IT

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PORTABLE AUDIOMETER

PICCOLO

FR

MULTILANGUAGE USER MANUAL

DE

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PICCOLO

AUDIOMETRO PORTATILE

MANUALE UTENTE

Leggere attentamente questo manuale prima di utilizzare lo strumento. Prestare particolare attenzione alle istruzioni riportate nel capitolo 1 ("Sicurezza: avvertenze e informazioni") e nel capitolo 2 ("Installazione").

Le riparazioni e le ispezioni interne devono essere eseguite esclusivamente da personale autorizzato.

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Sommario

Prefazione

Grazie per aver acquistato un dispositivo audiologico Inventis.

Nonostante dimensioni e peso siano contenuti, l'audiometro Piccolo è un dispositivo portatile potente e versatile, ideale per professionisti in movimento.

In Inventis abbiamo sempre considerato estremamente importante l'integrazione dei nostri dispositivi con il computer. Il software Maestro, disponibile in versione con o senza database proprietario o come modulo Noah, consente il collegamento di ogni dispositivo audiologico Inventis al computer, al fine di archiviare nel proprio database tutti gli esami effettuati.

Vi ricordiamo inoltre che Inventis ha sviluppato una linea completa di dispositivi audiologici: oltre agli audiometri, la nostra linea comprende diversi impedenzometri, dispositivi per fitting audioprotesico REM e HIT, un video otoscopio senza fili e molto altro.

Per ogni ulteriore informazione, nonché per segnalare qualsiasi tipo di problema, è possibile contattarci ai seguenti recapiti:

INVENTIS S.r.l.
Corso Stati Uniti, 1/3
35127 Padova, Italia
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CAPITOLO 1
Sicurezza: avvertenze e informazioni

MANUALE UTENTE

Si consiglia di leggere per intero questo manuale, allo scopo di utilizzare appieno tutte le possibilità offerte dallo strumento. In particolare, si invita a leggere per intero questo capitolo, che contiene importanti informazioni ed avvertenze fondamentali per un utilizzo sicuro e corretto del dispositivo.
All'interno di questo manuale, il simbolo di sicurezza sotto illustrato intende attirare l'attenzione del lettore su informazioni particolarmente importanti ai fini della sicurezza e della correttezza di utilizzo.

RESPONSABILITÀ DELL'OPERATORE

Un funzionamento affidabile ed efficiente dell'audiometro Piccolo è garantito solo se il dispositivo viene utilizzato in conformità alle istruzioni e alle procedure indicate in questo manuale.
Nel caso in cui il dispositivo debba essere sottoposto a riparazioni o manutenzione, non deve essere usato fino all'avvenuta riparazione e deve essere scollegato dalla rete elettrica. Le parti difettose e guaste devono essere sostituite soltanto con parti di ricambio originali fornite da INVENTIS S.r.l.. Tutte le riparazioni devono essere effettuate esclusivamente da Inventis o da personale autorizzato da Inventis.
Nessuna delle parti del dispositivo deve essere modificata o sostituita senza l'autorizzazione scritta di Inventis.
L'utente del dispositivo è pienamente responsabile di un eventuale malfunzionamento causato da uso o operazioni improprie, nonché da interventi di manutenzione o riparazione effettuati da terzi che non siano INVENTIS S.r.l. o Centri di Assistenza autorizzati. INVENTIS S.r.l. e i Centri di Assistenza saranno responsabili per le prestazioni e l'affidabilità dell'apparecchiatura solo se:

1. tutti i collegamenti, le regolazioni, le modifiche o le riparazioni sono effettuate esclusivamente da personale autorizzato da Inventis;

2. l’impianto elettrico e la messa a terra dell’installazione sono conformi alle specifiche degli standard per le apparecchiature elettromedicali.

DESTINAZIONE D’USO

Il dispositivo medico Piccolo è un audiometro. Un audiometro è un dispositivo che aiuta l'operatore a definire la sensibilità uditiva del paziente generando e inviando al paziente stimoli sonori di diversi tipi e intensità a scopo diagnostico.

INDICAZIONI D’USO E UTILIZZATORI

Piccolo è destinato all'uso da parte di professionisti ORL sanitari in ospedali, cliniche ORL e studi di audiologia per condurre valutazioni dell'udito e assistenza nella diagnosi di possibili disturbi otologici. Non vi è alcuna limitazione della popolazione di pazienti nell'uso del dispositivo; assicurarsi sempre di eseguire un'otoscopia prima di utilizzare il dispositivo.
Questi esami devono essere effettuati in un ambiente silenzioso, al fine di evitare artefatti.

CONDIZIONI MEDICHE

Condizioni di compromessa capacità uditiva o qualsiasi condizione nella quale si ritiene che il sistema uditivo influiscano in modo decisivo nella diagnosi.

PRECAUZIONI

Riferire qualsiasi incidente grave, che si è verificato in relazione all’utilizzo del dispositivo, al produttore e all’autorità competente dello Stato membro nel quale l’utente e/o il paziente si trova.

Per un utilizzo corretto e sicuro dell’audiometro è fondamentale attenersi alle seguenti precauzioni.

Installazione e precauzioni generiche

Garantire la conformità alle condizioni ambientali richieste (durante il trasporto, l'immagazzinamento e il funzionamento):

Funzionamento	*Temperatura: tra +15°C e +35°C* *Umidità relativa: tra 30% e 90% senza condensazione* *Pressione: da 700 hPa a 1060 hPa*
Trasporto e immagazzinamento	*Temperatura: tra -10°C e 50°C* *Umidità relativa: max 90%senza condensa* *Pressione: da 500 hPa a 1060 hPa*
Tempo di riscaldamento	*1 minuto*

L'audiometro Piccolo non è protetto in caso di uso in presenza di gas anestetici infiammabili o prodotti simili. Pericolo di esplosione.

Evitare l'installazione e l'uso dell'audiometro Piccolo in prossimità di sorgenti di intenso campo elettromagnetico: potrebbero interferire con il funzionamento dell'apparecchio.

Ove non espressamente consentito, utilizzare unicamente parti rimovibili originali forniti da INVENTIS S.r.l..

Utilizzare solamente alimentatori medicali, certificati secondo la normativa IEC 60601-1, con le seguenti specifiche:

Unità principale: 6V, 1.67A d.c.
Alimentatore esterno: SL POWER MENB1010A0603F02 100-240 Vac 50/60 Hz 0.9-0.34A (incluso) conforme alla normativa IEC 60601-1

L'audiometro Piccolo è un dispositivo medico: quando viene collegato ad un computer (o a qualsiasi dispositivo esterno, come un lettore di CD) e questo si trova nell'"area paziente" (come definita nella norma IEC 60601-1), anch'esso deve essere medicale, oppure protetto da trasformatore di isolamento, per assicurare che il sistema computer (dispositivo esterno) + audiometro sia conforme alla norma IEC 60601-1.

Piccolo può essere utilizzato con cabina silente per eseguire i test in condizioni acustiche ottimali. Prima di collegare l'audiometro a una cabina silente, assicurarsi che le prese siano di tipo compatibile con le specifiche previste per ciascun connettore.

Piccolo richiede precauzioni speciali sulla compatibilità elettromagnetica (EMC) e deve essere installato e messo in funzione attenendosi alle informazioni EMC fornite alla fine del presente manuale.

La presenza di apparecchi portatili e mobili per comunicazioni a RF può influire sulla funzionalità del dispositivo Piccolo. Fare riferimento alle informazioni EMC indicate alla fine del presente manuale.

Utilizzare il cavo dell'alimentatore e il cavo USB per scollegare il dispositivo dalla rete.

Non posizionare il dispositivo in una modalità tale che risulti difficile scollegare il dispositivo dalla rete di alimentazione.

Calibrazione

La calibrazione dev'essere eseguita almeno ogni 12 mesi e ogni volta che viene sostituito un trasduttore.

La calibrazione dell'audiometro è valida solamente per i trasduttori forniti in dotazione con il dispositivo. La sostituzione di un trasduttore richiede una nuova calibrazione dell'audiometro.

La calibrazione dell'audiometro è valida per i trasduttori forniti in dotazione con l'audiometro se collegati direttamente allo strumento, senza l'interposizione di prolunghe e senza il passaggio da connettori a pannello (come abitualmente accade nelle installazioni con cabina silente). Qualora i trasduttori non siano collegati direttamente all'audiometro, è necessaria una nuova calibrazione prima dell'utilizzo dello strumento.

La selezione di un trasduttore non calibrato viene evidenziato nelle schermate esame tramite uno sfondo di colore rosso in corrispondenza dell'indicazione dell'uscita selezionata. Non sarà possibile inviare alcun stimolo al paziente tramite trasduttori non calibrati.

Prendere nota dell'intervallo di calibrazione specifico dell'audiometro. L'utilizzo dello strumento oltre la data di scadenza della calibrazione può portare a diagnosi non corrette.

Igiene

I tappini degli auricolari ad inserzione sono monouso; non utilizzare lo stesso tappino per pazienti diversi. Smaltire i tappini monouso dopo l'utilizzo.

Disinfettare i cuscinetti delle cuffie tra un paziente ed il successivo con la procedura specificata nel CAPITOLO 3 "La manutenzione".

Utilizzo

L'audiometro può inviare toni con un'intensità potenzialmente dannosa per il paziente. Prestare particolare attenzione alla corretta intensità del tono prima di inviarlo per l'esame.

Quando si esegue l'audiometria utilizzando gli auricolari ad inserzione, non procedere alla misurazione senza aver posizionato correttamente la punta del cuscinetto.

Mantenere il precedente livello dell'intensità dello stimolo cambiando frequenza, trasduttore o lato di stimolazione può portare all'invio di toni potenzialmente dannosi per il paziente.

Per l'invio di un segnale di stimolo superiore a 100 dB HL, l'operatore deve prima premere il pulsante "dB PIÙ ALTI", attivo solo quando l'intensità di stimolo raggiunge 100 dB HL.

SMALTIMENTO

Come in tutti i dispositivi elettronici, nell'audiometro sono presenti, sebbene in quantità estremamente ridotta, alcune sostanze molto pericolose, come il cadmio o il mercurio. Tali sostanze, se entrano nel normale ciclo dei rifiuti senza un adeguato trattamento preliminare, provocano gravi danni ambientali e sanitari. Ciascun componente dell'audiometro, al termine del proprio ciclo di vita, deve essere pertanto oggetto di raccolta separata.
Pertanto, l'utente dovrà conferire (o far conferire) il rifiuto ai centri di raccolta differenziata predisposti dalle amministrazioni locali, oppure consegnarlo al rivenditore all'atto dell'acquisto di una nuova apparecchiatura di tipo equivalente.
La raccolta differenziata del rifiuto e le successive operazioni di trattamento, recupero e smaltimento favoriscono la produzione di nuovi dispositivi con materiali riciclati e limitano gli effetti negativi sull'ambiente e sulla salute eventualmente causati da una gestione impropria del rifiuto.

CONFORMITÀ

L'audiometro Piccolo è un dispositivo medico di classe IIa conforme all'Allegato VIII del Regolamento sui dispositivi medici (MDR) 2017/745/EU.
Il Sistema di gestione qualità Inventis è stato certificato dal principale organismo di valutazione TÜV come conforme alla normativa ISO 13485.

TABELLA DEI SIMBOLI SULLE ETICHETTE

Nome e indirizzo del fabbricante.

Attenzione: l'utilizzo di questo dispositivo richiede alcune precauzioni.
Per un utilizzo sicuro, consultare la documentazione inclusa.

Questo simbolo indica che questo prodotto è soggetto alla Direttiva 2012/19/EU sui rifiuti delle apparecchiature elettriche ed elettroniche (RAEE). In caso di alienazione e/o rottamazione, questo prodotto non deve essere smaltito come rifiuto indifferenziato, ma raccolto separatamente.

Riferirsi al manuale di istruzioni per l'utilizzo

Dispositivo con parti applicate, di Tipo B (IEC 60601-1).

Alimentazione DC

Prodotto conforme al Regolamento della Comunità europea sui dispositivi medici (MDR) 2017/745/EU. Dispositivo di classe IIa; numero dell'ente notificato: 0123 (TÜV SÜD Product Service GmbH).

Dispositivo medico

Rx only

Avvertenza: la legge federale degli Stati Uniti impone che la vendita del dispositivo avvenga tramite o su ordine di professionisti sanitari autorizzati.

IP20

Codice IP (Ingress Protection): questo dispositivo è protetto contro la penetrazione di oggetti di dimensione superiore a 12,5 mm; non è protetto contro l'accesso di liquidi.

REF *Codice di catalogo*

COMPATIBLE TRANSDUCERS *Parte che elenca i trasduttori compatibili*

SN *Il numero di serie del dispositivo è composto da 13 caratteri alfanumerici, che codificano il modello, l'anno di produzione ed il numero di serie. In particolare, il numero è così composto:*

- *primi 5 caratteri: codice Inventis del prodotto*
- *caratteri 6 e 7: anno di fabbricazione ("12" sta per 2012)*
- *caratteri 8-13: numero progressivo*

(01)08054187380372(21)AU1PH16200749

Codifica UDI

CAPITOLO 2
Installazione

L'installazione dell'audiometro Piccolo, sebbene sia una procedura relativamente semplice, deve essere effettuata da personale qualificato. Una non corretta installazione può infatti comportare problemi di sicurezza nell'utilizzo del sistema.
Questo capitolo descrive la procedura di installazione del sistema.

Conservare il materiale di imballaggio per un'eventuale spedizione dell'audiometro al distributore o a Inventis.

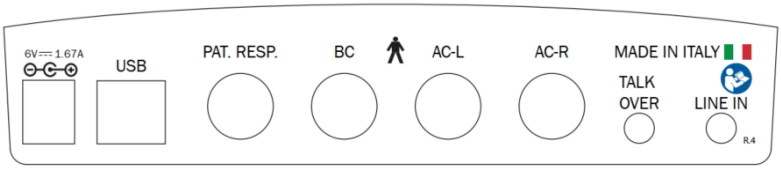
PRECAUZIONI

L'audiometro Piccolo, come qualsiasi altro dispositivo elettrico o elettronico, emette onde elettromagnetiche. Sebbene tali emissioni garantite rientrino nei limiti normativi, esse potrebbero disturbare altri dispositivi elettronici posti nelle vicinanze dell'audiometro e particolarmente suscettibili alle interferenze elettromagnetiche.
Se ciò dovesse accadere (verificarlo semplicemente spegnendo e riaccendendo l'audiometro), provare a eliminare l'interferenza adottando una o più delle seguenti soluzioni:

- cambiare l'orientamento e/o la posizione del dispositivo che subisce l'interferenza;
- allontanare dall'audiometro il dispositivo coinvolto;
- collegare il dispositivo specifico a una presa di rete appartenente a un circuito diverso da quello in cui è collegato l'audiometro;
- consultare il produttore o l'assistenza tecnica per ricevere aiuto.

I COLLEGAMENTI

Tutti i connettori di collegamento con le parti rimovibili sono posti sul pannello posteriore. Questo paragrafo fa riferimento al modello Piccolo Speech. Nella versione Piccolo Plus non è presente il connettore LINE IN per la sorgente audio esterna e nella versione Basic è assente anche il connettore BC per il vibratore osseo.



Collegare tutti i trasduttori e le parti rimovibili nei rispettivi connettori, come indicato nella seguente tabella:

Connettore	Parte rimovibile
6V⎓1.67A	Alimentatore. Quando Piccolo è collegato al computer tramite USB, non è necessario utilizzare l'alimentatore.
USB	Porta USB per collegamento al PC
PAT. RESP.	Pulsante di risposta del paziente
BC	Vibratore osseo
AC-L	Cuffia sinistra/auricolare ad inserzione sinistro
AC-R	Cuffia destra/auricolare ad inserzione destro
TALK OVER	Microfono operatore per comunicazione al paziente o per effettuare l'audiometria vocale
LINE IN	Linea esterna per il collegamento della sorgente audio per l'audiometria vocale

Utilizzare solamente alimentatori medicali, certificati secondo la normativa IEC 60601-1.

Accertarsi che l'impianto elettrico e la messa a terra dell'installazione siano conformi alle normative vigenti per i dispositivi elettromedicali. Rischio di scosse elettriche

Se Piccolo è alimentato solo tramite il cavo USB, i valori massimi (sia in AC che in BC) sono di 10 dB inferiori rispetto ai rispettivi valori nominali.

L'accensione del LED verde in corrispondenza del simbolo indica che l'audiometro è alimentato, tramite connessione alla rete elettrica mediante alimentatore o tramite collegamento USB al computer.

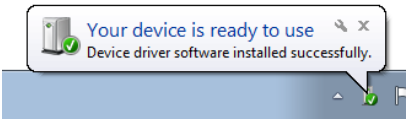
Il LED in corrispondenza del simbolo indica lo stato della comunicazione dell'audiometro con computer: è acceso e verde se l'audiometro sta comunicando con il computer.

COLLEGAMENTO A COMPUTER

Se controllato da computer, l'audiometro Piccolo va collegato a una porta USB utilizzando il cavo in dotazione (un comune cavo USB di tipo A/B).

Utilizzare il cavo fornito in dotazione per collegare l'audiometro Piccolo a una delle porte USB del computer

L'audiometro Piccolo non richiede particolari driver per l'installazione: dopo qualche secondo, verrà riconosciuto dal sistema operativo, che ne installerà automaticamente i driver visualizzando i seguenti messaggi:



L'audiometro Piccolo è controllabile tramite computer, utilizzando il software Inventis Maestro: per maggiori dettagli sull'utilizzo e sulle potenzialità del software Maestro, nonché per i requisiti minimi richiesti, si rimanda al *Manuale Utente di Maestro*.

CAPITOLO 3
La manutenzione

L’audiometro Piccolo non richiede particolari operazioni di manutenzione periodica oltre alla calibrazione e alle normali operazioni di pulizia, descritte in questo capitolo.
Le prestazioni e la sicurezza dello strumento saranno mantenute se si osservano le raccomandazioni per la cura e la manutenzione riportate in questo capitolo.
Per qualsiasi operazione di pulizia è necessario preventivamente spegnere lo strumento e scollegarlo dall’alimentazione.

L’ispezione e la manutenzione interna sono riservate al solo personale autorizzato da INVENTIS S.r.l..

I trasduttori sono realizzati con membrane molto fragili che potrebbero venire danneggiate in seguito ad urto. Maneggiarle con cura durante le operazioni di manutenzione.

CONTROLLI PERIODICI

La procedura descritta nel presente paragrafo deve essere effettuata regolarmente al primo avvio quotidiano dello strumento.

I test devono essere eseguiti con l’audiometro nella posizione di utilizzo.

- Prima di accendere lo strumento, verificare che nessun segno di danneggiamento sia visibile in nessuna parte del dispositivo, compresi le parti rimovibili e l'alimentatore esterno; verificare l'integrità visiva dell'isolamento del cavo di alimentazione e dei connettori, e verificare che non siano esposti a nessun tipo di carico meccanico che possa comportare danni; verificare che tutte le parti e i cavi siano collegati correttamente
- Controllare soggettivamente che le uscite con conduzione per via aerea e per via ossea siano uguali in entrambi i canali e a tutte le frequenze. Eseguire questo test con 10 o 15 dB, quanto basta per

sentire che lo stimolo è stato inviato. La persona che effettua questo controllo dovrebbe avere un ottimo udito

- Controllare per ogni frequenza che a 60 dB in AC e a 40 dB in BC non siano presenti distorsioni, rumori o segnali parassiti
- Controllare che il pulsante di risposta del paziente e le spie luminose funzionino correttamente.
- Controllare gli ingressi di audiometria vocale eseguendo una prova vocale con ogni ingresso vocale
- Controllare la tensione dell'archetto delle cuffie e del vibratore osseo.
- Controllare la comunicazione con il paziente.

Se una parte o un trasduttore presentano un guasto, consultare il Capitolo "Risoluzione dei problemi".

Controllare sempre che l'intervallo di calibrazione non sia trascorso: la data di scadenza dell'intervallo è indicata nella parte in alto a sinistra della schermata del software Maestro.

La calibrazione dev'essere affidata a personale tecnico autorizzato da INVENTIS S.r.l.. L'operazione dev'essere eseguita almeno ogni 12 mesi e ogni volta che viene sostituito un trasduttore.

MANUTENZIONE TRASDUTTORI

Non utilizzare liquidi o spray per la pulizia dell'audiometro.

Accertarsi che non si accumuli polvere sui trasduttori. Inoltre:

- I cuscinetti delle cuffie sono realizzati in materiale biocompatibile ma non sono sterili: per evitare la diffusione di infezioni e per garantirne la biocompatibilità è necessario disinfettarli prima dell'utilizzo su un nuovo paziente utilizzando:
    - per i cuscinetti delle cuffie DD45/TDH-39: salviette inumidite con alcool denaturato o panno in microfibra inumidito con alcool denaturato;
    - per tutti gli altri cuscinetti: disinfettante anallergico, secondo le istruzioni del produttore.

- I tappini monouso degli auricolari ad inserzione vengono inseriti nel condotto uditivo del paziente. Sono costituiti da materiale biocompatibile e sono monouso: utilizzare solo una volta e smaltire in conformità con le normative correnti in materia di salute e sicurezza.

I tappini monouso degli auricolari ad inserzione non sono sterili. L'utilizzo di tappini non sterili può causare infezioni all'orecchio.

Il vibratore osseo e i cuscinetti della cuffia possono essere puliti più volte nel modo descritto nel paragrafo "Manutenzione dei trasduttori". In caso di malfunzionamento dopo un'operazione di pulizia, contattare l'assistenza tecnica Inventis.

Sebbene il vibratore osseo e i cuscinetti della cuffia possano essere puliti più volte, verificare sempre che le loro caratteristiche e la loro integrità siano rimaste intatte. Per farlo, è sufficiente eseguire le prove descritte nel paragrafo "Controlli periodici". In caso di guasto, contattare l'assistenza tecnica Inventis per verificare se il trasduttore deve essere sostituito.

Per evitare di danneggiare le cuffie DD45/TDH39, non premerle contro una superficie dritta piatta in quanto si creerebbe un vuoto e si causerebbe un danno al trasduttore (effetto ventosa).

PULIZIA DELLO STRUMENTO

Per evitare l'accumulo di polvere sullo strumento, si raccomanda di coprirlo con l'apposito telo protettivo quando non viene utilizzato. Inoltre, rimuovere regolarmente la polvere che si deposita sotto lo strumento.
Per la pulizia di tutte le parti non elencate nel paragrafo precedente, utilizzare un panno morbido che non lasci pelucchi, inumidito con acqua e detergente delicato; in caso di sanitizzazione inumidire il panno con perossido di idrogeno concentrato al 3%. Il dispositivo può essere pulito più volte senza ridurre le prestazioni o la sicurezza di base; verificare sempre che le caratteristiche e l'integrità del dispositivo siano rimaste intatte. Per farlo, è sufficiente eseguire le prove descritte nel paragrafo "Controlli periodici". In caso di guasto, contattare l'assistenza tecnica Inventis per verificare se le parti devono essere sostituite.

PARTI SOSTITUIBILI

È possibile scollegare dal dispositivo i trasduttori e le parti rimovibili. In caso si verifichi un malfunzionamento di uno di questi dispositivi, è necessario staccarlo dall'unità principale dopo aver spento l'audiometro e averlo scollegato dalla rete elettrica.

Tutte le parti rimovibili dell'audiometro sono progettate specificatamente per l'uso con il dispositivo. Collegare all'audiometro solamente parti fornite da Inventis.

RIPARAZIONE E ASSISTENZA TECNICA

Prima di contattare l'assistenza tecnica, verificare di aver seguito tutte le indicazioni del Capitolo "*Risoluzione dei problemi*".

Le parti che devono tornare al fabbricante devono essere pulite e sanitizzate seguendo le indicazioni di questo manuale. I trasduttori devono essere inviati in busta trasparente chiusa e sigillata.

È importante utilizzare l'imballo originale per qualsiasi spedizione dello strumento al servizio d'assistenza Inventis o al distributore, ed inviare con lo strumento tutte le parti rimovibili e i trasduttori.

CAPITOLO 4
Risoluzione dei problemi

Problema	Possibile causa	Soluzione
Assenza di segnale da un trasduttore	Trasduttore non collegato all'uscita corretta	Collegare il trasduttore all'uscita corretta
	Trasduttore danneggiato	Contattare il distributore o il servizio di assistenza tecnica
Non viene rilevata la pressione del pulsante paziente	Connessione errata	Collegare il pulsante paziente al connettore preposto
	Pulsante paziente danneggiato	Contattare il distributore o il servizio di assistenza tecnica
Impossibile stabilire un collegamento tra PC e audiometro	Problemi nel collegamento USB	Ricontrollare il collegamento tramite USB tra lo strumento e il computer
	Cavo USB danneggiato	Sostituire il cavo USB (cavo USB standard di tipo A/B)
Risultati dell'esame inverosimili	Calibrazione scaduta	Effettuare la calibrazione dell'audiometro
	Tipo di trasduttore AC (cuffia o auricolare) selezionato incorretto	Dal software o dall'app Maestro, modificare la selezione del tipo di trasduttore AC in uso

Problema	Possibile causa	Soluzione
Non è possibile accedere ad un esame	Esame opzionale non attivato	Contattare il servizio di assistenza tecnica per ottenere la licenza, comunicando il numero di serie dello strumento

In caso di installazione con cabina audiometrica, occorre verificare sia i collegamenti interni alla cabina, sia i collegamenti fra cabina e audiometro.

BG

RO

PORTABLE AUDIOMETER

PICCOLO

EL

MULTILANGUAGE USER MANUAL

Document title: AU1P-Piccolo User Manual BG-RO-EL
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BG

PICCOLO

ПРЕНОСИМ АУДИОМЕТЪР

РЪКОВОДСТВО ЗА ПОТРЕБИТЕЛЯ

Прочетете внимателно настоящото ръководство, преди да използвате изделието. Обърнете специално внимание на глава 1 („Безопасност: предупреждения и информация“) и глава 2 („Инсталиране“).

Вътрешните проверки и поправки трябва да се извършват само от упълномощен персонал.

CE
0123

Обобщение

Предговор

Благодарим ви за закупуването на аудиологичното изделие на Inventis.

Изгодно преносим и лек, аудиометърът Piccolo е мощно и универсално преносимо медицинско изделие, идеално за професионалисти в движение.

Компанията Inventis винаги е имала предвид използването на нейните изделия заедно с компютри за фактор от ключово значение. Инсталирайки софтуерния пакет Maestro, предлаган с или без собствена база данни или като модул Noah, всяко аудиологично устройство на Inventis може да бъде свързано към компютър и всички проведени изследвания след това трябва да бъдат архивирани в собствената база данни на потребителя.

Имайте предвид също, че Inventis е разработила пълна гама от аудиологични устройства: в допълнение към аудиометрите, продуктовата линия на компанията включва набор от анализатори за средно ухо, устройства за поставяне на слухови апарати REM и HIT, безжичен видео отоскоп и много други.

За допълнителна информация и за докладване на всякакви проблеми, се свържете с компанията на следния адрес:

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

ГЛАВА 1
Безопасност: предупреждения и информация

РЪКОВОДСТВО ЗА ОПЕРАТОРА

Не забравяйте да прочетете изцяло настоящото ръководство, така че всички функции, предлагани от инструмента, да могат да бъдат използвани в пълния им потенциал. По-специално не забравяйте да прочетете тази глава изцяло, тъй като тя съдържа информация и предупреждения, които са от основно значение за осигуряване на безопасна и правилна употреба на изделието.
Предупредителният символ за безопасност, илюстриран по-долу, се използва в настоящото ръководство, за да привлече вниманието на читателя към информация от особено значение по въпросите на безопасността и да предпази от неправилна употреба.

ОТГОВОРНОСТИ НА ОПЕРАТОРА

Гарантирано е, че аудиометърът Piccolo работи ефективно и надеждно само, ако се използва в съответствие с инструкциите и процедурите, дадени в това ръководство.
Ако апаратът някога се повреди или се нуждае от поправка, изключете го електрическото захранване и не го използвайте отново, докато не бъдат завършени необходимите поправки и обслужване. Дефектните и неправилно функциониращи части трябва да се заменят само с оригинални резервни части, доставени от INVENTIS S.r.l.. Всички поправки трябва да се извършват изключително от Inventis или от персонал, упълномощен от Inventis.
Никакви части на изделието не могат да бъдат модифицирани или заменени без предварителното писмено разрешение на Inventis.
Потребителите носят пълна отговорност за всякакви неизправности, причинени от неправилна употреба или от операции по поддръжката или ремонта, извършени от страна, различна от INVENTIS S.r.l. или оторизиран сервизен център. INVENTIS S.r.l. и неговите сервизни

центрове поемат отговорност за работата и надеждността на апарата само ако:

1. всички свързвания, настройки, модификации и поправки/ремонти са извършени изключително от персонал, упълномощен от Inventis;
2. електрическото захранване и заземяващите връзки на системата отговарят на приложимите стандарти за електромедицински изделия.

Предназначение

Медицинското изделие Piccolo е аудиометър. Аудиометърът е изделие, което помага на оператора да определи слуховата чувствителност на пациента, като генерира и доставя на пациента звукови стимули от различен тип и интензитет за диагностични цели.

Показание за употреба и крайни потребители

Клиничният аудиометър Piccolo е предназначен за употреба от здравни УНГ специалисти в болници, УНГ клиники и аудиологични кабинети при извършване на оценки на слуха, както и за подпомагане при диагностицирането на възможни отологични разстройства. Няма ограничение за популацията на пациентите при използването на изделието; винаги правете отоскопия, преди да използвате изделието.
Тези тестове трябва да се провеждат в тиха среда, за да се избегнат артефакти.

Медицински състояния

Състояния на нарушена чувствителност на слуховата система или всякакви състояния, при които се смята, че слуховата система играе роля при диагностицирането.

ПРЕДПАЗНИ МЕРКИ

Всеки сериозен инцидент, възникнал във връзка с изделието, трябва да бъде докладван на производителя и на компетентния орган на държавата членка, в която е установен потребителят и/или пациентът.

За да се осигури правилно и безопасно използване на аудиометъра, трябва да се спазват следните предпазни мерки.

Инсталиране и общи предпазни мерки

Уверете се, че необходимите условия на околната среда са изпълнени по време на транспортиране, съхранение и работа:

Действие	*Температура: между 15°C (59°F) и 35°C (95°F)* *Относителна влажност: между 30% и 90% (некондензираща)* *Налягане: между 700 hPa и 1060 hPa*
Транспорт и съхранение	*Температура: между -10°C (14°F) и 50°C (122°F)* *Относителна влажност: макс. 90% некондензираща* *Налягане: между 500 hPa и 1060 hPa*
Време за загряване	*1 минута*

Аудиометърът Piccolo няма да бъде защитен, ако по време на употреба бъде изложен на запалими анестетични газове или подобни продукти. Риск от експлозия.

Избягвайте да инсталирате и използвате аудиометъра Piccolo в близост до източници на силни електромагнитни полета, тъй като те могат да попречат на работата на медицинското изделие.

Използвайте само оригинални разглобяеми части, предоставени от INVENTIS S.r.l., освен ако изрично не е посочено друго.

Използвайте само захранващи адаптери, предназначени за медицинско оборудване, сертифицирани по IEC 60601-1, със следните спецификации:

Главно устройство: 6 V, 1,67 A пост. ток
Външен адаптер: SL POWER MENB1010A0603F02
100-240Vac 50/60 Hz 0,9-0,34A (включено), отговарящ на стандарта IEC 60601-1

Аудиометърът Piccolo е медицинско изделие. Всяко друго външно устройство, към което той е свързан (като компютър или CD плейър) в рамките на „зоната на пациента“ (както е дефинирано в IEC 60601-1), също трябва да бъде медицинско изделие или трябва да бъде защитено от изолиращ трансформатор, за да се гарантира, че пълната комбинация (компютър или външно устройство + аудиометър) отговаря на IEC стандарта 60601-1.

Аудиометърът Piccolo може да се използва заедно със звукоизолирана кабина за провеждане на тестове при оптимални акустични условия. Преди да го свържете към звукоизолирана кабина, проверете дали гнездата са съвместими със спецификациите, предписани за всеки конектор.

Аудиометърът Piccolo се нуждае от специални предпазни мерки по отношение на EMC (Електромагнитна съвместимост) и трябва да бъде инсталиран и пуснат в експлоатация в съответствие с информацията за EMC (Електромагнитна съвместимост), предоставена в края на настоящото ръководство.

Използването на преносимо и мобилно RF комуникационно оборудване може да засегне правилната работа на медицинското изделие Piccolo. Направете справка с информацията за EMC (Електромагнитна съвместимост), поместена в края на настоящото ръководство.

Кабелът на захранващия адаптер и USB кабелът се считат за средства за изключване на медицинското изделие от електрическата мрежа.

Не позиционирайте медицинското изделие така, че да е трудно да го изключите от електрическата мрежа.

