

AUDIOMETERS BELL & HARP

MULTILINGUAL USER MANUAL

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EN

BELL & HARP

AUDIOMETERS

USER MANUAL



Read this manual thoroughly before using the device. Pay particular attention to Chapter 1 (“Safety: warnings and information”) and Chapter 2 (“Installation, power up and power down”).



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

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Summary

<i>Foreword</i>	v
CHAPTER 1: Safety: warnings and information	1
Operator Manual	1
Operator responsibilities	1
Intended purpose	2
Indication for use and end users of the device.....	2
Medical conditions	2
Precautions	2
Disposal	5
Conformity	6
Symbols on labels	6
CHAPTER 2: Installation, power up and power down	9
Precautions	9
Connections	9
Power-up and main screen	11
Power-down.....	11
Connection to PC	11
CHAPTER 3: Controls	13
Function buttons	13
Control of channels	13
Common controls	14
Gain control and playback of word lists (Harp model only)	15
Patient-operator communication.....	15
CHAPTER 4: Maintenance	17
Periodic checks.....	17
Maintenance of Transducers.....	18
Cleaning the instrument	19
Replaceable parts	19

Loading the print paper	20
Repairs and technical assistance.....	20
<i>CHAPTER 5: Troubleshooting</i>	<i>21</i>

Foreword

Thank you for purchasing an Inventis audiometer.

Bell and Harp audiometers offer a combination of innovative features placing them at the top of their class: a generously proportioned colour graphics display, internal flash memory, elegant design, and notable ease of use.

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

For further information, and to report any problems of whatever description that may be encountered, contact the company at:



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Safety: warnings and information

OPERATOR MANUAL

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

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



OPERATOR RESPONSIBILITIES

The Bell and Harp audiometers guarantee consistent and dependable performance only when used in accordance with the instructions and procedures described in this manual.

Should the device need to undergo repair or maintenance work, it must be disconnected from the electrical power supply, and not used again until after this work has been completed. When defective or failed parts must be renewed, accept only original replacement parts supplied by INVENTIS S.r.l. Any repairs must be entrusted exclusively to Inventis or to service technicians approved by Inventis.

No parts of the device must be modified or replaced without authorization from Inventis.

The user of the device assumes full responsibility for any malfunction resulting from improper use or operation, likewise from maintenance or repair work performed by third parties other than INVENTIS S.r.l. or Service Centers approved by Inventis. INVENTIS S.r.l. and approved Service Centers will answer for the performance and reliability of the equipment only if:

1. adjustments, modifications or repairs have been entrusted to persons authorized by Inventis;

2. the electrical power supply and ground connections of the system comply with applicable standards for electromedical devices.

INTENDED PURPOSE

Bell/Harp 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 OF THE DEVICE

Bell/Harp 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 certain that the required ambient conditions are met (during transport, storage, and operation):

	Temperature: between 15°C (59°F) and 35°C (95°F)
Operation	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



Bell and Harp audiometers will not be protected if exposed during use to flammable anaesthetic gases or similar products. Risk of explosion.



Avoid installing and using Bell and Harp audiometers close to any sources of strong electromagnetic field: these could interfere with the operation of the appliance.



Use only original detachable parts supplied by INVENTIS S.r.l., unless specifically indicated otherwise.



Use only power adapters intended for medical equipment provided with the device, certified to IEC 60601-1, with the following specifications:

- model without printer:

Main unit: 6V, 1.67A d.c.

External adapter: SL POWER MENB1010A0603F02
100-240Vac 50/60 Hz 0.3-0.1A (included) responding to IEC 60601-1 standard

- model with printer:

Main unit: 6V, 3.2A d.c.

External adapter: SINPRO MPU31-103
100-240Vac 50/60 Hz 0.9-0.34A (included) responding to IEC 60601-1 standard



Bell and Harp audiometers are medical devices: if connected to a computer (or any external device, such as a CD player) located within the "patient area" (as defined in IEC 60601-1), this likewise must be a medical device, or protected by an isolating transformer, in order to ensure that the computer (external device) + audiometer combination is in compliance with EN standard 60601-1.



Bell and Harp audiometers can be used in conjunction with a soundproof booth to conduct tests under optimum acoustic

conditions. Before connecting the audiometer to a soundproof booth, check that the sockets are compatible with the specifications prescribed for each connector.



Bell & Harp need special precautions regarding EMC and need 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 Bell & Harp devices. Make reference to the EMC information at the end of this manual.



The power adapter cable is 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 appliance. 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 colour. Moreover, you will not be able to send any stimulus through not-calibrated transducers.



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

Hygiene



The eartips of insert earphones are disposable, likewise that of the masking earphone; do not use the same eartip for different patients. Dispose of eartips after use.



Disinfect the cushions of audio cups between one patient and the next, following the procedure described in CHAPTER 4: Maintenance.

Use



The audiometer can generate tones at an intensity potentially damaging to the patient. Take particular care to set the intensity of the tone correctly before it is presented.



