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 3 ("Installation and power up").

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

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Summary

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.

At Inventis, we believe strongly in the desirability of *integrating* different diagnostic tools. Besides audiometers, we have developed many other devices for ENT specialists and audiologists, such as a wireless video otoscope, endoscopic video cameras and stroboscopic light sources. A significant advantage offered by all our diagnostic instruments is their ability to interface with the Daisy medical records application: tests of all kinds — audiometric, images or film clips, acquired even from different locations — are stored in the one archive and can therefore be consulted without difficulty from the user's computer.

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

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CHAPTER 1:

Safety: warnings and information

OPERATOR MANUAL

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

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

OPERATOR RESPONSIBILITIES

The Bell and Harp audiometers are 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 mains supply and do not use it again until the necessary repair and servicing have been completed. Defective and malfunctioning parts must only be replaced with original spare parts supplied by Inventis srl. All repairs must be performed exclusively by Inventis or by personnel authorised by Inventis.

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

Users are entirely responsible for any malfunction caused by improper use, or by maintenance or repair operations performed by any party other than

Inventis srl or an authorised Service Centre. Inventis srl and its Service Centres accept responsibility for the performance and reliability of the instrument only if:

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

INTENDED USE

Bell and Harp audiometers are designed for use by audiology specialists in conducting pure-tone and speech (Harp only) audiometry tests, and certain of the more important supra-threshold tests.

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

Bell and Harp audiometers are intended for use by persons who have a detailed knowledge of the procedures involved in conducting an audiometric test; the operator must therefore be either an audiologist (or a technician with knowledge and experience of audiometry) or a doctor in possession of specific skills (audiology specialist or occupational physician).

PRECAUTIONS

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

Installation and general precautions

Make certain that the required ambient conditions are met (during transport, storage and operation) as indicated in "APPENDIX A: Technical Specifications".

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 accessories supplied by Inventis srl, unless specifically indicated otherwise.

Use only power adapters intended for medical equipment, certified to EN 60601-1. For further information see "APPENDIX A: Technical Specifications".

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 EN 60601-1-1), 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 60601-1-1.

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.

Calibration

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 color. 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 EARTone 3A and EARTone 5A 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 12: 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.

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 IX of Medical Device Directive (MDD) 93/42/EEC as amended by 2007/47/EC directive.
The leading assessment company TÜV certified the Inventis Quality Management System as compliant to ISO 9001 and ISO 13485 standards.

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.*
📖ⓘ	*Consult instruction for use.*
🗑	*The instrument is marked with this symbol to indicate that it is electronic equipment covered by the Directive 2002/96/EC on waste electrical and electronic equipment (WEEE).*
🧍	*Device with applied parts of type BF (EN60601-1).*
CE 0123	*Product conforms to European Community Medical Device Directive (MMD) 93/42/EEC, as amended by 2007/47/EC directive. Class IIa device; number of notified body: 0123 (TÜV SÜD Product Service GmbH).*
Rx only	*Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner*
IP20	*IP (Ingress Protection) Code: this device is protected against the access of objects sized > 12.5 mm, not protected against liquid.*
MODEL	*Device model*
REF	*Catalogue number*
SN	*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:*

- *first 5 characters: Inventis product code*
- *characters 6 and 7: year of manufacture ("10" denotes 2010)*
- *character 8: model series*
- *characters 9… 13: serial number*

CHAPTER 2:

Introduction

This chapter describes the main features of the Inventis Bell and Harp audiometers, and in particular, explains the differences between the two models.

MAIN FEATURES

Inventis Bell and Harp audiometers are portable devices, with which audiometric tests can be conducted simply and swiftly. The two models, with their different configurations, cover a wide range of needs, including Occupational Medicine and Audiology Clinics.

The main strengths of Bell and Harp audiometers are:

- large and bright colour graphics display, which shows the entire audiogram even during the test;
- highly ergonomic keyboard layout, reflecting thorough research and extensive testing in the field;
- compact and intelligent design;
- interaction with computer, using dedicated Daisy and Noah modules;
- (Harp Plus only) internal flash memory in which to store word lists used for speech audiometry.

Bell and Harp audiometers are available in 2 versions, *Basic* and *Plus*, offering these key features:

- Bell Basic: screening pure-tone audiometry — air conduction only;
- Bell Plus: diagnostic pure-tone audiometry — air or bone conduction;

- Harp Basic: diagnostic speech and pure-tone audiometry — air conduction, bone conduction and free field;
- Harp Plus: all features of the Basic model, plus certain supra-threshold tests and an internal flash memory containing words lists used for speech audiometry.

The following tables indicate the types of tests that can be performed with each model.

Bell Basic			
Exam	Channel	Inputs	Outputs
PURE TONE AUDIOMETRY	Stimulus	Pure tone, warble	AC
	Masking	NBN	AC
AUTO THRESHOLD	Stimulus	Pure tone	AC

Bell Plus			
Exam	Channel	Inputs	Outputs
PURE TONE AUDIOMETRY	Stimulus	Pure tone, warble	AC, BC
	Masking	NBN, WN	AC, BC, Insert
AUTO THRESHOLD	Stimulus	Pure tone	AC

Harp Basic			
Exam	Channel	Inputs	Outputs
PURE TONE AUDIOMETRY	Ch. 1	Pure tone, warble	AC, BC, FF
	Ch. 2	NBN, WN	AC, BC, FF, Insert
AUTO-THRESHOLD	Ch. 1	Pure tone	AC
SPEECH AUDIOMETRY	Ch. 1	EXT1, EXT2, MIC	AC, BC, FF
	Ch. 2	SN, WN, EXT1, EXT2	AC, BC, FF, Insert

| ABLB | Ch. 1 | Pure tone | AC |
| | Ch. 2 | Pure tone | AC |

Harp Plus			
Exam	Channel	Inputs	Outputs
PURE TONE AUDIOMETRY	Ch. 1	Pure tone, warble	AC, BC, FF
	Ch. 2	NBN, WN	AC, BC, FF, Insert
AUTO-THRESHOLD	Ch. 1	Pure tone	AC
SPEECH AUDIOMETRY	Ch. 1	EXT1, EXT2, MIC, INT1, INT2	AC, BC, FF
	Ch. 2	SN, WN, EXT1, EXT2, INT1, INT2	AC, BC, FF, Insert
ABLB	Ch. 1	Pure tone	AC
	Ch. 2	Pure tone	AC
SISI	Ch. 1	Pure tone	AC, BC
	Ch. 2	NBN, WN	AC, BC, Insert
DLI	Ch. 1	Pure tone	AC, BC
	Ch. 2	NBN, WN	AC, BC, Insert
TONE DECAY	Ch. 1	Pure tone	AC, BC
	Ch. 2	NBN, WN	AC, BC, Insert
MASTER HEARING AID	Ch. 1	EXT1, EXT2, MIC, INT1, INT2	AC
	Ch. 2	EXT1, EXT2, MIC, INT1, INT2	AC
STENGER	Ch. 1	Pure tone, warble, EXT1, EXT2, MIC, INT1, INT2	AC

	Ch. 2	Pure tone, warble, EXT1, EXT2, MIC, INT1, INT2	AC
TEN TEST	Ch. 1	Pure tone	AC
	Ch. 2	TEN noise	AC
QuickSIN TEST	Ch. 1	INT1, INT2	AC, FF
	Ch. 2	INT1, INT2	AC, FF

Inputs INT1 and INT2 denote the internal flash memory, in which audio files can be stored.

ACCESSORIES

The following table lists the various accessories either supplied with or obtainable to order for the different audiometer models.

Part	Bell Basic	Bell Plus	Harp Basic/Plus
Telephonics TDH-39 or RadioEar DD45 supra-aural headphones	●	●	●
Sennheiser HDA-280 supra-aural headphones (alternative to TDH-39)	opt.	opt.	-
EARTone 5A insert earphones	opt.	opt.	opt.
EARTone 3A insert earphones	opt.	opt.	opt.
Amplivox Audiocups noise excluding enclosures (fit only on TDH-39 and DD45 headphones)	opt.	opt.	opt.
B71 bone vibrator	-	●	●
IME-100 Insert masking earphone	-	opt.	opt.
Patient response switch	●	●	●
Monitor headphones with microphone	-	-	●
Clip-on microphone for patient-to-operator communication	-	-	●
Desktop microphone for live speech test	-	-	opt.

Integrated thermal printer	-	-	opt.
Plastic cover sheet	●	●	●
Carrying case	opt.	opt.	opt.
Inventis Software Suite CD	●	●	●
USB cable	●	●	●
Medical grade power supply (6V)	●	●	●
User manual	●	●	●

CHAPTER 3:

Installation and power up

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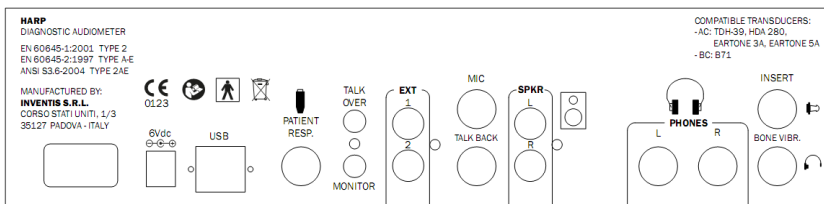
Plug all transducers and accessories into the respective sockets as indicated in the following table:

Connector	Attachment
INSERT	Insert earphone for masking
BONE VIBR.	Bone vibrator
PHONES	AC headphones: 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
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

Connect the power adapter to the 6Vdc ⊖-⊖-⊕ 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 power adapters intended for medical equipment, certified to EN 60601-1. For further information see "Appendix A – Technical Specifications".*

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, illustrated below.

```
15/2/2011    14:30                        Patient 1
┌────────────────────────────────────────────────┐
│            Pure tone audiometry                  │
└────────────────────────────────────────────────┘

              Auto threshold

            Speech audiometry

Calib. expiry date: 15/2/2012              AC: TDH 39
┌──────────┬──────────┬──────────┬──────────┐
│          │  SETUP   │ PATIENTS │    OK    │
└──────────┴──────────┴──────────┴──────────┘
```

The main screen lists all the tests available on the audiometer; to conduct one of these, select it by turning the left hand knob of the instrument to highlight the name, then press the OK function button (or touch the INTERRUPTER of channel 1).
The top part of the display shows the date and time and the name of the current patient, to whom all the tests conducted in the session will be associated (see Chapter 8: Patient archive).
The bottom part of the display indicates the calibration expiry date (12 months subsequent to the date of the last calibration) and the transducer

selected for an air conduction test (TDH-39, DD45 or HDA-280 supra-aural headphones, or ER-3A or ER-5A insert type earphones).