Калибриране

Калибрирането трябва да се извършва поне веднъж на всеки 12 месеца и при всяка смяна на трансдюсер.

Калибрирането на аудиометъра е валидно само за трансдюсери, предоставени с медицинското изделие. Ако трансдюсерът бъде заменен, аудиометърът трябва да бъде калибриран отново.

Калибрирането на аудиометъра е валидно за трансдюсери, предоставени с аудиометъра, ако са свързани директно към апарата, без поставяне на удължители и без преминаване от конектори към панел (както обикновено се случва при инсталации в звукоизолирана кабина). Ако трансдюсерите не са свързани директно към аудиометъра, ще е необходима нова процедура за калибриране, преди използването на апарата.

Във всеки тестов прозорец, когато изберете некалибриран трансдюсер, фонът на „изходната“ зона ще се покаже в червен цвят. Освен това няма да можете да изпращате никакви стимули през некалибрирани трансдюсери.

Обърнете внимание на посочения интервал на калибриране на аудиометъра. Използването на апарата след датата на изтичане на неговото калибриране може да доведе до ненадеждни диагнози.

Хигиена

Накрайниците за уши на слушалки с тапи са за еднократна употреба; не използвайте един и същ накрайник за уши за различни пациенти. Изхвърляйте накрайниците за уши след употреба.

Дезинфекцирайте възглавничките на слушалките между един пациент и следващия, като следвате процедурата, описана в ГЛАВА 3 “Поддръжка”:

Употреба

Аудиометърът може да генерира тонове с интензитет, потенциално увреждащ за пациента. Обърнете особено внимание, за да регулирате правилно интензитета на тона преди прегледите.

Когато провеждате аудиометрия с помощта на слушалки с тапи, не поставяйте и по никакъв начин не се опитвайте да провеждате измервания без поставен подходящ накрайник от пяна.

Поддържането на предишния интензитет на стимула при промяна на честотата, трансдюсера или страната на стимулацията може да доведе до представяне на потенциално вредни сигнали на пациента.

За да представи стимулен сигнал, по-силен от 100 dB HL, операторът трябва първо да натисне бутона "ПО-ВИСОКИ dB", който е активен само, когато интензитетът на стимула достигне 100 dB HL.

Изхвърляне

Както всички електронни устройства, аудиометърът съдържа изключително малки количества определени опасни вещества, като кадмий или живак. Ако се позволи на такива вещества да влязат в нормалния цикъл на изхвърляне на отпадъци без подходяща предварителна обработка, те могат да причинят щети на околната среда и здравето. Следователно всички части на аудиометъра трябва да се изхвърлят разделно.
В края на експлоатационния му живот занесете (или изпратете) изваденият от употреба апарат в обществено съоръжение за събиране и рециклиране на отпадъци или го върнете на търговеца срещу закупуването на еквивалентен нов инструмент.
Разделното събиране на отпадъци и последващите действия по обработване, рециклиране и изхвърляне улесняват производството на нови устройства от рециклирани материали, ограничавайки всяко отрицателно въздействие върху околната среда и общественото здраве, което иначе би могло да произтече от неправилно изхвърляне.

Съответствие

Аудиометърът Piccolo е медицинско изделие от клас IIa, съгласно Приложение VIII от Регламента за медицински изделия (MDR) 2017/745/ЕС.
Системата за управление на качеството на Inventis е сертифицирана от водещ орган за оценка TÜV като съвместима със стандарта ISO 13485.

СИМВОЛИ НА ЕТИКЕТИТЕ

Наименование и адрес на производителя

Предупреждение: използването на това медицинско изделие изисква определени предпазни мерки.
За да осигурите безопасна употреба, консултирайте се с придружаващата документация.

Този символ означава, че този продукт е обхванат от Директива 2012/19/ЕС относно отпадъци от електрическо и електронно оборудване (WEEE). Изисква се този продукт да не се изхвърля като несортиран битов отпадък, а да се събира разделно.

Направете справка с ръководството с инструкции за употреба.

Медицинско изделие с приложени части от типа B (IEC 60601-1).

Захранване с постоянен ток (DC)

Продуктът е в съответствие с Регламента за медицински изделия на Европейската общност (MDR) 2017/745/ЕС. Медицинско изделие от клас IIa; номер на нотифицирания орган: 0123 (TÜV SÜD Product Service GmbH).

Медицинско изделие

Rx only — *Внимание: Федералният закон ограничава продажбата на това медицинско изделие от или по поръчка на лицензиран медицински специалист.*

IP20 — *Код IP (Ingress Protection - Защита от проникване): това медицинско изделие е защитено срещу проникване на предмети с размер >12,5 mm, не е защитено срещу течности.*

REF — *Каталожен номер*

COMPATIBLE TRANSDUCERS — *Раздел, който изброява съвместимите трансдюсери*

Серийният номер на медицинското изделие се състои от 13 буквено-цифрови знака, указващи модела, годината на производство и серийния номер. По-специално номерът се състои от следните сегменти:

SN

- *първите 5 знака: Продуктов код на Inventis*
- *знаци 6 и 7: година на производство („12“ означава 2012 г.)*
- *знаци 8… 13: нарастващо число*

(01)08054187380372(21)AU1PH16200749

UDI код

ГЛАВА 2
Инсталиране

Въпреки че инсталирането на аудиометъра Piccolo е сравнително лесна процедура, тя трябва да бъде поверена на лице с необходимите умения. Ако инсталирането не е извършена правилно, системата може да бъде засегната от проблеми с безопасността, когато се използва.
Тази глава описва процедурата за инсталиране на системата.

Запазете опаковъчните материали, в случай че аудиометърът трябва да бъде изпратен на търговеца или на Inventis по някаква причина.

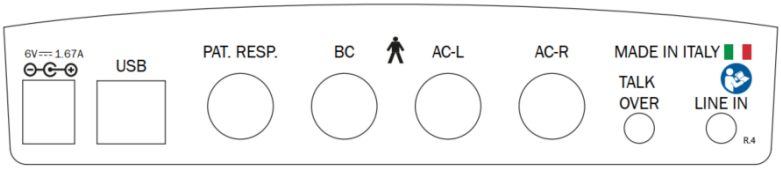
Предпазни мерки

Като всяко друго електрическо или електронно устройство, аудиометърът Piccolo ще излъчва електромагнитни вълни. Въпреки че неговите емисии са в рамките на границите на стандартите, други електронни устройства, разположени в близост до аудиометъра, могат да бъдат засегнати, ако са особено чувствителни на електромагнитни смущения.
Ако това се случи, проверете само като ИЗКЛЮЧИТЕ и ВКЛЮЧИТЕ аудиометъра и се опитайте да отстраните смущенията, като приложите едно или повече от следните решения:

- промените ориентацията и/или позицията на изделието, засегнато от смущения;
- отдалечете засегнатото устройство от аудиометъра;
- включете засегнатото устройство в електрически контакт на верига, различна от веригата, към която е свързан аудиометърът;
- консултирайте се с производителя или сервизен център за помощ.

Връзки

Всички точки за свързване на разглобяемите части са разположени на задния панел. Този раздел се отнася до говорния аудиометър Piccolo. Аудиометърът Piccolo Plus не разполага с конектор LINE IN за външен източник на звук. Базовият модел също няма BC конектор (за костен вибратор).



Включете всички трансдюсери и разглобяеми части в техните гнезда, както е посочено в следната таблица:

Конектор	Разглобяема част
6V⎓1.67A	Захранване. Когато аудиометърът Piccolo е свързан към USB порт на компютър, не е необходимо захранване.
USB	USB порт за свързване с компютъра
PAT. RESP.	Бутон за отговор на пациента
BC	Костен вибратор
AC-L	Лява слушалка/слушалка с тапа
AC-R	Дясна слушалка/слушалка с тапа
TALK OVER	Микрофон на оператора
LINE IN	Външна линия за говорна аудиометрия с външен аудио източник

Използвайте само захранващи адаптери, предназначени за медицинско оборудване, сертифицирани по IEC 60601-1.

Уверете се, че електрическото захранване и заземяващите връзки отговарят на приложимите стандарти за електромедицински изделия. Риск от токов удар

Ако аудиометърът Piccolo се захранва чрез USB кабел, максималните стойности (при AC и BC) са с 10 dB по-ниски от номиналните стойности.

Зеленият светодиод, който е разположен близо до ⏻ символа, покачва че аудиометърът се захранва или от мрежовия захранващ адаптер, или чрез USB кабела на компютъра.

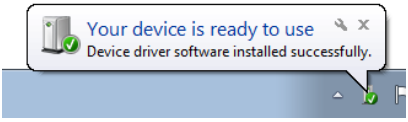
Светодиодът, който е разположен близо до символа, показва състоянието на комуникациите между аудиометъра и компютъра: този светодиод свети в зелено, ако аудиометърът комуникира с компютър.

СВЪРЗВАНЕ С КОМПЮТЪР

За да се позволи управление от компютър, аудиометърът Piccolo трябва да бъде свързан към един от USB портовете на компютъра с помощта на предоставения кабел (стандартен USB A/B кабел).

Използвайте предоставения кабел, за да свържете аудиометъра Piccolo към един от USB портовете на компютъра.

Връзката е plug-and-play, без да са необходими специални драйвери за целите на инсталацията: няколко секунди след включването, операционната система ще разпознае медицинското изделие и ще се появи следното съобщение:



Аудиометърът Piccolo може да се управлява от компютър с помощта на софтуера Inventis Maestro: за повече подробности относно използването и функциите на софтуера Maestro, както и за минималните изисквания за системата, вижте за справка *ръководството за потребителя за софтуера Maestro*.

ГЛАВА 3
Поддръжка

Аудиометърът Piccolo не изисква специално периодично поддържане, освен калибриране, проверки и нормално почистване, които са описани в тази глава.
Производителността и безопасността на инструмента ще се запазят, ако се спазват препоръките за грижа и поддържане, дадени в тази глава.
Апаратът трябва да бъде изключен и разкачен от захранването, преди да започнете каквото и да е действие по почистване.

Проверката и обслужването на вътрешните компоненти трябва да бъдат оставени изцяло на техници, одобрени от INVENTIS S.r.l..

Трансдюсерите се произвеждат с помощта на ултракрехки диафрагми, които могат да се повредят в случай на удар. Работете внимателно по време на действия по поддържане.

Периодични проверки

Процедурата, описана в този раздел, трябва да се извършва всеки ден, когато инструментът се използва за първи път.

Тестовете трябва да се извършват с аудиометър в неговата монтажна позиция.

- Преди да включите апарата, проверете дали няма видими признаци на повреда по която и да е част от него, включително разглобяеми части и външното електрозахранване; проверете отново визуалната цялост на изолацията на мрежовия кабел и конекторите и се уверете, че не са изложени на какъвто и да е вид механично натоварване, което може да доведе до повреда; проверете дали всички части и кабели са правилно свързани.
- Проверете субективно дали въздушната и костната проводимост са еднакви на двата канала и на всички честоти, за да направите това, се прилагат 10 или 15 dB, достатъчно, за да чуете. Лицето, което извършва тази проверка, трябва да има добър слух.

- Проверете при ниво от 60 dB в AC и 40 dB в BC, че няма дисторция, шум или паразитни сигнали за никоя от честотите.
- Проверете дали превключвателят за реакция на пациента и индикаторите функционират правилно.
- Проверете входовете за говорна аудиометрия, като направите тест за говор с всяко въвеждане на говор.
- Проверете напрежението на лентата за глава на слушалките и костния вибратор.
- Проверете комуникацията с пациента.

Ако по някоя част или трансдюсер се наблюдава каквато и да е неизправност, вижте за справка Глава „Отстраняване на неизправности“.

Винаги проверявайте дали интервалът на калибриране не е изтекъл: изтичането на интервала е указано в горната лява част на софтуера Maestro.

Калибрирането трябва да бъде поверено на техници, одобрени от INVENTIS S.r.l.. Тази операция трябва да се извършва поне веднъж на всеки 12 месеца и при смяна на трансдюсера.

ПОДДЪРЖАНЕ НА ТРАНСДЮСЕРИ

Не използвайте течности или спрейове за почистване на аудиометъра.

Не позволявайте да се събира прах върху трансдюсерите. В допълнение:

- Възглавничките на слушалките са изработени от биосъвместим материал, но не са стерилни: за да се предотврати разпространението на инфекция и да се гарантира биосъвместимостта на материала, когато слушалките трябва да се носят от нов пациент, възглавничките трябва да се избърсват с:
    - за възглавнички DD45/TDH-39, кърпичка, навлажнена с денатуриран алкохол или микрофибърна кърпа, навлажнена с денатуриран алкохол;
    - за всички други възглавнички: хипоалергенен дезинфектант, следвайки инструкциите на производителя.

- Накрайниците за уши на слушалките с тапи са предназначени за поставяне в ушния канал на пациента. Изработени са от биосъвместим материал и за еднократна употреба: използвайте само веднъж и изхвърлете в съответствие с действащите разпоредби за здраве и безопасност.

Накрайниците за уши на слушалки с тапи не са стерилни. Използването на нестерилизирани слушалки може да причини ушни инфекции.

Костният вибратор и възглавничките на слушалките могат да се почистват многократно, както е описано в параграфа „Поддържане на трансдюсери“. В случай на неизправна работа след почистване, се свържете със сервизен техник на Inventis.

Въпреки че костният вибратор и възглавничките на слушалките могат да се почистват многократно, винаги проверявайте дали характеристиките и целостта им се поддържат. За целта е достатъчно да извършите тестовете, описани в параграф „Периодични проверки“. Веднага след като бъде открита повреда, се свържете със сервизен техник на Inventis, за да проверите дали вашият трансдюсер трябва да бъде сменен.

За да избегнете повреда на слушалките DD45/TDH39, не ги натискайте срещу плоска права повърхност, тъй като това може да създаде вакуум и да причини повреда на трансдюсера (ефект на вендуза).

Почистване на инструмента

За да предотвратите натрупването на прах върху инструмента, винаги поставяйте защитния капак, когато анализаторът не се използва. Също така се уверете, че събиращият се прах под инструмента се почиства редовно.

Всички части, които не са споменати конкретно в предишния раздел, могат да се почистват като използвате мека кърпа без власинки, навлажнена с разтвор на вода и мек почистващ препарат; в случай на дезинфекция, навлажнете кърпата с водороден пероксид в концентрация 3%. Медицинското изделие позволява многократно почиствания без влошаване на основната безопасност или експлоатационните характеристики; винаги проверявайте дали характеристиките и целостта на медицинското изделие се поддържат. За целта е достатъчно да извършите тестовете, описани в параграф

„Периодични проверки“. Веднага след като бъде открита повреда, се свържете със сервизен техник на Inventis, за да проверите дали които и да е части трябва да бъдат сменени.

СМЕНЯЕМИ ЧАСТИ

Трансдюсерите и разглобяемите части могат да бъдат разкачени от медицинското изделие. Ако възникне повреда в някое от тези устройства, аудиометърът трябва да бъде изключен и изолиран от захранването, а дефектният елемент след това да бъде разкачен от изделието.

Всички разглобяеми части на аудиометъра са проектирани специално за използване с медицинското изделие. Към аудиометъра трябва да се свързват само части, доставени от Inventis.

РЕМОНТИ И ТЕХНИЧЕСКА ПОМОЩ

Преди да се свържете със сервизния отдел, се уверете, че всички възможни решения в глава „*Отстраняване на неизправности*“ са изпробвани.

Всички части, които се връщат на производителя за ремонт и обслужване, трябва да бъдат почистени и хигиенизирани. Трансдюсерите трябва да бъдат запечатани в прозрачен плик.

Важно: ако апаратът трябва да бъде изпратен до сервизния отдел на Inventis или върнат на търговеца, се уверете, че се използва оригиналната опаковка, както и, че всички разглобяеми части и трансдюсери са приложени.

ГЛАВА 4
Отстраняване на неизправности

Проблем	Възможна причина	Решение
Няма сигнал от трансдюсер	Трансдюсерът не е свързан към правилния изход	Свържете трансдюсера към правилния изход
	Трансдюсерът е повреден	Свържете се с Вашия търговец или сервизен център
Няма сигнал от бутона за отговор на пациента при натискане	Грешна връзка	Свържете бутона за реакция на пациента към правилното гнездо
	Бутонът за отговор на пациента е повреден	Свържете се с Вашия търговец или сервизен център
Не може да се установи връзка между компютър и аудиометър	Проблеми с USB връзка	Проверете USB връзката между апарата и компютъра
	USB кабелът е повреден	Сменете USB кабела (стандартен USB A/B кабел)
Малко вероятни резултати от прегледа	Калибриране с изтекъл срок	Извършете калибриране на аудиометъра
	Грешен тип избран AC трансдюсер (слушалки за глава или слушалки)	Променете избора на текущия AC трансдюсер от софтуера или приложението Maestro

Проблем	Възможна причина	Решение
Нямате достъп до тест	Незадължителният тест не е активиран	Свържете се с вашата референтна техническа служба, за да получите лицензия, като съобщите серийния номер на изделието

Когато аудиометърът се използва заедно със звукоизолирана кабина, проверете дали връзките както вътре в кабината, така и между кабината и апарата са правилни и безопасни.

IT

EN

PORTABLE AUDIOMETER

PICCOLO

FR

MULTILANGUAGE USER MANUAL

DE

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ES

PICCOLO

TRAGBARES AUDIOMETER

DE

BEDIENUNGSANLEITUNG

Bitte lesen Sie diese Anleitung vor der Verwendung des Geräts sorgfältig durch. Achten Sie besonders auf Kapitel 1 („Sicherheit: Warnhinweise und Informationen") und Kapitel 2 („Installation").

Interne Prüfungen und Reparaturen dürfen nur durch dazu befugtes Personal erfolgen.

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Vorwort

Wir danken Ihnen, dass Sie ein Audiologiegerät von Inventis erworben haben.

Durch seine Tragbarkeit und sein geringes Gewicht ist das Audiometer Piccolo ein leistungsstarkes und vielseitiges mobiles Gerät und ideal für Fachleute auf Achse.

Das Unternehmen Inventis ist seit jeher der Ansicht, dass die Verwendung seiner Geräte in Verbindung mit Computern einen ausschlaggebenden Faktor darstellt. Nach Installation der Software Suite Maestro, die mit oder ohne proprietäre Datenbank oder als Noah-Modul erhältlich ist, kann jedes beliebige Audiologie-Gerät von Inventis an einen Computer angeschlossen werden. So können alle durchgeführten Untersuchungen anschließend in der benutzereigenen Datenbank archiviert werden.

Bedenken Sie auch, dass Inventis eine komplette Linie an Audiologie-Geräten entwickelt hat: außer den Audiometern umfasst die Produktlinie des Unternehmens eine ganze Reihe von Mittelohr-Analysatoren, REM- und HIT-Geräten zur Hörgeräteanpassung, ein WLAN-Video-Otoskop und vieles mehr.

Für weitere Informationen und bei jeglichen Problemen wenden Sie sich bitte unter den folgenden Adressen an das Unternehmen:

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INVENTIS S.r.l.
Corso Stati Uniti, 1/3
35127 Padova, Italia
Tel.: 049.8962844 – Fax: 049,8966343
www.Inventis.it info@Inventis.it

KAPITEL 1
Sicherheit: Warnhinweise und Informationen

BEDIENUNGSANLEITUNG

Lesen Sie diese Anleitung vollständig, damit Sie das Potential der von dem Instrument gebotenen Funktionen in vollem Umfang ausschöpfen können. Achten Sie insbesondere darauf, dieses Kapitel in allen seinen Teilen zu lesen, da es Informationen und Warnhinweise umfasst, die zur Gewährleistung eines sicheren und korrekten Gebrauchs des Geräts von ausschlaggebender Bedeutung sind.
Das unten abgebildete Sicherheitswarnsymbol wird in dieser Anleitung verwendet, um die Aufmerksamkeit des Lesers auf Informationen mit besonderer Bedeutung bezüglich der Sicherheit zu lenken und unkorrekter Verwendung vorzubeugen.

VERANTWORTLICHKEITEN DES BEDIENERS

Der wirksame und zuverlässige Betrieb des Audiometers Piccolo ist nur gewährleistet, wenn es entsprechend den in dieser Anleitung enthaltenen Anweisungen und Vorgehensweisen verwendet wird.
Sollte das Gerät je Funktionsstörungen entwickeln oder Reparaturen erfordern, ist es von der Stromversorgung zu trennen und erst nach Abschluss der erforderlichen Reparatur und Instandhaltung wieder zu verwenden. Defekte und von Funktionsstörungen betroffene Teile dürfen nur durch von INVENTIS S.r.l. gelieferte Original-Ersatzteile ersetzt werden. Alle Reparaturen dürfen ausschließlich von Inventis oder von von Inventis autorisiertem Personal ausgeführt werden.
Ohne vorangegangene schriftliche Genehmigung von Inventis dürfen keinerlei Geräteteile verändert oder ersetzt werden.
Die Benutzer haften vollumfänglich für jegliche durch unsachgemäßen Gebrauch oder durch von anderen Parteien als INVENTIS S.r.l. oder einer anerkannten Kundendienststelle ausgeführte Instandhaltung oder Reparaturen verursache Funktionsstörungen. INVENTIS S.r.l. und seine

Kundendienststellen übernehmen die Verantwortung für die Leistung und Zuverlässigkeit des Geräts nur, wenn:

1. alle Verbindungen, Anpassungen, Änderungen oder Reparaturen ausschließlich durch von Inventis befugtes Personal erfolgen;
2. die elektrische Stromversorgung und Erdungsanschlüsse des Systems den geltenden Standards für elektromedizinische Geräte entsprechen.

VERWENDUNGSZWECK

Das Medizinprodukt Piccolo ist ein Audiometer. Ein Audiometer ist ein Gerät, das den Audiologen dabei unterstützt, die auditive Sensibilität durch Erzeugen und Darbieten von Schallstimuli unterschiedlicher Art und Intensität an den Patienten zu Diagnosezwecken festzustellen.

INDIKATION UND ENDBENUTZER

Piccolo ist für die Verwendung durch HNO-Fachleute in Krankenhäusern, HNO-Kliniken und Audiologie-Geschäften bei der Durchführung von Hörtests und der Unterstützung bei der Diagnose möglicher otologischer Störungen bestimmt. Bei der Verwendung des Geräts liegen keine Einschränkungen hinsichtlich der Patientenpopulation vor. Achten Sie stets darauf, vor der Verwendung des Geräts eine Otoskopie durchzuführen.
Diese Tests müssen in einer ruhigen Umgebung durchgeführt werden, um Störsignale zu vermeiden.

MEDIZINISCHE BEDINGUNGEN

Zustände beeinträchtigter Empfindlichkeit des Hörsystems oder jegliche Bedingungen, bei denen davon ausgegangen wird, dass das Hörsystem bei der Diagnose eine Rolle spielt.

VORSICHTSMAßNAHMEN

Jegliche in Verbindung mit dem Gerät aufgetretenen schweren Unfälle sollten dem Hersteller und der zuständigen Behörde des Mitgliedstaates mitgeteilt werden, in dem der Benutzer und/oder Patient niedergelassen sind.

Um die korrekte und sichere Verwendung des Audiometers zu gewährleisten, sind die folgenden Vorsichtshinweise zu beachten.

Installation und allgemeine Vorsichtsmaßnahmen

Sorgen Sie dafür, dass die erforderlichen Umgebungsbedingungen während Transport, Lagerung und Betrieb erfüllt werden:

Vorgang	*Temperatur: zwischen 15°C und 35°C* *Relative Feuchte: zwischen 30 % und 90 % (nicht kondensierend)* *Druck: zwischen 700 hPa und 1060 hPa*
Transport und Lagerung	*Temperatur: zwischen -10°C und 50°C* *Relative Feuchte: max. 90 % nicht kondensierend* *Druck: zwischen 500 hPa und 1060 hPa*
Aufwärmzeit	*1 Minute*

Das Audiometer Piccolo verfügt bei Gefährdung durch entzündliche Anästhesiegase oder ähnliche Produkte während der Verwendung über keinen Schutz. Explosionsgefahr.

Vermeiden Sie die Installation und die Verwendung des Audiometers Piccolo in der Nähe von Quellen starker elektromagnetischer Felder, da diese den Betrieb des Geräts stören könnten.

Verwenden Sie nur von INVENTIS S.r.l. gelieferte abnehmbare Original-Teile, außer dies wird ausdrücklich anders angewiesen.

Verwenden Sie nur für medizinische Geräte bestimmte, gemäß IEC 60601-1 zertifizierte Spannungsadapter mit den folgenden Spezifikationen:

Hauptgerät: 6V, 1,67 A DC
Externer Adapter: SL POWER MENB1010A0603F02
100-240 Vac 50/60 Hz 0,9-0,34 A (enthalten) gemäß dem Standard IEC 60601-1

Das Audiometer Piccolo ist ein medizinisches Gerät. Bei jedem anderen externen Gerät (wie einem Computer oder einem CD-Player), an das es im „Patientenbereich" angeschlossen ist (wie in IEC 60601-1 definiert), muss es sich ebenfalls um ein Medizinprodukt handeln oder es muss durch einen Trenntransformator geschützt sein, um zu gewährleisten, dass die

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komplette Kombination (Computer oder externes Gerät + Audiometer) den Standard IEC 60601-1 erfüllt.

Piccolo kann in Kombination mit einer schalldichten Kabine verwendet werden, um Tests unter optimalen akustischen Bedingungen auszuführen. Prüfen Sie vor seinem Anschluss an eine schalldichte Kabine, ob die Steckdosen mit den für jeden Stecker angegebenen technischen Daten kompatibel sind.

Piccolo erfordert spezielle Vorsichtsmaßnahmen in Hinblick auf EMC und muss entsprechend der am Ende dieser Anleitung erteilten EMC-Informationen installiert und in Betrieb genommen werden.

Die Verwendung tragbarer und mobiler RF-Kommunikationsgeräte kann den korrekten Betrieb des Geräts Piccolo beeinträchtigen. Beziehen Sie sich auf die EMC-Information am Ende dieser Anleitung.

Das Spannungsadapterkabel und das USB-Kabel werden als Mittel zum Trennen des Geräts vom Versorgungsnetz betrachtet.

Positionieren Sie das Gerät nicht so, dass es schwierig ist, das Gerät vom Versorgungsnetz zu trennen.

Kalibrierung

Die Kalibrierung sollte mindestens alle 12 Monate und bei jedem Wandlerwechsel erfolgen.

Die Kalibrierung des Audiometers gilt nur für die mit dem Gerät gelieferten Wandler. Wird ein Wandler ersetzt, muss das Audiometer erneut kalibriert werden.

Die Kalibrierung des Audiometers bezieht sich auf mit dem Audiometer gelieferte Wandler, wenn diese ohne Verlängerungskabel und ohne Übergang von Verbindern zur Tafel direkt an das Gerät angeschlossen sind (wie üblicherweise bei der Installation schalldichter Kabinen). Werden die Wandler nicht direkt an das Audiometer angeschlossen, ist vor dem Einsatz des Instruments ein neuer Kalibriervorgang erforderlich.

In jedem Testfenster wird, wenn Sie einen nicht kalibrierten Wandler auswählen, der Hintergrund des Ausgabebereichs rot angezeigt. Darüber hinaus werden Sie nicht in der Lage sein, jegliche Stimuli über nicht kalibrierte Wandler zu übertragen.

Beachten Sie das angegebene Kalibrierintervall des Audiometers. Die Verwendung des Instruments nach dem Ablaufdatum seiner Kalibrierung kann zu unzuverlässigen Diagnosen führen.

Hygiene

Die Eartips von Einsteckhörern sind wegwerfbar. Verwenden Sie denselben Eartip nicht für verschiedene Patienten. Entsorgen Sie die Eartips nach dem Gebrauch.

Desinfizieren Sie die Ohrpolster der Kopfhörer zwischen einem Patienten und dem nächsten wie in KAPITEL 3 „Wartung“ beschrieben.

Gebrauch

Das Audiometer kann Töne mit einem für den Patienten potentiell schädigenden Pegel erzeugen. Achten Sie besonders darauf, die Stärke des Tons vor den Untersuchungen korrekt einzustellen.

Versuchen Sie beim Ausführen der Audiometrie mit Einsteckhörern nicht, die Sonde einzusetzen und versuchen Sie in keiner Weise Messungen durchzuführen, wenn kein korrekter Polsterstöpsel angebracht ist.

Das Beibehalten der vorangegangenen Stärke des Stimulus beim Ändern von Frequenz, Wandler oder Stimulationsseite kann für den Patienten potenziell schädliche Signale ergeben.

Um ein stärkeres Stimulussignal als 100 dB HL darzubieten, muss der Audiologe zuerst die Taste „HÖHERE dB“ betätigen, die nur aktiv ist, wenn die Stärke des Stimulus 100 dB HL erreicht.

DE

ENTSORGUNG

Wie alle elektronischen Geräte enthält Ihr Audiometer extrem geringe Mengen bestimmter gefährlicher Substanzen wie Cadmium oder Quecksilber. Wenn diese Stoffe ohne geeignete Vorbehandlung in den normalen Abfallentsorgungskreislauf gelangen, können sie Umwelt- oder Gesundheitsschäden verursachen. Sämtliche Teile des Audiometers müssen daher getrennt entsorgt werden.
Führen Sie das nicht mehr verwendete Instrument am Ende seiner Lebensdauer einer öffentlichen Sammelstelle oder einer Entsorgungsstelle zu

oder geben Sie es gegen Kauf eines gleichwertigen neuen Geräts an den Händler zurück.
Die getrennte Müllsammlung und die nachfolgenden Aufbereitungs-, Recycling- und Entsorgungsvorgänge erleichtern die Herstellung neuer Geräte aus recycelten Werkstoffen und begrenzen die negativen Auswirkungen auf Umwelt und öffentliche Gesundheit, die sich andernfalls durch unsachgemäße Entsorgung ergeben könnten.

KONFORMITÄT

Das Audiometer Piccolo ist ein medizinisches Gerät der Klasse IIa gemäß Anhang VIII der Richtlinie über Medizinprodukte (MDR) 2017/745/EU.
Das Qualitätsmanagementsystem von Inventis wurde von der führenden Prüforganisation TÜV als dem Standard ISO 13485 entsprechend zertifiziert.

SYMBOLE AUF AUFKLEBERN

Name und Adresse des Herstellers.

Warnung: die Verwendung dieses Geräts erfordert bestimmte Vorsichtsmaßnahmen.
Sehen Sie zur Gewährleistung der sicheren Verwendung die Begleitdokumente ein.

Dieses Symbol bedeutet, dass dieses Produkt unter die Richtlinie 2012/19/EU über Elektro- und Elektronik-Altgeräte fällt (WEEE). Das Produkt darf nicht als unsortierter Siedlungsabfall entsorgt, sondern muss getrennt gesammelt werden.

Beziehen Sie sich auf die Gebrauchsanleitung

Gerät mit Anwendungsteilen des Typs B (IEC 60601-1).

DC-Stromversorgung

Das Produkt entspricht der Richtlinie über Medizinprodukte der Europäischen Gemeinschaft (MDR) 2017/745/EU. Gerät der Klasse IIa; Nummer der benannten Stelle: 0123 (TÜV SÜD Product Service GmbH).

MD	*Medizinisches Gerät*
Rx only	*Vorsicht: Der Verkauf dieses Geräts durch einen oder im Namen eines approbierten Arztes unterliegt den Beschränkungen des Bundesgesetzes.*
IP20	*IP-Code (Eindringschutz): Dieses Gerät ist gegen das Eindringen von Gegenständen mit einer Größe von > 12,5 mm geschützt. Es ist nicht gegen Flüssigkeiten geschützt.*
REF	*Katalognummer*
COMPATIBLE TRANSDUCERS	*Abschnitt, der die kompatiblen Wandler auflistet*
SN	*Seriennummer des Geräts, bestehend aus 13 alphanumerischen Zeichen, die Modell, Baujahr und Seriennummer angeben. Insbesondere umfasst die Nummer diese Segmente:* - *erste 5 Zeichen: Inventis-Produktcode* - *Zeichen 6 und 7: Baujahr (z. B. „12“ steht für 2012)* - *Zeichen 8… 13: fortlaufende Nummer*
(01)08054187380372(21)AU1PH16200749	*UDI-Code*

DE

KAPITEL 2
Installation

Auch wenn es sich bei der Installation eines Audiometers Piccolo um einen relativ einfachen Vorgang handelt, sollte er einer Person mit den erforderlichen Fähigkeiten übertragen werden. Wird die Installation nicht korrekt ausgeführt, könnten beim Betrieb des Systems Sicherheitsprobleme auftreten.
In diesem Kapitel wird die Vorgehensweise bei der Systeminstallation beschrieben.

Bewahren Sie das Verpackungsmaterial für den Fall auf, dass das Audiometer aus jeglichen Gründen beim Händler oder bei Inventis eingesandt werden muss.

