD45 or Telephonics TDH39 supra-aural headphones, DD65 circum-aural headphones	●	●	●
ER-3 or IP30 insert earphones	opt.	opt.	opt.

Amplivox Audiocups or Silenta Supermax noise excluding enclosures (fit only on TDH-39 and DD45 headphones)	opt.	opt.	opt.
B71 bone vibrator	-	●	●
Patient response switch	●	●	●
Clip-on microphone for talk-over	●	●	●
Jack / jack cable (diam. 3.5 mm)	-	-	●
Inventis Maestro Software	●	●	●
USB cable	●	●	●
Medical grade power supply (6V)	●	●	●
User manual	●	●	●
QuickSIN® test license	-	-	opt.

CHAPTER 3

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.

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

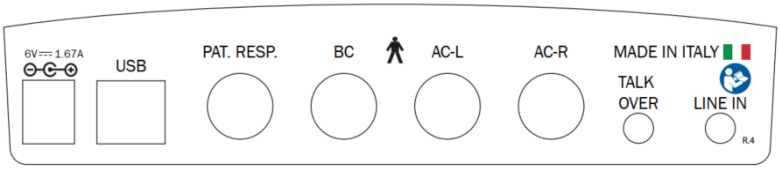
PRECAUTIONS

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 accessories are located on the rear panel, as also is the power switch. This section refers to the Piccolo Speech audiometer. The Piccolo Plus does not have a LINE IN connector for an external sound source (following reported as EXT1, EXT2). 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
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 a PC
PAT. RESP.	Patient response switch
BC	Bone vibrator
AC-L	Left headphone/insert earphone
AC-R	Right headphone/insert earphone
TALK OVER	Microphone for operator to patient communication
LINE IN	External line for speech audiometry with external audio source

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

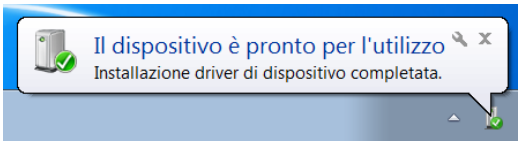
The green LED near the ⏻ symbol indicates that the audiometer is powered either from the mains power adapter or via the computer's USB cable.

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 COMPUTER/IPAD

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 for installation purposes: 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:



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.

Aero models permit to control the device via Bluetooth from an iPad using Inventis Maestro app. available free of charge from the Apple App Store: for further details about the use and the features of Maestro App, and for minimum system requirements, refer to the Maestro – App User Manual.

CHAPTER 4

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.

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

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

PERIODIC CHECKS

To maximize the audiometer life and all of its accessories service life, it's suggested to daily do the following tests.

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 accessories 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 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

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

It's basic also 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 srl. The operation should be performed at least once every 12 months, and whenever a transducer is replaced.

MAINTENANCE OF TRANSDUCERS

Do not use liquids or sprays to clean the 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.
- The ear tips of insert earphones and the masking insert earphones (IME-100) are made of biocompatible material and disposable: use once only and dispose of in accordance with current health and safety regulations.

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

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

To prevent the accumulation of dust on the audiometer, always cover the instrument with the protective cloth when not in use. Dust the audiometer regularly to ensure it is kept clean.
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.

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.
All the parts being returned to the manufacturer for repair and service shall be sterilized or disinfected and put in a transparent bag hermetically closed.
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 (IEC 60645-1 / ANSI S3.6)

Piccolo Plus

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

Piccolo Speech

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

AVAILABLE SIGNALS			
Type	*Basic*	*Plus*	*Speech*
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	1, 3, 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 IEC 60645-2 §13
External signals	EXT1 and EXT2 input: max 3 Vrms

AVAILABLE OUTPUTS			
Output	*Basic*	*Plus*	*Speech*
Air conduction (TDH-39, DD45 or DD65 headphones)	●	●	●
Air conduction (ER-3, IP30 or ER-5 insert earphones)	●	●	●
Bone conduction (B-71 bone vibrator)	-	●	●

PURE AND WARBLE TONE AVAILABLE FREQUENCIES AND MAXIMUM INTENSITES					
Freq. (Hz)	**AC TDH39 DD45 (dB HL)**	**AC DD65 (dB HL)**	**AC ER-3 IP30 (dB HL)**	**AC ER-5 (dB HL)**	**BC B71 (dB HL)**
125	80	80	90	90	-
250	100	95	105	100	45
500	110	110	110	110	65
750	115	110	115	120	70
1.000	120	110	120	120	75
1.500	120	110	120	120	80
2.000	120	110	120	115	80
3.000	120	110	120	115	75
4.000	120	110	110	110	75
6.000	105	95	95	100	55
8.000	95	90	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 DD45 (dB HL)	**AC DD65 (dB HL)**	**AC ER-3 IP30 (dB HL)**	**AC ER-5 (dB HL)**	**BC B71 (dB HL)**
100	90	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
Speed of the volume following	Increase: 60 dB/s Decrease: 60 dB/s