The instrument can be configured in such a way as to skip the main screen and go straight to the pure-tone audiometry window: see *Chapter 11: Settings.*

CHAPTER 4:

Controls on Bell and Harp audiometers

This chapter describes the controls incorporated into the keyboards of Bell and Harp audiometers. Reference is made to the Plus versions of the two models; the keyboard of the Basic version is essentially the same, but without certain of the controls on the Plus.

CONTROL OF CHANNELS

Bell and Harp audiometers have two separate and independent channels. This section describes the controls used to operate the two channels, which in the case of the Bell model are identified as "stimulus channel" and "masking channel", whereas in the case of the Harp model they are denoted simply as "channel 1" and "channel 2".
The controls for one channel are illustrated below (the layout is duplicated in mirror image for the other channel).
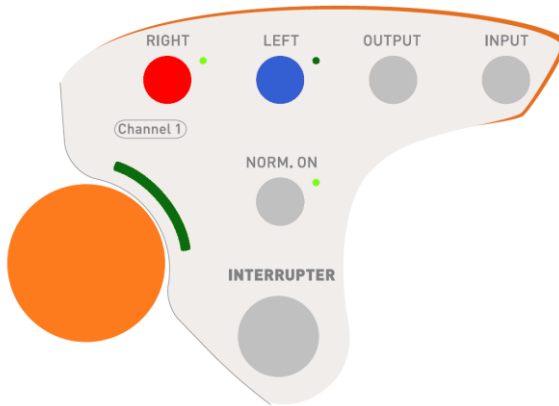
Right and Left. The Right and Left keys are used to select stimulation on either side. For stimulation on both sides, press the two keys simultaneously. By default, selecting one side as the stimulation side on channel 1, the opposite side is assigned automatically to channel 2; however, the operator can change the masking side, making it the same as the stimulation side.

Output. The Output key is used to select the transducer utilized, which can be one of various types, depending on the type of test, the channel and the audiometer model:
- air conduction (AC)
- bone conduction (BC)
- free field (FF)
- insert type earphones for masking (INS).

Input. The Input button is used to select the input signal. Various signals can be used according to the type of test, the channel and the audiometer model.
For pure-tone audiometry, possible inputs are:
- channel 1: tone and warble;
- channel 2: narrow band noise (NBN) and white noise (WN).

For speech audiometry, possible inputs are:
- channel 1: external signals 1 or 2 (EXT1, EXT2), internal flash memory (INT1, INT2) and external microphone (MIC);
- channel 2: external signals 1 or 2 (EXT1, EXT2), internal flash memory (INT1, INT2), speech noise (SN) and white noise (WN).

Interrupter. This key switches on the channel. On the Bell audiometer, there is no interrupter for the masking channel. To eliminate any possible

18

mechanical switch noise completely — as this could influence the response of the patient — the designers of the product opted for a capacitive touch button: the operator need only touch the metal cap to present the tone.

Norm. ON. Selecting the "Normally ON" function for the channel (with the green indicator alight), the relative output will be permanently active, unless the channel is switched off by touching the interrupter. Activating the "Normally ON" function, accordingly, the operating logic of the interrupter is inverted.

To reiterate, the Bell audiometer has no interrupter switch on the masking channel; consequently, the "Normally ON" button is replaced by an "Enable" button that switches the masking function on and off.

Knob. A knob associated with each channel is used by the operator to attenuate the output. In practice, these knobs are used in certain situations for other purposes; for example, with the Settings menu activated, the various settings of the instrument are selected with the two knobs. When the knobs are used to perform a specific function other than that of attenuating the channel output, the sector-shaped indicator adjacent to the knob will light up.

CONTROLS COMMON TO BOTH CHANNELS

At the top of the keyboard there are four buttons, illustrated below, controlling respective functions common to both channels.

Step dB. The first button (Harp model only) is used to select the incremental step for the attenuators, which can be 1 or 5 dB. The Bell audiometer allows a step of 5 dB only.

Pulsed. Allows the selection of pulsed mode for presentation of the stimulus signal. The pulse rate — 0.5 Hz, 1 Hz or 2 Hz — can be selected with the relative function key.

Tracking. When the tracking option is selected, the difference between the intensity of the stimulus and masking signals is maintained constant with any variation in the intensity of the stimulus signal.

Lock. When the lock option is selected, the masking tone will be switched on and switched off together with the stimulus tone. With lock enabled, the interrupter and the Normally ON button of channel 2 are deactivated.

FREQUENCY CHANGE AND STORE

The lower part of the audiometer keyboard includes two frequency change buttons and the *Store* button, which are illustrated below.

STORE

FREQUENCY

INCORRECT   CORRECT
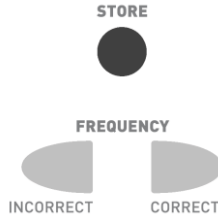
Frequency. The two frequency buttons are used to change to the previous frequency and the next frequency. In the case of speech audiometry, these two buttons are used to count the words recognized and not recognized by the patient.

Store. Store is pressed to memorize the threshold at each frequency, in pure-tone audiometry, and the values measured in all other tests. In pure-tone audiometry, furthermore, the instrument can be set so that the test moves on to the next frequency automatically, whenever the threshold is saved. For details on configuration of the automatic frequency change, see CHAPTER 11: *Settings.*

FUNCTION BUTTONS

The keyboards of Bell and Harp audiometers present two groups of function buttons:
-    four buttons associated with configurable soft keys, immediately below the display;
-    six dedicated function buttons, arranged across the top part of the keyboard.

The function of the soft keys is changeable according to the status of the instrument: for example, there will be one function when pure-tone audiometry is enabled, and a different function when speech audiometry is enabled. The soft key functions are indicated at the bottom of the display window, immediately above the buttons.
In this manual, the four buttons are denoted F1, F2, F3 and F4, from left to right.

F1   F2   F3   F4
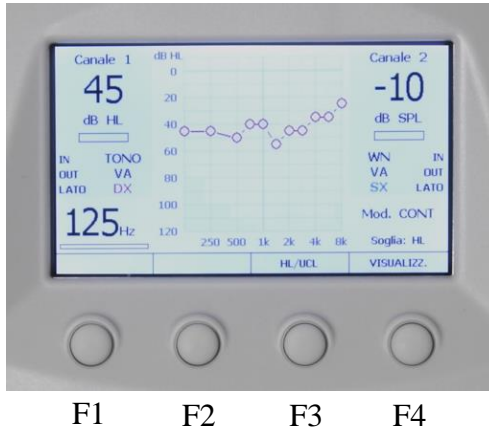
The six function buttons illustrated below are positioned uppermost in the keyboard area.

Back. This is pressed to go back to the previous window. For example, if Back is pressed during a pure-tone audiometry test, the main menu will reappear.

New Patient. The functionality of the New Patient key depends on whether or not patient management is enabled (see *CHAPTER 11: Settings*). If patient management is disabled, pressing the New Patient key will cancel all examinations conducted in the current session. With patient management enabled, conversely, it will be possible to save the current pure-tone audiometry examination. If examinations are not saved in the patient memory of the device or transferred to a computer, all the relevant data will be lost.

Save Exam. Saves the current test to the patient memory of the instrument, associating it with the patient indicated in the main window (please refer to *CHAPTER 8: Patient archive* for a detailed description of the archiving function). Remember:
- only pure-tone audiometry examinations can be saved to the patient memory;
- patient management can be disabled (see *CHAPTER 11: Settings*); in this situation, pressing the Save Exam button will have no effect.

Erase data. Cancels the current data. In pure-tone mode, for example, this clears the symbol on the audiogram corresponding to the selected side (L/R), transducer and frequency.

To Pc. Sends the current examination to a computer, on which the Daisy or Noah software application must be installed, with the relative Maestro module. In the case of the Harp model, equipped with a thermal printer, this button can also initiate a printout of the test.

Help. This button opens a context-sensitive help window, i.e. displaying information pertinent to the type of test being conducted. Pressing Help once, this window will open.

Press the button for which
help is required or press the
"HELP" button for information
on the current window

At this point:
- pressing Help a second time, the display shows general information on the functions of the current window;
- pressing any other button, the display will show information relating specifically to that button.

PATIENT-OPERATOR COMMUNICATION

The functions governing communication between the patient and the operator are Talk over, Talk back (available on the Harp model only), and the Response LED.

TALK OVER   RESPONSE   TALK BACK

Talk over. This enables the operator to talk to the patient, who will hear the operator's voice by way of the transducer currently selected.

Communication is enabled by pressing and holding the button, and disabled on release.

Harp and Bell audiometers have a microphone built into the chassis, which can be used to communicate with the patient. If an external microphone is plugged into the Talk over socket on the rear panel, the built-in microphone will be disabled.

Pressing and holding the Talk over button, the operator can control the communication volume by turning the Channel 1 knob.

If the MIC input is selected during speech audiometry so that the test can be conducted using the operator's own voice, the Talk over function is automatically directed through the same input, given that in this instance the operator will use the external microphone (connected to the MIC input on the rear panel) to communicate with the patient.

Talk back. This function enables the patient to communicate with the operator, and is available only on the Harp model. Unlike Talk over, Talk back remains enabled even after the control has been released; to deactivate the function, the operator must press the button a second time.

The voice of the patient can be heard:

1) through the speaker incorporated into the chassis;
2) through headphones or external speakers connected to the "Monitor" socket on the rear panel, which when plugged in will disable the internal speaker.

For information on adjustment of the Talkback volume, see the section on "Volume Control".

Response. The Response Led, located in the middle of the keyboard, will light up whenever the patient presses the response button.