VORSICHTSMAßNAHMEN

Wie jedes andere Elektro- oder Elektronikgerät sendet auch das Audiometer Piccolo elektromagnetische Wellen aus. Auch wenn die Emissionen innerhalb der Standardwerte liegen, könnten in unmittelbarer Nähe des Audiometers befindliche andere elektronische Geräte beeinträchtigt werden, die besonders empfindlich auf elektromagnetische Störungen reagieren.
Sollte dieser Fall eintreten, kontrollieren Sie dies einfach durch Ein- und Ausschalten des Audiometers und versuchen Sie die Störung durch eine der folgenden Lösungen zu beseitigen:

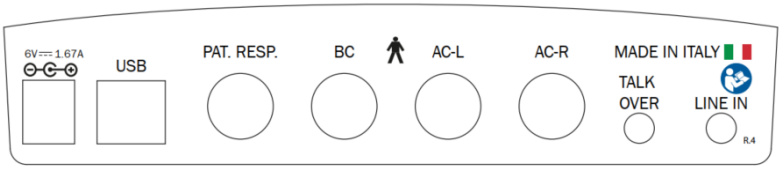
- ändern Sie die Ausrichtung und/oder die Position des von der Störung betroffenen Geräts;
- entfernen Sie das betroffene Gerät von dem Audiometer;
- stecken Sie das betroffene Gerät in eine Steckdose eines anderen Stromkreises als den ein, an den das Audiometer angeschlossen ist;
- wenden Sie sich wegen Hilfe an den Hersteller oder eine Kundendienststelle.

DE

ANSCHLÜSSE

Alle Anschlusspunkte für abnehmbare Teile befinden sich an der Rückwand. Dieser Abschnitt bezieht sich auf das Sprachaudiometer Piccolo. Piccolo Plus

verfügt über keinen LINE IN-Verbinder für eine externe Schallquelle. Beim Modell Basic fehlt auch der BC-Verbinder (für einen Knochenhörer).



Stecken Sie alle Wandler und abnehmbaren Teile in die jeweiligen Steckbuchsen ein, wie in der nachstehenden Tabelle angegeben:

Stecker	Abnehmbares Teil
6V⎓1.67A	Stromversorgung. Wenn Piccolo nicht an den USB-Port eines Computers angeschlossen ist, ist keine Stromversorgung erforderlich.
USB	USB-Port zum Anschluss an den PC
PAT. RESP.	Patientenantwort-Taste
BC	Knochenvibrator
AC-L	Linker Kopfhörer/Einsteckhörer
AC-R	Rechter Kopfhörer/Einsteckhörer
TALK OVER	Audiologenmikrofon
LINE IN	Externe Leitung für Sprachaudiometrie mit externer Audioquelle

Verwenden Sie nur für medizinische Geräte bestimmte, gemäß IEC 60601-1 zertifizierte Spannungsadapter.

Vergewissern Sie sich, dass die Stromversorgungs- und Erdungsanschlüsse den geltenden Standards für elektromedizinische Geräte entsprechen. Stromschlaggefahr

Wird das Audiometer Piccolo über ein USB-Kabel versorgt, liegen die Höchstwerte (in AC und BC) 10 dB unter den Nennwerten.

Die grüne LED neben dem Symbol gibt an, dass das Audiometer entweder über den Stromnetzadapter oder das USB-Kabel des Computers versorgt wird.

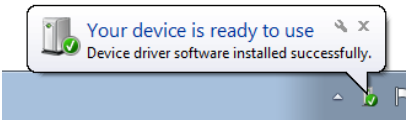
Die LED neben dem Symbol gibt den Kommunikationsstatus zwischen Audiometer und Computer: diese LED leuchtet grün, wenn das Audiometer mit dem PC kommuniziert.

ANSCHLUSS AN COMPUTER

Um die Steuerung über einen Computer zu gestatten, muss das Audiometer Piccolo unter Verwendung des mitgelieferten Kabels (ein USB A/B Standardkabel) an einen der USB-Ports des Computers angeschlossen werden.

Verwenden Sie das Kabel aus dem Lieferumfang, um das Audiometer Piccolo an einen der USB-Ports des Computers anzuschließen.

Der Anschluss ist des Typs Plug-and-Play und erfordert für die Installation keine speziellen Treiber: Einige Sekunden nach dem Einstecken erkennt das Betriebssystem die Geräte und die folgende Meldung erscheint:



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Das Audiometer Piccolo kann unter Verwendung der Software Maestro von Inventis über einen Computer gesteuert werden: Für weitere Details hinsichtlich der Verwendung und der Merkmale der Software Maestro und zu den Mindestsystemanforderungen siehe *Bedienungsanleitung Maestro*.

KAPITEL 3
Wartung

Das Audiometer Piccolo erfordert, abgesehen von der Kalibrierung, Kontrollen und der normalen Reinigung, die alle in diesem Kapitel beschrieben werden, keine besondere regelmäßige Wartung.
Die Leistung und Sicherheit des Instruments bleiben erhalten, wenn die in diesem Kapitel erteilten Empfehlungen zu Pflege und Wartung beachtet werden.
Das Instrument muss vor dem Beginn jeglicher Reinigungsvorgänge abgeschaltet und von der Stromversorgung getrennt werden.

Inspektion und Instandhaltung der internen Bauteile sind vollumfänglich den von INVENTIS S.r.l. anerkannten Technikern zu überlassen.

Wandler werden unter Verwendung hochempfindlicher Membranen gefertigt, die bei Stoßwirkung beschädigt werden könnten. Während der Wartungsvorgänge vorsichtig handhaben.

REGELMÄßIGE ÜBERPRÜFUNGEN

Die hier beschriebenen Vorgänge sind bei der ersten täglichen Verwendung des Instruments auszuführen.

Die Tests müssen bei Audiometer in Installationsposition ausgeführt werden.

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- Kontrollieren Sie vor dem Einschalten des Instruments, dass keine Anzeichen von Schäden an jeglichen Geräteteilen, einschließlich der abnehmbaren Teile und der externen Stromversorgung, vorliegen. Kontrollieren Sie die äußere Unversehrtheit der Isolierung von Netzkabel und Verbindern doppelt und überprüfen Sie, dass diese keinerlei mechanischen Lasten ausgesetzt sind, die zu Schäden führen könnten. Überprüfen Sie, ob alle Teile und Kabel korrekt angeschlossen sind.
- Kontrollieren Sie subjektiv, dass der Luft- und Knochenleitungsausgang auf beiden Kanälen und allen Frequenzen gleich ist, indem Sie zum Beispiel einen gerade hörbaren Stimulus

bei 10 oder 15 dB erzeugen. Die Person, die diese Kontrolle durchführt, sollte über ein gutes Gehör verfügen.

- Prüfen Sie bei einem Pegel von 60 dB in AC und 40 dB in BC, dass alle Frequenzen frei von Verzerrung, Rauschen oder Störsignalen sind.
- Prüfen Sie, dass die Patientenantwort-Taste und die Anzeigen korrekt funktionieren.
- Prüfen Sie die Sprachaudiometrieeingaben durch Ausführen eines Sprachtests mit jeder Spracheingabe.
- Prüfen Sie die Spannung des Kopfbands des Headsets und des Knochenvibrators.
- Prüfen Sie die Kommunikation mit dem Patienten.

Sollten jegliche Teile oder Wandler Funktionsstörungen aufweisen, konsultieren Sie das Kapitel „Fehlersuche".

Prüfen Sie stets, ob das Kalibrierintervall nicht abgelaufen ist: Das Ablaufdatum des Intervalls ist oben links in der Software Maestro angegeben.

Mit der Kalibrierung müssen von INVENTIS S.r.l. anerkannte Techniker betraut werden. Die Kalibrierung sollte mindestens alle 12 Monate und bei jedem Wandlerwechsel erfolgen.

WARTUNG DER WANDLER

Verwenden Sie zum Reinigen des Audiometers keine Flüssigkeiten oder Sprays.

Vermeiden Sie Staubansammlungen auf den Wandlern. Außerdem:

- Die Ohrpolster der Kopfhörer bestehen aus biokompatiblem Material, sind jedoch nicht steril: Um die Ausbreitung von Infektionen zu verhindern und die Biokompatibilität des Materials zu garantieren, müssen die Polster, wenn sie von einem neuen Patienten getragen werden sollen, wie folgt gereinigt werden:
    - für die Polster DD45/TDH-39: mit Reinigungstüchern mit denaturiertem Alkohol oder denaturiertem Alkohol und Mikrofasertuch;
    - für alle anderen Polster: Hypoallergenes Desinfektionsmittel entsprechenden den Herstelleranweisungen.

- Die Eartips der Einsteckhörer sind dazu bestimmt, in den Gehörgang des Patienten eingeführt zu werden. Sie sind aus biokompatiblen Material hergestellt und Einwegprodukte: Verwenden Sie sie nur einmal und entsorgen Sie sie gemäß den geltenden Gesundheits- und Sicherheitsbestimmungen.

Die Ohrstöpsel der Einsteckhörer sind nicht steril. Die Verwendung von nicht sterilisierten Ohrstöpseln kann Infektionen verursachen.

Der Knochenvibrator und die Kopfhörerpolster können wiederholt gereinigt werden, wie im Absatz „Wartung der Wandler“ beschrieben. Bei eventuellen Funktionsstörungen nach jeglichen Reinigungsvorgängen, wenden Sie sich an einen Kundendiensttechniker von Inventis.

Prüfen Sie, obwohl der Knochenvibrator und die Kopfhörerpolster mehrmals gereinigt werden können, stets, dass ihre Eigenschaften und Unversehrtheit unverändert bleiben. Dazu genügt es, die im Absatz „Regelmäßige Überprüfungen“ beschriebenen Tests auszuführen. Wenden Sie sich, sobald Fehler festgestellt werden, an einen Kundendiensttechniker von Inventis, um zu überprüfen, ob Ihr Wandler ersetzt werden muss.

Um Schäden an den DD45/TDH39-Kopfhörern zu vermeiden, drücken Sie diese nicht gegen flache gerade Oberflächen, da dies ein Vakuum erzeugen und Schäden am Wandler verursachen könnte (Saugglockeneffekt).

REINIGEN DES INSTRUMENTS

Um Staubansammlungen auf dem Instrument vorzubeugen, stets die Schutzabdeckung anbringen, wenn der Analysator nicht verwendet wird. Achten Sie außerdem darauf, Staubansammlungen unter dem Instrument regelmäßig zu beseitigen.

DE

Alle im vorangegangenen Abschnitt nicht ausdrücklich erwähnten Teile können mit einem mit einer Lösung aus Wasser und mildem Reinigungsmittel angefeuchteten fusselfreien Tuch gereinigt werden. Zur Desinfizierung das Tuch mit einer 3%igen Wasserstoffperoxidlösung anfeuchten. Das Gerät gestattet wiederholte Reinigungen ohne Beeinträchtigung der grundlegenden Sicherheit oder der Leistungen. Prüfen Sie stets, dass die Eigenschaften und die Unversehrtheit des Geräts erhalten bleiben. Dazu genügt es, die im Absatz „Regelmäßige Überprüfungen“ beschriebenen Tests auszuführen. Wenden Sie sich, sobald Fehler festgestellt

werden, an einen Kundendiensttechniker von Inventis, um zu überprüfen, ob jegliche Teile ersetzt werden müssen.

ERSETZBARE TEILE

Die Wandler und abnehmbaren Teile können vom Gerät getrennt werden. Sollten an einer beliebigen dieser Vorrichtungen Defekte auftreten, muss das Audiometer ausgeschaltet und von der Stromversorgung isoliert und dann das defekte Teil vom Gerät getrennt werden.

Alle abnehmbaren Teile des Audiometers sind spezifisch für die Verwendung mit diesem Gerät ausgelegt. Es sollten nur von Inventis gelieferte Teile an das Audiometer angeschlossen werden.

REPARATUREN UND TECHNISCHER KUNDENDIENST

Vergewissern Sie sich, bevor Sie sich an den Kundendienst wenden, dass alle in dem Kapitel „*Fehlersuche*“ enthaltenen möglichen Lösungen versucht wurden.

Alle Teile, die für Reparatur und Wartung beim Hersteller eingesandt werden, müssen sauber und desinfiziert sein. Die Wandler sollten in einem durchsichtigen Beutel versiegelt sein.

Wichtig: Sollte das Gerät beim Kundendienst von Inventis eingesandt oder an den Händler zurückgegeben werden müssen, ist sicherzustellen, dass dazu die Originalverpackung verwendet wird und sämtliche abnehmbaren Teile und Wandler beigefügt wurden.

KAPITEL 4
Fehlersuche

Problem	Mögliche Ursache	Lösung
Kein Signal von einem Wandler	Wandler nicht an den korrekten Ausgang angeschlossen	Wandler an den korrekten Ausgang anschließen
	Wandler beschädigt	Wenden Sie sich an Ihren Händler oder Dienstleister
Bei Betätigung kein Signal von der Patientenantwort-Taste	Falscher Anschluss	Schließen Sie die Patientenantwort-Taste an die korrekte Buchse an
	Patientenantwort-Taste beschädigt	Wenden Sie sich an Ihren Händler oder Dienstleister
Verbindung zwischen PC und Audiometer kann nicht hergestellt werden	Probleme mit dem USB-Anschluss	Prüfen Sie den USB-Anschluss zwischen Instrument und Computer
	USB-Kabel beschädigt	Wechseln Sie das USB-Kabel (USB A/B Standardkabel)
Unwahrscheinliche Untersuchungsergebnisse	Abgelaufene Kalibrierung	Audiometerkalibrierung durchführen

Problem	Mögliche Ursache	Lösung
	Falsche Art des ausgewählten AC-Wandlers (Kopfhörer oder Einsteckhörer)	Auswahl des aktuellen AC-Wandlers ändern, über Software oder App Maestro
Sie können nicht auf einen Test zugreifen	Optionaler Test nicht aktiviert	Wenden Sie sich an den für Sie zuständigen technischen Kundendienst, um die Lizenz zu erhalten und geben Sie dazu die Seriennummer des Geräts an.

Wenn das Audiometer in Verbindung mit einer schalldichten Kabine verwendet wird, prüfen, ob sowohl die Verbindungen im Inneren der Kabine als auch zwischen der Kabine und dem Instrument korrekt und sicher sind.

DA

PORTABLE AUDIOMETER

PICCOLO

MULTILANGUAGE USER MANUAL

Document title: AU1P-Piccolo User Manual DA
Code: AU1-MA303_D
Revision: Rev. 02
Date: 2025.03.07

DA

PICCOLO

BÆRBART AUDIOMETER

BRUGERVEJLEDNING

Læs grundigt denne vejledning, før enheden bruges. Vær især opmærksom på Kapitel 1 ("Sikkerhed: Advarsler og information") og Kapitel 2 ("Installation").

Indvendige inspektioner og reparationer må kun foretages af autoriseret personale.

CE
0123

Dokumenttitel: AU1P-brugervejledning Da
Revision: 17
Dato: 2025.03.07

DA

Resumé

Forord

Tak for at have købt Inventis-audiologisk udstyr.

Piccolo-audiometeret er let og og bærbart, men samtidig kraftigt og alsidigt udstyr, der er ideelt til professionelle på farten.

Inventis-virksomheden har altid anset brugen af deres apparater i sammenhæng med computere som en afgørende faktor. Ved at installere Maestro-software-suite, som fås med eller uden selvejet database eller som et Noah-modul, kan alle Inventis audiologienheder tilsluttes en computer, og alle udførte undersøgelser arkiveres i brugerens egen database.

Husk også, at Inventis har udviklet en fuld liste over audiologienheder: Udover audiometere omfatter virkomhedens produktlinje en række mellemøreanalysatorer, REM og HIT høreapparater, et trådløst video-otoskop og meget mere.

For flere oplysninger og for at rapportere problemer af enhver art, kontakt virksomheden på:

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

KAPITEL 1
Sikkerhed: Advarsler og information

OPERATØRMANUAL

Sørg for at læse denne vejledning grundigt igennem, så alle funktionerne, som tilbydes af instrumentet, kan bruges til deres fulde potentiale. Sørg især for at læse kapitlet i dets helhed, da det indeholder information og advarsler, der er af fundamental betydning ift. at sikre sikker og korrekt brug af udstyret.
Sikkerhedsadvarselssymbolet illustreret herunder anvendes i denne vejledning for at trække læserens opmærksomhed hen mod information af særlig betydning for hvad angår sikkerhed og for at beskytte mod ukorrekt brug.

OPERATØRENS ANSVAR

Piccolo-audiometeret fungerer med garanti effektivt og pålideligt, hvis det anvendes ifølge instruktionerne og procedurerne i denne vejledning.
Hvis instrumentet nogensinde udvikler en funktionsfejl eller kræver reparation, frakobles det fra strømforsyningen og må ikke bruges igen, indtil de nødvendige reparationer og service er blevet udført. Defekte og forkert fungerende dele må kun udskiftes med originale reservedele, leveret af INVENTIS S.r.l.. Alle reparationer må udelukkende udføres af Inventis eller af personale, der er godkendt af Inventis.
Ingen af enhedens dele må ændres eller udskiftes uden forhåndsgodkendelse fra Inventis.
Brugere er ansvarlige for alle funktionsfejl forårsaget af upassende brug, eller af vedligeholdelse eller reparationer, der er udført af andre end INVENTIS S.r.l. eller et autoriseret servicecenter. INVENTIS S.r.l. og deres servicecentre hæfter kun for præstationen og pålideligheden af instrumentet, hvis:

1. Alle forbindelser, justeringer, ændringer og reparationer udføres udelukkende af personale, der er godkendt af Inventis;

2. den elektriske strømforsyning og systemets jordforbindelser overholder gældende standarder for elektromedicinsk udstyr.

TILSIGTET FORMÅL

Piccolo-lægeudstyr er et audiometer. Et audiometer er en enhed, der hjælper operatøren med at definere patientens høreføl somhed ved at generere og levere lydstimuli af forskellig slags og intensitet til patienten mhp. diagnosticering.

TILSIGTET ANVENDELSE OG SLUTBRUGERE

Piccolo er beregnet til brug af ENT-sundhedsprofessionelle på hospitaler, ENT-klinikker og audiologiske klinikker, der udfører høreevalueringer og hjælper med at diagnosticere mulige otologiske lidelser. Der er ingen begrænsning i patientpopulationen for hvad angår brugen af enheden; men sørg altid for at udføre en otoskopi, før enheden benyttes.
Disse test skal udføres i et stille miljø for at undgå falske resultater.

SYGDOMSTILSTANDE

Tilstande med svækket følsomhed i det auditoriske system eller sygdomme, hvor det auditoriske system spiller en rolle i diagnosticeringen.

FORHOLDSREGLER

Enhver alvorlig hændelse, der er opstået i relation til enheden, bør rapporteres til fabrikanten og den kompetente myndighed i medlemslandet, hvor brugeren og/eller patienten befinder sig.

For at sikre korrekt og sikker brug af audiometeret skal følgende forholdsregler overholdes.

Installation og generelle forholdsregler

Sørg for, at kravene til det omgivende miljø er opfyldt under transport, opbevaring og drift:

Drift	*Temperatur: Mellem 15 °C og 35 °C* *Relativ luftfugtighed: Mellem 30 % og 90 % (ikke-kondenserende)* *Tryk: Mellem 700 hPa og 1060 hPa*
Transport og opbevaring	*Temperatur: Mellem -10 °C og 50 °C* *Relativ luftfugtighed: Maks. 90 % ikke-kondenserende* *Tryk: Mellem 500 hPa og 1060 hPa*
Opvarmningstid	*1 minut*

Piccolo-audiometeret vil ikke blive beskyttet, hvis det eksponeres for antændelig anæstesigas eller lignende produkter under brug. Risiko for eksplosion.

Undgå at installere og anvende Piccolo-audiometeret tæt ved stærke elektromagnetiske kilder, da dette kan forstyrre enhedens drift.

Brug kun originale aftagelige dele leveret af INVENTIS S.r.l., medmindre du er instrueret i andet.

Brug kun strømadaptere, der er beregnet til medicinsk udstyr, certificeret til IEC 60601-1, med de følgende specifikationer:

Hovedenhed: 6V, 1.67A d.c.
Ekstern adapter: SL POWER MENB1010A0603F02
100-240Vac 50/60 Hz 0.9-0.34A (medfølger) svarer til IEC 60601-1 standard

Piccolo-audiometeret er medicinsk udstyr. Alle andre eksterne enheder, som den er forbundet til (så som en computer eller CD-afspiller) inden for "patientområdet" (som angivet i IEC 60601-1), skal også være medicinsk udstyr eller være beskyttet af en isolerende transformer for at sikre, at hele kombinationen (computer eller ekstern enhed + audiometer) overholder IEC standard 60601-1.

Piccolo kan bruges i sammenhæng med en lydtæt bås for at udføre test under optimale akustiske forhold. Før den forbindes til en lydtæt bås, skal man tjekke, at stikkene er kompatible med specifikationerne for hvert stik.

Piccolo har brug for specielle forholdsregler vedrørende EMC og skal installeres og sættes i drift ifølge EMC-informationen, som kan findes i slutningen af denne vejledning.

Brug af bærbart og mobilt RF-kommunikationsudstyr kan påvirke korrekt drift af Piccolo-enheden. Se EMC-informationen i slutningen af denne vejledning.

Strømadapterkablet og USB-kablet anses for at være frakoblingsmidler til at frakoble enheden fra elforsyningen.

Placér ikke enheden på en måde, hvor det er svært at frakoble enheden fra elforsyningen.

Kalibrering

Kalibreringen skal udføres mindst hver 12. måned, og når en transducer udskiftes.

Kalibreringen af audiometeret gælder kun for transducere, som leveres med enheden. Hvis en transducer udskiftes, skal audiometeret rekalibreres.

Kalibreringen af audiometeret er gyldig til transducere forsynet med audiometeret, hvis forbundet direkte til instrumentet, uden nogen mellemliggende forlængerledninger og uden passage fra stik til panel (som det normalt forekommer i lydtætte båse). Hvis transducerne ikke er forbundet direkte til audiometeret, vil en ny kalibreringsprocedure være påkrævet, før instrumentet anvendes.

I hvert testvindue vil baggrunden for "output"-området vises i rød, når du vælger en ikke-kalibreret transducer. Desuden vil du ikke kunne sende nogen stimuli gennem ikke-kalibrerede transducere.

Bemærk audiometerets angivne kalibreringsinterval. Brug af instrumentet ud over dets kalibreringsudløbsdato kan føre til upålidelige diagnoser.

Hygiejne

Øreproppерne til høretelefoner er til engangsbrug; brug ikke den samme øreprop til forskellige patienter. Smid øreproppер ud efter brug.

Desinficér høretelefonernes puder mellem patienterne, og følg proceduren beskrevet i KAPITEL 3 "Vedligeholdelse".

Brug

Audiometeret kan generere toner ved en høj intensitet og potentielt beskadige patienten. Vær især omhyggelig med at justere intensiteten af tonen korrekt før undersøgelser.

Ved udførsel af audiometri vha. høretelefoner skal man ikke indsætte eller på nogen måde forsøge at foretage målinger uden at den rigtige skumspids er på plads.

Opretholdelse af den forrige intensitet af stimuli ved ændring af frekvens, transducer eller stimuleringsside kan resultere i at potentielt skadelige signale bliver præsenteret for patienten.

For at præsentere et stimulisignal, der er stærkere end 100 dB HL, skal operatøren først trykke på "HØJERE dB"-knappen, som kun er aktiv, når intensiteten af stimuli når 100 dB HL.

BORTSKAFFELSE

Som alt elektronisk udstyr indeholder dit audiometer ekstremt små mængder farlige stoffer så som cadmium eller kviksølv. Hvis sådanne stoffer kommer ind i den normale affaldssortering uden passende bearbejdning, kan de forårsage skader på miljø og menneskers helbred. Alle dele af audiometeret skal derfor bortskaffes separat.
Ved slutningen af dets levetid skal det udtjente instrument bringes til et kommunalt affaldsbortskaffelses- og genbrugsanlæg, eller det skal returneres til forhandleren mod køb af et tilsvarende nyt instrument.
Separat affaldsindsamling og den efterfølgende bearbejdning, genbrug og bortskaffelse letter fremstillingen af nye enheder af genbrugsmaterialer, hvilket begrænser enhver negativ indvirkning på miljøet og folkesundheden, som ellers kunne stamme fra forkert bortskaffelse.

OVERENSSTEMMELSE

Piccolo-audiometer er klasse IIa medicinsk udstyr ifølge Bilag VIII i Medical Device Regulation (MDR) 2017/745/EU.
Inventis Quality Management System er blevet certificeret af førende vurderingsorgan TÜV i overensstemmelse med ISO 13485 standard.

SYMBOLER PÅ ETIKETTER

Navn og adresse på fabrikant.

Advarsel: Brugen af denne enhed kræver bestemte forholdsregler.
Se den medfølgende dokumentation for at sikre korrekt brug.

Dette symbol betyder, at produktet er dækket af direktiv 2012/19/EU om elektrisk og elektronisk affald (WEEE). Det er påkrævet ikke at bortskaffe dette produkt som usorteret kommunalt affald, men at aflevere det separat.

Se instruktionsvejledningen

Enhed med anvendte dele af type B (IEC 60601-1).

DC-strømforsyning

Produktet overholder den europæiske unions forordning om medicinsk udstyr (MDR) 2017/745/EU. Klasse IIa enhed; det underrettede organs nummer: 0123 (TÜV SÜD Product Service GmbH).

Medicinsk udstyr

Rx only

Forsigtig: Føderal lovgivning begrænser denne enhed til at blive solgt af eller på ordre af en autoriseret læge.

IP20

IP (Ingress Protection)-kode: Denne enhed er beskyttet mod indgang af genstande der er > 12,5 mm; den er ikke beskyttet mod væske.

REF

Katalognummer

COMPATIBLE TRANSDUCERS

Afsnit der oplister de kompatible transducere

Serienummer på enheden, lavet af 13 alfanumeriske tegn, der angiver model, fabrikationsår og serienummer. Nummeret består især af disse segmenter:

- *De første 5 tegn: Inventis-produktkode*
- *tegn 6 og 7: Fabrikationsår (f.eks. "12" står for 2012)*
- *Tegn 8 ... 13: Stigende tal*

UDI-kode

KAPITEL 2
Installation

Mens installationen af et Piccolo-audiometer er en relativt enkel procedure, bør den tiltros en person med de rette færdigheder. Hvis installationen ikke udføres korrekt, kan systemet blive påvirket af sikkerhedsproblemer, når det er i brug.
Dette kapitel beskriver proceduren for installering af systemet.

Behold emballagen i det tilfælde at audiometeret skal sendes tilbage til forhandleren eller til Inventis af hvilket som helst årsag.

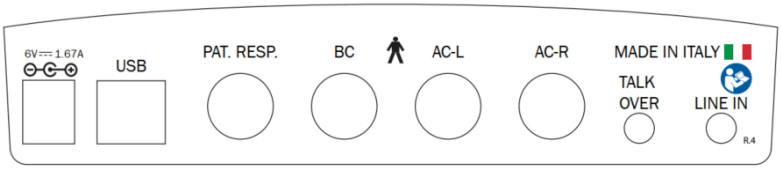
FORHOLDSREGLER

Som alt andet elektrisk eller elektronisk udstyr vil Piccolo-audiometeret udsende elektromagnetiske bølger. Selvom dets bølger er indenfor standardgrænserne, kan andre elektroniske enheder tæt på audiometeret blive påvirket, hvis de er særligt følsomme over for elektromagnetisk interferens.
Hvis dette forekommer, kan du blot tjekke ved at tænde og slukke audiometeret og forsøge at eliminere interferensen ved at bruge en eller flere af følgende løsninger:

- Skifte retning og/eller position af enheden, som er påvirket af interferensen;
- skabe afstand mellem den påvirkede enhed og audiometeret;
- slutte den påvirkede enhed til en stikkontakt i et andet kredsløb end det kredsløb, hvortil audiometeret er tilsluttet;
- bede om hjælp hos fabrikanten eller et servicecenter.

FORBINDELSER

Alle forbindelsespunkter til aftagelige dele er placeret på bagpanelet. Dette afsnit refererer til Piccolo-taleaudiometer. Piccolo Plus har ikke et LINE IN-stik til en ekstern lydkilde. Basic-modellen mangler også et BC-stik (til en knoglevibrator).



Tilslut alle transducere og aftagelige dele til deres respektive stikkontakter som angivet i den følgende tabel:

Stik	Aftagelig del
6V⎓1.67A	Strømforsyning. Når Piccolo er tilsluttet en computers USB-port, er der ikke brug for strømforsyningen.
USB	USB-port til forbindelse til PC'en
PAT. RESP.	Patients svarknap
BC	Knoglevibrator
AC-L	Venstre høretelefon/øreprop
AC-R	Højre høretelefon/øreprop
TALK OVER	Operatørmikrofon
LINE IN	Ekstern linje til taleaudiometri med ekstern lydkilde

Brug kun strømadaptere, der er beregnet til medicinsk udstyr, certificeret til IEC 60601-1.

Sørg for, at strømforsyningen og jordforbindelserne overholder de gældende standarder for elektromedicinsk udstyr. Risiko for stød

Hvis Piccolo-audiometeret strømforsynes via et USB-kabel, er maksimumværdierne (i AC og BC) 10 dB lavere end de nominelle værdier.

Det grønne LED-lys nær ⏻-symbolet angiver, at audiometeret strømforsynes enten fra elnettets adapter eller via computerens USB-kabel.

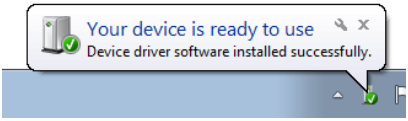
LED-lyset nær -symbolet angiver status for kommunikationen mellem audiometeret og computeren: dette LED-lys er grønt, hvis audiometeret kommunikerer med en PC.

FORBINDELSE TIL COMPUTER

For at tillade styring fra en computer skal Piccolo-audiometeret tilsluttes en af computernes USB-porte vha. det medfølgende kabel (et standard USB A/B-kabel).

Brug det medfølgende kabel for at tilslutte Piccolo-audiometeret til en af USB-portene på computeren

Tilslutningen er plug-and-play, uden behov for specielle drev til installation: Få sekunder efter tilslutning vil operativsystemet genkende enhederne, og den følgende meddelelse vises:



Piccolo-audiometeret kan styres fra en computer, der bruger Inventis Maestro-software: For flere oplysninger om brug og funktioner i Maestro-software, og for minimum systemkrav se *Maestro-brugervejledning*.

KAPITEL 3
Vedligeholdelse

Piccolo-audiometeret kræver ikke nogen speciel regelmæssig vedligeholdelse udover kalibrering, tjek og normal rengøring, som alle beskrives i dette kapitel.
Instrumentets præstation og sikkerhed opretholdes, hvis anbefalingerne til pleje og vedligeholdelse i dette kapitel overholdes.
Instrumentet skal slukkes og afkobles strømforsyningen, før rengøring påbegyndes.

Inspektionen og serviceringen af indvendige dele skal foretages af teknikere, der er godkendt af INVENTIS S.r.l..

Transducere fremstilles vha. ultraskrøbelige membraner, der kan blive beskadiget i tilfælde af slag. Håndtér med omhu under vedligeholdelse.

REGELMÆSSIGE TJEK

Proceduren beskrevet under denne overskrift skal udføres, når instrumentet bruges for første gang hver dag.

Tests skal udføres med audiometeret i installationspositionen.

- Før du tænder for instrumentet, skal du kontrollere, at der ikke er synlige tegn på beskadigelse i nogen del af enheden, inklusive aftagelige dele og den eksterne strømforsyning; dobbelttjek den visuelle integritet af isoleringen af netkablet og stikkene, og kontroller, at de ikke udsættes for nogen form for mekanisk belastning, der kan medføre beskadigelse; kontroller desuden, at alle dele og kabler er korrekt tilsluttet
- Tjek subjektivt, at luftlednings- og knogleledningsoutput er ens på begge kanaler og alle frekvenser, for at gøre dette påføres 10 eller 15 dB, lige nok til at høre. Personen, som udfører dette tjek, bør have god hørelse

- Tjek på niveau med 60 dB i AC og 40 dB i BC, at der ikke er nogen forvrængning, støj eller parasitiske signaler i nogen af frekvenserne
- Tjek, at patientresponskontakten og -indikatorerne fungerer korrekt
- Tjek taleaudiometerets inputs ved at foretage en taletest for hver taleinput
- Tjek headsettets og knoglevibratorens pandebåndsbelastning
- Tjek kommunikationen med patienten

Hvis en del eller transduceren har nogle funktionsfejl, se kapitel "Fejlfinding".

Tjek altid, at kalibreringsintervallet ikke er udløbet: Udløbet for intervallet er angivet øverst til venstre for Maestro-software.

Kalibrering skal tiltros teknikere, der er godkendt af INVENTIS S.r.l. Driften skal udføres mindst hver 12. måned, og når en transducer udskiftes.