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



The desktop microphone shall be placed at a distance not greater than 15 cm from the mouth to reduce the background noise



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 F1 function button (HIGHER dB), 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 appliances from

recycled materials, limiting any negative impact on the environment and public health that might otherwise derive from improper disposal.

CONFORMITY

Bell and Harp audiometers are 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



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



Refer to instruction manual for use



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



Device with applied parts of type BF (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).

Rx only

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



Medical device

IP20 *IP (Ingress Protection) Code: this device is protected against the access of objects sized > 12.5 mm, not protected against liquid.*

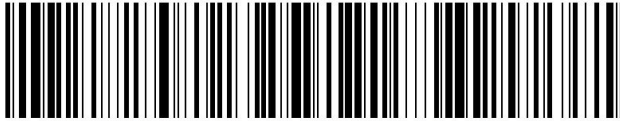
REF *Catalogue number*

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

SN

- *first 5 characters: Inventis product code*
- *characters 6 and 7: year of manufacture ("10" denotes 2010)*
- *characters 8... 13: incremental number*

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UDI code

(01)08054187380068(21)AU1DC16200570

CHAPTER 2:

Installation, power up and power down

Whilst the installation of a Bell or Harp audiometer is a relatively simple procedure, it should be entrusted to a person with the requisite skills. If the installation is not performed correctly, the system could be affected by safety problems when in use.

This chapter describes the procedure for installing the system.



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

PRECAUTIONS

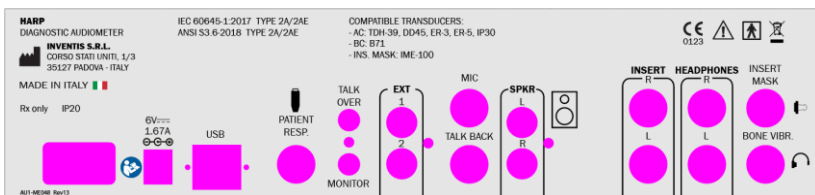
Like any other electric or electronic device, the Bell and Harp audiometers will emit electromagnetic waves. Even though its emissions are within the limits of standards, other electronic devices close to the audiometer might be affected, if particularly sensitive to electromagnetic interference.

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, as also is the power switch. This section refers to the Harp model. In the case of the Bell audiometer, certain connectors are not included.



Plug all detachable parts into the respective sockets as indicated in the following table:

Connector	Detachable part
 INSERT MASK	Insert earphone for masking
 BONE VIBR.	Bone vibrator
HEADPHONES	AC headphones: Right R and Left L
INSERT	AC Insert earphones: Right R and Left L
 SPKR	Free field speaker: Right R and Left L
MIC	Operator microphone for live speech tests
TALK BACK	Patient microphone
TALK OVER	Microphone for operator to patient communications or live speech test
MONITOR	Monitor headphones
EXT	External inputs 1 and 2 for speech audiometry with external audio source
 PATIENT RESP.	Patient response switch
USB	USB cable for the connection to the PC

6V---
1.67A
⊖⊕⊖

Connect the power adapter to the $\ominus\oplus\ominus$ input and to the relative power cord, which should be plugged into an a.c. mains socket supplying the voltage indicated on the adapter label.



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



Use only the power adapters included in the package, 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

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The rear panel also lists the available transducers (*COMPATIBLE TRANSDUCERS*), depending on the device model.

POWER-UP AND MAIN SCREEN

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

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

POWER-DOWN

Press the switch on the rear panel to safely power down the device.

CONNECTION TO PC

Bell and Harp audiometers can be interfaced with a computer with Maestro software, by way of a USB connection. The connection is plug-and-play, with no special drivers required for installation purposes: a few seconds after plugging in, the operating system will recognize the devices and install the drivers automatically.



Use the supplied cable (standard USB A/B cable) to connect the Bell/Harp audiometer to one of the USB ports of the computer

Refer to Maestro user manual for more details about the software.







CHAPTER 3:

Controls


FUNCTION BUTTONS






There are four buttons associated with configurable soft keys, whose functions are indicated at the bottom of the display window, immediately above the buttons. Moreover, there are six dedicated function buttons:

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



Control	Operation
	Go back to the previous window
	Clear all examinations conducted in the current session
	Save the current test to the patient memory of the instrument
	Delete data pertinent to the current graph of the examination
	Send the current examination to a computer, on which Maestro software must be installed
	Provide general information on the functions of the current window

CONTROL OF CHANNELS








Control	Operation
	Select stimulation on either side

	Select the output type
	Select the input signal
	Switch on the channel
	Enable the “Normally ON” option (the output will be permanently active, unless the channel is switched off by touching the interrupter)
	Attenuate the output (a knob for each channel)

COMMON CONTROLS


Control	Operation
	Select the pulsed mode for presentation of the stimulus signal
	Select the pulsed mode for presentation of the stimulus signal
	Enable tracking (keep the same difference in dB between stimulus and masking)
	Enable lock (the masking tone will be switched on / off together with the stimulus tone)
	Change to the previous/next frequency. In speech audiometry, count the words recognized and not recognized by the patient
	Store the hearing level