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

Grouped together at the top right of the Harp keyboard are three buttons controlling gain of external inputs, communications between patient and operator, and the operator's monitor output, as illustrated below.

Talk. Pressing the Talk button, the display will show a volume control window for communications between patient and operator. The left hand knob controls the volume of communication from operator to patient, and the right hand knob, of communication from patient to operator. To quit the window, press Talk a second time, or press function button F1.
The volume settings are retained even after the instrument has been switched off.

Gain. Pressing the Gain button, which is active only when conducting speech audiometry, the display will show a gain control window for the speech material. Gain — controlled using the two knobs — determines the level of the input signal currently selected, or the external input (EXT1 or EXT2), or the internal flash memory (INT1 or INT2, available on the Harp Plus model only), or the microphone (MIC). Gain values for each input are saved internally of the audiometer, and remain stored even after the instrument has been switched off. See *CHAPTER 6: Speech audiometry* for a detailed description of the gain setting procedure.

Monitor. Pressing the Monitor button, the display will show a volume control window for monitor signals used by the operator. Control is by way of the two knobs, each serving one respective channel. To switch off the monitor on either channel, simply turn the knob anti-clockwise right down to zero volume. The monitor signal can be heard either on the internal speaker of the instrument, or on headphones or external speakers connected to the Monitor socket on the rear panel. The level of the monitor signal set during a speech audiometry test is saved internally of the instrument and remains stored even after the power has been switched off. For other examinations, the initial level of the monitor signal can be the same as the level set for speech audiometry, or can be set to zero, according to the type of setting selected (see *Chapter 11: Settings*).

The Plus version of the Harp audiometer is equipped with an internal flash memory of 2 GB capacity, where the operator can store lists of words in *.wav* format for speech audiometry (see *CHAPTER 10: Customizing the word lists,* for a description of the uploading procedure); accordingly, tests can be conducted without the need for an external CD or cassette tape drive. The top left of the keyboard on the Harp Plus audiometer presents four buttons, illustrated below, which are used to manage the playback of word lists stored in the flash memory. The buttons are enabled in speech audiometry mode only, when internal material (INT1 or INT2) is selected as the input signal.
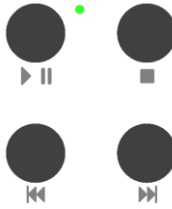
Play / Pause. This button is pressed to start playing the current list (indicated in the display), or to pause the list if already playing. The Led remains permanently alight during Play, and blinks as long as Pause is selected. For a detailed description of how word lists are organized in the internal memory, see the final section of *CHAPTER 6: Speech audiometry*.

Stop. Terminates playback of the current list.

Previous. If there is no audio material being played currently, pressing the Previous button will bring up the list preceding the current list. If there is a list playing when the Previous button is pressed, the playback will jump back to the previous word, if the list is indexed, or by 5 seconds if not indexed.

Next. If there is no audio material being played currently, pressing the Next button will bring up the list that follows the current list. If there is a list playing when the Next button is pressed, the playback will jump forward to the next word, if the list is indexed, or by 5 seconds if not indexed.

CHAPTER 5:

Pure tone audiometry

Pure tone audiometry is the standard hearing test used in audiology clinical practice, providing the basis for patient diagnosis and management.

This chapter describes the procedure for conducting pure tone audiometry tests with Bell and Harp audiometers.

HEARING THRESHOLD

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

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

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

The tone signals generated by the audiometer, and the level of the audiometric threshold, are measured in decibels (dB). In reality, the unit of measure is the dB HL (Hearing Level); in contrast to the dB SPL (Sound Pressure Level), which represents the actual intensity of the sound, the dB HL includes a compensating factor whereby a person with normal hearing tested under ideal conditions will have a hearing threshold of 0 dB HL at every frequency. These compensating factors, which are different for each frequency and each type of transducer, have been calculated from studies conducted on a large number of patients and are published in international standards (EN ISO 389-1, 389-2, 389-3, 389-4, 389-5 and 389-7).

PURE TONE AUDIOMETRY WINDOW

To conduct a pure-tone audiometry test, the operator must first bring up the relative window from the main menu (the instrument can be set up in such a way that the pure-tone audiometry window appears automatically after switching on: see *CHAPTER 11: Settings*).

Once accessed, the window in question can be presented in one of two ways, depending on the viewing mode selected.
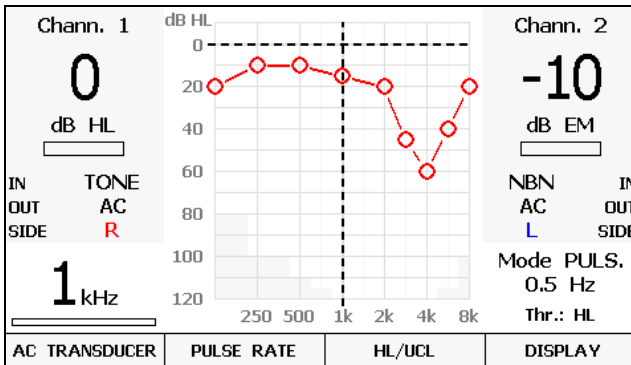
Viewing mode with audiogram
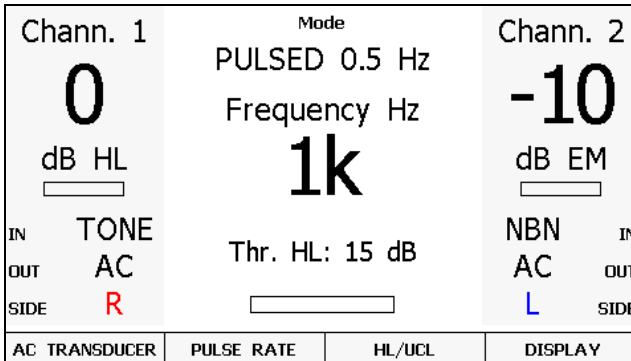
Viewing mode without audiogram

To toggle between these two modes, simply press the F4 (View) button; the current mode will be "remembered" by the instrument when it is next powered up.

Selecting the first mode, the screen will show the audiogram for the stimulation side currently selected, with the various items of information displayed in smaller characters to accommodate the graph.

In either mode, the left and right hand sides of the screen will show the information, on a grey background, relating respectively to channel 1 (stimulus) and to channel 2 (masking), namely:
- level of intensity;
- status of channel (active or inactive);
- input signal (IN);
- transducer (OUT);
- stimulation side.

Also displayed, at the bottom right and left in the case of the audiogram viewing mode, or centrally in the case of text-only mode, are:
- stimulation frequency;
- presentation mode (continuous or pulsed, with or without the pulse frequency);
- type of threshold selected (HL or UCL, available only in the case of air conduction), which in text-only mode can also be accompanied by the threshold level saved for the current type of transducer, side and frequency of channel 1;
- status of patient response button.

In the graphic viewing mode, the central area of the screen is occupied by the audiogram relating to the stimulation side currently selected. The horizontal and vertical lines on the audiogram indicate the frequency and sound intensity values currently selected for channel 1. The grey area in the lower part of the audiogram indicates the frequency and intensity values that cannot be covered with the selected transducer.

From the pure tone window, you may directly change the transducer used for air conduction tests by pressing the AC TRANSDUCER function button, which is active only when one of the current outputs is the air conduction. Note that it is also possible to select the air conduction transducer in the settings menu (see Chapter 10: *Settings*).

PRESENTING THE TONES AND SAVING THE REPLY

Before commencing a pure tone audiometry test, the stimulation parameters must be set, and in particular:
1) the input signal on channel 1 (stimulus): tone or warble;
2) the input signal on channel 2 (masking): NBN or WN;

3) the transducer for channel 1: headphone (AC), bone vibrator (BC) or speakers (FF);
4) the transducer that delivers the masking signal: headphone (AC), bone vibrator (BC), speakers (FF) or insert earphone (INS);
5) the method of presenting the stimulus — continuous or pulsed (PULSED button); in the case of pulsed mode, the pulse frequency (0.5, 1 or 2 Hz) can be selected with function button F2 (PULSE RATE);
6) the side to which the stimulus is presented: right (R), left (L) or bilateral (BIL, not available if the output is BC);
7) the side on which the masking signal is generated, which is set automatically as the side opposite to that of the stimulus, but can also be set as ipsilateral;
8) the intensity and the frequency of the stimulus and of the masking signal.

Once these parameters have been set, the signal can be presented by touching the INTERRUPTER button for channel 1 (stimulus), or the NORM.ON can be pressed to keep the signal constantly active (in this instance, touching the INTERRUPTER button will have the effect of discontinuing the signal)

The same principle applies for activation of the masking signal on channel 2: in the case of the Bell audiometer, however, there is no INTERRUPTER on the masking channel, which can be enabled continuously by means of the ENABLE button. For a description of the TRACKING and LOCK functions on the masking channel, see *CHAPTER 4: Controls on Bell and Harp audiometers*.

Remember that for safety reasons, if the intention is to present a stimulus signal stronger than 100 dB HL, the operator must first press the F1 button (Higher dB), which is active only when the intensity of the stimulus reaches 100 dB HL.

Having identified the audiometric threshold of the current frequency, it can be saved by pressing the STORE button. In graphic viewing mode, a symbol will appear on the audiogram, corresponding to the signal presented at the frequency and intensity currently selected (see Appendix C for a list of the symbols utilized). In text-only viewing mode, on the other hand, the hearing threshold saved for the frequency in current use is indicated below the frequency display field.

If, at a given frequency, the tone presented is not heard by the patient even at the maximum available intensity, the signal can be marked as "not heard"

by pressing the F1 function button (NOT HEARD), which will be active only when the intensity of the signal is at its maximum value.

Should an error occur when saving a threshold, the operator can press the STORE button a second time, at the correct intensity — which will have the effect of repositioning the threshold at the new value — or delete the threshold value using the ERASE DATA button.