VEDLIGEHOLDELSE AF TRANSDUCERE

Brug ikke væske eller spray til at rengøre audiometeret.

Lad ikke støv samle sig på transducerne. Derudover:

- Høretelefonpuderne er lavet af biokompatibelt materiale, men er ikke sterile: For at forhindre spredning af infektion og garantere materialets biokompatibilitet, skal puderne tørres af, hver gang høretelefonerne skal bæres af en ny patient, med
    - for DD45/TDH-39 puder, aftørring med denatureret alkohol;
    - for alle andre puder: Hypoallergenisk desinfektionsmiddel, som følger fabrikantens instruktioner.
- Øreproppernes spidser er beregnet til at blive sat ind i patientens ørekanal. De er lavet af biokompatibelt materiale og er til engangsbrug: Brug kun én gang, og smid ud i overensstemmelse med gældende sundheds- og sikkerhedsregler

Øreproppernes spidser er ikke sterile. Brug af usteriliserede høretelefoner kan forårsage øreinfektioner.

Knoglevibratoren og høretelefonernes puder kan rengøres gentagne gange, som beskrevet i afsnittet "Vedligeholdelse af transducere". I tilfælde af funktionsfejl efter rengøring kontaktes en Inventis-servicetekniker.

Selvom knoglevibratoren og høretelefonpuderne kan rengøres gentagne gange, skal man altid tjekke, at de er intakte. For at gøre dette er det tilstrækkeligt at udføre de test, som er beskrevet i afsnittet "Regelmæssige tjek". Så snart man støder på en fejl kontaktes en Inventis-servicetekniker for at tjekke, om transduceren skal udskiftes.

For at undgå beskadigelse af DD45/TDH39 høretelefoner skal man ikke skubbe den mod en flad jævn overflade, da det kan skabe et vakuum og forårsage skade på transduceren (sugekopeffekt).

RENGØRING AF INSTRUMENTET

For at forhindre akkumulering af støv på instrumentet skal man altid tilpasse beskyttelsesdækslet, når analysatoren ikke er i brug. Sørg også for, at støvakkumulering under instrumentet rengøres regelmæssigt.
Alle dele, der ikke nævnes specifikt i det forrige afsnit, kan rengøres vha. en fnugfri klud, der er vædet med en opløsning af vand og mild sæbe; i tilfælde af sanering fugtes kluden med brintoverilte i en 3 % koncentration. Enheden tillader flere rengøringer uden forværring af grundlæggende sikkerhed eller ydeevne; tjek altid, at enheden er intakt. For at gøre dette er det tilstrækkeligt at udføre de test, som er beskrevet i afsnittet "Regelmæssige tjek". Så snart man støder på en fejl kontaktes en Inventis-servicetekniker for at tjekke, om der er nogle dele, der skal udskiftes.

UDSKIFTELIGE DELE

Transducerne og de aftagelige dele kan frakobles enheden. Hvis en fejl skulle udvikle sig i en af disse enheder, skal audiometeret slukkes og isoleres fra strømforsyningen, og den defekte genstand skal så frakobles enheden.

Alle aftagelige dele af audiometeret er designet specifikt til brug med enheden. Kun dele leveret af Inventis bør forbindes til audiometeret.

REPARATIONER OG TEKNISK ASSISTANCE

Før man tager kontakt til serviceafdelingen skal man sikre, at alle de mulige løsninger i kapitlet *"Fejlfinding"* er blevet afprøvet.

Alle dele der returneres til fabrikanten for reparation og service skal rengøres og desinficeres. Transducere skal forsegles i en gennemsigtig pose.

Vigtigt: Hvis instrumentet skal sendes til Inventis-serviceafdeling eller returneres til forhandleren, skal du sørge for, at den originale emballage anvendes, og at alle aftagelige dele og transducere er pakket ind.

KAPITEL 4
Fejlfinding

Problem	Mulig årsag	Løsning
Intet signal fra en transducer	Transducer ikke tilsluttet det korrekte output	Forbind transduceren til det korrekte output
	Transducer beskadiget	Kontakt din forhandler eller serviceleverandør
Intet signal fra patients svarknap, når den trykkes ned	Forkert forbindelse	Tilslut patientens svarknap til den rigtige kontakt
	Patients svarknap beskadiget	Kontakt din forhandler eller serviceleverandør
Forbindelsen mellem pc og audiometer kan ikke etableres	Problemer med USB-forbindelse	Tjek USB-forbindelsen mellem instrument og computer
	USB-kabel beskadiget	Skift USB-kabel (standard USB A/B-kabel)
Usandsynlige undersøgelsesresultater	Udløbet kalibrering	Foretag audiometerkalibrering
	Forkert slags udvalgt AC-transducer (høretelefoner eller øreproppper)	Modificér valget af den nuværende AC-transducer, fra Maestro-software eller -app
Du kan ikke få adgang til en test	Valgfri test ikke aktiveret	Kontakt teknisk service for at få licensen vha. enhedens serienummer

Når audiometeret benyttes i sammenhæng med en lydtæt bås, skal man tjekke, at forbindelserne både inde i båsen og mellem båsen og instrumentet er korrekte og sikre.

Annex A

Technical Specifications

APPLICABLE STANDARDS	
Performance	Piccolo Basic IEC 60645-1 / ANSI S3.6 type 4 Piccolo Plus IEC 60645-1 / ANSI S3.6 type 3 Piccolo Speech IEC 60645-1 / ANSI S3.6 type 3B
Calibration	AC: ISO 389-1, ISO 389-2 BC: ISO 389-3
Electrical safety	IEC 60601-1 Class I, Type B
Electromagnetic compatibility	IEC 60601-1-2
Enclosures	IEC 60601-1 IP20
Operation mode	Continuous

CE CERTIFICATE	
MDR 2017/745/EU Classification	Class IIa
Classification rule (Annex VIII, 2017/745)	10
Notified body	TÜV SÜD Product Service GmbH Ridlerstrasse 65 D-80339 Műnchen, Germany
Notified body number	0123

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

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 device powered by mains power adapter. In case of device 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 device powered by mains power adapter. In case of device 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 device powered by mains power adapter. In case of device 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	•	•	•

AUDIOMETER CONTROL	
Required Software	Inventis Maestro
Communication protocol	USB 1.1
PC communication requirements	USB 2.0 port minimum

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.

Annex B

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 such use is necessary, this instrument and the other equipment should be observed to verify that they are operating normally.

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 mains power adapter
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 2m shielded signal cable

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 does not have any ESSENTIAL PERFORMANCE as per the IEC 60601 1 standard.

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.

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">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.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment-guidance</th></tr>
<tr><td>RF emissions
CISPR11</td><td>Group 1</td><td>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.</td></tr>
<tr><td>RF emissions
CISPR11</td><td>Class B</td><td rowspan="3">Piccolo is suitable for use in professional healthcare facility environment and directly connected to the public low-voltage power supply network.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations / flickers emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

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 on power supply input lines IEC 61000-4-11	< 5% U_T (2) (> 95% dip in U_T) for 0,5 cycle. 40% U_T (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.	< 5% U_T (2) (> 95% dip in U_T) for 0,5 cycle. 40% U_T (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.	Mains power quality should be that of a professional healthcare facility environment. If the 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.			

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">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.</td></tr>
<tr><th>Immunity Test</th><th>IEC 60601 Test Level</th><th>Compliance Level</th><th>Electromagnetic environment – Guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
0.15 – 80 MHz

6 Vrms
in ISM bands between
0.15 - 80 MHz</td><td>3 Vrms
0.15 – 80 MHz

6 Vrms
in ISM bands between
0.15 - 80 MHz</td><td rowspan="5">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(1), should be less than the compliance level in each frequency range.(2) Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radieted RF
IEC 61000-4-3</td><td>3 V/m

80 Mhz - 2,7 Ghz</td><td>3 V/m

80 Mhz to 2,7 Ghz</td></tr>
<tr><td rowspan="3">Radiated RF

(from RF Wireless communication equipment)

IEC 61000-4-3</td><td>9 V/m

704-787 MHz
5100 – 5800 MHz</td><td>9 V/m

704-787 MHz
5100 – 5800 MHz</td></tr>
<tr><td>27 V/m

380 - 390 Mhz</td><td>27 V/m

380 - 390 Mhz</td></tr>
<tr><td>28 V/m

430 - 470 Mhz
800 - 960 Mhz
1700 - 1990 Mhz
2400 - 2570 Mhz</td><td>28 V/m

430 - 470 Mhz
800 - 960 Mhz
1700 - 1990 Mhz
2400 - 2570 Mhz</td></tr>
<tr><td>Proximity Fields

IEC 61000-4-39</td><td>8A/m
30KHz CW

65 A/m
134.2KHz
Pulse Mod 2.1KHz

7.5 A/m
13.56MHz
Pulse Mod 50KHz</td><td>8A/m
30KHz CW

65 A/m
134.2KHz
Pulse Mod 2.1KHz

7.5 A/m
13.56MHz
Pulse Mod 50KHz</td></tr>
<tr><td colspan="4">Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">Note:
(1) 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 Triangle is used in exceeds the applicable RF compliance level above, Triangle should be observed to verify its normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Triangle.
(2) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

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 transducers exceeding 80dBHL; a lock or reboot of the device is acceptable

IT

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PORTABLE AUDIOMETER

PICCOLO

FR

MULTILANGUAGE USER MANUAL

DE

Document title: AU1P-Piccolo User Manual IT-EN-FR-DE-ES
Code: AU1-MA303_A
Revision: Rev. 02
Date: 2025.03.07

ES

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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

EN

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.

EN

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

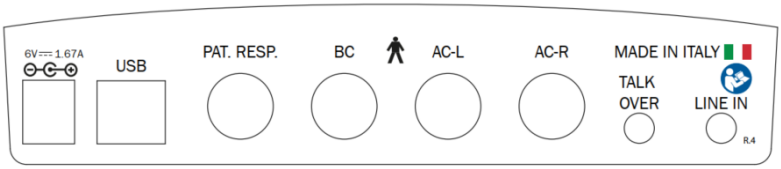
PRECAUTIONS

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.

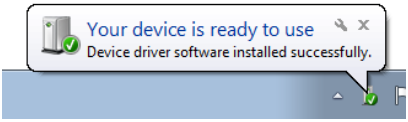
The LED near the symbol indicates the status of communications between the audiometer and computer: this LED lights in green if the audiometer is communicating with a PC.

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.

EN

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

EN

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.

IT

EN

PORTABLE AUDIOMETER

PICCOLO

FR

MULTILANGUAGE USER MANUAL

DE

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ES

PICCOLO

AUDIÓMETRO PORTÁTIL

MANUAL DEL USUARIO

ES

Lea este manual en su totalidad antes de usar el dispositivo. Preste especial atención al Capítulo 1 ("Seguridad: advertencias e información") y al Capítulo 2 ("Instalación").

Las inspecciones y reparaciones internas solo las debe realizar personal autorizado.

CE
0123

Resumen

ES

Preámbulo

Gracias por comprar un dispositivo de audiología de Inventis.

El audiómetro Piccolo, portátil y ligero, es un dispositivo portátil potente y versátil, ideal para profesionales que se desplazan.

La empresa Inventis siempre ha considerado que el uso de estos dispositivos combinados con ordenadores es un factor con una importancia fundamental. Al instalar el paquete de software Maestro, disponible con o sin una base de datos de código cerrado o como un módulo de Noah, cualquier dispositivo de audiología Inventis se puede conectar a un ordenador, y todos los exámenes realizados se pueden archivar en la propia base de datos del usuario.

Tenga en cuenta también que Inventis ha desarrollado una línea completa de dispositivos de audiología: además de los audiómetros, la línea de productos de la empresa incluye una gama de impedanciómetros, dispositivos de ajuste de audífonos REM y HIT, así como videotoscopia inalámbrica y muchos más.

Para obtener más información y para informar sobre cualquier tipo de problema, póngase en contacto con la empresa en las siguientes señas:

INVENTIS S.r.l.
Corso Stati Uniti, 1/3
35127 Padova, Italia
Tel.: 049.8962844 – Fax: 049,8966343
www.Inventis.it info@Inventis.it

CAPÍTULO 1
Seguridad: advertencias e información

MANUAL DEL OPERADOR

Asegúrese de leer este manual completamente, para poder aprovechar todo el potencial de las características que ofrece el instrumento. En especial, asegúrese de leer todo este capítulo, ya que contiene información y advertencias que tienen una importancia fundamental para asegurar un uso seguro y correcto del dispositivo.
El símbolo de advertencia de seguridad mostrado a continuación se usa en este manual para llamar la atención del lector ante información de especial importancia sobre seguridad y para proteger de un uso incorrecto.

RESPONSABILIDADES DEL OPERADOR

Únicamente se garantiza el funcionamiento efectivo y fiable del audiómetro Piccolo si se utiliza de acuerdo con las instrucciones y procedimientos incluidos en el presente manual.
Si el instrumento funciona mal o es necesario repararlo, desconéctelo de la red eléctrica y no lo use hasta que se haya realizado la reparación necesaria y se haya arreglado. Las partes defectuosas o que no funcionen correctamente solo deben sustituirse con las piezas de repuesto originales suministradas por INVENTIS S.r.l.. Todas las reparaciones deben ser realizadas exclusivamente por Inventis o por personal autorizado por Inventis.
Ninguna de las piezas del dispositivo puede ser modificada o sustituida sin la autorización previa por escrito de Inventis.
Los usuarios son completamente responsables por cualquier mal funcionamiento provocado por un uso inadecuado o si se realizan operaciones de mantenimiento o reparación por cualquier otra parte que no sea INVENTIS S.r.l. o un Centro de servicio autorizado. INVENTIS S.r.l. y sus Centros de Reparaciones autorizados responderán del rendimiento y la fiabilidad del equipo únicamente si:

1. todas las conexiones, los ajustes, las modificaciones o reparaciones los realiza exclusivamente personal autorizado por Inventis;

2. la alimentación eléctrica y las conexiones de tierra del sistema cumplen las normas aplicables para productos electromédicos.

FIN PREVISTO

El aparato sanitario Piccolo es un audiómetro. Un audiómetro es un dispositivo que ayuda al operador a determinar la sensibilidad auditiva del paciente generando y enviando al paciente estímulos sonoros de diferentes tipos e intensidades para fines diagnósticos.

INDICACIONES DE USO Y USUARIOS FINALES

Piccolo está destinado al uso por parte de profesionales de la otorrinolaringología en hospitales, clínicas de otorrinolaringología y oficinas de audiología para realizar evaluaciones de la audición y ayudar en el diagnóstico de posibles trastornos otológicos. No hay una restricción en la población de pacientes para el uso del dispositivo; asegúrese siempre de realizar una otoscopia antes de usar el dispositivo.
Estas pruebas deben ser realizadas en un entorno tranquilo para evitar interferencias.

PROBLEMAS MÉDICOS

Los problemas de falta de sensibilidad del sistema auditivo o cualquier problema en el que se considere que el sistema auditivo tiene un papel importante para el diagnóstico.

PRECAUCIONES

Debe informarse de cualquier accidente grave que se produzca relacionado con el dispositivo al fabricante y a la autoridad competente del Estado miembro en que está establecido el usuario o el paciente.

Para garantizar un uso correcto y seguro del audiómetro, es necesario observar las siguientes precauciones.

Instalación y precauciones generales

Asegúrese de que se cumplan las condiciones ambientales necesarias durante el transporte y funcionamiento:

Funcionamiento	*Temperatura: entre 15°C (59°F) y 35°C (95°F)* *Humedad relativa: entre 30% y 90% (sin condensación)* *Presión: entre 700 hPa y 1060 hPa*
Transporte y almacenamiento	*Temperatura: entre -10°C (14°F) y 50°C (122°F)* *Humedad relativa: máximo 90% sin condensación* *Presión: entre 500 hPa y 1060 hPa*
Tiempo de calentamiento	*1 minuto*

El audiómetro Piccolo no estará protegido si al usarlo se le expone a gases anestésicos inflamables o productos similares. Riesgo de explosión.

Evite instalar y usar el audiómetro Piccolo cerca de fuentes de campos electromagnéticos fuertes, podrían interferir en el funcionamiento del aparato.

Utilice solo piezas desechables originales suministradas por INVENTIS S.r.l. salvo que se indique específicamente lo contrario.

Use solo adaptadores de potencia ideados para equipamiento médico, certificados según la norma IEC 60601-1, que cumplan las siguientes especificaciones:

Unidad principal: 6V, 1,67A d.c.
Adaptador externo: SL POWER MENB1010A0603F02 100-240Vac 50/60 Hz 0.9-0.34A (incluido) que cumple la norma IEC 60601-1

El audiómetro Piccolo es un aparato sanitario. Cualquier otro dispositivo externo al que esté conectado (como ordenador o reproductor de CD) en el «área de paciente» (como definido en IEC 60601-1) también debe ser un aparato sanitario o debe estar protegido por un transformador de aislamiento a fin de asegurar que la combinación completa (ordenador o dispositivo exterior + audiómetro) cumple los requisitos de la norma IEC 60601-1.

Piccolo se puede usar junto con una cabina insonorizada para realizar pruebas en condiciones acústicas óptimas. Antes de

conectarlo a una cabina insonorizada, compruebe que los enchufes sean compatibles con las especificaciones indicadas para cada conector.

Piccolo necesita algunas precauciones especiales sobre EMC y debe instalarse y ponerse en servicio de acuerdo con la información EMC que se incluye al final de este manual.

El uso de equipo de comunicaciones RF portátil y móvil puede afectar al correcto funcionamiento del dispositivo Piccolo. Consulte la información sobre EMC disponible al final de este manual.

El cable del adaptador de alimentación y el cable USB debe considerarse la manera de desconectar el aparato de la red de alimentación.

No coloque el dispositivo de manera que sea difícil desconectarlo de la alimentación de red.

Calibración.

La calibración se debe realizar como mínimo una vez cada 12 meses y siempre que se sustituya un transductor.

La calibración del audiómetro es válida solo para los transductores suministrados con el aparato. Si se sustituye un transductor, es necesario recalibrar el audiómetro.

La calibración del audiómetro es válida para los transductores suministrados con el equipo, si se conectan directamente al instrumento, sin ninguna interposición de cables de extensión y sin el paso de conectores al panel (como ocurre habitualmente cuando se conectan a una cabina insonorizada). Si los transductores no están conectados directamente al audiómetro, será necesario un nuevo procedimiento de calibración antes de usar el instrumento.

En cada ventana de prueba, cuando seleccione un transductor no calibrado, el fondo del área de «salida» se mostrará en color rojo. Asimismo, no podrá enviar ningún estímulo si los transductores están mal calibrados.

Tome nota del intervalo de calibración especificado del audiómetro. Usar el dispositivo después de la fecha de caducidad del de calibración puede dar lugar a diagnósticos poco fiables.

Higiene

Los moldes de los auriculares son desechables; no usar el mismo molde para diferentes pacientes. Tírelos después de usarlos.

Desinfecte las almohadillas de los auriculares entre un paciente y el siguiente, con arreglo al procedimiento que se describe en el CAPÍTULO 3 «Mantenimiento».

Uso

El audiómetro puede generar tonos a una intensidad que puede provocar daños al paciente. Tenga especial cuidado al ajustar la intensidad del tono correctamente antes de los exámenes.

Al realizar una audiometría usando auriculares de inserción, no introduzca ni intente realizar medidas sin una punta de la sonda colocada en el lugar adecuado.

Mantener la intensidad previa del estímulo cuando se cambia la frecuencia, el transductor o el lado de estimulación puede provocar señales potencialmente dañinas que se presentarán al paciente.

Para presentar una señal de estímulo superior a 100 dB HL, en primer lugar el operador debe apretar el » botón de función DB MÁS ELEVADOS, que está activo solo cuando la intensidad del estímulo alcanza los 100 dB HL.

ELIMINACIÓN DE RESIDUOS

Como todos los dispositivos electrónicos, el audiómetro contiene cantidades muy pequeñas de determinadas sustancias dañinas, como cadmio y mercurio. Si se permite que dichas sustancias entren en el ciclo normal de eliminación de residuos sin un tratamiento previo adecuado, pueden provocar daños al medio ambiente y a la salud. Todas las piezas del audiómetro deben eliminarse por separado.
Al final de su vida, tomar o enviar el instrumento que ya no se usa a una planta pública de recogida de residuos o instalación de reciclaje, o devolverlo al vendedor al comprar un instrumento nuevo equivalente.
La recogida separada y las posteriores operaciones de tratamiento, reciclaje y eliminación facilitan la fabricación de nuevos dispositivos a partir de materiales reciclados, limitando cualquier impacto negativo en el medio

ambiente y la salud pública que en caso contrario podrían derivarse de una eliminación no correcta.

CONFORMIDAD

El audiómetro Piccolo es un aparato sanitario de clase IIa según el Anexo VIII del Reglamento sobre Aparatos sanitarios (MDR) 2017/745/EU.
El Sistema de Gestión de Calidad de Inventis ha sido certificado por un ente de evaluación de primer nivel TÜV que certifica el cumplimiento de la norma ISO 13485.

SÍMBOLOS EN LAS ETIQUETAS

Nombre y dirección del fabricante.

Advertencia: para usar este dispositivo se deben tomar ciertas precauciones.
Para garantizar un uso seguro, consulte la documentación adjunta.

Este símbolo significa que el producto está protegido por la Directiva 2012/19/EU sobre residuos de equipos eléctricos y electrónicos (RAEE). Este producto no se debe eliminar este producto como residuo urbano no seleccionado, sino separando los diversos componentes.

Consulte el manual de instrucciones de uso

Dispositivos con piezas aplicadas de tipo B (IEC 60601-1).

Fuente de alimentación DC

El producto cumple el Reglamento sobre aparatos sanitarios de la Comunidad Europea (MDR) 2017/745/EU. Dispositivo de clase IIa; número del organismo notificado: 0123 (TÜV SÜD Product Service GmbH).

Aparato sanitario

Rx only

Precaución: La legislación federal limita la venta de este dispositivo a profesionales sanitarios colegiados.

IP20	*Código IP (protección de entrada): este dispositivo está protegido contra la entrada de objetos con un tamaño > 12,5 mm, no está protegido contra líquidos.*
REF	*Número de catálogo*
COMPATIBLE TRANSDUCERS	*Sección que indica los transductores compatibles*
SN	*Número de serie del dispositivo, compuesto de 13 caracteres alfanuméricos que indican el modelo, serie, año de fabricación y número de serie. En especial, el número incluye estos segmentos:* - *Primeros 5 caracteres: Código de producto Inventis* - *caracteres 6 y 7: año de fabricación (por ejemplo, «12» se refiere al 2012)* - *caracteres 8… 13: número incremental*
(01)08054187380372(21)AU1PH16200749	*Código UDI*

CAPÍTULO 2
Instalación

A pesar de que la instalación del audiómetro Piccolo es un procedimiento relativamente sencillo, debe confiarse a una persona con las habilidades necesarias. Si la instalación no se realiza correctamente, el sistema podría verse afectado por problemas de seguridad durante la utilización.
Este capítulo describe el procedimiento para la instalación del sistema.

Conserve los materiales de embalaje por si necesitara enviar el audiómetro al distribuidor o a Inventis por cualquier motivo.

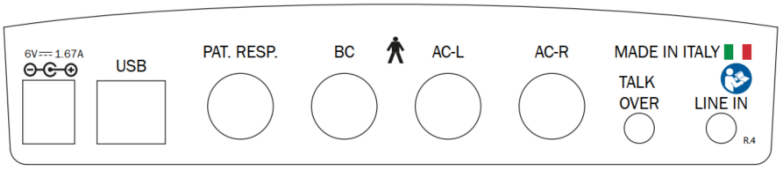
PRECAUCIONES

Como cualquier otro dispositivo eléctrico o electrónico, el audiómetro Piccolo emitirá ondas electromagnéticas. A pesar de que estas emisiones se sitúan en los límites indicados por las normas, otros aparatos sanitarios situados cerca del audiómetro podrían verse afectados, si son especialmente sensibles a las interferencias electromagnéticas.
Si se produce esta situación, compruebe si es así encendiendo y apagando el audiómetro e intente eliminar la interferencia recurriendo a una o varias de estas soluciones.

- cambie la orientación y/o la posición del dispositivo afectado por la interferencia;
- separe el dispositivo afectado del audiómetro;
- enchufe el dispositivo afectado a una toma de electricidad en un circuito que sea diferente del circuito al que se ha conectado el audiómetro;
- consulte al fabricante o a un centro de servicio para recibir asistencia.

CONEXIONES

Todos los puntos de conexión para piezas separadas se ubican en el panel trasero. Esta sección trata sobre el audiómetro vocal Piccolo. Piccolo Plus no tiene un conector LINE IN para la fuente de sonido externa. El modelo Basic tampoco tiene un conector BC (para un vibrador óseo).



Enchufe todos los transductores y piezas que se pueden separar a sus tomas correspondientes tal y como se indica en la siguiente tabla:

Conector	Pieza que se puede separar
6V⎓1.67A	Fuente de alimentación Cuando Piccolo se conecta al puerto USB de un ordenador, no es necesaria la fuente de alimentación.
USB	Puerto USB para la conexión al equipo
PAT. RESP.	Botón de respuesta del paciente
BC	Vibrador óseo
AC-L	Auricular/auricular de inserción izquierdo
AC-R	Auricular/auricular de inserción derecho
TALK OVER	Micrófono del operador
LINE IN	Línea externa para audiometría de voz con fuente de audio externa

Use solo adaptadores de potencia ideados para equipamiento médico, certificados según la norma IEC 60601-1.

Asegúrese de que la alimentación de potencia eléctrica y las conexiones de tierra cumplen las normas aplicables para los dispositivos electromédicos. Riesgo de descarga eléctrica

Si el audiómetro Piccolo se alimenta por un cable USB, los valores máximos (en AC y BC) son 10 dB inferiores a los valores nominales.

El LED verde cerca del símbolo ⏻ indica que le audiómetro está alimentado desde la red o desde el cable USB del ordenador.

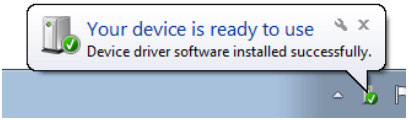
El LED cerca del símbolo indica el estado de las comunicaciones entre el audiómetro y el ordenador: este LED se enciende en verde si el audiómetro se está comunicando con el ordenador.

CONEXIÓN AL ORDENADOR

Para permitir el control desde un ordenador, el audiómetro Piccolo debe conectarse a uno o varios puertos USB del ordenador usando el cable incluido (un cable USB A/B estándar).

Use el cable suministrado para conectar el audiómetro Piccolo a uno de los puertos USB del ordenador

La conexión es «Plug-and-play», sin que sea necesario instalar controladores especiales para la instalación: unos segundos después de enchufar, el sistema operativo reconocerá los dispositivos y aparece el siguiente mensaje:



El audiómetro Piccolo puede controlarse desde un ordenador usando el software Inventis Maestro: para más detalles sobre el uso y las características del software Maestro, y para los requisitos de sistema mínimos, consulte el Manual del usuario de *Maestro.*

CAPÍTULO 3
Mantenimiento

El audiómetro Piccolo no requiere ningún mantenimiento periódico especial más allá de la calibración y la limpieza normales, ambas descritas en el presente capítulo.
El rendimiento y la seguridad del instrumento se mantendrá si se respetan las recomendaciones para el cuidado y mantenimiento que se incluyen en este capítulo
El dispositivo debe apagarse y desconectarse de la red antes de iniciar cualquier operación de limpieza.

La inspección y reparación de componentes internos deben ser realizadas únicamente por técnicos autorizados por INVENTIS S.r.l..

Los transductores se fabrican utilizando diafragmas superfrágiles que se pueden dañar si se golpean. Manipúlelos con cuidado durante las operaciones de mantenimiento.

INSPECCIONES PERIÓDICAS

El procedimiento que se describe en este epígrafe se debe realizar cuando se utilice el instrumento por primera vez cada día.

Las pruebas deben realizarse con el audiómetro en la posición de instalación.

- Antes de encender el instrumento, compruebe que no hay signos de daños visibles en ninguna parte del dispositivo, incluyendo las piezas que se pueden separar y la alimentación exterior; compruebe dos veces la integridad visual del aislamiento del cable de red y los conectores y verifique que no están expuestos a ningún tipo de carga mecánica que pueda implicar un daño; compruebe que todas las piezas y cables se han conectado adecuadamente
- Compruebe subjetivamente que la salida de conducción aérea y la de conducción ósea sea igual en ambos canales y todas las frecuencias, por ejemplo, generando un estímulo a 10 o 15 dB, suficiente para oír. La persona que realice esta comprobación debe tener una buena audición

- Compruebe al nivel de 60 dB en AC y 40 dB en BC que no haya ninguna distorsión, ruido o señales parasíticas en ninguna de las frecuencias
- Compruebe que el interruptor y los indicadores funcionan correctamente
- Compruebe las entradas de audiometría vocal realizando una prueba vocal con cada entrada vocal
- Compruebe la tensión de la diadema de los cascos y del vibrador óseo
- Compruebe la comunicación con el paciente

Si cualquier parte del transductor funciona mal, consulte el Capítulo "Resolución de problemas".

Compruebe siempre que no ha transcurrido el intervalo de calibración: el vencimiento del intervalo se indica en la parte superior derecha de la pantalla de Maestro.

La calibración solo se debe confiar a técnicos autorizados por INVENTIS S.r.l.. La operación se debe realizar como mínimo una vez cada 12 meses y siempre que se sustituya un transductor.

MANTENIMIENTO DE LOS TRANSDUCTORES

No utilice líquidos ni aerosoles para limpiar el audiómetro.

No deje que se acumule polvo en los transductores. Además:

- Las almohadillas de los auriculares están fabricadas con material biocompatible, pero no son estériles: para evitar que se propaguen infecciones y garantizar la biocompatibilidad del material, si los auriculares deben ser utilizados por un nuevo paciente, las almohadillas deben limpiarse con:
    - Para las almohadillas DD45/TDH-39, toallitas con alcohol desnaturalizado o un paño de microfibra empapado en alcohol desnaturalizado;
    - Para todas las otras almohadillas: Desinfectante hipoalergénico, según las instrucciones del fabricante.
- Los moldes de la sonda de inserción se han diseñado para ser introducidos en el canal del oído del paciente. Se han fabricado con

material biocompatible y desechable: usar solo una vez y eliminar de acuerdo con los reglamentos sanitarios y de seguridad actuales

Los moldes de los auriculares de inserción no son estériles. El uso de moldes no esterilizados puede provocar infecciones de oído.

El vibrador óseo y las almohadillas de los altavoces pueden limpiarse repetidamente como se describe en el párrafo «Mantenimiento de los transductores». En caso de mal funcionamiento después de una operación de limpieza, póngase en contacto con un técnico de servicio Inventis.

Dado que el vibrador óseo y las almohadillas de los altavoces pueden limpiarse repetidamente, compruebe siempre que se mantienen las características y la integridad de estos. Para ello, basta con realizar todas las pruebas descritas en el párrafo «Comprobaciones periódicas». En cuanto se detecte un fallo, póngase en contacto con un técnico de servicio Inventis para comprobar si es necesario sustituir el transductor.

Para evitar dañar los auriculares DD45/TDH39, no los empuje contra una superficie recta plana, ya que esto crea el vacío y puede dañar el transductor (efecto de la copa de succión).

LIMPIEZA DEL INSTRUMENTO

Para evitar la acumulación de polvo en el instrumento, ponga siempre la tapa de protección cuando no se use el impedanciómetro. Asimismo, asegúrese de que se limpia de manera regular la recogida de polvo situada debajo del instrumento.

Todas las partes no mencionadas de manera específica en la anterior sección puede limpiarse con un paño suave sin pelusa humedecido con una solución de agua y detergente suave; en caso de esterilización, limpie el paño con peróxido de hidrógeno con una concentración del 3%. El dispositivo permite que se realicen múltiples operaciones de limpieza sin que se reduzca la seguridad básica o el rendimiento; compruebe siempre que se mantienen las características y la integridad del dispositivo. Para ello, basta con realizar todas las pruebas descritas en el párrafo «Comprobaciones periódicas». En cuanto se detecte un fallo, póngase en contacto con un técnico de servicio Inventis para comprobar si es necesario sustituir alguna de las partes.

PARTES SUSTITUIBLES

Los transductores y las partes extraíbles pueden desconectarse del dispositivo. Si se genera un fallo en uno de estos dispositivos, el audiómetro debe apagarse y aislarse de la alimentación, y entonces desconectar el elemento defectuoso del dispositivo.

Todas las piezas del audiómetro se han diseñado específicamente para usarse en este dispositivo. Solo los accesorios suministrados por Inventis se deben conectar al audiómetro.

REPARACIONES Y ASISTENCIA TÉCNICA

Antes de ponerse en contacto con el departamento de reparaciones, asegúrese de haber intentado todas las soluciones posibles indicadas en el Capítulo *"Resolución de problemas"*.