MASKING AVAILABLE FREQUENCIES AND MAXIMUM INTENSITES				
Freq. (Hz)	**AC TDH39 DD45 (dB EM)**	**AC DD65 (dB EM)**	**AC ER-3 IP30 (dB EM)**	**AC ER-5 (dB EM)**
125	60	55	70	65
250	80	75	85	85
500	95	90	95	95
750	100	90	100	100
1.000	105	95	105	100
1.500	105	95	105	100
2.000	105	95	105	100
3.000	105	95	105	100
4.000	105	95	100	100
6.000	100	85	90	95
8.000	90	85	80	80
WN	90	80	80	80
SN	90	75	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 (IEC 60645-1, §5.2)
Safety measures in alert condition	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		
Type	*Manufacturer*	*Model*
Supra-aural headphones	Telephonics Corp.	TDH39
Supra-aural headphones	Radioear Corp.	DD45
Circum-aural headphones	Radioear Corp.	DD65
Insert earphones	Etymotic Research Inc.	ER-3
Insert earphones	Etymotic Research Inc.	ER-5
Insert earphones	Radioear Corp.	IP30
Bone vibrator	Radioear Corp.	B71

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

AVAILABLE TESTS*			
	Basic	*Plus*	*Speech*
Pure tone audiometry	●	●	●
Auto-threshold	●	●	●
Speech audiometry	-	-	●
QuickSIN™	-	-	opt.
Master Hearing Aid	-	-	●

(*) available when controlled from the computer.

AUDIOMETER CONTROL		
	Without AERO option	*With AERO option*
Through computer with Inventis Maestro software.	●	●

Through iPad with Maestro App	-	●

COMUNICATION WITH THE AUDIOMETER		
	Computer control	*iPad control*
USB 1.1	●	-
Bluetooth 4	-	●

MINIMUM REQUIREMENTS FOR THE CONTROL DEVICE	
Computer	
Operating system	Microsoft Windows 7 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 768
iPad	
Operating system	Apple iOS 7.1 or sup.
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 (0.3 A – 0.1 A)power supply (included), compliant to IEC 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		
Description	*Type*	*Connector*
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
Only on Piccolo Speech		
LINE IN	In	Audio jack, 3.5 mm stereo

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

SPECS OF OUTPUT FACILITIES		
Output	***Available Voltage***	***Nominal Impedance***
L and R phones	8Vpp	10 Ω
Bone vibrator	8Vpp	10 Ω

SOUND ATTENUATION VALUES			
Frequency	**TDH 39 (*) DD45 (*)**	**DD65**	**ER-3 ER-5 IP30**
[Hz]	**[dB]**	**[dB]**	**[dB]**
125	3.0	8.3	33.5
250	5.0	15.5	34.5
500	7.0	26.1	34.5
750	-	-	-
1000	15.0	32.4	35

1500	-	-	-
2000	26.0	43.6	33
3000	-	-	-
4000	32.0	43.8	39.5
6000	-	-	-
8000	24.0	45.6	43.5

(*) With MX41\AR or PN 51 cushions

REFERENCE EQUIVALENT THRESHOLD LEVELS						
	TDH 39	**DD45**	**DD65**	**ER-3 IP30**	**ER-5**	**B71***
Ref. std.	**ISO 389-1 (ANSI S3.6)**	**ISO 389-1 (ANSI S3.6)**	**Vendor Tech. Specificat.**	**ISO 389-2 (ANSI S3.6)**	**ISO 389-2**	**ISO 389-3 (ANSI S3.6)**
Freq. *[Hz]*	**dB [re 20µPa]**	**dB [re 20µPa]**	**dB [re 20µPa]**	**dB [re 20µPa]**	**dB [re 20µPa]]**	**dB [re 1µN]**
125	45	47.5	30.5	26	26	-
250	25.5	27	17.0	14	14	67
500	11.5	13	8.0	5.5	5.5	58
750	7.5 (8)	6.5	5.5	2	2	48.5
1000	7	6	4.5	0	0	42.5
1500	6.5	8	2.5	2	2	36.5
2000	9	8	2.5	3	3	31
3000	10	8	2.0	3.5	3.5	30
4000	9.5	9	9.5	5.5	5.5	35.5
6000	15.5	20.5	21.0	2	2	40
8000	13	12	21.0	0	0	40