MASKING

When a signal is presented to one ear, the cochlea of the other ear can also be stimulated, in dissimilar measure, as a result of the sound being transmitted through the bones of the skull. The mechanism whereby a signal presented to one ear stimulates the cochlea of the opposite ear is known as *cross-hearing*. In situations where cross-hearing could occur, a masking signal must be used.
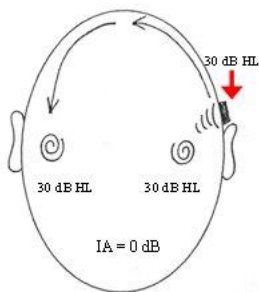
Masking consists in raising the threshold of the contralateral ear by presenting an appropriate masking signal (generally a narrow band noise, NBN, centred on the current stimulation frequency) at a predetermined level. This prevents the contralateral ear from sensing the stimulus presented to the ear being tested, which could lead to the responses of the patient registering false positives and affecting the measured threshold.

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

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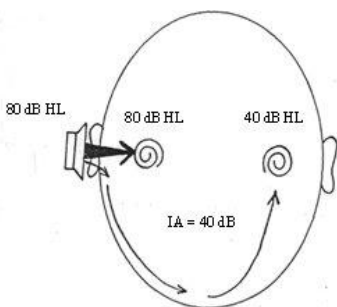
Interaural attenuation with AC   *Interaural attenuation with BC*

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

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

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

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

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

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

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

where: AC_{TE} = the air conduction threshold for the Test Ear
          IA = interaural attenuation
          BC_{NTE} = bone conduction threshold for the Non-Test (contralateral) Ear

In the same way as for a test tone, if the masking noise is of sufficiently powerful intensity, it can be transmitted by bone conduction to the test ear.

If the intensity of the masking noise is sufficient to mask not only the non-tested ear but the test ear as well, the effect is referred to as *overmasking*. The maximum intensity of masking noise above which overmasking occurs (M_{max}) is given by this formula:

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

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

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

The masking signal can be delivered through the same headphones as used for the test, or alternatively, the IME-100 insert earphone, which is supplied as an optional accessory with Bell and Harp audiometers. This type of transducer has a much higher IA than that of supra-aural headphones (from 70 to 100 dB), which helps to reduce cases of overmasking.

AIR CONDUCTION AUDIOMETRY

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

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

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

Instructions to the patient

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

Presentation and interruption of test tones

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

Initial familiarization

Before determining the hearing threshold, the patient must be familiarized with the task by presenting a signal of intensity sufficient to elicit a precise response. After this familiarization step, the operator can be confident that the patient understands the procedure and is able to respond correctly.
The following method of familiarization can be used:
1) present a 1000 Hz tone at a clearly perceptible level, say, 40 dB HL for a person with normal hearing;
2) reduce the level of the tone by steps of 20 dB until there is no longer any response;
3) increase the level of the tone by steps of 10 dB until a response is elicited;
4) present the tone again at the same level.

If the responses are consistent with the presentation of the tones, the familiarization process is complete. If not, the procedure should be repeated. Following a second failure, repeat the instructions.
In cases of profound deafness, these procedures may not be applicable.

Estimation of hearing threshold (ascending method)

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

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

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

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

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

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

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

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

BONE CONDUCTION AUDIOMETRY

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

Follow the steps indicated below to establish the threshold level.

1) Position the bone vibrator on the patient's mastoid, behind and as near as possible to the conch, without touching, and place the masking headphone over the non-test ear (the unused headphone should be positioned forward of the test ear, leaving the cavity exposed). Make certain that the head bands of the two transducers do not interfere with one another.

2) Begin the test with the ear the patient considers to be the better ear, at a frequency of 1000 Hz.

3) Establish the threshold level without the masking signal, using the shortened ascending method described in the previous section.

Bear in mind that the result of this operation cannot serve as a true estimate of the bone-conduction threshold, given the possibility that the non-test ear could be affected by occlusion (see next section).

4) Activate the masking noise and establish the correct intensity of the masking component — hence the hearing threshold — using the Plateau method described in the next section.

5) Move on to the other frequencies, following the same sequence as indicated for air-conduction testing. Continue until the test has been completed on both ears.

HOW MASKING IS APPLIED

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

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

The plateau technique involves the following three steps.

1) Find the threshold for the ear being tested, without masking.

2) Activate the masking noise at an initial level of 10 dB higher than the air conduction threshold for the non-tested ear (in the case of bone conduction, see the following note); except in certain particular cases, this level will not produce overmasking.

3) Check the threshold of the test ear again. If the threshold of the test ear has not changed, increase the intensity of the noise by steps of 5 (or 10) dB, checking the value after each increment; if there is no change in the threshold over three successive increases in the intensity of the noise (or two increases, for steps of 10 dB), this means that the plateau has been found, and the value can be considered as the threshold. Conversely, if there is a change in the threshold value, this indicates that it was influenced by undermasking, and the procedure must be repeated with the new threshold level.

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

UCL AUDIOMETRY

The UCL (Uncomfortable Level) test is used to determine the sound intensity at which acoustic stimuli become intolerable to the patient. This information is important in establishing the upper limit of the patient's hearing range, typically for the purpose of fitting hearing aids, as well as for detecting instances of recruitment.

To run a UCL test, which is possible only by air conduction, simply press the F3 function key (HL/UCL); the audiometer display will indicate the type of threshold currently selected.

AUTO THRESHOLD

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

To run the Auto Threshold test, the relative window must be opened from the main menu. As long as the automatic procedure is not initiated, a classic pure tone audiometry session can still be performed from the Auto Threshold window, using either air or bone conduction. The Auto Threshold test window is illustrated below.
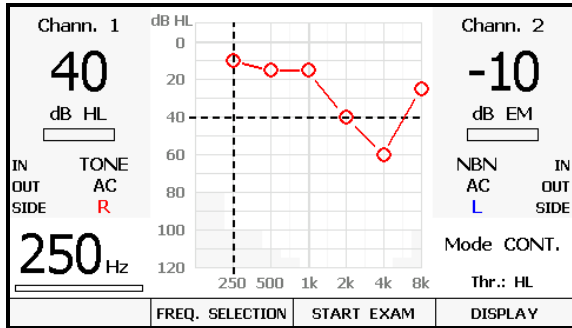
Auto Threshold window

Pressing the *FREQ. SELECTION* function button, another window opens, from which to select the frequencies that will be examined during the course of the test. Bear in mind that the 1 kHz frequency cannot be deselected. The selection or omission of each frequency is a parameter that will be retained even after the instrument has been switched off. The following frequencies are enabled initially: 250 Hz, 500 Hz, 1 kHz, 2 kHz, 4 kHz and 8 kHz.

To begin the test, simply press the *START* button. The test finishes automatically once all the enabled frequencies have been analyzed for both ears. The procedure can be interrupted if necessary, by pressing the *END* button (which replaces *START* once the test is in progress).
After pressing *START*, a message will appear warning the operator that any air-conduction-related threshold data saved previously will be erased.

The Auto Threshold test comprises an initial familiarization step serving to train the patient in the threshold identification procedure. The patient must press the response button every time the stimulus is heard, and release the button thereafter. In particular, the stimulus is presented for a duration of 1.7 seconds, followed by a pause of random duration between 1.7 seconds and 2.5 seconds.
The adopted method of determining the threshold envisages an increase of 5 dB in the level of the stimulus, and a reduction of 10 dB. The threshold is established as the level for which at least 2 positive responses are elicited from the patient over 3 sequences.

During this initial step, the message *FAMILIARIZATION* appears in the display. The stimulus presented to the patient is generated at a frequency of 1 kHz and an initial intensity of 40 dB HL (which cannot be changed). Once

the threshold has been identified, the familiarization step ends, and the test begins automatically.

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

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

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

The audiogram will be updated in real time during the course of the test, to show the results obtained.
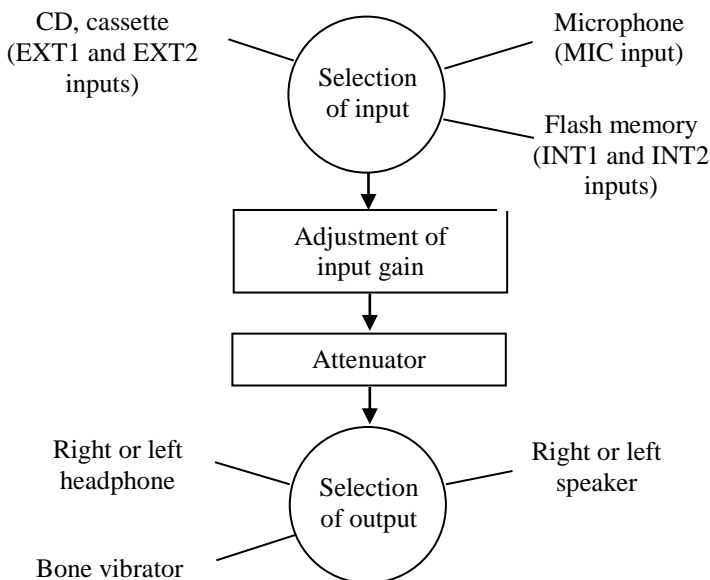
CHAPTER 6:

Speech audiometry

In addition to pure tone audiometry, there are various other tests that can be conducted with the audiometer, of which the most important and widespread is speech audiometry. This chapter explains how to conduct a speech audiometry test using the Inventis Harp audiometer.

SPEECH AUDIOMETRY TEST

Pure tone audiometry provides only partial information on the abilities of the patient to hear and understand the spoken voice, which is the most important of audible signals. To understand how a patient hears the spoken voice, speech stimuli must be utilized, and the testing method is referred to as "speech audiometry".

In speech audiometry, the patient is presented with a succession of standardized speech stimuli, typically single syllables, words or phrases, designed to assess certain aspects of the patient's hearing ability. The speech material can be presented directly by the operator, talking into a microphone, or recorded on a CD or a tape cassette and reproduced by a player connected to the EXT inputs of the audiometer, or alternatively, stored in a flash memory with which the instrument is equipped, as in the case of the Harp Plus.