Deben limpiarse y esterilizarse todas las piezas que deban devolverse al fabricante para la reparación y sustitución. Los transductores deben sellarse en una bolsa transparente.

Importante: Si el instrumento tuviera que enviarse al departamento de reparaciones Inventis o devolverse al distribuidor, asegúrese de que se usa el embalaje original, junto con todas piezas extraíbles y los transductores.

CAPÍTULO 4
Resolución de problemas

Problema	Posible causa	Solución
Un transductor no emite señal	El transductor no está conectado a la salida correcta	Conecte el transductor a la salida correcta
	Transductor dañado	Póngase en contacto con el vendedor o proveedor de servicios
Sin señal del botón de respuesta del paciente cuando se pulsa	Conexión equivocada	Conecte el botón de respuesta del paciente en la toma correcta
	Botón de respuesta del paciente dañado	Póngase en contacto con el vendedor o proveedor de servicios
No puede establecerse conexión entre ordenador e audiómetro	Problemas con la conexión USB	Compruebe la conexión USB entre el dispositivo y ordenador
	Cable USB dañado	Cambie el cable USB (cable estándar USB A/B)
Resultados del examen inesperados	Calibración caducada	Realización de la calibración del audiómetro
	Tipo equivocado de transductor AC seleccionado (auriculares o micrófonos)	Modificar la selección del transductor AC actual, desde el software o aplicación Maestro

Problema	Posible causa	Solución
No se puede acceder a la prueba	Prueba opcional no habilitada	Póngase en contacto con el servicio técnico para obtener la licencia, comunicando el número de serie del dispositivo

Si el audiómetro se usa junto a una cabina insonorizada, compruebe que tanto las conexiones dentro de la cabina como aquellas entre la cabina y el instrumento son correctas y están bien sujetas.

Annex A

Technical Specifications

APPLICABLE STANDARDS	
Performance	Piccolo Basic IEC 60645-1 / ANSI S3.6 type 4 Piccolo Plus IEC 60645-1 / ANSI S3.6 type 3 Piccolo Speech IEC 60645-1 / ANSI S3.6 type 3B
Calibration	AC: ISO 389-1, ISO 389-2 BC: ISO 389-3
Electrical safety	IEC 60601-1 Class I, Type B
Electromagnetic compatibility	IEC 60601-1-2
Enclosures	IEC 60601-1 IP20
Operation mode	Continuous

CE CERTIFICATE	
MDR 2017/745/EU Classification	Class IIa
Classification rule (Annex VIII, 2017/745)	10
Notified body	TÜV SÜD Product Service GmbH Ridlerstrasse 65 D-80339 Műnchen, Germany
Notified body number	0123

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

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 device powered by mains power adapter. In case of device 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 device powered by mains power adapter. In case of device 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 device powered by mains power adapter. In case of device 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	•	•	•

AUDIOMETER CONTROL	
Required Software	Inventis Maestro
Communication protocol	USB 1.1
PC communication requirements	USB 2.0 port minimum

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.

Annex B

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 such use is necessary, this instrument and the other equipment should be observed to verify that they are operating normally.

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 mains power adapter
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 2m shielded signal cable

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 does not have any ESSENTIAL PERFORMANCE as per the IEC 60601 1 standard.

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.

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">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.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment-guidance</th></tr>
<tr><td>RF emissions
CISPR11</td><td>Group 1</td><td>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.</td></tr>
<tr><td>RF emissions
CISPR11</td><td>Class B</td><td rowspan="3">Piccolo is suitable for use in professional healthcare facility environment and directly connected to the public low-voltage power supply network.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations / flickers emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

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 on power supply input lines IEC 61000-4-11	< 5% U_T (2) (> 95% dip in U_T) for 0,5 cycle. 40% U_T (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.	< 5% U_T (2) (> 95% dip in U_T) for 0,5 cycle. 40% U_T (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.	Mains power quality should be that of a professional healthcare facility environment. If the 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.			

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">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.</td></tr>
<tr><th>Immunity Test</th><th>IEC 60601 Test Level</th><th>Compliance Level</th><th>Electromagnetic environment – Guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
0.15 – 80 MHz

6 Vrms
in ISM bands between
0.15 - 80 MHz</td><td>3 Vrms
0.15 – 80 MHz

6 Vrms
in ISM bands between
0.15 - 80 MHz</td><td rowspan="5">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(1), should be less than the compliance level in each frequency range.(2) Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radieted RF
IEC 61000-4-3</td><td>3 V/m

80 Mhz - 2,7 Ghz</td><td>3 V/m

80 Mhz to 2,7 Ghz</td></tr>
<tr><td rowspan="3">Radiated RF

(from RF Wireless communication equipment)

IEC 61000-4-3</td><td>9 V/m

704-787 MHz
5100 – 5800 MHz</td><td>9 V/m

704-787 MHz
5100 – 5800 MHz</td></tr>
<tr><td>27 V/m

380 - 390 Mhz</td><td>27 V/m

380 - 390 Mhz</td></tr>
<tr><td>28 V/m

430 - 470 Mhz
800 - 960 Mhz
1700 - 1990 Mhz
2400 - 2570 Mhz</td><td>28 V/m

430 - 470 Mhz
800 - 960 Mhz
1700 - 1990 Mhz
2400 - 2570 Mhz</td></tr>
<tr><td>Proximity Fields

IEC 61000-4-39</td><td>8A/m
30KHz CW

65 A/m
134.2KHz
Pulse Mod 2.1KHz

7.5 A/m
13.56MHz
Pulse Mod 50KHz</td><td>8A/m
30KHz CW

65 A/m
134.2KHz
Pulse Mod 2.1KHz

7.5 A/m
13.56MHz
Pulse Mod 50KHz</td></tr>
<tr><td colspan="4">Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">Note:
(1) 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 Triangle is used in exceeds the applicable RF compliance level above, Triangle should be observed to verify its normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Triangle.
(2) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

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 transducers exceeding 80dBHL; a lock or reboot of the device is acceptable

IT

EN

PORTABLE AUDIOMETER

PICCOLO

FR

MULTILANGUAGE USER MANUAL

DE

Document title: AU1P-Piccolo User Manual IT-EN-FR-DE-ES
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ES

FR

PICCOLO

AUDIOMETRE PORTABLE

MANUEL UTILISATEUR

Veuillez lire très attentivement ce manuel avant d'utiliser l'appareil. Veuillez porter une attention particulière au chapitre 1 (« Sécurité : avertissements et informations ») et au chapitre 2 (« Installation »).

Les inspections et réparations internes ne doivent être effectuées que par du personnel autorisé.

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Sommaire

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Avant-propos

Nous vous remercions d'avoir acheté un appareil d'audiologie Inventis.

Avantageusement portable et léger, l'audiomètre Piccolo est un appareil portable puissant et polyvalent, idéal pour les professionnels en déplacement.

La société Inventis a toujours considéré que l'utilisation de ses appareils, conjointement à des ordinateurs, était un facteur d'importance capitale. En installant la suite logicielle Maestro, disponible avec ou sans base de données propriétaire ou en tant que module Noah, tout appareil d'audiologie Inventis peut être branché à un ordinateur, et tous les examens effectués sont ensuite archivés dans la propre base de données de l'utilisateur.

N'oubliez pas non plus qu'Inventis a développé une gamme complète d'appareils d'audiologie : en plus des audiomètres, la gamme de produits de la société comprend une série d'impédancemètres, des dispositifs d'adaptation et des prothèses auditives REM et HIT, un otoscope vidéo sans fil et bien plus encore.

Pour plus d'informations et pour signaler tout problème de quelque nature que ce soit, contactez l'entreprise à l'adresse suivante :

INVENTIS S.r.l.
Corso Stati Uniti, 1/3
35127 Padova, Italia
Tél. : 0039 049.8962844 – Fax : 049,8966343
www.Inventis.it info@Inventis.it

CHAPITRE 1
Sécurité : avertissements et informations

MANUEL DE L'OPERATEUR

Veuillez lire ce manuel dans son intégralité, afin que toutes les fonctionnalités offertes par l'instrument puissent être utilisées au mieux. En particulier, veillez à lire ce chapitre dans son intégralité, car il contient des informations et des avertissements qui sont d'une importance fondamentale pour garantir une utilisation sûre et correcte de l'appareil.
Le symbole d'avertissement de sécurité illustré ci-dessous est utilisé dans ce manuel pour attirer l'attention du lecteur sur des informations particulièrement importantes en matière de sécurité et pour éviter toute utilisation incorrecte.

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RESPONSABILITES DE L'OPERATEUR

Le fonctionnement efficace et fiable de l'audiomètre Piccolo est garanti uniquement s'il est utilisé conformément aux instructions et procédures fournies dans ce manuel.
Si l'instrument présente un dysfonctionnement ou nécessite une réparation, débranchez-le de l'alimentation électrique et ne l'utilisez plus jusqu'à ce que les réparations et l'entretien nécessaires aient été effectués. Les pièces défectueuses et en mauvais état de fonctionnement doivent être remplacées uniquement par des pièces de rechange originales fournies par INVENTIS S.r.l.. Toutes les réparations doivent être effectuées exclusivement par Inventis ou par du personnel autorisé par Inventis.
Aucune pièce de l'appareil ne doit être modifiée ou remplacée sans l'autorisation écrite préalable d'Inventis.
Les utilisateurs sont entièrement responsables des dysfonctionnements causés par une utilisation incorrecte, ou par un entretien ou une réparation effectuée par toute partie autre que INVENTIS S.r.l. ou un Centre

d'Assistance agréé. INVENTIS S.r.l. et ses Centres d'Assistance ne répondront des performances et de la fiabilité de l'instrument que si :

1. tous les branchements, réglages, modifications et réparations sont effectués exclusivement par du personnel autorisé par Inventis ;
2. l'alimentation électrique et les connexions à la terre du système sont conformes aux normes applicables aux appareils électromédicaux.

UTILISATION PREVUE

Le dispositif médical Piccolo est un audiomètre. Un audiomètre est un appareil qui aide l'opérateur à définir la sensibilité auditive du patient en générant et en délivrant au patient des stimuli sonores de différents types et de différentes intensités à des fins de diagnostic.

INDICATION D'UTILISATION ET UTILISATEURS FINAUX

Piccolo est destiné à être utilisé par les professionnels de santé O.R.L. dans les hôpitaux, les cliniques O.R.L. et les cabinets d'audiologie pour effectuer des évaluations auditives et aider au diagnostic d'éventuels troubles otologiques. L'utilisation de l'appareil n'est pas limitée à une population de patients ; veillez toujours à effectuer une otoscopie avant d'utiliser l'appareil. Ces tests doivent être effectués dans un environnement calme pour éviter les artéfacts.

CONDITIONS MEDICALES

Conditions d'altération de la sensibilité du système auditif ou toute condition dans laquelle on pense que le système auditif joue un rôle dans le diagnostic.

PRECAUTIONS A PRENDRE

Tout incident grave survenu en relation avec le dispositif doit être signalé au fabricant et à l'autorité compétente de l'État membre dans lequel l'utilisateur et/ou le patient est établi.

Pour garantir une utilisation correcte et sûre de l'audiomètre, les précautions suivantes doivent être observées.

Installation et précautions générales

Assurez-vous que les conditions ambiantes requises sont remplies pendant le transport, le stockage et le fonctionnement :

Opération	*Température : entre 15 et 35°C* *Humidité relative : entre 30 et 90 % (sans condensation)* *Pression : entre 700 et 1060 hPa*
Transport et stockage	*Température : entre -10° et 50°C* *Humidité relative : max. 90 % sans condensation* *Pression : entre 500 et 1060 hPa*
Temps de mise en route	*1 minute*

L'audiomètre Piccolo ne sera pas protégé s'il est exposé, pendant son utilisation, à des gaz anesthésiques inflammables ou à des produits similaires. Risque d'explosion.

Évitez d'installer et d'utiliser l'audiomètre Piccolo à proximité de sources de champs électromagnétiques puissants, dans la mesure où ceux-ci pourraient interférer avec le fonctionnement de l'appareil.

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Utilisez uniquement les pièces détachables d'origine fournies par INVENTIS S.r.l., sauf instructions contraire.

Utilisez uniquement des adaptateurs de courant destinés aux équipements médicaux, certifiés selon la norme IEC 60601-1, ayant les spécifications suivantes :

Unité principale : 6 V, 1,67 A c.c.
Adaptateur externe : SL POWER MENB1010A0603F02
100-240 Vca 50/60 Hz 0,9-0,34 A (inclus) répondant à la norme IEC 60601-1

L'audiomètre Piccolo est un dispositif médical. Tout autre appareil externe auquel il est connecté (tel qu'un ordinateur ou un lecteur de CD) dans la « zone du patient » telle que définie dans la norme IEC 60601-1) doit également être un dispositif médical, ou protégé par un transformateur d'isolement, afin de garantir que la combinaison complète (ordinateur ou dispositif externe + audiomètre) est conforme à la norme IEC 60601-1.

Piccolo peut être utilisé avec une cabine insonorisée pour effectuer des tests dans des conditions acoustiques optimales. Avant de le brancher à une cabine insonorisée, vérifiez que les

prises sont compatibles avec les spécifications prescrites pour chaque connecteur.

Piccolo nécessite des précautions particulières concernant la CEM et doit être installé et mis en service conformément aux informations sur la CEM fournies à la fin de ce manuel.

L'utilisation d'équipements de communication RF portables et mobiles peut affecter le bon fonctionnement de l'appareil Piccolo. Reportez-vous aux informations sur la CEM à la fin de ce manuel.

Le câble de l'adaptateur d'alimentation et le câble USB sont considérés comme des moyens de déconnecter l'appareil du réseau électrique.

Ne placez pas l'appareil de manière à ce qu'il soit difficile de le débrancher du réseau électrique.

Étalonnage

L'étalonnage doit être effectué au moins une fois tous les 12 mois, et à chaque remplacement d'un transducteur.

L'étalonnage de l'audiomètre n'est valable que pour les transducteurs fournis avec l'appareil. En cas de remplacement d'un transducteur, l'audiomètre doit être à nouveau étalonné.

L'étalonnage de l'audiomètre est valable pour les transducteurs fournis avec l'audiomètre, s'ils sont connectés directement à l'instrument, sans interposition de rallonges et sans passage des connecteurs au panneau (comme cela se produit habituellement dans les installations de cabines insonorisées). Si les transducteurs ne sont pas connectés directement à l'audiomètre, une nouvelle procédure d'étalonnage sera nécessaire avant d'utiliser l'instrument.

Dans chaque fenêtre de test, lorsque vous sélectionnez un transducteur non calibré, l'arrière-plan de la zone de sortie (output) s'affiche en rouge. De plus, vous ne pourrez pas envoyer de stimulus à travers les transducteurs non calibrés.

Prenez note de l'intervalle d'étalonnage spécifié pour l'audiomètre. L'utilisation de l'instrument au-delà de la date d'expiration de l'étalonnage peut conduire à des diagnostics peu fiables.

Hygiène

Les embouts des écouteurs intra-auriculaires sont jetables ; n'utilisez pas le même embout pour différents patients. Jetez les embouts après usage.

Désinfectez les coussinets du casque entre un patient et le suivant, en suivant la procédure décrite au CHAPITRE 3 « Entretien ».

Utilisation

L'audiomètre peut générer des sons d'une intensité potentiellement dommageable pour le patient. Prenez soin de régler correctement l'intensité du son avant d'effectuer les examens.

Lorsque vous effectuez une audiométrie à l'aide d'écouteurs intra-auriculaires, n'insérez pas ou n'essayez pas d'effectuer des mesures sans que l'embout en mousse approprié soit en place.

Le maintien de l'intensité précédente du stimulus lors du changement de fréquence, de transducteur ou de côté de stimulation peut entraîner la présentation de signaux potentiellement dangereux au patient.

Pour présenter un signal de stimulus plus fort que 100 dB HL, l'opérateur doit d'abord appuyer sur le bouton « dB PLUS ÉLEVÉ », qui n'est actif que lorsque l'intensité du stimulus atteint 100 dB HL.

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MISE AU REBUT

Comme tous les appareils électroniques, votre audiomètre contient de très faibles quantités de certaines substances dangereuses telles que le cadmium ou le mercure. Si ces substances peuvent entrer dans le cycle normal d'élimination des déchets sans traitement préalable approprié, elles peuvent causer des dommages à l'environnement et à la santé. Toutes les pièces de l'audiomètre doivent donc être éliminées séparément.
À la fin de sa vie, amenez (ou faites amener) l'instrument désaffecté à une installation publique de mise au rebut et de recyclage des déchets, ou renvoyez-le au revendeur contre l'achat d'un nouvel instrument équivalent.
La collecte sélective des déchets et les opérations ultérieures de traitement, de recyclage et d'élimination facilitent la fabrication de nouveaux appareils à partir de matériaux recyclés, limitant ainsi tout impact négatif sur

l'environnement et la santé publique qui pourrait autrement découler d'une élimination inappropriée.

CONFORMITE

L'audiomètre Piccolo est un dispositif médical de classe IIa, conformément à l'annexe VIII du règlement sur les dispositifs médicaux (MDR) 2017/745/EU. Le système de management de la qualité d'Inventis a été certifié par le principal organisme d'évaluation TÜV comme étant conforme à la norme ISO 13485.

SYMBOLES SUR LES ETIQUETTES

Nom et adresse du fabricant.

Attention : l'utilisation de cet appareil nécessite certaines précautions.
Pour garantir une utilisation sûre, consultez la documentation jointe.

Ce symbole signifie que ce produit est couvert par la directive 2012/19/EU relative aux déchets d'équipements électriques et électroniques (DEEE). Il est demandé de ne pas jeter ce produit comme un déchet municipal non trié, mais de le collecter séparément.

Se référer au manuel d'instructions pour l'utilisation

Dispositif avec des parties appliquées de type B (IEC 60601-1).

Alimentation en DC

Le produit est conforme au règlement de la Communauté européenne sur les dispositifs médicaux (MDR) 2017/745/EU. Dispositif de classe IIa ; numéro de l'organisme notifié : 0123 (TÜV SÜD Product Service GmbH).

Dispositif médical

Rx only

Avertissement : La loi fédérale restreint la vente de ce dispositif à un praticien de santé agréé ou sur son ordre.

IP20	*Code IP (Indice de Protection) : ce dispositif est protégé contre la pénétration d'objets de taille > 12,5 mm, mais pas contre les liquides.*
REF	*Numéro de catalogue*
COMPATIBLE TRANSDUCERS	*Section répertoriant les transducteurs compatibles*
SN	*Numéro de série du dispositif, composé de 13 caractères alphanumériques indiquant le modèle, l'année de fabrication et le numéro de série. En particulier, le numéro comprend les segments suivants :* - *les 5 premiers caractères : Code produit Inventis* - *caractères 6 et 7 : année de fabrication (exemple : « 12 » correspond à 2012)* - *caractères 8... 13 : numéro d'incrémentation*

Code UDI

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CHAPITRE 2
Installation

Bien que l'installation d'un audiomètre Piccolo soit une procédure relativement simple, elle doit être confiée à une personne ayant les compétences requises. Si l'installation n'est pas effectuée correctement, le système pourrait présenter des problèmes de sécurité lors de son utilisation. Ce chapitre décrit la procédure d'installation du système.

Conservez les matériaux d'emballage, au cas où l'audiomètre devrait être envoyé au revendeur ou à Inventis pour une raison quelconque.

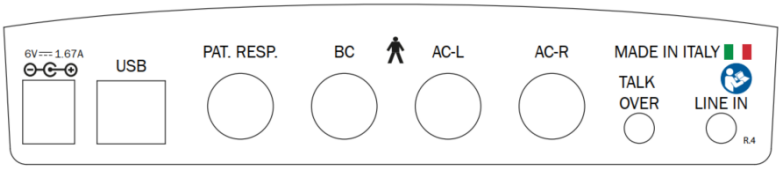
PRECAUTIONS A PRENDRE

Comme tout autre appareil électrique ou électronique, l'audiomètre Piccolo émet des ondes électromagnétiques. Même si ses émissions sont dans les limites des normes, d'autres appareils électroniques proches de l'audiomètre peuvent être affectés, s'ils sont particulièrement sensibles aux interférences électromagnétiques.
Si cela se produit, vérifiez simplement en éteignant et en rallumant l'audiomètre et essayez d'éliminer l'interférence en utilisant une ou plusieurs des solutions suivantes :

- modifier l'orientation et/ou la position de l'appareil affecté par l'interférence ;
- éloigner l'appareil affecté de l'audiomètre ;
- brancher l'appareil affecté dans une prise de courant sur un circuit autre que celui auquel l'audiomètre est branché ;
- consulter le fabricant ou le centre d'assistance pour obtenir l'assistance désirée.

CONNEXIONS

Tous les points de connexion des pièces détachées sont situés sur le panneau arrière. Cette section concerne l'audiomètre Piccolo Speech. Le Piccolo Plus ne dispose pas d'un connecteur LINE IN pour une source sonore externe. Le modèle Basic ne dispose pas non plus d'un connecteur BC (pour un vibrateur à conduction osseuse).



Branchez tous les transducteurs et les pièces détachables dans leurs prises respectives comme indiqué dans le tableau suivant :

Connecteur	Pièce détachable
6V⎓1.67A	Alimentation électrique. Lorsque le Piccolo est raccordé au port USB d'un ordinateur, l'alimentation électrique n'est pas nécessaire.
USB	Port USB pour la connexion à l'ordinateur
PAT. RESP.	Bouton de réponse du patient
BC	Vibrateur à conduction osseuse
AC-L	Écouteur gauche/écouteur intra-auriculaire
AC-R	Écouteur droit/écouteur intra-auriculaire
TALK OVER	Microphone de l'opérateur
LINE IN	Ligne externe pour l'audiométrie vocale avec source audio externe

Utilisez uniquement des adaptateurs de courant destinés aux équipements médicaux, certifiés selon la norme IEC 60601-1.

Assurez-vous que l'alimentation électrique et les mises à la terre sont conformes aux normes applicables aux appareils électromédicaux. Risque de choc électrique

Si l'audiomètre Piccolo est alimenté par un câble USB, les valeurs maximales (en AC et BC) sont inférieures de 10 dB aux valeurs nominales.

La LED verte près du ⏻ symbole indique que l'audiomètre est alimenté soit par l'adaptateur alimenté par le secteur, soit par le câble USB de l'ordinateur.

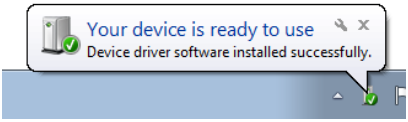
La LED près du symbole indique l'état des communications entre l'audiomètre et l'ordinateur : cette LED s'allume en vert si l'audiomètre communique avec un PC.

BRANCHEMENT A L'ORDINATEUR

Pour permettre la commande à partir d'un ordinateur, l'audiomètre Piccolo doit être branché à l'un des ports USB de l'ordinateur à l'aide du câble fourni (un câble USB A/B standard).

Utilisez le câble fourni pour brancher l'audiomètre Piccolo à l'un des ports USB de l'ordinateur

La connexion est de type « prête à l'emploi », aucun pilote spécial n'est nécessaire pour l'installation : quelques secondes après le branchement, le système d'exploitation reconnaît les appareils et le message suivant apparaît :



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l'audiomètre Piccolo peut être commandé à partir d'un ordinateur à l'aide du logiciel Inventis Maestro : pour plus de détails sur l'utilisation et les fonctionnalités du logiciel Maestro, et pour connaître la configuration minimale requise, reportez-vous au Manuel de l'utilisateur de Maestro.

CHAPITRE 3
Entretien

L'audiomètre Piccolo ne nécessite aucun entretien périodique particulier autre que l'étalonnage, les vérifications et le nettoyage normal, qui sont tous décrits dans ce chapitre.
Les performances et la sécurité de l'instrument seront maintenues si les recommandations d'entretien et de maintenance données dans ce chapitre sont respectées.
L'instrument doit être éteint et débrancher de l'alimentation électrique avant de commencer toute opération de nettoyage.

L'inspection et l'entretien des composants internes doivent être confiés exclusivement à des techniciens agréés par INVENTIS S.r.l..

Les transducteurs sont fabriqués en utilisant des membranes ultra-fragiles qui pourraient être endommagées en cas de choc. Manipuler avec précaution lors des opérations d'entretien.

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CONTROLES PERIODIQUES

La procédure décrite dans cette rubrique doit être effectuée chaque jour lors de la première utilisation de l'instrument.

Les tests doivent être effectués avec l'audiomètre dans sa position d'installation.

- Avant d'allumer l'instrument, vérifiez qu'aucun signe de dommage n'est visible sur aucune partie du dispositif, y compris les pièces détachables et l'alimentation externe ; vérifiez deux fois visuellement l'intégrité de l'isolation du câble d'alimentation et des connecteurs, et vérifiez qu'ils ne sont exposés à aucun type de charge mécanique qui pourrait entraîner des dommages ; vérifiez que toutes les parties et les câbles sont correctement branchés
- Vérifier subjectivement que le rendement de la conduction aérienne et de la conduction osseuse est égal sur les deux canaux et sur toutes les fréquences, pour ce faire on applique 10 ou 15 dB, juste assez pour entendre. La personne qui effectue ce contrôle doit avoir une bonne audition

- Vérifiez à un niveau de 60 dB en AC et 40 dB en BC qu'il n'y a pas de distorsion, de bruit ou de signaux parasites dans aucune des fréquences
- Vérifiez que le bouton de réponse du patient et les indicateurs fonctionnent correctement
- Vérifiez les entrées d'audiométrie vocale en effectuant un test vocal avec chaque entrée vocale
- Vérifiez la tension du serre-tête du casque et du vibrateur à conduction osseuse.
- Vérifiez la communication avec le patient

En cas de dysfonctionnement d'une pièce ou d'un transducteur, consultez le Chapitre « Résolution des problèmes ».

Vérifiez toujours que l'intervalle d'étalonnage n'a pas expiré : l'expiration de l'intervalle est indiquée en haut à gauche du logiciel Maestro.

L'étalonnage doit être confié à des techniciens agréés par INVENTIS S.r.l.. L'opération doit être effectuée au moins une fois tous les 12 mois, et à chaque fois qu'un transducteur est remplacé.

ENTRETIEN DES TRANSDUCTEURS

N'utilisez pas de liquides ou de vaporisateurs pour nettoyer l'audiomètre.

Ne laissez pas la poussière s'accumuler sur les transducteurs. De plus :

- les coussinets du casque sont fabriqués dans un matériau biocompatible mais ne sont pas stériles : pour éviter la propagation d'infections et garantir la biocompatibilité du matériau, chaque fois que le casque doit être porté par un nouveau patient, les coussinets doivent être essuyés avec :
    - pour les coussinets DD45/TDH-39, une lingette d'alcool dénaturé ou de l'alcool dénaturé avec un chiffon microfibre ;
    - pour tous les autres coussinets : un désinfectant hypoallergénique, en suivant les instructions du fabricant.
- Les embouts des écouteurs intra-auriculaires sont destinés à être introduits dans le conduit auditif du patient. Ils sont fabriqués dans un matériau biocompatible et sont jetables : à n'utiliser qu'une seule fois et

à éliminer conformément aux réglementations en vigueur en matière de santé et de sécurité.

Les embouts des écouteurs intra-auriculaires ne sont pas stériles. L'utilisation d'écouteurs non stérilisés peut provoquer des infections de l'oreille.

Le vibrateur à conduction osseuse et les coussinets du casque peuvent être nettoyés à plusieurs reprises comme décrit dans le paragraphe « Entretien des transducteurs ». En cas de dysfonctionnement après une opération de nettoyage, contactez un technicien d'entretien d'Inventis.

Bien que le vibrateur à conduction osseuse et les coussinets du casque puissent être nettoyés à plusieurs reprises, vérifiez toujours que leurs caractéristiques et leur intégrité sont maintenues. Pour ce faire, il suffit d'effectuer les tests décrits dans le paragraphe « Contrôles périodiques ». Dès qu'une défaillance est constatée, contactez un technicien d'entretien d'Inventis pour vérifier si votre transducteur doit être remplacé.

Pour éviter d'endommager le casque DD45/TDH39, ne le poussez pas contre une surface plane et rectiligne car cela peut créer une dépression et endommager le transducteur (effet ventouse).

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NETTOYAGE DE L'INSTRUMENT

Pour éviter l'accumulation de poussière sur l'instrument, toujours mettre le couvercle de protection lorsque l'analyseur n'est pas utilisé. Veillez également à ce que la poussière accumulée sous l'instrument soit régulièrement nettoyée. Toutes les parties non mentionnées spécifiquement dans la section précédente peuvent être nettoyées à l'aide d'un chiffon doux non pelucheux humidifié avec une solution d'eau et de détergent doux ; en cas de désinfection, humidifiez le tissu avec du peroxyde d'hydrogène à une concentration de 3 %. Le dispositif peut être nettoyé plusieurs fois sans dégradation de la sécurité de base ou des performances ; toujours vérifier que les caractéristiques et l'intégrité du dispositif sont maintenues. Pour ce faire, il suffit d'effectuer les tests décrits dans le paragraphe « Contrôles périodiques ». Dès qu'une défaillance est constatée, contactez un technicien d'entretien d'Inventis pour vérifier si des pièces doivent être remplacées.

PIECES REMPLAÇABLES

Les transducteurs et les parties détachables peuvent être déconnectés de l'appareil. En cas de défaillance de l'un de ces dispositifs, l'audiomètre doit être mis hors tension et isolé de l'alimentation électrique, puis l'élément défectueux doit être débranché de l'appareil.

Tous les pièces détachables de l'audiomètre sont conçues spécifiquement pour être utilisées avec l'appareil. Seuls les pièces fournies par Inventis doivent être connectées à l'audiomètre.

REPARATIONS ET ASSISTANCE TECHNIQUE

Avant de contacter le département d'assistance, assurez-vous que toutes les solutions possibles figurant dans le Chapitre « *Résolution des problèmes* » ont été essayées.

Toutes les pièces renvoyées au fabricant pour réparation et entretien doivent être nettoyées et désinfectées. Les transducteurs doivent être scellés dans un sac transparent.

Important : si l'instrument doit être envoyé au département d'assistance d'Inventis ou retourné au revendeur, assurez-vous que l'emballage d'origine est utilisé et que toutes les pièces détachables et les transducteurs y sont inclus.

CHAPITRE 4
Résolutions des problèmes

Problème	Cause possible	Solution
Aucun signal provenant d'un transducteur	Le transducteur n'est pas branché à la bonne sortie	Brancher le transducteur à la bonne sortie
	Transducteur endommagé	Contactez votre revendeur ou votre fournisseur de services
Aucun signal du bouton de réponse du patient lorsqu'il est pressé	Branchement défectueux	Brancher le bouton de réponse du patient à la bonne prise
	Bouton de réponse du patient endommagé	Contactez votre revendeur ou votre fournisseur de services
La connexion entre le PC et l'audiomètre ne peut pas être établie	Problèmes de connexion USB	Vérifiez la connexion USB entre l'instrument et l'ordinateur
	Câble USB endommagé	Changez le câble USB (câble Standard USB A/B)
Résultats d'examen improbables	L'étalonnage a expiré	Effectuez l'étalonnage de l'audiomètre
	Mauvais type de transducteur AC sélectionné (casque ou écouteurs)	Modifiez la sélection du transducteur AC actuel, à partir du logiciel ou de l'App Maestro

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Problème	Cause possible	Solution
Vous ne pouvez pas accéder à un test	Le test optionnel n'est pas activé	Contactez votre service technique de référence pour obtenir la licence, en communiquant le numéro de série de l'appareil

Lorsque l'audiomètre est utilisé avec une cabine insonorisée, vérifiez que les branchements, à l'intérieur de la cabine et entre la cabine et l'instrument, sont corrects et sûrs.

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PORTABLE AUDIOMETER

PICCOLO

EL

MULTILANGUAGE USER MANUAL

Document title: AU1P-Piccolo User Manual BG-RO-EL
Code: AU1-MA303_C
Revision: Rev. 02
Date: 2025.03.07

EL

PICCOLO

ΦΟΡΗΤΟ ΑΚΟΟΜΕΤΡΟ

ΕΓΧΕΙΡΙΔΙΟ ΧΡΗΣΗΣ

Διαβάστε διεξοδικά το παρόν εγχειρίδιο πριν από τη χρήση της συσκευής. Δώστε ιδιαίτερη προσοχή στο κεφάλαιο 1 («Ασφάλεια: προειδοποιήσεις και πληροφορίες») και στο κεφάλαιο 2 («Εγκατάσταση»).

Οι επιθεωρήσεις στα εσωτερικά μέρη και οι επισκευές πρέπει να εκτελούνται μόνο από εξουσιοδοτημένο προσωπικό.

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Περιεχόμενα

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Πρόλογος

Ευχαριστούμε που αγοράσατε μια συσκευή ακοολογίας της Inventis.