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

APPLICABLE STANDARDS			
	Basic	*Plus*	*Speech*
IEC 60645-1:2017 / ANSI S3.6-2018	Type 4	Type 3	Type 3B
Electrical safety	IEC 60601-1 Class I Type B		
EMC	IEC 60601-1-2		
Radio Equipment Directive (RE-D) 2014/53/EU			
Operating Frequency Range (OFR)			2402 - 2480 MHz
Channels			40
Channel separation			2 MHz
Channel bandwidth			1.056 MHz
Effective isotropic radiated power (e.i.r.p.)			6.66 dBm
Transmission technique			DSSS

Modulation	GFSK
Integral antenna gain	0.5 dBi
FCC ID:	QOQBLE11
transmission module with IC: 5123A-BGTBLE112	

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 Műnchen
Number of the notified body	0123

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)

Problem	Possible cause	Solution
	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 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.

APPENDIX C

Electromagnetic compatibility

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

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

This instrument is suitable for use in professional healthcare facility environment, i.e. in hospital environments, except for near active HF surgical equipment and RF shielded rooms of systems for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high.

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

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

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

List of cables, transducers and accessories

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

1) 6Vdc Medical Grade Power
2) Power supply cable (maximum length: 1.8 m)

3) TDH39, DD45 and DD65 transducers with 2 m double signal shielded cable
4) Insert earphone: ER-3 (Etymotic) or IP30 (RadioEar)
5) Bone vibrator B-71 transducer with twisted not shielded double signal cable 2m
6) Patient response switch (manufactured by Inventis) with 2 m shielded cable
7) Talk over microphone with 2m shielded cable
8) Stereo cable 3.5mm plug to 3.5mm plug, 1.8m, shielded
9) USB cable, shielded, maximum length: 2 m

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

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of Piccolo, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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

The instrument has no ESSENTIAL PERFORMANCE as related to IEC 60601-1

Note: All necessary instruction for maintaining compliance with regard to electromagnetic compatibility can be found in the maintenance section in this manual. No further steps are required.

Guidance and manufacturer's declaration – electromagnetic emissions		
Piccolo is intended for use in the electromagnetic environment specified below. The customer or the user of Piccolo should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment-guidance**

RF emissions CISPR11	Group 1	Piccolo uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	Piccolo is suitable for use in professional healthcare facility environment and directly connected to the public low-voltage power supply network.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flickers emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
Piccolo is intended for use in the electromagnetic environment specified below. The customer or the user of Piccolo should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact (1) ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air (1)	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV for power supply lines ± 1 kV for input / output lines	Mains power quality should be that of a professional healthcare facility environment.
Surge IEC 61000-4-5	± 1 kV differential mode ±2 kV common mode	± 1 kV differential mode ±2 kV common mode	Mains power quality should be that of a professional healthcare facility environment.
Voltage dips, short interruptions and voltage variations	< 5% U_T (2) (> 95% dip in U_T) for 0,5 cycle. 40% U_T	< 5% U_T (2) (> 95% dip in U_T) for 0,5 cycle. 40% U_T	Mains power quality should be that of a professional healthcare facility environment. If the

on power supply input lines IEC 61000-4-11	(60% dip in U_T) for 5 cycles. 70% U_T (30% dip in U_T) for 25 cycles. <5% U_T (> 95% dip in U_T) for 5 s.	(60% dip in U_T) for 5 cycles. 70% U_T (30% dip in U_T) for 25 cycles. <5% U_T (> 95% dip in U_T) for 5 s.	user of Piccolo requires continued operation during power mains interruptions, it is recommended that Piccolo be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields at power frequencies must correspond to the levels typical of professional healthcare facilities.
Note: (1) A lock or reboot of the device with no permanent damage is acceptable (2) U_T is the a.c. main voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
Piccolo is intended for use in the electromagnetic environment specified below. The customer or the user of Piccolo should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compl. Level**	**Electromagnetic environment – Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 0.15 MHz to 80 Mhz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz	3 Vrms 0.15 MHz to 80 Mhz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer than 30cm (12 inches) to any part of Piccolo, including cables specified by the manufacturer. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radieted RF IEC 61000-4-3	3 V/m 80 Mhz to 2,7 Ghz	3 V/m 80 Mhz to 2,7 Ghz	
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.			

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular / Cordless) telephones and land mobile, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If measured field strength in the location in which Piccolo is used exceeds the applicable RF compliance level above, Piccolo should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Piccolo. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and manufacturer's declaration – electromagnetic immunity	
Function to verify for freedom from unacceptable risk	**Acceptance pass/fail criteria**
Sound generation operating correctly	No sound from trasnducers exceeding 80dB; a lock or reboot of the device is acceptable

The Areo version contains a transmission module with FCC ID: QOQBLE112
The Areo version contains a transmission module with IC: 5123A-BGTBLE112

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