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

Selection of input

CD, cassette
(EXT1 and EXT2
inputs)

Microphone
(MIC input)

Flash memory
(INT1 and INT2
inputs)

Adjustment of
input gain

Attenuator

Selection
of output

Right or left
headphone

Right or left
speaker

Bone vibrator

Selection of input

The input signal for speech audiometry can be the microphone (connected to the MIC input on the rear panel), an external audio source (CD or cassette player) connected to inputs EXT1 and EXT2 or, in the case of the Harp Plus model, the internal flash memory (INT1 and INT2), on which the speech material is already stored. The signal is selected by pressing the INPUT button on the audiometer.

Adjustment of input gain

Before starting a speech audiometry test, the level of gain on the selected input must be adjusted. The purpose of this operation is to ensure that recorded speech material utilized for the test (or the operator voice in case of live speech test) will be played back at the correct volume. In case of recorded speech material, the input gain will be correct if, applying a calibration tone supplied with the speech material, the loudness measured on the VU-meters of the two channels — displayed on the Harp screen — touches 0 dB, that is to say, the point at which the meter changes from green to red. In case of live speech test, the gain will be correct if the mean value measured by the VU-meter of channel 1 is 0 dB while you speak test words

and the distance between yourself and the microphone is the usual kept during the test.

If the level is incorrect, press the GAIN button and make the necessary adjustment using the two knobs on the audiometer.

The gain level for each input is saved by the instrument and will be set again at the same level even when the instrument is switched off and powered up subsequently.

Attenuator

The speech signal is adjusted to the level set by the operator (level of channel 1).

Selection of output

The speech signal can be presented to the patient though headphones (AC), on loudspeakers (FF), or by way of the bone vibrator (BC). In the first two instances, the operator can select the side to which the stimulus is directed, namely right, left or bilateral (pressing the LEFT and RIGHT buttons simultaneously). To select the output transducer, press the OUTPUT button.

MASKING AND COMPETING SIGNAL

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

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

ARTICULATION FUNCTION, SPEECH RECOGNITION AND SPEECH DETECTION THRESHOLDS

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

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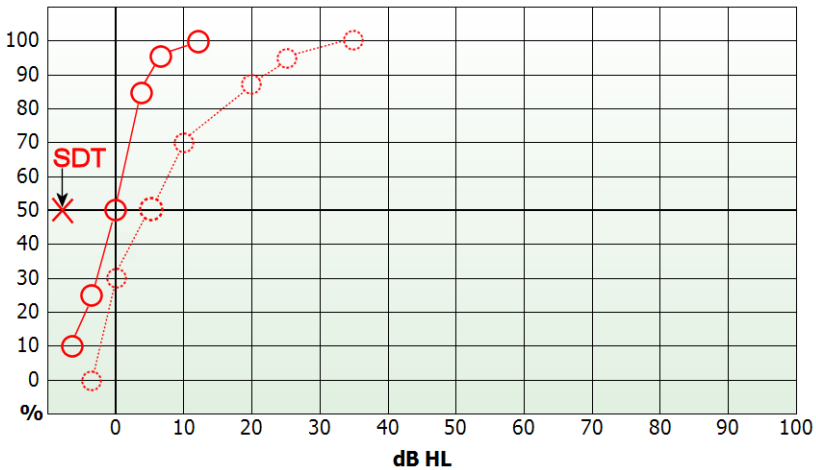
The two curves in the graph relate to two different types of speech material, and more exactly, lists of spondaic words (continuous line) and of monosyllabic, phonetically balanced words (dotted line). The level of intensity at which 50% of correct responses are obtained with lists of spondaic words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

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

Also indicated in the foregoing graph is the *Speech Detection Threshold* (SDT), that is, the intensity at which the patient detects the speech signal

(without comprehending it) 50% of the times it is presented. The SDT value for a person with normal hearing is around 13 dB SPL (or −7 dB HL).

SPEECH AUDIOMETRY WINDOW

To run a speech audiometry test, the relative window must be opened from the main menu.
Harp audiometer can perform four different speech tests:
- Word Recognition Score (WRS)
- Speech Recognition Threshold (SRT)
- Most comfortable Level (MCL)
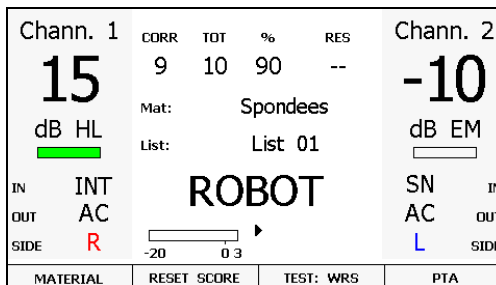- Uncomfortable Level (UCL)

Use the function button F3 to change the current test.

WRS test
Depending on the current viewing mode (see *Chapter 11: Settings*), the WRS window will be as in one of the following pictures.
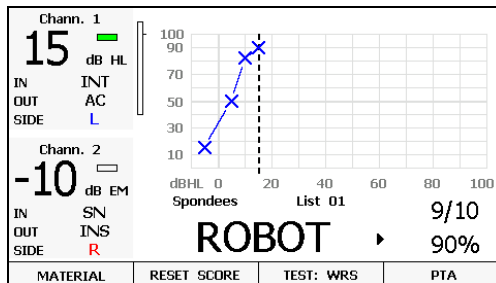
Viewing mode with articulation function

Viewing mode without articulation function

In the graphical display mode, the screen will show the articulation curve for the stimulation side currently selected, with the various items of information displayed in smaller characters to accommodate the graph.

The items of information relating to channel 1 and to channel 2, i.e.:

- level of intensity,
- status of channel (active or inactive),
- input signal (IN),
- transducer (OUT),
- stimulation side,

are grouped together in an area with a grey background located, in the graphic viewing mode, on the left hand side of the screen, whereas in text-only viewing mode the items are displayed on the left (channel 1) and on the right (channel 2) of the screen.

The remaining part of the screen shows:

- number of correct and incorrect responses elicited from the patient;
- percentage of correct responses. This value is determined on the basis of the method selected in the settings (see *Chapter 11: Settings*);
- VU-meters relative to the two channels (or channel 1 only, if the channel 2 input is SN or WN).

If the input selected for channel 1 is the internal flash memory, the following information will also be displayed:

- speech material currently selected;
- number of the current list;
- the last word presented to the patient (only if the material is indexed: see next section);
- symbol indicating the status of the player (play, pause or stop).

The responses given by the patient are saved by pressing the two frequency selection buttons, which are also labelled CORRECT and INCORRECT. The mode in which the responses are saved will depend on the "Speech score mode" option selected in the settings for the instrument (see *CHAPTER 11: Settings*).

Whatever the counting method selected, a correct response is recorded by pressing the CORRECT button. In the event of an incorrect response, press INCORRECT if Mode 1 is selected; if Mode 2 is selected, do not press any button. With Mode 2, in effect, pressing the INCORRECT button will have the effect of reducing the 'correct' count by one; accordingly, this is used only to rectify an error, when an incorrect response has been identified mistakenly as correct.

With Mode 1, the function key F2 (RESET SCORE) is active, which resets the current correct / incorrect answer counters and the percentage.

If the option 'WRS single point' has been enabled from the setting menu, the Word Recognition Score is calculated as a single point instead of using a graph. In this case, when the current outputs are either air conduction or free field, you can select the same input for both channels. Therefore, it is possible to simultaneously send the stimulus to the right and left ear at different levels.

Pressing the F4 function button (PTA), you can go directly to the pure-tone audiometry window.

SRT, MCL and UCL tests
When one of these tests is selected, the Articulation function and the information about the number of correct answers are not displayed. You will find instead the result for the current test, both for the left and for the right ear, as shown in the pictures below.
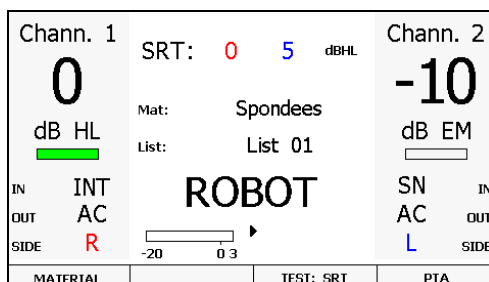
SRT test window (Numeric viewing)
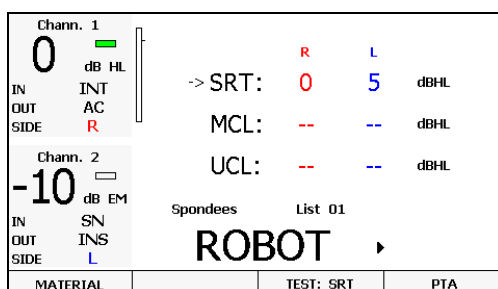
SRT test window (Graphic viewing)

Remember that if the equalization filter for the TDH-39 headphone output has been enabled in the settings, this information will appear in the top part of the window. The purpose of this filter (the pertinent specifications are

indicated in reference standards) is to render the results of speech audiometry conducted through headphones as similar as possible to those obtained in free field conditions.

USE OF INTERNAL SPEECH MATERIAL

The Harp Plus audiometer is equipped with a 2 GB flash memory, on which preferred speech material can be stored using the *Audio Tracks Indexing Tool* (*ATIT*). The use of ATIT software is fully described in the *ATIT User Manual* located in the *Inventis Software Suite CD*. The use of material stored in this way has two key advantages:
1) CD players or external cassette tape machines can be dispensed with (these tend to be delicate and cumbersome, and are not medical devices);
2) if the material is indexed using the ATIT software application, each word will be displayed on the screen as it is presented, and there is no need to activate the monitor signal.

To use material stored in the flash memory, simply select INT1 (or INT2) as the input on channel 1, and possibly on channel 2 if a competing sound is to be utilized for the test.

The internal flash memory is organized as follows:
- a directory with a set of folders, each one identifying the type of material stored (for example, logotomes, spondees, phrases, etc.);
- each folder contains a set of *wave* files, corresponding to the lists of words of the type identified by the name of the folder; the filename, attributed by the ATIT software, will generally be a label such as "Track 1", "Track 2", etc.

Bear in mind that the organization of the flash memory is entrusted to the user (or the dealer), and implemented by means of the ATIT software; consequently, it could be different to that described above.