Με πλεονεκτήματα ότι είναι φορητό και ελαφρύ, το ακοόμετρο Piccolo είναι μια ισχυρή και πολλαπλών χρήσεων φορητή συσκευή, ιδανική για επαγγελματίες που μετακινούνται.

Η εταιρεία Inventis ανέκαθεν θεωρούσε ότι είναι εξαιρετικά ουσιώδους σημασίας η χρήση των συσκευών της σε συνδυασμό με υπολογιστές. Με την εγκατάσταση της οικογένειας λογισμικού Maestro, που διατίθεται με ή χωρίς ιδιόκτητη βάση δεδομένων ή ως μονάδα Noah, κάθε συσκευή ακοολογίας Inventis μπορεί να συνδεθεί σε υπολογιστή και στη συνέχεια όλες οι εξετάσεις που εκτελούνται αρχειοθετούνται στη βάση δεδομένων του χρήστη.

Λάβετε επίσης υπόψη ότι η Inventis έχει αναπτύξει μια πλήρη σειρά συσκευών ακοολογίας: εκτός των ακοόμετρων, η σειρά προϊόντων της εταιρείας περιλαμβάνει διάφορους αναλυτές μέσου ωτός, τις συσκευές REM και HIT για την εφαρμογή βοηθημάτων ακοής, ασύρματο βίντεο ωτοσκόπιο και πολλά ακόμα.

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Για περισσότερες πληροφορίες και για να αναφέρετε τυχόν προβλήματα οποιουδήποτε είδους, επικοινωνήστε με την εταιρεία στα εξής στοιχεία:

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ΚΕΦΑΛΑΙΟ 1
Ασφάλεια: προειδοποιήσεις και πληροφορίες

ΕΓΧΕΙΡΙΔΙΟ ΛΕΙΤΟΥΡΓΙΑΣ

Βεβαιωθείτε ότι έχετε διαβάσει ολόκληρο το παρόν εγχειρίδιο, ώστε να μπορέσετε να αξιοποιήσετε πλήρως όλες τις δυνατότητες που παρέχει το όργανο. Ειδικότερα, βεβαιωθείτε ότι διαβάσατε ολόκληρο αυτό το κεφάλαιο, καθώς περιέχει πληροφορίες και προειδοποιήσεις θεμελιώδους σημασίας ώστε να εξασφαλιστεί η ασφάλεια και η σωστή χρήση της συσκευής.
Το προειδοποιητικό σύμβολο που απεικονίζεται παρακάτω, χρησιμοποιείται στο παρόν εγχειρίδιο για να επιστήσει στον αναγνώστη την προσοχή σε πληροφορίες ιδιαίτερης σημασίας όσον αφορά ζητήματα ασφάλειας, καθώς και για να αποφευχθεί η εσφαλμένη χρήση.

ΕΥΘΥΝΕΣ ΧΕΙΡΙΣΤΗ

Η αποδοτική και αξιόπιστη λειτουργία του ακοόμετρου Piccolo είναι εγγυημένη μόνο εφόσον το ακοόμετρο χρησιμοποιείται σύμφωνα με τις οδηγίες και τις διαδικασίες που περιγράφονται στο παρόν εγχειρίδιο.
Εάν παρουσιαστεί δυσλειτουργία στο όργανο ή αν απαιτείται επισκευή του οργάνου, αποσυνδέστε το όργανο από την πρίζα παροχής ηλεκτρικού ρεύματος και μην το ξαναχρησιμοποιήσετε έως ότου ολοκληρωθούν οι απαραίτητες επισκευές και εργασίες σέρβις. Τα ελαττωματικά και δυσλειτουργικά εξαρτήματα πρέπει να αντικαθίστανται μόνο με γνήσια ανταλλακτικά που παρέχει η INVENTIS S.r.l. Όλες οι επισκευές πρέπει να εκτελούνται αποκλειστικά από την Inventis ή από προσωπικό εξουσιοδοτημένο από την Inventis.
Τα εξαρτήματα της συσκευής δεν πρέπει να τροποποιούνται ή να αντικαθίστανται χωρίς την προηγούμενη γραπτή εξουσιοδότηση από την Inventis.
Οι χρήστες έχουν την αποκλειστική ευθύνη για δυσλειτουργίες που προκαλούνται από ακατάλληλη χρήση ή από συντήρηση ή επισκευές που εκτελέστηκαν από τρίτο μέρος και όχι από την INVENTIS S.r.l. ή από

εξουσιοδοτημένο κέντρο σέρβις. Η INVENTIS S.r.l. και τα κέντρα σέρβις της αναλαμβάνουν την ευθύνη για την απόδοση και την αξιοπιστία του εξοπλισμού μόνο αν:

1. όλες οι συνδέσεις, οι ρυθμίσεις, οι τροποποιήσεις και οι επισκευές εκτελούνται αποκλειστικά από προσωπικό εξουσιοδοτημένο από την Inventis,
2. η ηλεκτρική τροφοδοσία και οι συνδέσεις γείωσης του συστήματος συμμορφώνονται με τα ισχύοντα πρότυπα για τις ηλεκτροϊατρικές συσκευές.

ΠΡΟΒΛΕΠΟΜΕΝΗ ΧΡΗΣΗ

Το ιατροτεχνολογικό προϊόν Piccolo είναι ακοόμετρο. Ακοόμετρο είναι μια συσκευή που βοηθά τον χειριστή να προσδιορίσει την ακουστική ευαισθησία του ασθενούς δημιουργώντας και παρέχοντας στον ασθενή ηχητικά ερεθίσματα διαφορετικών ειδών και εντάσεων για διαγνωστικούς σκοπούς.

ΕΝΔΕΙΞΕΙΣ ΧΡΗΣΗΣ ΚΑΙ ΤΕΛΙΚΟΙ ΧΡΗΣΤΕΣ

Το Piccolo προορίζεται για χρήση από επαγγελματίες υγείας ΩΡΛ σε νοσοκομεία, κλινικές ΩΡΛ και ιατρεία ακοολογίας, στη διεξαγωγή αξιολογήσεων ακοής και την υποβοήθηση της διάγνωσης πιθανών ακοολογικών διαταραχών. Δεν υπάρχει περιορισμός στον πληθυσμό ασθενών όσον αφορά τη χρήση της συσκευής. Να διασφαλίζετε πάντα ότι διενεργείτε ωτοσκόπηση πριν από τη χρήση της συσκευής.
Οι εξετάσεις αυτές πρέπει να εκτελούνται σε ήσυχο περιβάλλον για την αποφυγή πλαστών αποτελεσμάτων.

ΚΑΤΑΣΤΑΣΕΙΣ ΥΓΕΙΑΣ

Παθήσεις διαταραχής της ευαισθησίας του συστήματος ακοής ή οποιαδήποτε πάθηση στην οποία θεωρείται ότι το σύστημα ακοής διαδραματίζει κάποιον ρόλο ως προς τη διάγνωση.

ΠΡΟΦΥΛΑΞΕΙΣ

Κάθε σοβαρό συμβάν το οποίο προκύπτει σε σχέση με τη συσκευή θα πρέπει να αναφέρεται στον κατασκευαστή και στην αρμόδια αρχή του κράτους μέλους στο οποίο διαμένει ο χρήστης ή/και ο ασθενής.

Προκειμένου να διασφαλιστεί η σωστή και ασφαλής χρήση του ακοόμετρου, θα πρέπει να τηρούνται οι ακόλουθες προφυλάξεις.

Προφυλάξεις εγκατάστασης και γενικές προφυλάξεις

Βεβαιωθείτε ότι πληρούνται οι απαιτούμενες συνθήκες περιβάλλοντος κατά τη μεταφορά, την αποθήκευση και τη λειτουργία:

Λειτουργία	*Θερμοκρασία: μεταξύ 15 °C (59 °F) και 35 °C (95 °F)* *Σχετική υγρασία: μεταξύ 30% και 90% (χωρίς συμπύκνωση)* *Πίεση: μεταξύ 700 hPa και 1.060 hPa*
Μεταφορά και αποθήκευση	*Θερμοκρασία: μεταξύ -10 °C (14 °F) και 50 °C (122 °F)* *Σχετική υγρασία: μέγ. 90% χωρίς συμπύκνωση* *Πίεση: μεταξύ 500 hPa και 1.060 hPa*
Χρόνος προθέρμανσης	*1 λεπτό*

Το ακοόμετρο Piccolo δεν διαθέτει προστασία σε περίπτωση που, κατά τη διάρκεια της χρήσης, εκτεθεί σε εύφλεκτα αναισθητικά αέρια ή παρόμοια προϊόντα. Κίνδυνος έκρηξης.

Αποφύγετε την εγκατάσταση και χρήση του ακοόμετρου Piccolo κοντά σε πηγές ισχυρών ηλεκτρομαγνητικών πεδίων, καθώς μπορεί να προκύψει παρεμβολή στη λειτουργία της συσκευής.

Χρησιμοποιείτε μόνο τα αυθεντικά αφαιρούμενα εξαρτήματα που παρέχονται από την INVENTIS S.r.l., εκτός εάν υπάρχει διαφορετική ρητή οδηγία.

EL

Χρησιμοποιείτε μόνο μετασχηματιστές που προορίζονται για ιατρικό εξοπλισμό και είναι πιστοποιημένοι σύμφωνα με το πρότυπο IEC 60601-1, με τις εξής προδιαγραφές:

Κύρια μονάδα: συνεχές ρεύμα 6 V, 1,67 A
Εξωτερικός μετασχηματιστής: SL POWER MENB1010A0603F02
100-240 Vac 50/60 Hz 0,9-0,34 A (συμπεριλαμβάνεται) που ανταποκρίνεται στο πρότυπο IEC 60601-1

Το ακοόμετρο Piccolo είναι ιατροτεχνολογικό προϊόν. Οποιαδήποτε άλλη εξωτερική συσκευή στην οποία συνδέεται (όπως υπολογιστής ή συσκευή αναπαραγωγής CD) εντός της «περιοχής ασθενούς» (όπως ορίζεται στο πρότυπο IEC 60601-1) πρέπει επίσης να είναι ιατροτεχνολογικό προϊόν ή πρέπει να προστατεύεται μέσω μετασχηματιστή απομόνωσης, ώστε να διασφαλιστεί ότι ο πλήρης συνδυασμός (υπολογιστής ή εξωτερική συσκευή + ακοόμετρο) συμμορφώνεται με το πρότυπο IEC 60601-1.

Το Piccolo μπορεί να χρησιμοποιηθεί σε συνδυασμό με ηχομονωτικό θάλαμο για τη διεξαγωγή εξετάσεων υπό τις βέλτιστες ακουστικές συνθήκες. Πριν από τη σύνδεσή του σε ηχομονωτικό θάλαμο, ελέγξτε ότι οι υποδοχές είναι συμβατές με τις προδιαγραφές που προβλέπονται για κάθε βύσμα.

Για το Piccolo απαιτούνται ειδικές προφυλάξεις όσον αφορά την EMC και η εγκατάστασή του, καθώς και η θέση του σε χρήση, πρέπει να εκτελούνται σύμφωνα με τις πληροφορίες περί EMC που παρέχονται στο τέλος του παρόντος εγχειριδίου.

Η χρήση φορητού και κινητού εξοπλισμού επικοινωνιών με RF μπορεί να επηρεάσει τη σωστή λειτουργία της συσκευής Piccolo. Ανατρέξτε στις πληροφορίες περί EMC που παρέχονται στο τέλος του παρόντος εγχειριδίου.

Το καλώδιο μετασχηματιστή και το καλώδιο USB θεωρούνται τα μέσα για την αποσύνδεση της συσκευής από την ηλεκτρική τροφοδοσία.

Μην τοποθετείτε τη συσκευή σε θέση στην οποία είναι δύσκολη η αποσύνδεσή της από την ηλεκτρική τροφοδοσία.

Βαθμονόμηση

Η βαθμονόμηση θα πρέπει να εκτελείται τουλάχιστον μία φορά κάθε 12 μήνες και σε κάθε αντικατάσταση μετατροπέα.

Η βαθμονόμηση του ακοόμετρου είναι έγκυρη μόνο για τους μετατροπείς που παρέχονται με τη συσκευή. Σε περίπτωση αντικατάστασης ενός μετατροπέα, το ακοόμετρο πρέπει να βαθμονομηθεί εκ νέου.

Η βαθμονόμηση του ακοόμετρου είναι έγκυρη για μετατροπείς που παρέχονται με το ακοόμετρο, εάν συνδέονται απευθείας με το όργανο, χωρίς την παρέμβαση καλωδίων επέκτασης και χωρίς διέλευση από υποδοχές στον πίνακα (όπως συμβαίνει συνήθως στις εγκαταστάσεις ηχομονωτικών θαλάμων). Εάν οι μετατροπείς δεν συνδέονται απευθείας στο ακοόμετρο, θα πρέπει να εκτελείται νέα διαδικασία βαθμονόμησης πριν από τη χρήση του οργάνου.

Σε κάθε παράθυρο εξέτασης, όταν επιλέξετε μη βαθμονομημένο μετατροπέα, το φόντο της περιοχής «output» θα εμφανίζεται με κόκκινο χρώμα. Επιπλέον, δεν θα είναι δυνατή η αποστολή ερεθισμάτων μέσω μη βαθμονομημένων μετατροπέων.

Δώστε προσοχή στο υποδεικνυόμενο διάστημα βαθμονόμησης του ακοόμετρου. Η χρήση του οργάνου μετά την ημερομηνία λήξης της βαθμονόμησης μπορεί να έχει ως αποτέλεσμα μη αξιόπιστες διαγνώσεις.

EL

Υγιεινή

Τα άκρα αυτιών των ένθετων ακουστικών είναι μίας χρήσης. Μη χρησιμοποιείτε το ίδιο άκρο αυτιού σε διαφορετικούς ασθενείς. Απορρίπτετε τα άκρα αυτιών μετά τη χρήση.

Απολυμαίνετε τα μαξιλαράκια των ακουστικών κεφαλής μεταξύ των ασθενών, ακολουθώντας τη διαδικασία που περιγράφεται στο ΚΕΦΑΛΑΙΟ 3 «Συντήρηση».

Χρήση

Το ακοόμετρο μπορεί να δημιουργήσει τόνους σε ένταση δυνητικά επιβλαβή για τον ασθενή. Προσέξτε ιδιαιτέρως ώστε να ρυθμίσετε την ένταση του τόνου σωστά πριν από κάθε εξέταση.

Όταν εκτελείτε ακοομέτρηση με τη χρήση βυσματοειδών ακουστικών, μην εισάγετε και σε καμία περίπτωση μην επιχειρείτε να εκτελέσετε μετρήσεις χωρίς να έχετε τοποθετήσει το κατάλληλο αφρώδες άκρο.

Η διατήρηση της προηγούμενης έντασης ερεθίσματος όταν αλλάζετε συχνότητα, μετατροπέα ή πλευρά διέγερσης μπορεί

δυνητικά να προκαλέσει επιβλαβή σήματα που μεταδίδονται στον ασθενή.

Για την αναπαραγωγή ενός σήματος διέγερσης ισχυρότερου από 100 dB HL, ο χειριστής πρέπει πρώτα να πατήσει το κουμπί «ΠΙΟ ΥΨΗΛΟ dB», το οποίο ενεργοποιείται μόνο όταν η ένταση του ερεθίσματος φτάνει τα 100 dB HL.

ΑΠΟΡΡΙΨΗ

Όπως όλες οι ηλεκτρονικές συσκευές, το ακοόμετρο σας περιέχει εξαιρετικά μικρές ποσότητες συγκεκριμένων επιβλαβών ουσιών, όπως κάδμιο ή υδράργυρος. Εάν επιτραπεί η εισαγωγή τέτοιων ουσιών στον κύκλο απόρριψης συνήθων απορριμμάτων, χωρίς την κατάλληλη προκαταρκτική επεξεργασία, οι ουσίες αυτές μπορεί να προκαλέσουν ζημιά στο περιβάλλον και την υγεία. Συνεπώς, όλα τα εξαρτήματα του ακοόμετρου πρέπει να απορρίπτονται χωριστά.
Στο τέλος του κύκλου ζωής του, μεταφέρετε (ή ζητήστε να μεταφερθεί) το όργανο εκτός χρήσης σε μια δημόσια εγκατάσταση διάθεσης και ανακύκλωσης απορριμμάτων ή επιστρέψτε το στον μεταπωλητή για να αγοράσετε ένα αντίστοιχο νέο όργανο.
Ο διαχωρισμός κατά την αποκομιδή των απορριμμάτων, καθώς και οι επακόλουθες διαδικασίες επεξεργασίας, ανακύκλωσης και απόρριψης, συμβάλλουν στην κατασκευή νέων συσκευών από ανακυκλωμένα υλικά, περιορίζοντας τις αρνητικές επιπτώσεις στο περιβάλλον και τη δημόσια υγεία, που διαφορετικά θα μπορούσαν να προκύψουν από την ακατάλληλη απόρριψη.

ΣΥΜΜΟΡΦΩΣΗ

Το ακοόμετρο Piccolo είναι ιατροτεχνολογικό προϊόν κατηγορίας IIa σύμφωνα με το παράρτημα VIII του κανονισμού για τα ιατροτεχνολογικά προϊόντα (MDR) 2017/745/ΕΕ.
Το σύστημα διαχείρισης ποιότητας της Inventis έχει πιστοποιηθεί από τον κύριο οργανισμό αξιολογήσεων TÜV ότι συμμορφώνεται με το πρότυπο ISO 13485.

ΣΥΜΒΟΛΑ ΣΤΙΣ ΕΤΙΚΕΤΕΣ

Όνομα και διεύθυνση του κατασκευαστή.

Προειδοποίηση: η χρήση αυτής της συσκευής απαιτεί ειδικές προφυλάξεις.
Για να διασφαλίσετε την ασφαλή χρήση, συμβουλευθείτε τα συνοδευτικά έγγραφα.

Το σύμβολο αυτό σημαίνει ότι το προϊόν καλύπτεται από την οδηγία για τα απόβλητα ηλεκτρικού και ηλεκτρονικού εξοπλισμού (ΑΗΗΕ) 2012/19/ΕΕ. Το προϊόν δεν πρέπει να απορρίπτεται ως αταξινόμητα αστικά απορρίμματα, αλλά να συλλέγεται χωριστά.

Ανατρέξτε στο εγχειρίδιο χρήσης για οδηγίες

Συσκευή με εφαρμοζόμενα μέρη τύπου B (IEC 60601-1).

Τροφοδοσία ρεύματος DC

Το προϊόν συμμορφώνεται με το κανονισμό της Ευρωπαϊκής Κοινότητας για τα ιατροτεχνολογικά προϊόντα (MDR) 2017/745/ΕΕ. Προϊόν κατηγορίας IIα, αριθμός κοινοποιημένου οργανισμού: 0123 (TÜV SÜD Product Service GmbH).

Ιατροτεχνολογικό προϊόν

Rx only

Προσοχή: Η ομοσπονδιακή νομοθεσία επιτρέπει την πώληση αυτής της συσκευής μόνο από ιατρό ή κατόπιν εντολής αδειοδοτημένου επαγγελματία υγείας.

IP20

Κωδικός IP (Προστασία από εισχώρηση): η συσκευή αυτή προστατεύεται από την εισχώρηση αντικειμένων μεγέθους > 12,5 mm, ενώ δεν προστατεύεται από την εισχώρηση υγρών.

REF

Αριθμός καταλόγου

COMPATIBLE TRANSDUCERS

Τμήμα στο οποίο παρατίθενται οι συμβατοί μετατροπείς

SN

Ο αριθμός σειράς της συσκευής αποτελείται από 13 αλφαριθμητικούς χαρακτήρες που υποδεικνύουν το μοντέλο, το έτος κατασκευής και τον αριθμό σειράς. Συγκεκριμένα, ο αριθμός αποτελείται από τα εξής τμήματα:

- *πρώτοι 5 χαρακτήρες: κωδικός προϊόντος Inventis*
- *χαρακτήρες 6 και 7: έτος κατασκευής (π.χ. το «12» σημαίνει 2012)*
- *χαρακτήρες 8… 13: αύξων αριθμός*

Κωδικός UDI

ΚΕΦΑΛΑΙΟ 2
Εγκατάσταση

Ενώ η εγκατάσταση ενός ακοόμετρου Piccolo είναι μια σχετικά απλή διαδικασία, θα πρέπει να ανατεθεί σε άτομο με τα απαιτούμενα προσόντα. Εάν η εγκατάσταση δεν πραγματοποιηθεί σωστά, το σύστημα μπορεί, κατά τη χρήση, να εμφανίσει προβλήματα ασφαλείας.
Το κεφάλαιο αυτό περιγράφει τη διαδικασία εγκατάστασης του συστήματος.

Διατηρήστε τα υλικά συσκευασίας, σε περίπτωση που, για οποιονδήποτε λόγο, το ακοόμετρο πρέπει να αποσταλεί στον αντιπρόσωπο ή στην Inventis.

ΠΡΟΦΥΛΑΞΕΙΣ

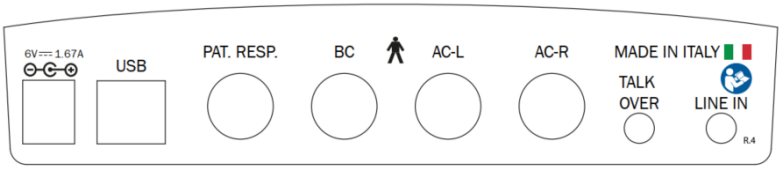
Όπως κάθε άλλη ηλεκτρική ή ηλεκτρονική συσκευή, το ακοόμετρο Piccolo εκπέμπει ηλεκτρομαγνητικά κύματα. Παρόλο που οι εκπομπές του κυμαίνονται εντός των ορίων που ορίζονται στα πρότυπα, άλλες ηλεκτρονικές συσκευές σε κοντινή απόσταση με το ακοόμετρο ενδέχεται να επηρεαστούν, αν είναι ιδιαιτέρως ευαίσθητες στις ηλεκτρομαγνητικές παρεμβολές.
Εάν συμβεί κάτι τέτοιο, ελέγξτε απενεργοποιώντας και ενεργοποιώντας το ακοόμετρο και προσπαθήστε να εξαλείψετε τις παρεμβολές χρησιμοποιώντας μία ή περισσότερες από τις παρακάτω λύσεις:

- αλλαγή του προσανατολισμού ή/και της θέσης της συσκευής που επηρεάζεται από την παρεμβολή·
- απομάκρυνση της επηρεαζόμενης συσκευής από το ακοόμετρο·
- σύνδεση της επηρεαζόμενης συσκευής σε πρίζα ρεύματος σε κύκλωμα διαφορετικό από το κύκλωμα στο οποίο είναι συνδεδεμένο το ακοόμετρο·
- συμβουλευθείτε τον κατασκευαστή ή κάποιο κέντρο σέρβις, για βοήθεια.

ΣΥΝΔΕΣΕΙΣ

Όλα τα σημεία σύνδεσης για αφαιρούμενα εξαρτήματα βρίσκονται στον πίσω πίνακα. Η ενότητα αυτή αφορά το ομιλιακό ακοόμετρο Piccolo. Το Piccolo Plus δεν έχει σύνδεσμο εισόδου γραμμής για εξωτερική πηγή ήχου.

Το μοντέλο Basic δεν έχει επίσης σύνδεσμο BC (για δονητή οστέινης αγωγής).



Συνδέστε όλους τους μετατροπείς και τα αφαιρούμενα εξαρτήματα στις αντίστοιχες υποδοχές τους, όπως υποδεικνύεται στον πίνακα που ακολουθεί:

Υποδοχή	Αφαιρούμενο εξάρτημα
6V⎓1.67A	Ηλεκτρική τροφοδοσία. Όταν το Piccolo είναι συνδεδεμένο σε θύρα USB υπολογιστή, δεν χρειάζεται ηλεκτρική τροφοδοσία.
USB	Θύρα USB για σύνδεση στον υπολογιστή
PAT. RESP.	Κουμπί απόκρισης ασθενούς
BC	Δονητής οστέινης αγωγής
AC-L	Αριστερό ακουστικό κεφαλής/ένθετο ακουστικό
AC-R	Δεξιό ακουστικό κεφαλής/ένθετο ακουστικό
TALK OVER	Μικρόφωνο χειριστή
LINE IN	Εξωτερική γραμμή για ομιλητική ακοομετρία με εξωτερική πηγή ήχου

Χρησιμοποιείτε μόνο μετασχηματιστές που προορίζονται για ιατρικό εξοπλισμό και είναι πιστοποιημένοι σύμφωνα με το πρότυπο IEC 60601-1.

Βεβαιωθείτε ότι η ηλεκτρική τροφοδοσία και οι συνδέσεις γείωσης συμμορφώνονται με τα ισχύοντα πρότυπα για ηλεκτροϊατρικές συσκευές. Κίνδυνος ηλεκτροπληξίας

Εάν το ακοόμετρο Piccolo τροφοδοτείται μέσω καλωδίου USB, οι μέγιστες τιμές (σε AC και BC) είναι 10 dB χαμηλότερες από τις ονομαστικές τιμές.

Η πράσινη ενδεικτική λυχνία LED κοντά στο σύμβολο υποδεικνύει ότι το ακοόμετρο τροφοδοτείται είτε από τον μετασχηματιστή ρεύματος είτε μέσω του καλωδίου USB του υπολογιστή.

Η ενδεικτική λυχνία LED κοντά στο σύμβολο υποδεικνύει την κατάσταση επικοινωνίας μεταξύ του ακοόμετρου και του υπολογιστή: h ενδεικτική λυχνία LED ανάβει με πράσινο αν το ακοόμετρο επικοινωνεί με PC.

ΣΥΝΔΕΣΗ ΣΕ ΥΠΟΛΟΓΙΣΤΗ

Για να επιτραπεί ο χειρισμός από υπολογιστή, το ακοόμετρο Piccolo πρέπει να συνδεθεί σε μία από τις θύρες USB του υπολογιστή χρησιμοποιώντας το καλώδιο που παρέχεται (τυπικό καλώδιο USB A/B).

Χρησιμοποιήστε το καλώδιο που παρέχεται για να συνδέσετε το ακοόμετρο Piccolo σε μία από τις θύρες USB του υπολογιστή

Η σύνδεση είναι τύπου plug-and-play, χωρίς να απαιτούνται ειδικά προγράμματα οδήγησης για την εγκατάσταση: λίγα λεπτά μετά τη σύνδεση, το λειτουργικό σύστημα αναγνωρίζει τις συσκευές και εμφανίζεται το ακόλουθο μήνυμα.

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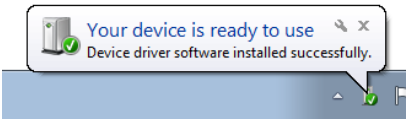

Ο χειρισμός του ακοόμετρου Piccolo μπορεί να εκτελείται από υπολογιστή χρησιμοποιώντας το λογισμικό Inventis Maestro: για περισσότερες λεπτομέρειες σχετικά με τη χρήση και τις δυνατότητες του λογισμικού Maestro, και για τις ελάχιστες απαιτήσεις συστήματος, ανατρέξτε στο *εγχειρίδιο χρήσης του Maestro*.

ΚΕΦΑΛΑΙΟ 3
Συντήρηση

Το ακοόμετρο Piccolo δεν απαιτεί κάποια ειδική περιοδική συντήρηση, εκτός της βαθμονόμησης, των ελέγχων και του συνήθη καθαρισμού, τα οποία όλα περιγράφονται σε αυτό το κεφάλαιο.
Η απόδοση και η ασφάλεια του οργάνου διατηρούνται εφόσον τηρούνται οι συστάσεις όσον αφορά τη φροντίδα και τη συντήρηση, οι οποίες παρέχονται σε αυτό το κεφάλαιο.
Το όργανο πρέπει να απενεργοποιείται και να αποσυνδέεται από την ηλεκτρική τροφοδοσία πριν από την έναρξη οποιασδήποτε εργασίας καθαρισμού.

Η επιθεώρηση και η εκτέλεση εργασιών σέρβις στα εσωτερικά εξαρτήματα πρέπει να ανατίθεται αποκλειστικά σε τεχνικούς εγκεκριμένους από την INVENTIS S.r.l.

Οι μετατροπείς κατασκευάζονται με τη χρήση εξαιρετικά εύθραυστων διαφραγμάτων, τα οποία μπορεί να υποστούν ζημιά σε περίπτωση πρόσκρουσης. Ο χειρισμός τους κατά τις εργασίες συντήρησης πρέπει να γίνεται με προσοχή.

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ΠΕΡΙΟΔΙΚΟΙ ΕΛΕΓΧΟΙ

Η διαδικασία που περιγράφεται σε αυτή την ενότητα πρέπει να εκτελείται καθημερινά κατά την πρώτη χρήση του οργάνου.

Οι δοκιμές πρέπει να πραγματοποιούνται με το ακοόμετρο στη θέση εγκατάστασής του.

- Πριν ενεργοποιήσετε το όργανο, ελέγξτε ότι δεν υπάρχουν ορατές ενδείξεις ζημιάς σε κανένα μέρος της συσκευής, συμπεριλαμβανομένων των αφαιρούμενων εξαρτημάτων και της εξωτερικής ηλεκτρικής τροφοδοσίας. Πραγματοποιήστε διπλό οπτικό έλεγχο της ακεραιότητας της μόνωσης των καλωδίων ρεύματος και των βυσμάτων, και επαληθεύστε ότι δεν εκτίθενται σε κανενός είδους μηχανικό φορτίο που θα μπορούσε να προκαλέσει ζημιά. Επαληθεύστε ότι όλα τα εξαρτήματα και τα καλώδια είναι σωστά συνδεδεμένα.

- Ελέγξτε προσωπικά ότι η έξοδος αγωγιμότητας αέρα και οστικής αγωγιμότητας είναι ίση και στα δύο κανάλια και σε όλες τις συχνότητες, και για να γίνει αυτό εφαρμόζονται 10 ή 15 dB τα οποία επαρκούν για την ακρόαση. Το άτομο που διενεργεί αυτούς τους ελέγχους θα πρέπει να έχει καλή ακοή
- Ελέγξτε ότι σε επίπεδο 60 dB σε AC και 40 dB σε BC δεν υπάρχει παραμόρφωση, θόρυβος ή σήματα παρασιτικά, σε καμία από τις συχνότητες
- Ελέγξτε ότι ο διακόπτης απόκρισης ασθενούς και οι ενδείξεις λειτουργούν σωστά
- Ελέγξτε τις εισόδους ομιλητικής ακοομετρίας, διενεργώντας εξέταση ομιλίας με κάθε είσοδο ομιλίας
- Ελέγξτε την πίεση της κορδέλας των ακουστικών και του δονητή οστέινης αγωγής
- Ελέγξτε την επικοινωνία με τον ασθενή

Εάν οποιοδήποτε μέρος του μετατροπέα έχει κάποια δυσλειτουργία, συμβουλευθείτε το Κεφάλαιο «Αντιμετώπιση προβλημάτων».

Ελέγχετε πάντα ότι δεν έχει παρέλθει το διάστημα βαθμονόμησης: η λήξη του διαστήματος υποδεικνύεται επάνω αριστερά στο λογισμικό Maestro.

Η βαθμονόμηση πρέπει να ανατίθεται σε τεχνικούς εγκεκριμένους από την INVENTIS S.r.l. Η εργασία θα πρέπει να εκτελείται τουλάχιστον μία φορά κάθε 12 μήνες και σε κάθε αντικατάσταση μετατροπέα.

ΣΥΝΤΗΡΗΣΗ ΤΩΝ ΜΕΤΑΤΡΟΠΕΩΝ

Μη χρησιμοποιείτε υγρά ή σπρέι για τον καθαρισμό του ακοόμετρου.

Μην αφήνετε να συσσωρεύεται σκόνη πάνω στους μετατροπείς. Επιπλέον:
- Τα μαξιλαράκια των ακουστικών κεφαλής είναι κατασκευασμένα από βιοσυμβατό υλικό, αλλά δεν είναι αποστειρωμένα: για να αποτρέψετε τη μετάδοση λοιμώξεων και να διασφαλίσετε τη βιοσυμβατότητα του υλικού, κάθε φορά που πρόκειται να χρησιμοποιηθούν από έναν νέο ασθενή πρέπει να καθαρίζετε τα ακουστικά με

- για μαξιλαράκια DD45/TDH-39, μαντηλάκι ή πανί από μικροΐνες εμποτισμένο με μετουσιωμένη αλκοόλη·
- για όλα τα άλλα μαξιλαράκια: υποαλλεργικό απολυμαντικό, ακολουθώντας τις οδηγίες του κατασκευαστή.