GAIN CONTROL AND PLAYBACK OF WORD LISTS (HARP MODEL ONLY)

Control	Operation
TALK 	Show the volume control window for communications between patient and operator
GAIN 	Show the gain control window for the speech material
MONITOR 	Show the volume control window for monitor signals used by the operator
	Harp Plus: Start playing the current list, or pause the list if already playing. The Led remains permanently alight during Play, and blinks as long as Pause is selected
	Harp Plus: Terminates playback of the current list
	Harp Plus: <ul style="list-style-type: none"> - Bring up the list preceding the current list, if no list is playing - Jump back either to the previous word (if the list is indexed), or by 5 seconds, if a list is playing
	Harp Plus: <ul style="list-style-type: none"> - Bring up the list that follows the current list, if no list is playing - Jump forward either to the next word (if the list is indexed), or by 5 seconds, if a list is playing

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PATIENT-OPERATOR COMMUNICATION

Control	Operation
TALK OVER 	Enable the operator to talk to the patient (by way of the transducer currently selected). Communication is enabled by pressing and holding the button disabled on release

	Enable the patient to communicate with the operator. The voice of the patient can be heard: <ol style="list-style-type: none">1) through the speaker incorporated into the chassis;2) through headphones or external speakers connected to the “Monitor” socket on the rear panel
	Light up whenever the patient presses the response button

CHAPTER 4:

Maintenance

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Bell and Harp audiometers do not require any special periodic maintenance other than calibration, checks and normal cleaning, all of which are described in this chapter.

The performance and safety of the instrument will be maintained if the recommendations for care and maintenance given in this chapter are observed.

The instrument must be switched off and disconnected from the power supply before commencing any kind of cleaning operation.



The inspection and servicing of internal components must be left entirely to technicians approved by INVENTIS S.r.l., included the internal coin cell replacement.



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



Do not perform any service or maintenance operation when the device is used on a patient.

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 60dB in AC and 40dB in BC that there is no distortion, noise or parasitic signals in any of the frequencies
- Check that the interrupter key(s), the patient response switch(es) and the keyboard indicators function correctly
- Check that the attenuator knobs function correctly without noises or interference between channels
- 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 bottom of the main presentation screen.



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 DD45/TDH-39 cushions must be wiped with denatured alcohol wipe or denatured alcohol with a microfiber cloth
- The ear tips of insert earphones and the masking insert earphones (IME-100) 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 bone vibrator comes into contact with the patient's uninjured skin. It is made of biocompatible material, but it is not sterile: whenever this transducer has to be worn by a new patient, it must be wiped with denatured alcohol wipe or denatured alcohol with a microfiber cloth.



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.



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 audiometer, always cover the instrument with the protective cloth when not in use. Dust the audiometer regularly to ensure it is kept clean.

All parts not mentioned specifically in the previous section can be cleaned using a lint-free soft cloth moistened with a solution of water and mild detergent; in case of sanitization, moisten the cloth with hydrogen peroxide at a 3% concentration. The device allows multiple cleanings without degradation of basic safety or performances; 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 appliance. 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 appliance.



All detachable parts of the audiometer are designed specifically for use with the appliance. Only parts supplied by Inventis should be connected to the audiometer.

LOADING THE PRINT PAPER

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



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

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



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

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

REPAIRS AND TECHNICAL ASSISTANCE

Before contacting the service department, make certain that all the possible solutions in the “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.

Troubleshooting

Problem	Possible cause	Solution
No signal from a transducer	Transducer not connected to the correct output	Connect the transducer to the correct output
	Transducer damaged	Contact Inventis service department or dealer
No signal from patient response button when pressed	Wrong connection	Connect the patient response button to the correct socket
	Patient response button damaged	Contact Inventis service department or dealer
No signal from monitor headphones	Wrong connection	Connect the monitor headphones to the correct socket
	Headphone volume too low	Press the MONITOR button to increase the volume
Patient's voice cannot be heard	Problems with TALKBACK input connection	Check the connection to the TALKBACK input
	TALKBACK volume too low	Adjust the TALKBACK volume control
Connection between PC and audiometer	Problems with USB connection	Check the USB connection between instrument and computer

cannot be established	USB cable damaged	Change the USB cable (standard USB A/B cable)
INT1 or INT2 input cannot be selected in speech audiometry mode	Internal memory not enabled	Verify that the audiometer model has an internal memory
	No speech material stored in the internal memory	Use <i>ATIT</i> software to check that the internal memory contains speech material
Date and time prompt appears when instrument is powered up	Internal battery failure	Contact Inventis service department or dealer to have the battery replaced
Display remains blank	Instrument not powered up correctly	Check the connection to the power supply and make certain the switch is in position “1”
	Adapter damaged	Contact Inventis service department or dealer
You cannot access to a test	Optional test not enabled	Contact your reference technical service to obtain the licence, communicating the device serial number



Where 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.