Before playing a list from the flash memory, the required material must first be selected by pressing the F1 function button (MATERIAL). Pressing F1 repeatedly has the effect of scrolling cyclically through the folders. The folder currently selected appears in the display.

Once the material has been selected, the files of the first list in the folder can be played by pressing the relative button — "Play" — located at the top left of the Harp keyboard. For a detailed description of the controls used to play word lists, see *CHAPTER 4: Controls on Bell and Harp audiometers.*

Remember that the GAIN levels for internal inputs 1 and 2 (carrying the speech material and the competing sound, respectively) are calibrated in the same way as adopted normally for the external inputs, that is to say

presenting a test tone, which in the case of the internal inputs will be a *wave* file stored in the flash memory, pressing the GAIN button and adjusting the levels so that the volume of the sound registering on the two VU-meters is 0 dB. This level is saved by the audiometer, consequently there will be no need to repeat the operation after the instrument has been switched off.

CHAPTER 7:

# Supra-threshold and special tests

Whilst the measurements obtained with pure-tone and speech audiometry tests can give an indication of conduction, sensory or mixed problems, supraliminal tests allow the audiologist to identify the level of hearing damage in greater detail, and in particular to differentiate between cochlear and retrocochlear disorders. This chapter describes the supraliminal tests that can be conducted with the Harp audiometer, along with two other tests — Stenger and Master Hearing Aid — likewise available on the Harp model.

ABLB (FOWLER)

The Alternate Binaural Loudness Balance test (ABLB) is a procedure for determining the presence of recruitment. It is applied in cases of unilateral hearing loss or where there is an asymmetry of 25-60 dB between the tone hearing thresholds of the two ears, measured by air conduction at a given frequency.

The ABLB test involves presenting a tone to the two ears alternately, at the same frequency, but at a different intensity. The aim is to present a stimulus to the good ear (the reference ear) at different intensities, and to find the corresponding levels of stimuli presented to the poor ear that are perceived as being of the same loudness. The pairs of values obtained in this way go to make up a "loudness balance graph".

The graphic interface of the ABLB window is illustrated below.
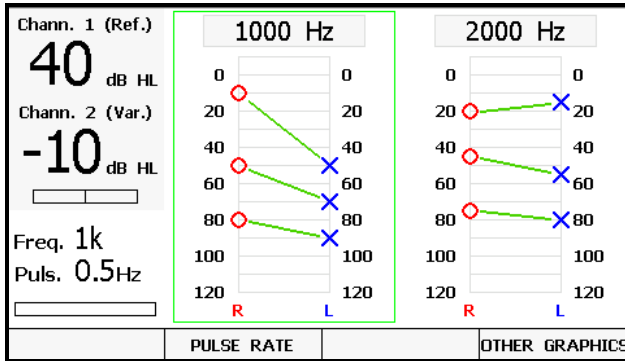
ABLB test window

The channel associated with the good ear is denoted *Ref*, and the channel associated with the poor ear denoted *Var*.

Two graphs are displayed side by side, showing the results of tests conducted under different conditions (frequency of stimulus signal or side).

The active graph (that relating to frequency, on the side currently selected) is highlighted by a green rectangle.

Up to four different graphs can be saved and stored. When more than two graphs have been saved, function F4 (*OTHER GRAPHS*), will be activated, allowing the other graphs to be viewed.

The *PULSE RATE* function button serves to set the frequency with which the tone is alternated between the two ears. Permissible values are 0.5 Hz, 1 Hz and 2 Hz.

Once four different tests have been saved, the operator can navigate between those for which the side of the good ear is the same as the side selected currently as the *Ref* channel, using the *Frequency* buttons.

The ABLB test starts generally with the levels of the tone on the two sides equal to the hearing threshold values for the given frequency. The level of intensity is then raised for the good ear by increments of 10 to 30 dB. Following each such increase, the intensity of the signal presented to the poor ear is also raised until the patient experiences a sensation of equal loudness on both sides. Having arrived at the pair of signals perceived by the patient as being the same, the STORE button can be pressed to save the combination on the loudness balance graph.

SISI (JERGER)

The Short Increment Sensitivity Index (SISI) test assesses the ability of the ear to identify brief variations of intensity in a continuous pure tone.

As a rule, the test is conducted by presenting a continuous pure tone at different frequencies, selecting an intensity 20 dB above the hearing threshold identified previously for the ear and at the test frequency, introducing small increments in intensity of short duration and asking the patient to press the button each time an increment is perceived.

The SISI test window is illustrated below.
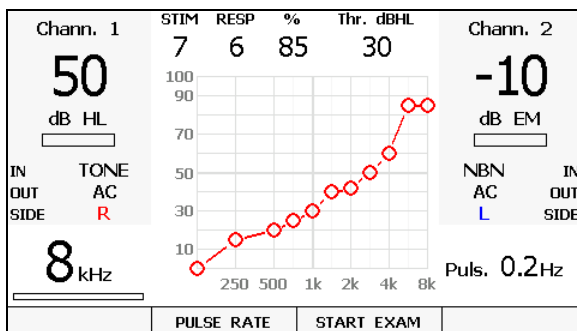
SISI test window

The areas with the grey background on the left and right of the window show the same items of information, relating to the status of channels 1 and 2, as appear in the pure tone audiometry window.

The frequency of the tone is indicated at the bottom left, whereas the bottom right shows the rate at which the increments are presented. This value can be changed by pressing the F2 function button (PULSE RATE); permissible settings are 0.2 Hz, 0.5 Hz and Random (between 0.2 Hz and 0.5 Hz, changing at each increment).

The upper half of the window displays information on the progress of the test. Indicated on the top line are the number of increments presented (*STIM*), the number of responses made by the patient to the stimuli (*RESP*), and the percentage of responses to the total number of stimuli generated (%). Also indicated are the level of the tone threshold for the type of output, and the side, selected currently for channel 1.

The central part of the screen is occupied by the SISI graph: this shows the percentage of increments perceived by the patient for each frequency analysed.

The amplitude of the increments can be set, using the "dB" button on the keyboard, to either 1 dB or 5 dB; increments of 5 dB should be used only for the initial familiarization stage of the test, during which the responses made by the patient to the stimuli will not be counted.

The SISI test is an automatic procedure. Once the frequency and the intensity of the tone have been set, the procedure is set in motion by pressing the F3 function button (START). A sequence of 20 increments will be presented to the patient, during which the responses are counted only if the button is pressed within one second of the increment being generated. The analysis of the selected frequency ends automatically once the 20 increments have been presented; the sequence can however be aborted by pressing the END function key (which replaces the START key once the test is in progress).

Increments of 1 dB should be imperceptible, or no more than barely perceptible, to patients with normal hearing or with transmission or retro cochlear hearing loss; accordingly, if the percentage of increments perceived by the patient is higher than 30%, this could be an indication of cochlear disorder.

DLI (LŰSCHER)

The Difference Limen for Intensity (DLI) test is very similar to the SISI; the purpose of the DLI test is to evaluate the amplitude of the smallest variation in intensity of a pure tone that can be perceived by a patient. In effect, there would appear to be a connection between recruitment and the ability to distinguish increments of less than 1.5 dB HL.
The DLI test window is illustrated below.
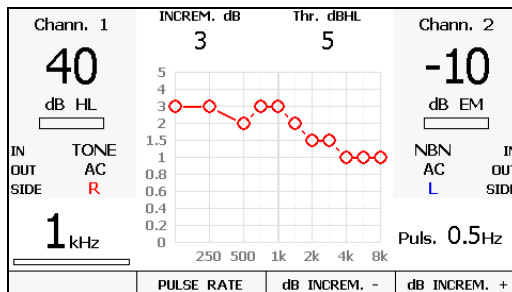
DLI test window

The areas on the right and left of the display show the same information as for the SISI test.

In this instance the top part shows the amplitude of the increments currently selected, and the tone threshold measured previously at the current frequency for the selected side and transducer.

The DLI graph in the centre shows the minimum amplitude of the increment perceived by the patient at the indicated stimulus frequency.

The test involves presenting a pure tone to the patient, at an intensity around 40 dB higher than the measured audiometric threshold, introducing increments of a given intensity at regular intervals (0.5 Hz, 1 Hz or 2 Hz), selected with the F2 function button (PULSE RATE). The value of the increments is then set to 0 dB, and gradually raised (function button F4 dB INCREM +), asking the patient to indicate when the continuous tone seems to change to a pulsed tone. Once the level has been identified, it is saved on the graph by pressing STORE.

Possible increments are: 0, 0.2, 0.3, 0.4, 0,5, 0.6, 0,7, 0.8, 0,9, 1, 1.5, 2, 3, and 5 dB.

TONE DECAY

This is a monoaural test that can reveal instances of pathological adaptation and fatigue, in other words, loss of hearing sensitivity associated with continuous acoustic stimulation.

The Tone Decay test window is illustrated below.
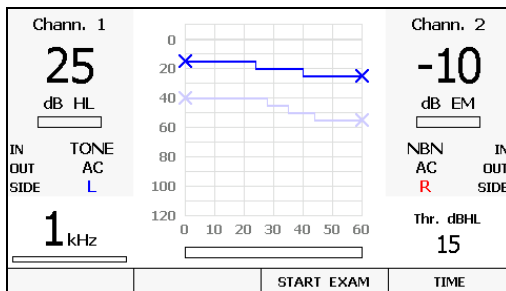
Tone Decay test window

As in the case of the tests described previously, the right and left hand portions of the window show the status of channels 1 and 2; displayed at the bottom right is the tone threshold identified previously for the frequency

and the ear (R/L) currently selected. This information is useful in determining the intensity at which to conduct the test.

The central part of the screen is occupied by the tone decay graph: the 'x' axis indicates the time, in seconds, whilst the 'y' axis indicates the level of the tone presented to the patient. The graph can show up to 4 traces — relative to the stimulation side currently selected — each relating to a specific stimulation frequency. The trace for the current frequency is brought to the front (displayed in a stronger colour).

Located below the graph is a progress bar showing the total time, and the time elapsed since the start of the test.