- Τα άκρα αυτιού των ένθετων ακουστικών προορίζονται να εισαχθούν στον ακουστικό πόρο του ασθενούς. Κατασκευάζονται από βιοσυμβατό υλικό και είναι μίας χρήσης: χρησιμοποιείτε μόνο μία φορά και απορρίπτετε σύμφωνα με τους ισχύοντες κανονισμούς για την υγεία και την ασφάλεια

Τα άκρα αυτιού δεν είναι αποστειρωμένα. Η χρήση μη αποστειρωμένων ακουστικών μπορεί να προκαλέσει ωτίτιδες.

Ο δονητής οστέινης αγωγής και τα μαξιλαράκια ακουστικών μπορούν να καθαρίζονται επαναλαμβανόμενα, όπως περιγράφεται στην παράγραφο «Συντήρηση των μετατροπέων». Σε περίπτωση δυσλειτουργίας μετά από εργασία καθαρισμού, επικοινωνήστε με έναν τεχνικό σέρβις της Inventis.

Παρόλο που ο δονητής οστέινης αγωγής και τα μαξιλαράκια ακουστικών μπορούν να καθαρίζονται επαναλαμβανόμενα, ελέγχετε πάντα ότι διατηρούνται τα χαρακτηριστικά και η ακεραιότητά τους. Ως προς αυτό, αρκεί να εκτελείτε τους ελέγχους που περιγράφονται στην παράγραφο «Περιοδικοί έλεγχοι». Αμέσως μόλις εντοπίσετε κάποια βλάβη, επικοινωνήστε με έναν τεχνικό σέρβις της Inventis για να διαπιστώσετε αν ο μετατροπέας σας πρέπει να αντικατασταθεί.

Για να αποφύγετε την πρόκληση ζημιάς στα ακουστικά κεφαλής DD45/TDH39, μην τα πιέζετε πάνω σε επίπεδη επιφάνεια, καθώς μπορεί να δημιουργηθεί κενό και να προκληθεί ζημιά στον μετατροπέα (φαινόμενο βεντούζας).

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ΚΑΘΑΡΙΣΜΟΣ ΤΟΥ ΟΡΓΑΝΟΥ

Για να αποτρέψετε τη συσσώρευση σκόνης στο όργανο, τοποθετείτε πάντα ένα προστατευτικό κάλυμμα όταν δεν χρησιμοποιείτε τον αναλυτή. Επίσης, βεβαιωθείτε ότι καθαρίζετε τακτικά τη σκόνη που συσσωρεύεται κάτω από το όργανο.
Μπορείτε να καθαρίζετε όλα τα εξαρτήματα που αναφέρονται συγκεκριμένα στην προηγούμενη ενότητα, χρησιμοποιώντας ένα μαλακό πανί που δεν αφήνει χνούδι, υγραμένο με διάλυμα από νερό και ήπιο απορρυπαντικό. Για λόγους υγιεινής, υγράνετε το πανί με υπεροξείδιο του υδρογόνου σε συγκέντρωση 3%. Επιτρέπονται οι πολλαπλοί καθαρισμοί της συσκευής χωρίς να υποβαθμίζεται η βασική ασφάλεια ή οι επιδόσεις. Ελέγχεται πάντα

ότι διατηρούνται τα χαρακτηριστικά και η ακεραιότητα της συσκευής. Ως προς αυτό, αρκεί να εκτελείτε τους ελέγχους που περιγράφονται στην παράγραφο «Περιοδικοί έλεγχοι». Αμέσως μόλις εντοπίσετε κάποια βλάβη, επικοινωνήστε με έναν τεχνικό σέρβις της Inventis για να διαπιστώσετε αν κάποια εξαρτήματα πρέπει να αντικατασταθούν.

ΑΝΤΙΚΑΤΑΣΤΑΣΙΜΑ ΕΞΑΡΤΗΜΑΤΑ

Οι μετατροπείς και τα αφαιρούμενα μέρη μπορούν να αποσυνδεθούν από τη συσκευή. Εάν προκύψει κάποιο ελάττωμα σε οποιοδήποτε από αυτά τα προϊόντα, πρέπει να απενεργοποιήσετε το ακοόμετρο, να το απομονώσετε από την ηλεκτρική τροφοδοσία και στη συνέχεια να αποσυνδέσετε το ελαττωματικό στοιχείο από τη συσκευή.

Όλα τα αφαιρούμενα εξαρτήματα του ακοόμετρου έχουν σχεδιαστεί ειδικά για χρήση με τη συσκευή. Στο ακοόμετρο θα πρέπει να συνδέονται μόνο εξαρτήματα που παρέχονται από την Inventis.

ΕΠΙΣΚΕΥΕΣ ΚΑΙ ΤΕΧΝΙΚΗ ΒΟΗΘΕΙΑ

Πριν επικοινωνήσετε με το τμήμα σέρβις, βεβαιωθείτε ότι έχετε δοκιμάσει τις πιθανές λύσεις που αναφέρονται στο Κεφάλαιο *«Αντιμετώπιση προβλημάτων»*.

Όλα τα εξαρτήματα που επιστρέφονται στον κατασκευαστή για επισκευή και σέρβις πρέπει να έχουν καθαριστεί και απολυμανθεί. Οι μετατροπείς θα πρέπει να σφραγίζονται σε διαφανή σάκο.

Σημαντικό: εάν το όργανο πρέπει να αποσταλεί στο τμήμα σέρβις της Inventis ή να επιστραφεί στον αντιπρόσωπο, βεβαιωθείτε ότι θα χρησιμοποιηθεί η αρχική συσκευασία και ότι θα περιλαμβάνονται όλα τα αφαιρούμενα εξαρτήματα και οι μετατροπείς.

ΚΕΦΑΛΑΙΟ 4
Αντιμετώπιση προβλημάτων

Πρόβλημα	Πιθανή αιτία	Λύση
Απουσία σήματος από μετατροπέα	Ο μετατροπέας δεν είναι συνδεδεμένος στη σωστή έξοδο	Συνδέστε τον μετατροπέα στη σωστή έξοδο
	Ο μετατροπέας έχει υποστεί ζημιά	Επικοινωνήστε με τον προμηθευτή ή τον πάροχο υπηρεσιών σας
Απουσία σήματος από το κουμπί απόκρισης ασθενούς, όταν το πατάτε	Εσφαλμένη σύνδεση	Συνδέστε το κουμπί απόκρισης ασθενούς στη σωστή υποδοχή
	Το κουμπί απόκρισης ασθενούς έχει υποστεί ζημιά	Επικοινωνήστε με τον προμηθευτή ή τον πάροχο υπηρεσιών σας
Δεν είναι δυνατή η σύνδεση μεταξύ υπολογιστή και ακοόμετρου	Προβλήματα με τη σύνδεση USB	Ελέγξτε τη σύνδεση USB μεταξύ οργάνου και υπολογιστή
	Το καλώδιο USB έχει υποστεί ζημιά	Αλλάξτε το καλώδιο USB (τυπικό καλώδιο USB A/B)
Μη αναμενόμενα αποτελέσματα εξετάσεων	Η βαθμονόμηση έληξε	Εκτελέστε βαθμονόμηση του ακοόμετρου
	Εσφαλμένος τύπος επιλεγμένου μετατροπέα AC (ακουστικά κεφαλής ή ακουστικά)	Τροποποιήστε την επιλογή του τρέχοντος μετατροπέα AC, από το λογισμικό ή την εφαρμογή Maestro

EL

Πρόβλημα	Πιθανή αιτία	Λύση
Δεν είναι δυνατή η πρόσβαση σε εξέταση	Δεν είναι ενεργοποιημένη η προαιρετική εξέταση	Επικοινωνήστε με την αρμόδια τεχνική υπηρεσία για να λάβετε άδεια, παρέχοντας τον αριθμό σειράς της συσκευής

Όταν το ακοόμετρο χρησιμοποιείται σε συνδυασμό με ηχομονωτικό θάλαμο, ελέγξτε ότι οι συνδέσεις τόσο στο εσωτερικό του θαλάμου όσο και μεταξύ του θαλάμου και του οργάνου, είναι σωστές και ασφαλείς.

Annex A

Technical Specifications

APPLICABLE STANDARDS	
Performance	Piccolo Basic IEC 60645-1 / ANSI S3.6 type 4 Piccolo Plus IEC 60645-1 / ANSI S3.6 type 3 Piccolo Speech IEC 60645-1 / ANSI S3.6 type 3B
Calibration	AC: ISO 389-1, ISO 389-2 BC: ISO 389-3
Electrical safety	IEC 60601-1 Class I, Type B
Electromagnetic compatibility	IEC 60601-1-2
Enclosures	IEC 60601-1 IP20
Operation mode	Continuous

CE CERTIFICATE	
MDR 2017/745/EU Classification	Class IIa
Classification rule (Annex VIII, 2017/745)	10
Notified body	TÜV SÜD Product Service GmbH Ridlerstrasse 65 D-80339 Műnchen, Germany
Notified body number	0123

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

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 device powered by mains power adapter. In case of device 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 device powered by mains power adapter. In case of device 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 device powered by mains power adapter. In case of device 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	•	•	•

AUDIOMETER CONTROL	
Required Software	Inventis Maestro
Communication protocol	USB 1.1
PC communication requirements	USB 2.0 port minimum

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.

Annex B

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 such use is necessary, this instrument and the other equipment should be observed to verify that they are operating normally.

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 mains power adapter
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 2m shielded signal cable

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 does not have any ESSENTIAL PERFORMANCE as per the IEC 60601 1 standard.

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.

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">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.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment-guidance</th></tr>
<tr><td>RF emissions
CISPR11</td><td>Group 1</td><td>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.</td></tr>
<tr><td>RF emissions
CISPR11</td><td>Class B</td><td rowspan="3">Piccolo is suitable for use in professional healthcare facility environment and directly connected to the public low-voltage power supply network.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations / flickers emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

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 on power supply input lines IEC 61000-4-11	< 5% U_T (2) (> 95% dip in U_T) for 0,5 cycle. 40% U_T (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.	< 5% U_T (2) (> 95% dip in U_T) for 0,5 cycle. 40% U_T (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.	Mains power quality should be that of a professional healthcare facility environment. If the 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.			

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">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.</td></tr>
<tr><th>Immunity Test</th><th>IEC 60601 Test Level</th><th>Compliance Level</th><th>Electromagnetic environment – Guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
0.15 – 80 MHz

6 Vrms
in ISM bands between
0.15 - 80 MHz</td><td>3 Vrms
0.15 – 80 MHz

6 Vrms
in ISM bands between
0.15 - 80 MHz</td><td rowspan="5">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(1), should be less than the compliance level in each frequency range.(2) Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radieted RF
IEC 61000-4-3</td><td>3 V/m

80 Mhz - 2,7 Ghz</td><td>3 V/m

80 Mhz to 2,7 Ghz</td></tr>
<tr><td rowspan="3">Radiated RF

(from RF Wireless communication equipment)

IEC 61000-4-3</td><td>9 V/m

704-787 MHz
5100 – 5800 MHz</td><td>9 V/m

704-787 MHz
5100 – 5800 MHz</td></tr>
<tr><td>27 V/m

380 - 390 Mhz</td><td>27 V/m

380 - 390 Mhz</td></tr>
<tr><td>28 V/m

430 - 470 Mhz
800 - 960 Mhz
1700 - 1990 Mhz
2400 - 2570 Mhz</td><td>28 V/m

430 - 470 Mhz
800 - 960 Mhz
1700 - 1990 Mhz
2400 - 2570 Mhz</td></tr>
<tr><td>Proximity Fields

IEC 61000-4-39</td><td>8A/m
30KHz CW

65 A/m
134.2KHz
Pulse Mod 2.1KHz

7.5 A/m
13.56MHz
Pulse Mod 50KHz</td><td>8A/m
30KHz CW

65 A/m
134.2KHz
Pulse Mod 2.1KHz

7.5 A/m
13.56MHz
Pulse Mod 50KHz</td></tr>
<tr><td colspan="4">Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">Note:
(1) 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 Triangle is used in exceeds the applicable RF compliance level above, Triangle should be observed to verify its normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Triangle.
(2) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

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 transducers exceeding 80dBHL; a lock or reboot of the device is acceptable

PT

PORTABLE AUDIOMETER

PICCOLO

MULTILANGUAGE USER MANUAL

Document title: AU1P-Piccolo User Manual PT
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Revision: Rev. 02
Date: 2025.03.07

PT

PICCOLO

AUDIÓMETRO PORTÁTIL

MANUAL DO UTILIZADOR

Leia este manual cuidadosamente antes da utilização do dispositivo. Preste especial atenção ao Capítulo 1 ("Segurança: avisos e informações") e ao Capítulo 2 ("Instalação").

As inspeções e reparações internas devem ser realizadas apenas por pessoal autorizado.

CE
0123

PT

Índice

Preâmbulo

Obrigado por ter adquirido um dispositivo de audiologia Inventis.

Vantajosamente portátil e ligeiro, o audiómetro Piccolo é um dispositivo portátil potente e versátil, ideal para profissionais em movimento.

A empresa Inventis considerou sempre a utilização dos seus dispositivos em conjunto com os computadores um fator de importância fundamental. Com a instalação do pacote de software Maestro, disponível com ou sem base de dados proprietário ou como um módulo Noah, qualquer dispositivo de audiologia Inventis pode ser conectado a um computador e todos os exames efetuados serão arquivados na própria base de dados do utilizador.

Recordar-se também que a Inventis desenvolveu uma linha completa de dispositivos de audiologia: além dos audiómetros, a linha de produtos da empresa inclui uma gama de analisadores do ouvido médio, dispositivos de ajuste para correção auditiva REM e HIT, um otoscópio vídeo sem fios e muito mais.

Para mais informações e relatar quaisquer tipos de problemas, contactar a empresa em:

INVENTIS S.r.l.
Corso Stati Uniti, 1/3
35127 Padova, Italia
Tel.: 049.8962844 – Fax: 049,8966343
www.Inventis.it info@Inventis.it

CAPÍTULO 1
Segurança: avisos e informações

MANUAL DO OPERADOR

Leia este manual completamente, para que todos os recursos oferecidos pelo instrumento possam ser utilizados em todo o seu potencial. Em particular, certifique-se de ler este capítulo na íntegra, pois contém informações e avisos de importância fundamental para garantir a utilização segura e correta do dispositivo.
O símbolo de aviso de segurança ilustrado infra é utilizado neste manual para chamar a atenção do leitor para informações de particular importância em questões de segurança e para se proteger contra a sua utilização incorreta.

RESPONSABILIDADES DO OPERADOR

O audiómetro Piccolo garante um funcionamento eficiente e confiável apenas se utilizado de acordo com as instruções e procedimentos fornecidos neste manual.
Se o instrumento apresentar alguma anomalia ou necessita de reparação, desligue-o da alimentação e não o utilize novamente até que a reparação e a manutenção necessárias tenham sido concluídas. As peças defeituosas e com mau funcionamento devem ser substituídas apenas por peças originais fornecidas pela INVENTIS S.r.l.. Todas as reparações devem ser realizadas exclusivamente pela Inventis ou por pessoal autorizado pela Inventis.
Nenhuma parte do dispositivo pode ser modificada ou substituída sem a autorização prévia por escrito da Inventis.
Os utilizadores são inteiramente responsáveis por quaisquer maus funcionamentos causados por uma utilização inadequada ou por operações de manutenção ou reparação realizadas por qualquer parte que não seja a INVENTIS S.r.l. ou um Centro de Serviço autorizado. A INVENTIS S.r.l. e os seus Centros de Serviço aceitam a responsabilidade pelo desempenho e confiabilidade do instrumento apenas se:

1. todas as conexões, ajustes, alterações e reparações são realizados exclusivamente por pessoal autorizado pela Inventis;

2. a fonte de alimentação elétrica e as ligações à terra do sistema cumprem as normas aplicáveis aos dispositivos electromédicos.

FINS PREVISTOS

O dispositivo médico Piccolo é um audiómetro. Um audiómetro é um dispositivo de auxílio ao operador para a definição da sensibilidade auditiva do paciente, que gera e fornece ao paciente estímulos sonoros de diferentes tipos e intensidades para propósitos de diagnóstico.

INDICAÇÃO DE UTILIZAÇÃO E UTILIZADORES FINAIS

Piccolo destina-se á utilização por parte de profissionais otorrinolaringológicos em hospitais, clínicas otorrinolaringológicas e consultórios de audiologia na avaliação auditiva e no diagnóstico de possíveis distúrbios otológicos. Não há restrição de população de pacientes na utilização do dispositivo; certifique-se sempre de realizar uma otoscopia antes de utilizar o dispositivo.
Estes testes devem ser realizados num ambiente silencioso para evitar artefatos.

CONDIÇÕES MÉDICAS

Condições de sensibilidade prejudicada do sistema auditivo ou quaisquer condições em que o sistema auditivo é pensado para desempenhar um papel no diagnóstico.

PRECAUÇÕES

Qualquer acidente grave que tenha ocorrido em relação ao dispositivo deve ser comunicado ao fabricante e à autoridade competente do Estado-Membro em que o utilizador e/ou paciente estão estabelecidos.

Para garantir a utilização correta e segura do audiómetro, devem ser observadas as seguintes precauções.

Instalação e precauções gerais

Certifique-se de que as condições ambientais exigidas sejam atendidas (durante o transporte, armazenamento e funcionamento):

Operação	*Temperatura: entre 15°C (59°F) e 35°C (95°F)* *Humidade relativa: entre 30% e 90% (sem condensação)* *Pressão: entre 700 hPa e 1060 hPa*
Transporte e armazenamento	*Temperatura: entre -10°C (14°F) e 50°C (122°F)* *Humidade relativa: máx. 90% sem condensação* *Pressão: entre 500 hPa e 1060 hPa*
Tempo de pré-aquecimento	*1 minuto*

O audiómetro Piccolo não estará protegido se exposto durante a utilização de gases anestésicos inflamáveis ou produtos similares durante a utilização. Risco de explosão.

Evite instalar e usar o audiómetro Piccolo perto de fontes de campos eletromagnéticos fortes, uma vez que tal pode interferir no funcionamento do dispositivo.

Utilize apenas peças originais destacáveis fornecidas pela INVENTIS S.r.l., a menos que seja instruído de outra forma.

Utilize apenas adaptadores de energia destinados a equipamentos médicos, certificados de acordo com a IEC 60601-1, com as seguintes especificações:

Unidade principal: 6V, 1.67A cc
Adaptador externo: SL POWER MENB1010A0603F02
100-240Vac 50/60 Hz 0,9-0,34A (incluído) respondendo à norma IEC 60601-1

O audiómetro Piccolo é um dispositivo médico. Qualquer outro dispositivo externo ao qual esteja conectado (como um computador ou leitor de CD) dentro da "área do paciente" (conforme definido na IEC 60601-1) também deve ser um dispositivo médico ou deve ser protegido por um transformador isolador de forma a garantir que a combinação completa (computador ou dispositivo externo + audiómetro) esteja em conformidade com a norma IEC 60601-1.

Piccolo pode ser utilizado em conjunto com uma cabina à prova de som para realizar testes em condições acústicas ideais. Antes de conectá-lo a uma cabina à prova de som, controle se as tomadas são compatíveis com as especificações prescritas para cada conector.

Piccolo necessita de precauções especiais quanto à EMC e necessita de ser instalado e colocado em funcionamento de acordo com as informações EMC fornecidas no final deste manual.

O uso de equipamentos de comunicações RF portáteis e móveis pode afetar o funcionamento correto dos dispositivos Piccolo. Consulte as informações de CEM no final deste manual.

O cabo do adaptador de alimentação e o cabo USB são considerados os meios para desconectar o dispositivo da fonte de alimentação.

Não posicione o dispositivo de modo que seja difícil desconectá-lo da fonte de alimentação.

Calibração

A calibração deve ser realizada pelo menos uma vez a cada 12 meses e sempre que um transdutor seja substituído.

A calibração do audiómetro é válida somente para os transdutores fornecidos com o dispositivo. Se um transdutor for substituído, o audiómetro deve ser recalibrado.

A calibração do audiómetro é válida para os transdutores fornecidos com o audiómetro, se conectados diretamente ao instrumento, sem interposição de extensões e sem a passagem dos conectores para o painel (como habitualmente ocorre em instalações de cabinas à prova de som). Se os transdutores não estiverem conectados diretamente ao audiómetro, será necessário um novo procedimento de calibração antes que o instrumento seja utilizado.

Em cada janela de teste, quando selecionar um transdutor não calibrado, o plano de fundo da área de 'saída' será exibido na cor vermelha. Além disso, não poderá enviar nenhum estímulo por meio de transdutores não calibrados.

Anote o intervalo de calibração especificado pelo audiómetro. A utilização do instrumento além da data de expiração da calibração pode levar a diagnósticos não confiáveis.

Higiene

As pontas dos auriculares de inserção são descartáveis; não use a mesma ponta para pacientes diferentes. Elimine as pontas dos ouvidos após o uso.

Desinfete as almofadas dos auriculares entre um paciente e o seguinte, da forma descrita no CAPÍTULO 3 "Manutenção".

Utilização

O audiómetro pode gerar tons com uma intensidade potencialmente prejudicial para o paciente. Tenha cuidado especial para ajustar a intensidade do tom corretamente antes dos exames.

Ao realizar audiometria utilizando auriculares de inserção, não insira ou de qualquer forma tente realizar medições sem a ponta de espuma adequada no lugar.

Manter a intensidade prévia do estímulo ao alterar a frequência, o transdutor ou o lado da estimulação pode resultar na apresentação de sinais potencialmente prejudiciais ao paciente.

Para apresentar um sinal de estímulo maior que 100 dB HL, o operador deve primeiro pressionar o botão de função "DB MAIOR", que está ativo somente quando a intensidade do estímulo atingir 100 dB HL.

ELIMINAÇÃO

Como todos os dispositivos eletrónicos, o seu audiómetro contém quantidades extremamente pequenas de certas substâncias perigosas, como cádmio ou mercúrio. Se estas substâncias forem permitidas entrarem no ciclo normal de eliminação dos resíduos sem um tratamento preliminar adequado, poderão causar danos ao meio ambiente e à saúde. Por conseguinte, todas as partes do audiómetro devem ser eliminadas separadamente.
No final da sua vida útil, leve o instrumento não utilizado para uma instalação de eliminação e reciclagem de resíduos cívicos, ou devolvê-lo ao revendedor contra a compra de um novo instrumento equivalente.
A recolha separada de resíduos e as operações subsequentes de tratamento, reciclagem e eliminação facilitam a fabricação de novos dispositivos a partir de materiais reciclados, limitando qualquer impacto negativo no ambiente e na saúde pública que, de outra forma, possa derivar de uma eliminação inadequada.

CONFORMIDADE

O audiómetro Piccolo é um dispositivo médico de classe IIa, de acordo com o Anexo VIII do Regulamento de Dispositivos Médicos (MDR) 2017/745/UE.
O Sistema de Gestão da Qualidade da Inventis foi certificado pelo principal organismo de avaliação TÜV como estando em conformidade com a norma ISO 13485.

SÍMBOLOS NAS ETIQUETAS

Nome e endereço do fabricante.

Aviso: a utilização deste dispositivo requer certas precauções. Para garantir uma utilização segura, consultar a documentação que o acompanha.

Este símbolo significa que este produto está abrangido pela Diretiva 2012/19/UE relativa aos resíduos de equipamentos elétricos e eletrónicos (REEE). É necessário não descartar este produto como resíduos municipais não separados, mas coletá-lo separadamente.

Consulte o manual de instruções de utilização

Dispositivo com peças aplicadas de tipo B (IEC 60601-1).

Fonte de alimentação DC

O produto está em conformidade com o Regulamento de Dispositivos Médicos da Comunidade Europeia (MDR) 2017/745/EU. Dispositivo de Classe IIa; número do organismo notificado: 0123 (TÜV SÜD Product Service GmbH).

Dispositivo médico

Rx only

Cuidado: A Lei Federal restringe a venda, distribuição, e uso deste dispositivo apenas por e sob a ordem de um médico ou outro profissional de saúde.

IP20 *Código IP (Proteção de entrada): este dispositivo é protegido contra a entrada de objetos de tamanho > 12,5 mm; não é protegido contra líquidos.*

REF *Número de catálogo*

COMPATIBLE TRANSDUCERS *Secção que lista os transdutores compatíveis*

SN *O número de série do dispositivo é composto por 13 caracteres alfanuméricos que indicam o modelo, o ano de fabricação e o número de série. Em particular, o número é composto por estes segmentos:*

- *primeiros 5 caracteres: Código do produto Inventis*
- *caracteres 6 e 7: ano de fabricação (por exemplo, "12" significa 2012)*
- *caracteres 8… 13: número incremental*

Código UDI

CAPÍTULO 2
Instalação

Embora a instalação de um audiómetro Piccolo ser um procedimento relativamente simples, este deve ser confiado a uma pessoa com as habilidades necessárias. Se a instalação não for executada corretamente, o sistema pode ser afetado por problemas de segurança durante a utilização.
Este capítulo descreve o procedimento de instalação do sistema.

Guarde os materiais da embalagem, caso o audiómetro precise ser enviado ao revendedor ou à Inventis por qualquer motivo.

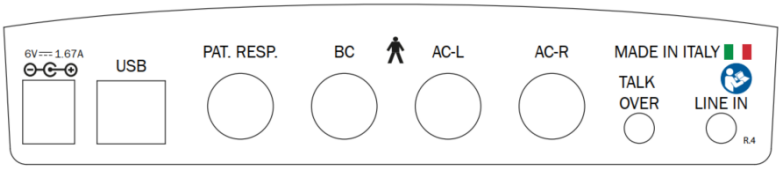
PRECAUÇÕES

Como qualquer outro dispositivo elétrico ou eletrónico, o audiómetro Piccolo emitirá ondas eletromagnéticas. Embora as suas emissões estejam dentro dos limites das normas, os outros dispositivos eletrónicos próximos do audiómetro podem ser afetados se forem particularmente sensíveis às interferências eletromagnéticas.
Caso tal ocorra, verifique apenas desligando e ligando o audiómetro e tente eliminar a interferência usando uma ou mais das seguintes soluções:

- alterar a orientação e/ou posição do dispositivo afetado pela interferência.
- distância entre o dispositivo afetado e o audiómetro;
- conecte o dispositivo afetado a uma tomada elétrica num circuito diferente daquele ao qual o audiómetro está ligado;
- consulte o fabricante ou o centro de serviço para assistência.

CONEXÕES

Todos os pontos de conexão para peças destacáveis estão localizados no painel traseiro. Esta seção refere-se ao audiómetro de fala Piccolo. Piccolo Plus não tem um conector de entrada de LINHA para uma fonte de som externa. O modelo Basic também carece de um conector BC (para um vibrador ósseo).



Conecte todos os transdutores e peças destacáveis nas suas respetivas tomadas, conforme indicado na seguinte tabela:

Conector	Peça destacável
6V⎓1.67A	Alimentação elétrica. Quando Piccolo está conectado a uma porta USB do computador, a fonte de alimentação não é necessária.
USB	Porta USB para ligação ao PC
PAT. RESP.	Botão de resposta do paciente
BC	Vibrador ósseo
AC-L	Auscultador esquerdo/auricular de inserção
AC-R	Auscultador direito/auricular de inserção
TALK OVER	Microfone do operador
LINE IN	Linha externa para audiometria de fala com fonte de áudio externa

Utilize apenas adaptadores de energia destinados a equipamentos médicos, certificados de acordo com a IEC 60601-1.

Certifique-se de que a fonte de alimentação elétrica e as conexões de aterramento estejam em conformidade com as normas aplicáveis para dispositivos eletromédicos. Risco de choque elétrico

Se o audiómetro Piccolo for alimentado por um cabo USB, os valores máximos (em AC e BC) são 10 dB menores que os valores nominais.

O LED verde próximo ao símbolo indica que o audiómetro é alimentado pelo adaptador de alimentação ou pelo cabo USB do computador.

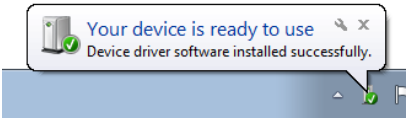
O LED próximo ao símbolo indica o estado das comunicações entre o audiómetro e o computador: esta luz LED acende-se a verde se o audiómetro estiver a comunicar com um PC.

CONEXÃO AO COMPUTADOR

Para permitir o controlo a partir de um computador, o audiómetro Piccolo deve ser ligado a uma das portas USB do computador utilizando o cabo fornecido (um cabo USB A/B padrão).

Use o cabo fornecido para conectar o audiómetro Piccolo a uma das portas USB do computador

A conexão é plug-and-play, sem necessidade de drivers especiais para fins de instalação: alguns segundos após a conexão, o sistema operativo reconhecerá os dispositivos e aparecerá a seguinte mensagem:



O audiómetro Piccolo pode ser controlado a partir de um computador usando o software Inventis Maestro: para obter mais detalhes sobre o uso e os recursos do software Maestro, e para os requisitos mínimos do sistema, consulte o *Manual do Utilizador do Maestro*.

CAPÍTULO 3
Manutenção

O audiómetro Piccolo não requer nenhuma manutenção periódica especial além da calibração, inspeções e da normal limpeza, ambas as quais descritas neste capítulo.
O desempenho e a segurança do instrumento serão mantidos se as recomendações de cuidados e manutenção fornecidas neste capítulo forem realizadas.
O instrumento deve ser desligado e desconectado da fonte de alimentação antes de iniciar qualquer tipo de operação de limpeza.

A inspeção e a manutenção dos componentes internos devem ser deixadas inteiramente a técnicos aprovados pela INVENTIS S.r.l.

Os transdutores são fabricados utilizando diafragmas ultra-frágeis que podem ser danificados em caso de impacto. Manuseie com cuidado durante as operações de manutenção.

VERIFICAÇÕES PERIÓDICAS

O procedimento descrito sob este cabeçalho deve ser executado quando o instrumento for utilizado pela primeira vez todos os dias.

Os testes devem ser feitos com o audiómetro na sua posição de instalação.

- Antes de ligar o instrumento se nenhum sinal de dano está visível em qualquer parte do dispositivo, incluindo as peças destacáveis e a fonte de alimentação externa; verifique a integridade visual do isolamento do cabo de alimentação e dos conectores e verifique se não estão expostos a qualquer tipo de carga mecânica que possa envolver danos; verifique se todas as peças e cabos estão conectados corretamente.
- Controle subjetivamente se a saída de condução aérea e óssea é igual nos canais e em todas as frequências, para fazer isso são aplicados 10 ou 15 dB, apenas o suficiente para ser ouvido. A pessoa que realiza esta verificação deve ter boa audição.

- Controle a um nível de 60 dB em AC e 40 dB em BC se não há distorção, ruído ou sinais parasitas em nenhuma das frequências.
- Controle se o interruptor de resposta do paciente e os indicadores estão a funcionar corretamente
- Controle as entradas da audiometria de fala fazendo um teste de fala com cada entrada de fala
- Controle a tensão da banda da cabeça dos fones de ouvido e do vibrador ósseo
- Controle a comunicação com o paciente

Se qualquer peça ou transdutor apresentar qualquer avaria, consulte o Capítulo "Resolução de problema".

Sempre verifique se o intervalo de calibração não expirou: o prazo de validade do intervalo é indicado na parte superior esquerda do software Maestro.

A calibração deve ser confiada a técnicos aprovados pela INVENTIS S.r.l. A operação deve ser realizada pelo menos uma vez a cada 12 meses e sempre que um transdutor seja substituído.

MANUTENÇÃO DOS TRANSDUTORES

Não utilizar líquidos ou sprays para limpar o audiómetro.

Não permitir acumulações de pó nos transdutores. Além disso:

- As almofadas dos auscultadores são compostas por material biocompatível mas não são estéreis: para a prevenção da propagação de infeções e garantir a biocompatibilidade do material, sempre que os auscultadores forem utilizados por um novo paciente, as almofadas devem ser limpas
    - para almofadas DD45/TDH-39, pano desnaturado com álcool ou álcool desnaturado com um pano de microfibra;
    - para todas as outras almofadas: Desinfetante hipoalergénico, seguindo as instruções do fabricante.
- As pontas dos auriculares de inserção devem ser inseridas no canal auditivo do paciente. São compostos por material biocompatível e descartáveis: utilizar apenas uma vez e descartar de acordo com os regulamentos atuais de saúde e segurança

As pontas dos fones intraauriculares não são estéreis. A utilização de fones não esterilizados pode causar infeções no ouvido.

O vibrador ósseo e as almofadas dos auscultadores podem ser limpos repetidamente conforme descrito no parágrafo "Manutenção dos transdutores". Em caso de mau funcionamento após qualquer operação de limpeza, contacte um técnico de manutenção da Inventis.

Embora o vibrador ósseo e as almofadas dos auscultadores possam ser limpos repetidamente, verifique sempre se as suas características e integridade são mantidas. Para isso, basta realizar os testes descritos no parágrafo "Verificações periódicas". Assim que qualquer falha for encontrada, entre em contacto com um técnico de serviço da Inventis para verificar se o seu transdutor precisa ser substituído.

Para evitar danificar os auscultadores DD45/TDH39, não o empurre contra uma superfície plana e reta, pois isso pode criar vácuo e causar danos ao transdutor (efeito ventosa).

LIMPEZA DO INSTRUMENTO

Para evitar a acumulação de poeira no instrumento, ajustar sempre a tampa de proteção quando o analisador não estiver em utilização. Além disso, garantir que a coleta de poeira por baixo do instrumento seja limpa regularmente.
Todas as peças não mencionadas especificamente na secção anterior podem ser limpas com um pano macio sem fiapos humedecido com uma solução de água e detergente neutro; em caso de higienização, humedeça o pano com água oxigenada a uma concentração de 3%. O dispositivo permite várias limpezas sem degradação da segurança básica ou dos desempenhos; verifique sempre se as características e a integridade do dispositivo são mantidas. Para isso, basta realizar os testes descritos no parágrafo "Verificações periódicas". Assim que qualquer falha for encontrada, entre em contacto com um técnico de serviço da Inventis para verificar se alguma peça precisa ser substituída.

PEÇAS SOBRESSELENTES

Os transdutores e as peças destacáveis podem ser desconectados do dispositivo. Se ocorrer uma falha em qualquer um desses dispositivos, o

audiómetro deve ser desligado e isolado da fonte de alimentação, e o item defeituoso deve ser desconectado do dispositivo.

Todas as partes destacáveis do audiómetro foram concebidas especificamente para utilização com o dispositivo. Apenas as peças fornecidas pela Inventis devem ser conectados ao audiómetro.

REPARAÇÕES E ASSISTÊNCIA TÉCNICA

Antes de entrar em contacto com o departamento de serviço, certifique-se que todas as soluções possíveis no Capítulo *"Resolução de problemas"* foram tentadas.

Todas as peças que estão vão ser devolvidas ao fabricante para reparo e serviço devem ser limpas e higienizadas. Os transdutores devem ser selados numa bolsa transparente.

Importante: caso o instrumento deva ser enviado para o departamento de serviço da Inventis ou devolvido ao revendedor, certifique-se que a embalagem original seja utilizada e que todas as peças destacáveis e transdutores estejam incluídos.

CAPÍTULO 4
Resolução de problemas

Problema	Causa possível	Solução
Nenhum sinal de um transdutor	Transdutor não conectado à saída correta	Ligue o transdutor à saída correta
	Transdutor danificado	Entre em contacto com o vendedor ou o representante de serviço
Nenhum sinal do botão de resposta do paciente quando pressionado	Ligação errada	Conecte o botão de resposta do paciente à tomada correta
	Botão de resposta do paciente danificado	Entre em contacto com o vendedor ou o representante de serviço
A conexão entre o PC e o audiómetro não pode ser estabelecida	Problemas com a conexão USB	Controle a conexão USB entre o instrumento e o computador
	Cabo USB danificado	Troque o cabo USB (cabo USB A/B padrão)
Resultados improváveis do exame	Calibração expirada	Realize a calibração do audiómetro
	Tipo errado de transdutor CA selecionado (auscultadores ou auriculares)	Modifique a seleção do transdutor AC atual, do software ou app Maestro

Problema	Causa possível	Solução
Não é possível aceder a um teste	Teste opcional não habilitado	Contacte o seu serviço técnico de referência para obter a licença, comunicando o número de série do dispositivo

Quando o audiómetro for utilizado em conjunto com uma cabina à prova de som, verifique se as ligações tanto dentro da cabina como entre a cabina e o instrumento estão corretas e seguras.

Annex A

Technical Specifications

APPLICABLE STANDARDS	
Performance	Piccolo Basic IEC 60645-1 / ANSI S3.6 type 4 Piccolo Plus IEC 60645-1 / ANSI S3.6 type 3 Piccolo Speech IEC 60645-1 / ANSI S3.6 type 3B
Calibration	AC: ISO 389-1, ISO 389-2 BC: ISO 389-3
Electrical safety	IEC 60601-1 Class I, Type B
Electromagnetic compatibility	IEC 60601-1-2
Enclosures	IEC 60601-1 IP20
Operation mode	Continuous

CE CERTIFICATE	
MDR 2017/745/EU Classification	Class IIa
Classification rule (Annex VIII, 2017/745)	10
Notified body	TÜV SÜD Product Service GmbH Ridlerstrasse 65 D-80339 Műnchen, Germany
Notified body number	0123

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

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 device powered by mains power adapter. In case of device 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 device powered by mains power adapter. In case of device 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 device powered by mains power adapter. In case of device 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	•	•	•

AUDIOMETER CONTROL	
Required Software	Inventis Maestro
Communication protocol	USB 1.1
PC communication requirements	USB 2.0 port minimum

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.

Annex B

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 such use is necessary, this instrument and the other equipment should be observed to verify that they are operating normally.

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 mains power adapter
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 2m shielded signal cable

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 does not have any ESSENTIAL PERFORMANCE as per the IEC 60601 1 standard.

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.

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">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.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment-guidance</th></tr>
<tr><td>RF emissions
CISPR11</td><td>Group 1</td><td>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.</td></tr>
<tr><td>RF emissions
CISPR11</td><td>Class B</td><td rowspan="3">Piccolo is suitable for use in professional healthcare facility environment and directly connected to the public low-voltage power supply network.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations / flickers emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

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 on power supply input lines IEC 61000-4-11	< 5% U_T (2) (> 95% dip in U_T) for 0,5 cycle. 40% U_T (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.	< 5% U_T (2) (> 95% dip in U_T) for 0,5 cycle. 40% U_T (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.	Mains power quality should be that of a professional healthcare facility environment. If the 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.			

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">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.</td></tr>
<tr><th>Immunity Test</th><th>IEC 60601 Test Level</th><th>Compliance Level</th><th>Electromagnetic environment – Guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
0.15 – 80 MHz

6 Vrms
in ISM bands between
0.15 - 80 MHz</td><td>3 Vrms
0.15 – 80 MHz

6 Vrms
in ISM bands between
0.15 - 80 MHz</td><td rowspan="5">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(1), should be less than the compliance level in each frequency range.(2) Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radieted RF
IEC 61000-4-3</td><td>3 V/m

80 Mhz - 2,7 Ghz</td><td>3 V/m

80 Mhz to 2,7 Ghz</td></tr>
<tr><td rowspan="3">Radiated RF

(from RF Wireless communication equipment)

IEC 61000-4-3</td><td>9 V/m

704-787 MHz
5100 – 5800 MHz</td><td>9 V/m

704-787 MHz
5100 – 5800 MHz</td></tr>
<tr><td>27 V/m

380 - 390 Mhz</td><td>27 V/m

380 - 390 Mhz</td></tr>
<tr><td>28 V/m

430 - 470 Mhz
800 - 960 Mhz
1700 - 1990 Mhz
2400 - 2570 Mhz</td><td>28 V/m

430 - 470 Mhz
800 - 960 Mhz
1700 - 1990 Mhz
2400 - 2570 Mhz</td></tr>
<tr><td>Proximity Fields

IEC 61000-4-39</td><td>8A/m
30KHz CW

65 A/m
134.2KHz
Pulse Mod 2.1KHz

7.5 A/m
13.56MHz
Pulse Mod 50KHz</td><td>8A/m
30KHz CW

65 A/m
134.2KHz
Pulse Mod 2.1KHz

7.5 A/m
13.56MHz
Pulse Mod 50KHz</td></tr>
<tr><td colspan="4">Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">Note:
(1) 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 Triangle is used in exceeds the applicable RF compliance level above, Triangle should be observed to verify its normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Triangle.
(2) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

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 transducers exceeding 80dBHL; a lock or reboot of the device is acceptable

BG

RO

PORTABLE AUDIOMETER

PICCOLO

EL

MULTILANGUAGE USER MANUAL

Document title: AU1P-Piccolo User Manual BG-RO-EL
Code: AU1-MA303_C
Revision: Rev. 02
Date: 2025.03.07

RO

PICCOLO

AUDIOMETRU PORTABIL

MANUAL DE UTILIZARE

Citiți cu atenție acest manual înainte de a utiliza dispozitivul. Acordați o atenție deosebită Capitolului 1 („Siguranța: avertismente și informații”) și Capitolului 2 („Instalare”).

Inspecțiile în interior și reparațiile trebuie efectuate numai de personal autorizat.

CE
0123

Cuprins

RO

Introducere

Vă mulțumim că ați cumpărat un echipament audiologic Inventis.

Portabil și ușor, audiometrul Piccolo este un dispozitiv portabil puternic și versatil, ideal pentru profesioniștii aflați în mișcare.

RO

Compania Inventis a considerat întotdeauna că utilizarea dispozitivelor sale împreună cu computerele reprezintă un factor extrem de important. Instalând software-ul Maestro, disponibil cu sau fără baza de date proprietară sau ca modul Noah, orice echipament audiologic Inventis poate fi conectat cu un computer, investigațiile fiind astfel arhivate în baza de date a utilizatorului.

Nu uitați că Inventis a dezvoltat o linie completă de echipamente audiologice: pe lângă audiometre, linia de produse a companiei include o gamă de timpanometre, aparatele auditive REM și HIT, un video otoscop wireless și multe altele.

Pentru mai multe informații și pentru a comunica orice probleme contactați compania la:

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

CAPITOLUL 1
Siguranța: avertismente și informații

MANUAL DE UTILIZARE

RO

Asigurați-vă că citiți în întregime acest manual, astfel încât toate funcțiile oferite de instrument să poată fi utilizate la maximul performanțelor lor. În special asigurați-vă că citiți acest capitol în întregime, deoarece conține informații și avertismente care sunt de o importanță fundamentală pentru utilizarea corectă și sigură a dispozitivului.
Simbolul de avertizare ilustrat mai jos este utilizat în acest manual pentru a atrage atenția cititorului asupra informațiilor de o importanță deosebită în domeniul siguranței și pentru a preveni utilizarea incorectă.

RESPONSABILITĂȚILE OPERATORULUI

Funcționarea audiometrului Piccolo va fi eficientă și fiabilă numai dacă acesta este utilizat conform instrucțiunilor și procedurilor indicate în acest manual.
Dacă instrumentul prezintă vreodată o defecțiune sau necesită reparații, deconectați-l de la rețeaua electrică și nu îl mai utilizați până la finalizarea reparației și întreținerii necesare. Piesele defecte și care funcționează necorespunzător trebuie înlocuite numai cu piese de schimb originale, furnizate de INVENTIS S.r.l.. Toate reparațiile trebuie efectuate numai de Inventis sau de personal autorizat de Inventis.
Nicio componentă a dispozitivului nu trebuie modificată sau înlocuită fără autorizația prealabilă a companiei Inventis.
Utilizatorii își asumă întreaga răspundere pentru orice defecțiune cauzată de utilizarea necorespunzătoare sau de operațiuni de întreținere sau reparații efectuate de oricine altcineva în afară de INVENTIS S.r.l. sau un Centru de service autorizat. INVENTIS S.r.l. și Centrele de service își asumă responsabilitatea pentru performanțele și fiabilitatea instrumentului numai dacă:

1. toate conexiunile, reglajele, modificările și reparațiile sunt efectuate numai de persoane autorizate de Inventis;

2. sursa de alimentare electrică și împământarea sistemului respectă standardele aplicabile pentru echipamentele electromedicale.

DESTINAȚIA DE UTILIZARE

Dispozitivul medical Piccolo este un audiometru. Un audiometru este un dispozitiv care ajută operatorul să definească sensibilitatea auditivă a pacientului prin generarea și transmiterea către pacient a unor stimuli sonori de diferite tipuri și intensități în scopuri de diagnostic.

INDICAȚII DE UTILIZARE ȘI UTILIZATORI FINALI

Piccolo este destinat utilizării de către profesioniștii în domeniul ORL care lucrează în spitale, clinici ORL și cabinete de audiologie pentru efectuarea evaluărilor auditive și a permite diagnosticarea posibilelor afecțiuni auriculare. Nu există restricții privind pacienții care pot folosi acest dispozitiv; asigurați-vă întotdeauna că efectuați o otoscopie înainte de a utiliza dispozitivul.
Aceste teste trebuie efectuate într-un mediu liniștit pentru a evita artefactele.

CONDIȚII MEDICALE

Reducerea sensibilității sistemului auditiv sau orice condiții în care se consideră că sistemul auditiv joacă un rol în diagnostic.

PRECAUȚII

Orice incident grav în legătură cu dispozitivul trebuie comunicat producătorului și autorității competente din Statul membru în care este stabilit utilizatorul și/sau pacientul.

Pentru a asigura utilizarea corectă și sigură a audiometrului trebuie respectate următoarele măsuri de precauție.

Instalare și măsuri generale de precauție

Asigurați-vă că sunt îndeplinite condițiile de mediu necesare în timpul transportului, depozitării și funcționării:

Funcționare	*Temperatură: între 15°C (59°F) și 35°C (95°F)* *Umiditate relativă: între 30% și 90% (fără condens)* *Presiune: între 700 hPa și 1060 hPa*
Transport și depozitare	*Temperatură: între -10°C (14°F) și 50°C (122°F)* *Umiditate relativă: max. 90% fără condens* *Presiune: între 500 hPa și 1060 hPa*
Timp de încălzire	*1 minut*

Audiometrul Piccolo nu va fi protejat dacă în timpul utilizării este expus gazelor anestezice inflamabile sau altor produse similare. Pericol de explozie.

Evitați instalarea și utilizarea audiometrului Piccolo în apropierea oricărei surse de câmpuri electromagnetice puternice, acestea ar putea interfera cu funcționarea dispozitivului.

Utilizați numai componente detașabile originale furnizate de INVENTIS S.r.l., dacă nu este specificat altfel.

Folosiți numai adaptoare de alimentare destinate echipamentelor medicale, certificate conform IEC 60601-1, cu următoarele specificații:

Unitatea principală: 6V, 1.67A c.c.
Adaptor extern: SL POWER MENB1010A0603F02
100-240Vac 50/60 Hz 0.9-0.34A (inclus) conform cu standardul IEC 60601-1

Audiometrul Piccolo este un dispozitiv medical: Orice alte dispozitive externe la care este conectat (cum ar fi un computer sau un dispozitiv de redare a CD-urilor), situate în „zona pacientului" (conform definiției din IEC 60601-1), trebuie să fie dispozitive medicale sau trebuie să fie protejate printr-un transformator de izolare, pentru a asigura conformitatea combinației (computer sau dispozitiv extern + audiometru) cu standardul IEC 60601-1.

Piccolo poate fi utilizat împreună cu o cabină izolată fonic pentru efectuarea testelor în condiții acustice optime. Înainte de a-l conecta la o cabină izolată fonic, asigurați-vă că porturile sunt compatibile cu specificațiile fiecărui conector.

Piccolo necesită precauții speciale în ceea ce privește EMC și trebuie instalat și pus în funcțiune în conformitate cu informațiile privind EMC furnizate la sfârșitul acestui manual.

Utilizarea echipamentelor de comunicații RF portabile și mobile poate afecta funcționarea corectă a dispozitivului Piccolo. Consultați informațiile referitoare la EMC de la sfârșitul acestui manual.

Cablul adaptorului de alimentare și cablul USB sunt considerate mijlocul de deconectare a dispozitivului de la sursa de alimentare.

Nu poziționați dispozitivul astfel încât deconectarea acestuia de la sursa de alimentare să fie dificilă.

Reglare

Reglarea trebuie efectuată cel puțin o dată la 12 luni și ori de câte ori este înlocuit un traductor.

Reglarea audiometrului este valabilă numai pentru traductoarele furnizate cu dispozitivul. Dacă este înlocuit un traductor, audiometrul trebuie reglat din nou.

Reglarea audiometrului este valabilă pentru traductoarele furnizate împreună cu acesta, dacă sunt conectate direct la instrument, fără prelungitoare și fără interpuneri între conectori și panou (cum se întâmplă de obicei în cazul cabinelor izolate fonic). Dacă traductoarele nu sunt conectate direct la audiometru va fi necesară o nouă procedură de reglare înainte ca instrumentul să poată fi utilizat.

Atunci când selectați un traductor nereglat, în fiecare fereastră de testare fundalul zonei de „ieșire” va fi afișat în culoarea roșie. În plus, nu veți putea trimite niciun stimul prin traductoarele care nu sunt reglate.

Acordați atenție intervalului de reglare specificat al audiometrului. Utilizarea instrumentului după data de expirare a reglării poate determina obținerea unor diagnostice nesigure.

Igienă

Pernuțele căștilor intra-aurale sunt de unică folosință; nu utilizați aceleași pernuțe pentru diferiți pacienți. Aruncați pernuțele după utilizare.

Dezinfectați cupele căștii între un pacient și altul, urmând procedura descrisă în CAPITOLUL 3 „Întreținerea”.

Utilizare

RO

Audiometrul poate genera tonuri la o intensitate potențial dăunătoare pentru pacient. Este foarte important să reglați corect intensitatea tonului înainte de efectuarea investigațiilor.

Când efectuați teste audiometrice folosind căști intra-aurale nu introduceți și nu încercați în niciun fel să efectuați măsurători fără o pernuță adecvată.

Menținerea intensității anterioare a stimulului atunci când se schimbă frecvența, traductorul sau partea stimulată poate cauza semnale potențial dăunătoare pentru pacient.

Pentru a emite un semnal de stimulare mai puternic de 100 dB HL operatorul trebuie mai întâi să apese butonul „dB MAI MARE”, care este activ doar atunci când intensitatea stimulului atinge 100 dB HL.

ELIMINARE

Ca toate dispozitivele electronice, audiometrul dvs. conține cantități extrem de mici de anumite substanțe periculoase, cum ar fi cadmiul sau mercurul. Dacă astfel de substanțe sunt lăsate să intre în ciclul normal de eliminare a deșeurilor fără un tratament prealabil adecvat, ele pot cauza daune mediului și sănătății. Prin urmare, toate componentele audiometrului trebuie eliminate separat.
La sfârșitul duratei sale de viață, predați sau trimiteți instrumentul dezafectat unui centru de colectare și reciclare a deșeurilor sau returnați-l vânzătorului la achiziționarea unui instrument nou echivalent.
Colectarea separată a deșeurilor și operațiunile ulterioare de tratare, reciclare și eliminare facilitează fabricarea unor noi dispozitive din materiale reciclate, limitând orice impact negativ asupra mediului și sănătății publice care ar putea rezulta altfel din eliminarea necorespunzătoare.

CONFORMITATE

Audiometrul Piccolo este un dispozitiv medical de clasă IIa, conform Anexei VIII la Regulamentul privind dispozitivele medicale (MDR) 2017/745/UE. Sistemul de management al calității al Inventis a fost certificat de organismul de evaluare TÜV ca fiind conform cu standardul ISO 13485.

SIMBOLURI PE ETICHETE

Numele și adresa producătorului.

Atenţie: utilizarea acestui dispozitiv necesită anumite precauții.
Pentru a asigura utilizarea în siguranță, consultați documentația însoțitoare.

Acest simbol indică faptul că acest produs este reglementat de Directiva 2012/19/UE privind deșeurile de echipamente electrice și electronice (DEEE). Acest produs nu trebuie eliminat ca deșeu urban nesortat, ci trebuie colectat separat.

Consultați manualul de instrucțiuni pentru utilizare

Dispozitiv cu componente aplicate de tip B (IEC 60601-1).

Sursa de curent continuu

Produs conform cu Regulamentul Comunității Europene privind dispozitivele medicale (MDR) 2017/745/UE. Dispozitiv clasa IIa; numărul organismului notificat: 0123 (TÜV SÜD Product Service GmbH).

Dispozitiv medical

Rx only

Atenţie: Legea federală limitează vânzarea acestui dispozitiv de către sau la comanda unui profesionist autorizat din domeniul sănătății.

IP20

Cod IP (protecție la intrare): acest dispozitiv este protejat împotriva pătrunderii obiectelor de dimensiuni > 12,5 mm; nu este protejat împotriva lichidelor.

REF

Număr de catalog

COMPATIBLE TRANSDUCERS *Secțiune în care sunt indicate traductoarele compatibile*

SN

Numărul de serie al dispozitivului este alcătuit din 13 caractere alfanumerice indicând modelul, anul de fabricație și numărul de serie. Mai precis, numărul cuprinde următoarele segmente:

- *primele 5 caractere: codul produsului Inventis*
- *caracterele 6 și 7: anul de fabricație (de ex. „12" înseamnă 2012)*
- *caracterele 8... 13: număr incremental*

(01)08054187380372(21)AU1PH16200749

Cod UDI

RO

CAPITOLUL 2
Instalarea

Deși instalarea unui audiometru Piccolo este o procedură relativ simplă, trebuie oricum să fie încredințată unei persoane care deține competențele necesare. Dacă instalarea nu este efectuată corect, sistemul ar putea fi afectat de probleme de siguranță în timpul utilizării.
Acest capitol descrie procedura de instalare a sistemului.

RO

Păstrați ambalajele în cazul în care audiometrul trebuie trimis distribuitorului sau companiei Inventis din orice motiv.

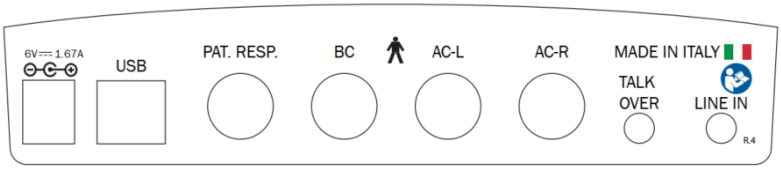
PRECAUȚII

Ca orice alt dispozitiv electric sau electronic, audiometrul Piccolo va emite unde electromagnetice. Chiar dacă nivelul emisiilor se încadrează în limitele legale, alte dispozitive electronice care funcționează în imediata apropiere ar putea fi afectate dacă sunt deosebit de sensibile la interferențele electromagnetice.
În acest caz efectuați o probă prin oprirea și pornirea audiometrului și încercați să eliminați interferența folosind una sau mai multe dintre următoarele soluții:

- schimbați orientarea și/sau poziția dispozitivului afectat de interferență;
- îndepărtați dispozitivul afectat de audiometru;
- conectați dispozitivul afectat la o priză de alimentare pe un alt circuit decât cel la care este conectat audiometrul;
- consultați producătorul sau un centru de service pentru asistență.

CONEXIUNI

Toate punctele de conectare a componentelor detașabile sunt situate pe panoul din spate. Această secțiune se referă la audiometrul Piccolo cu audiometrie vocală. Piccolo Plus nu este prevăzut cu conector LINE IN pentru o sursă externă de sunet. Nici modelul Basic nu deține un conector BC (pentru un vibrator osos).



Introduceți toate traductoarele și componentele detașabile în porturile respective, așa cum este indicat în tabelul următor:

Conector	Componentă detașabilă
6V⎓1.67A	Sursă de alimentare. Când Piccolo este conectat la un port USB al computerului, sursa de alimentare nu este necesară.
USB	Port USB pentru conectarea la PC
PAT. RESP.	Buton de răspuns pentru pacient
BC	Vibrator osos
AC-L	Căști supra-aurale/intra-aurale stânga
AC-R	Căști supra-aurale/intra-aurale dreapta
TALK OVER	Microfon pentru operator
LINE IN	Linie externă pentru audiometrie vocală cu sursă audio externă

Folosiți numai adaptoare de alimentare destinate echipamentelor medicale, certificate conform IEC 60601-1.

Asigurați-vă că sursa de alimentare electrică și conexiunile de împământare respectă standardele aplicabile pentru echipamentele electromedicale. Risc de electrocutare

Dacă audiometrul Piccolo este alimentat printr-un cablu USB, valorile maxime (în AC și BC) sunt cu 10 dB mai mici decât valorile nominale.

LED-ul verde de lângă simbolul indică faptul că audiometrul este alimentat fie prin adaptorul de alimentare, fie prin cablul USB al computerului.

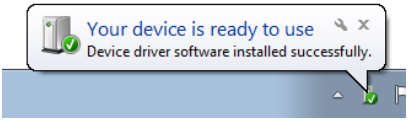
LED-ul de lângă simbolul indică starea comunicațiilor dintre audiometru și computer: acest LED se aprinde verde atunci când audiometrul comunică cu PC-ul.

CONECTAREA CU UN COMPUTER

Pentru a permite controlul folosind un computer, audiometrul Piccolo trebuie conectat la unul dintre porturile USB ale computerului folosind cablul furnizat (un cablu USB A/B standard).

Utilizați cablul furnizat pentru a conecta audiometrul Piccolo la unul dintre porturile USB ale computerului

Conexiunea este plug-and-play, fără a fi necesare drivere speciale pentru instalare: la câteva secunde după conectare, sistemul de operare va recunoaște dispozitivele și se va afișa următorul mesaj:



Audiometrul Piccolo poate fi controlat prin intermediul unui computer folosind software-ul Inventis Maestro: pentru mai multe detalii despre utilizarea și caracteristicile software-ului Maestro și pentru cerințele minime de sistem, consultați *Manualul de utilizare Maestro.*

CAPITOLUL 3
Întreținerea

Audiometrul Piccolo nu necesită nicio întreținere periodică specială în afară de reglare, verificări și curățarea normală, toate acestea fiind descrise în acest capitol.
Pentru a menține performanțele și siguranța instrumentului trebuie respectate recomandările de îngrijire și întreținere din acest capitol.
Instrumentul trebuie oprit și deconectat de la sursa de alimentare înainte de a începe orice operațiune de curățare.

RO

Inspecția și întreținerea componentelor interne trebuie efectuate numai de tehnicienii aprobați de INVENTIS S.r.l..

Traductoarele sunt fabricate folosind diafragme ultra-fragile care s-ar putea deteriora la impact. Manevrați-le cu grijă în timpul lucrărilor de întreținere.

VERIFICĂRI PERIODICE

Procedura descrisă în acest paragraf trebuie efectuată în fiecare zi, înaintea primei utilizări a instrumentului.

Testele trebuie efectuate cu audiometrul în poziția de instalare.

- Înainte de a porni instrumentul asigurați-vă că nu se vede niciun semn de deteriorare pe nicio parte a dispozitivului, inclusiv componentele detașabile și sursa de alimentare externă; verificați bine integritatea izolației cablului de alimentare și a conectorilor și asigurați-vă că acestea nu sunt expuse niciunui fel de sarcini mecanice care le-ar putea deteriora; verificați conectarea corectă a tuturor pieselor și cablurilor
- Verificați în mod subiectiv dacă ieșirea aferentă conducției aeriene și celei osoase este egală pe ambele canale și pe toate frecvențele, pentru aceasta aplicați 10 sau 15 dB, cât este suficient pentru a auzi. Persoana care efectuează această verificare trebuie să aibă un auz bun

- Asigurați-vă că la nivelul de 60 dB în AC și 40 dB în BC nu există distorsiuni, zgomote sau paraziți pe niciuna dintre frecvențe
- Verificați dacă întrerupătorul de răspuns al pacientului și indicatorii funcționează corect
- Verificați intrările audiometriei vocale făcând un test de vorbire pentru fiecare intrare vocală
- Verificați apăsarea benzii căștilor și a vibratorului osos
- Verificați comunicarea cu pacientul

În cazul defectării unei piese sau a unui traductor consultați Capitolul „Rezolvarea problemelor”.

Verificați întotdeauna dacă intervalul de reglare nu a expirat: expirarea intervalului este indicată în partea din stânga-sus a software-ului Maestro.

Reglarea trebuie efectuată de tehnicieni aprobați de INVENTIS S.r.l.. Operațiunea trebuie efectuată cel puțin o dată la 12 luni și ori de câte ori se înlocuiește un traductor.

ÎNTREȚINEREA TRADUCTOARELOR

Nu folosiți lichide sau spray-uri pentru a curăța audiometrul.

Nu lăsați praful să se depună pe traductoare. În plus:

- Cupele căștilor sunt realizate din material biocompatibil, dar nu sunt sterile: pentru a preveni răspândirea infecției și a garanta biocompatibilitatea materialului, ori de câte ori căștile urmează să fie purtate de un pacient nou cupele trebuie șterse cu:
    - pentru cupele DD45/TDH-39 folosiți șervețele cu alcool denaturat sau alcool denaturat folosind o lavetă din microfibră;
    - pentru toate celelalte cupe: folosiți dezinfectant hipoalergenic, urmând instrucțiunile producătorului.
- Pernuțele căștilor intra-aurale sunt destinate introducerii în canalul urechii pacientului. Acestea sunt realizate din material biocompatibil și de unică folosință: trebuie folosite o singură dată și apoi eliminate în conformitate cu reglementările de sănătate și siguranță în vigoare

Pernuțele căștilor intra-aurale nu sunt sterile. Utilizarea pernuțelor nesterilizate poate provoca infecții ale urechii.

Vibratorul osos și cupele căștilor pot fi curățate în mod repetat, conform descrierii din paragraful „Întreținerea traductoarelor”. În cazul apariției defecțiunilor după orice operațiune de curățare contactați un tehnician de întreținere Inventis.

Deși vibratorul osos și cupele căștilor pot fi curățate în mod repetat, verificați întotdeauna menținerea caracteristicilor și a integrității acestora. Pentru aceasta este suficient să efectuați testele descrise în paragraful „Verificări periodice”. Ori de câte ori apare o defecțiune contactați un tehnician de întreținere Inventis care va verifica dacă traductorul dvs. trebuie înlocuit.

Pentru a evita deteriorarea căștilor DD45/TDH39 nu le apăsați pe o suprafață dreaptă plană, deoarece acest lucru poate crea vid și poate cauza deteriorarea traductorului (efect de ventuză).

RO

CURĂȚAREA INSTRUMENTULUI

Pentru a preveni acumularea de praf pe instrument puneți întotdeauna capacul de protecție atunci când acesta nu este folosit. De asemenea, asigurați-vă că praful acumulat sub instrument este curățat în mod regulat.
Toate componentele care nu sunt menționate în mod specific în secțiunea anterioară pot fi curățate folosind o cârpă moale umezită cu o soluție de apă și detergent slab; pentru igienizare umeziți cârpa cu peroxid de hidrogen cu concentrație de 3%. Dispozitivul permite curățări multiple fără ca siguranța de bază sau performanțele să fie afectate; verificați întotdeauna menținerea caracteristicilor și a integrității sale. Pentru aceasta este suficient să efectuați testele descrise în paragraful „Verificări periodice”. Ori de câte ori apare o defecțiune contactați un tehnician de întreținere Inventis care va verifica dacă există componente ce trebuie înlocuite.

COMPONENTE CE POT FI ÎNLOCUITE

Traductoarele și componentele detașabile pot fi deconectate de la dispozitiv. În cazul în care apare o defecțiune la oricare dintre aceste dispozitive, audiometrul trebuie oprit și sursa de alimentare scoasă, iar elementul defect trebuie deconectat de la dispozitiv.

Toate componentele detașabile ale audiometrului sunt proiectate special pentru a fi utilizate cu dispozitivul. Doar piesele furnizate de Inventis trebuie conectate la audiometru.

REPARAȚII ȘI ASISTENȚĂ TEHNICĂ

Înainte de a contacta departamentul de service, asigurați-vă că au fost încercate toate soluțiile posibile din Capitolul *„Rezolvarea problemelor”*.

Toate piesele care sunt returnate producătorului pentru reparații și întreținere trebuie curățate și igienizate. Traductoarele trebuie sigilate într-o pungă transparentă.

Important: în cazul în care instrumentul trebuie trimis departamentului de service al Inventis sau returnat distribuitorului, asigurați-vă că este utilizat ambalajul original și că toate componentele detașabile și traductoarele sunt incluse.

CAPITOLUL 4
Rezolvarea problemelor

RO

Problema	Cauza posibilă	Soluția
Niciun semnal de la un traductor	Traductorul nu este conectat la ieșirea corectă	Conectați traductorul la ieșirea corectă
	Traductorul este deteriorat	Contactați distribuitorul sau furnizorul de servicii
Niciun semnal de la butonul de răspuns al pacientului când este apăsat	Conexiune greșită	Conectați butonul de răspuns al pacientului la portul corect
	Butonul de răspuns al pacientului este deteriorat	Contactați distribuitorul sau furnizorul de servicii
Conexiunea dintre PC și audiometru nu poate fi stabilită	Probleme cu conexiunea USB	Verificați conexiunea USB dintre instrument și computer
	Cablul USB este deteriorat	Schimbați cablul USB (cablu standard USB A/B)
Rezultate puțin probabile ale investigației	Reglarea a expirat	Efectuați reglarea audiometrului
	Tipul traductorului AC (căști supra-aurale sau căști intra-aurale) a fost selectat greșit	Modificați traductorul AC selectat în prezent din software-ul sau aplicația Maestro
Nu puteți accesa un test	Testul opțional nu este activat	Contactați serviciul tehnic de referință pentru a obține licența, comunicând numărul de serie al dispozitivului

Când audiometrul este utilizat împreună cu o cabină izolată fonic, verificați realizarea corectă și în siguranță a conexiunilor atât în interiorul cabinei, cât și între cabină și instrument.