The test consists in presenting a continuous stimulating tone to the patient, generally by air conduction, at a given frequency and at an intensity equal to the hearing threshold for that frequency; the patient is required to press and hold the button for as long as the signal can be heard, and release when the signal can no longer be heard. At this point, the operator increases the intensity of the sound by 5 dB and the test proceeds.

The test can last for 60 or 120 seconds, the duration being selected with the F4 function button (DURATION).

The test is started by pressing function button F3 (START), and can be stopped at any time before the set time elapses by way of the END function button (which replaces START once the test is in progress)

As mentioned previously, the graph can contain up to four traces; once the test has been run on four frequencies, the START function will be disabled and no further traces can be added unless one of the existing four is first removed by pressing the ERASE DATA button.

The difference between the initial intensity of the stimulus and the intensity at the end of the test reflects the degree of *adaptation*. Adaptation values of 5 – 10 dB for a test of 60 seconds duration are considered physiological.

STENGER

The Stenger test can be used to establish whether or not a measured hearing threshold is genuine. It is based on the 'Stenger effect': if a sound is presented to both ears of an individual at a single frequency, but simultaneously at different intensities, it will be heard only by the ear exposed to the higher intensity.

Having established the hearing threshold for a given frequency, the tone is presented to the good ear at a level 5-10 dB higher than the threshold, and

presented to the bad ear at a level slightly lower than the supposed threshold.

If there is a genuine loss of hearing in the bad ear, the individual will indicate that the sound can be heard in the good ear. A different response means that the hearing loss is not genuine.

The Stenger test can be conducted using pure tone signals or speech material.

The Stenger test window is illustrated below.
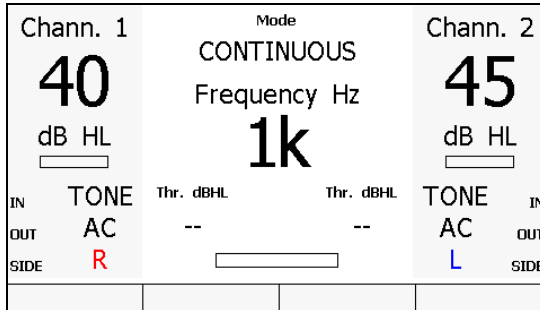
Stenger test window

Selecting a pure tone or warble input, the central area of the display will show the stimulation frequency and the thresholds established previously in the course of pure tone audiometry tests conducted on the right ear and the left ear.

If on the other hand the test is conducted using speech material, selecting the EXT1, EXT2, INT1, INT2 or MIC as the input, the central area of the display will show the VU-meter and, in the case of the INT1 or INT2 input, the selected speech material and list.

No results are saved for this type of test. Consequently, there is no function allowing reports to be printed or sent to a computer.

MASTER HEARING AID

The Master Hearing Aid (MHA) test can be used to assist the selection of a hearing aid for patients with impaired hearing. With the MHA test, the audiometer can simulate the use of a hearing aid by filtering the speech signal sent to the patient; in this way it is possible to verify and quantify any improvement in speech recognition attributable to the introduction of a hearing aid.

Various different filters can be selected and activated independently for each channel. These are high-pass type filters with amplification of 6 dB, 12 dB, 18 dB and 24 dB per octave.

The MHA test window is illustrated below.
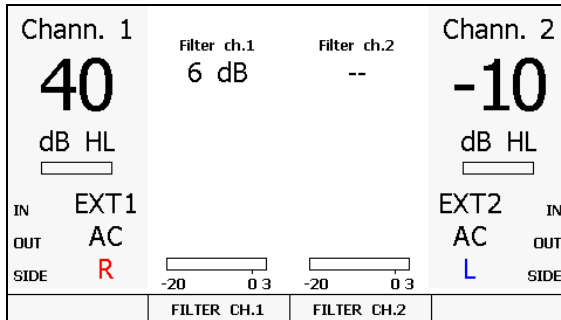
MHA test window

The filters active on each channel are displayed at the top of the window, and the two VU-meters at the bottom.

If the INT1 or INT2 input is selected, the window also shows the speech material, the name of the list, and the word presented to the patient. To change the speech material, press function button F1 (MATERIAL).

Function buttons F2 (FILTER CH.1) and F3 (FILTER CH.2) are used to select the type of filter applied to the corresponding channel 1 and 2, or to disable the filter.

As in the case of the Stenger test, no results are saved for the MHA, which means therefore that reports cannot be printed or sent to a computer.

TEN TEST

The TEN test can be used to assist the detection of a dead region in the cochlea. The test is designed to be quick and easy to administer and hence suitable for use in clinical practice. The development and validation of the test were made by Dr Brian C. J. Moore at the University of Cambridge.

The test involves measuring the threshold for detecting a pure tone presented in a background noise called "threshold-equalizing noise" (TEN).

To perform the test, it is mandatory to previously assess the patient's pure-tone threshold levels between 500 and 4000 Hz. After the pure-tone audiogram is obtained, the user can access the TEN test screen from the main menu and see it displayed on the background of the graph. During the

execution of the exam, the noise must be added to each frequency of the pure-tone signal with a level at least 10 dB above that of the threshold. Both the tone and the noise are presented to the same ear of the patient. So far, if the obtained masked threshold is 10 dB or more above that of both the threshold and the TEN noise, the cochlea is considered "dead" at that frequency.

On Harp, the TEN test has its dedicated screen accessible from the main menu. Here, the user can set the side to be stimulated and the intensities relative to the stimuli and noise. Similar to pure-tone audiometry, during TEN test it is possible to present a pulsed stimuli, enable the tracking or lock options.
Stored masked thresholds are displayed on the audiogram using "T" symbols and the masking level indicated below.

Following, a TEN test window is illustrated.
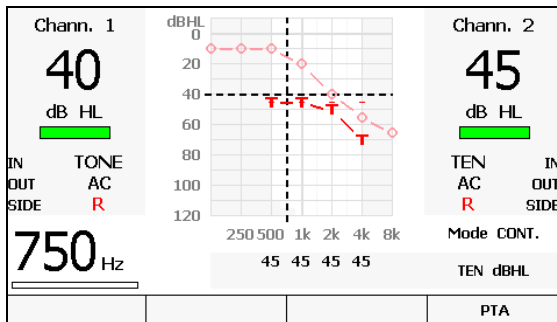
TEN test window

How to enable the TEN test

In order to enable the TEN test, access the test window from the main menu, press the ENABLE function button and fill in the licence number.

QUICKSIN TEST

Difficulty with hearing in background noise is a common complaint among hearing-impaired persons. The measurement of SNR loss (signal-to-noise-ratio) is important because speech understanding in noise cannot be reliably predicted from the pure tone audiogram (Killion & Niquette, 2000).

The QuickSIN™ test was developed to provide a quick estimate of SNR loss and it is comprised of sentences recorded in four-talker babble. Each of the lists has six sentences with five key words per sentence, one sentence at each SNR of 25, 20, 15, 10, 5 and 0. SNR loss can be estimated scoring the five key words in each sentence, giving one point to each word repeated correctly.

QuickSIN™ sentences are loaded in the flash memory of the audiometer which is organized as described in *CHAPTER 6: Speech audiometry*. Before playing a list from the flash memory, the required material must first be selected by pressing the MATERIAL function button. Once the QuickSIN material has been selected, the list can be played by pressing the PLAY button located at the top left of the keyboard. If there is no audio material being played currently, pressing PREVIOUS/NEXT buttons will bring up the precedent/following list.

Once the desired list has been selected and is playing, PREVIOUS/NEXT buttons can be used to jump back/forward among the sentences of the list, currently played sentence is displayed in the audiometer's screen. Each sentence is presented at pre-recorded signal-to-noise ratios which decrease in 5-dB steps from 25 (very easy) to 0 (extremely difficult). At the end of each sentence the list pauses and the score of the sentence can be stored using CORRECT/INCORRECT buttons: CORRECT button to increase the score and INCORRECT button to decrease it. Pressing PLAY button will advance to next sentence and play.

After all six sentences are scored, SNR loss can be estimated and saved using STORE button. To interpret the SNR loss score, see the following table.

SNR LOSS	*DEGREE OF SNR LOSS*	*EXPECTED IMPROVEMENT WITH DIRECTIONAL MIC*
0-3 dB	Normal/near normal	May hear better than normal hear in noise
3-7 dB	Mild SNR loss	May hear almost as well as normals hear in noise
7-15 dB	Moderate SNR loss	Directional microphones help. Consider array mic
>15 dB	Severe SNR loss	Maximum SNR improvement is needed. Consider FM system

QuickSIN™ lists can be presented through headphones (AC) or on loudspeakers (FF). Presentation level can be set to 70 dB HL for pure tone average (PTA) ≤ 45 dB HL, for PTA of 50 dB HL or greater set the attenuator dial to a level that is judged to be "loud, but OK".
QuickSIN™ window is illustrated below.
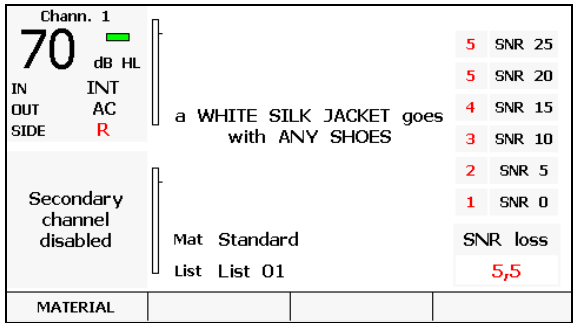
QuickSIN™ window

Before starting QuickSIN™ test, adjust the level of gains using the 1-kHz calibration tone so that the VU-meters of the two channels read "0". Once the gain values for QuickSIN™ input have been set, they are saved internally on the audiometer, and remain stored even after the instrument has been switched off.

QuickSIN™ material include:
- 1-kHz calibration tone
- 12 standard lists with speech and 4-talker babble noise combined on the same channels for basic SNR loss testing.
- Practice lists A, B and C that can be used to familiarize the patient with the task. These lists are not equivalent to the standard lists and cannot be used to calculate SNR loss.
- 12 standard split-track lists recorded with sentences on channel 1 and babble noise on channel 2. These lists can be used to verify the effectiveness of hearing aids that have switchable directional microphones. Two types of demonstrations are possible and can be selected using the MODE function button:
  o Subjective: both speech and noise levels can be manually adjusted. Having the patient switch back and forth between OMNI and directional positions on the hearing aid/s gets a basic measure of directional benefits. In this mode SNR loss can't be estimated.

- o Objective: once the speech level has been set, the noise level is automatically adjusted so that the SNR decreases from 25 to 0 by 5 dB for each succeeding sentence. In this mode lists can be scored to obtain SNR loss, and SNR loss obtained in OMNI and Directional positions can be compared.
- 12 HFE lists recorded with 30 dB high-frequency emphasis (HFE). The HFE is used to make speech sounds audible for persons with ski-slpoe loss.
- 12 HFE-LP lists recorded with HFE plus 3-kHz low-pass brickwall filter, these lists can be used in combination with the HFE lists to predict the outcome of fitting hearing aids with extended HFE.

How to enable the QuickSIN™ test

In order to enable the QuickSIN™ test, access the test window from the main menu, press the ENABLE function button and fill in the licence number.

CHAPTER 8:

Patient archive

Bell and Harp audiometers have an internal memory allowing the user to store the results of pure tone audiometry tests for 100 patients. This chapter describes the archive functionality in detail.

MANAGEMENT OF THE ARCHIVE

First of all, remember that if it is not actually required, the patient management function can be deactivated by unchecking the relative item in the settings window (see *Chapter 11: Settings)*. This will simplify the graphics interface, which in turn simplifies the use of the instrument.

If archive management is active, the main screen will display:

- the identity of the current patient (top right);
- the function button F3 (PATIENTS) giving access to the archive window, which is illustrated below.

Pat. 1:	AC-R AC-L
Pat. 2:	AC-R BC-R
Pat. 3:	BC-R BC-L FF-R FF-L

| BACK | DELETE | DELETE ALL | SELECT |

Patient archive window

Every time the instrument is switched on, a new patient is created, attributing the index relative to the first available position in the memory (e.g. *Patient 10*); if the details of a test are then saved on completion of the session by pressing the "Save data" button, the information is associated with the current patient. Pressing the "New patient" button, on the other hand, a new patient is created, and the next available index associated with the new i/d.

The patient archive screen displays all the patients currently stored in the memory. Also displayed, beside each name, are the audiometric traces currently stored (for example, AC-R, denoting air-conduction, right ear).
The knob of channel 1 can be used to scroll through the list of patients. Pressing the F2 function button (DELETE), the patient highlighted in the rectangle will be erased from the internal memory, whereas pressing F4 (SELECT), the patient highlighted is selected as the current patient: it will then be possible to look again at the test associated with this patient by opening the pure-tone audiometry window.
Pressing F3 (DELETE ALL), all patients stored in the memory of the instrument will be removed from the archive.

Pressing the "TO PC" button when the archive window is open, the tests associated with all patients stored in the memory will be sent to the computer. The index number of the patient is also associated with each test; on exiting the Daisy Maestro module, if no patients were previously selected from Daisy, the user will be asked to associate each test transferred — identifiable from the patient index — with a patient in the Daisy archive. This function is not available when using the Noah application.

CHAPTER 9:

Interface with the computer

Bell and Harp audiometers are able to interface with a computer by way of a USB connection, for the purpose of copying tests to the computer hard disk. Either the Daisy or the Noah software application must be installed on the computer, with the relative Maestro module. This chapter explains how to connect the audiometer to the PC and how to transfer the data in question.

CONNECTION TO PC

Bell and Harp audiometer are connected to one of the USB ports on the computer using the cable supplied (standard USB A/B cable). 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 device and install the drivers automatically. The installation is complete when the following message appears at the bottom right of the screen:
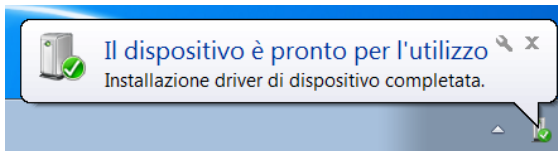
Bell and Harp audiometers are compatible with computers using a Microsoft Windows 32 or 64 bit operating system, XP SP3 or later.

DAISY SOFTWARE

Daisy is a software application developed by Inventis for computerized management of medical records, which can be used to store the clinical details of patients together with a variety of instrumental tests, acquired by connecting directly to the instruments.

All diagnostic devices developed by Inventis can be interfaced with Daisy by way of *modules*. Modules are software libraries installable internally of the Daisy environment, which are designed to interface with the various instruments and transfer tests to the Daisy archive.

The Daisy module designed to interface with Inventis audiometers is *Maestro*.

For more details on the features and capabilities of the Daisy application, and on minimum system requirements for the computer, refer to the Daisy operator manual.

THE DAISY MAESTRO MODULE

Maestro is the Daisy module used to interface with Inventis audiometers.

The installation procedure for the Maestro (identical to that of any other Daisy module), is described in the Daisy operator manual.

To access all the functionalities of the Maestro module, the user must purchase a software license. In effect, the user purchases a dongle that will activate the functionalities of the product when plugged into any USB port of the computer.

Even without the dongle, the Maestro can still be installed and utilized on the computer. In this instance however, it will be possible to use only the *Monitor* function of the module, in other words the facility of following the progress of a test on the computer screen rather than on the audiometer display. Without the license, it will not be possible to send the data to the Daisy archive.

MONITOR FUNCTION

The *Monitor* function of the Maestro module can be used to view a test currently in progress on the computer screen, rather than on the graphic display of the audiometer. This function is available only for pure-tone and speech audiometry tests.

To access the Monitor function, first open the Maestro module by clicking the "Maestro" button located at the bottom of the Daisy archive window.

With the module open, the user can select the instrument with which the interface is to be established (should there happen to be more than one Inventis audiometer connected), using the relative button located on the left panel of the screen.

⚠️ *The audiometer must be plugged into the PC before opening the Maestro module, otherwise the connection will not be established.*

The following illustration shows the monitor window that will appear in the case of a pure-tone audiometry session.
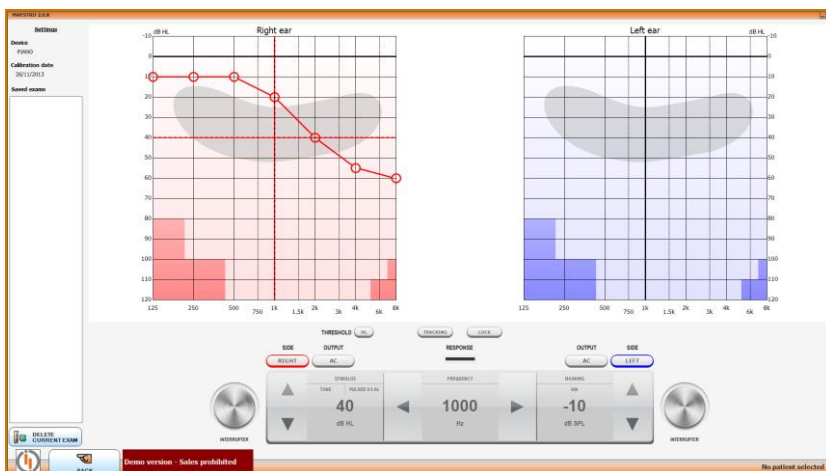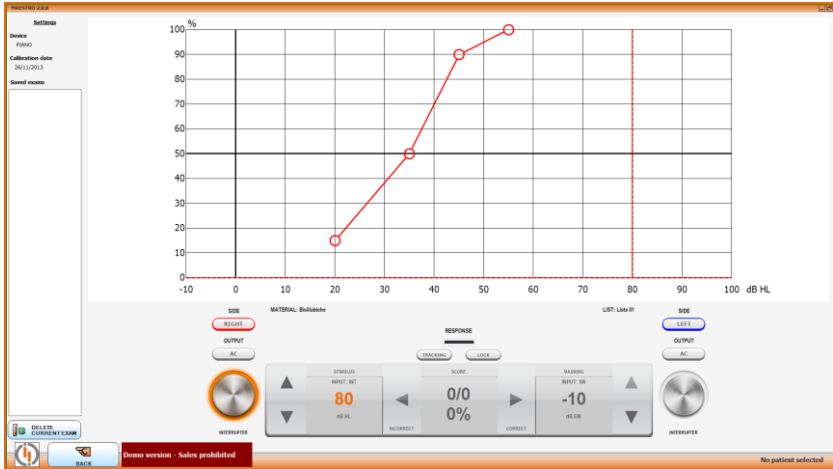

The window shows:
- status, level, side (R/L), input and output of channels 1 and 2;
- frequency currently selected;
- status of the response button (green Led lights up when the patient presses the button);
- presentation mode of the stimulus signal (continuous or pulsed);
- audiogram.

If a patient has been selected in Daisy before opening the Maestro module, the pure-tone audiometry test currently in progress can be shown together with the audiometric test conducted during a previous visit; this is done simply by checking the box located on the left panel. Selecting this option, the user can then select the date of the second test to be displayed (the *default* setting is the date of the most recent test).

The left and right hand traces can be shown on two separate graphs, or one above the other on a single audiogram; this option, together with other display options, can be changed from the Daisy settings panel (see Daisy manual for further details).

The following illustration shows the monitor window for a speech audiometry test.

In this instance, the window shows:
- status, level, side (R/L), input and output of channels 1 and 2;
- if the selected input is the internal flash memory, the selected material, the name of the current word list and the last word played back;
- the articulation function, on which you can also see the current percentage of correct answers.

# TRANSFERRING TESTS DURING MONITOR

To transfer tests from the audiometer to the Daisy archive, first open the Maestro module by clicking the "Maestro" button at the bottom of the Daisy archive window, then — should there happen to be more than one audiometer connected — select the instrument from which the information is to be transferred.

To send the data to the computer, simple press the "TO PC" button on the audiometer. Pressing the button when there is a test displayed in the window, only this one test will be transferred; conversely, pressing the button with the main screen of the audiometer currently displayed (or rather,

the screen showing the list of tests available), all tests conducted on the patient will be sent to the computer.

Finally, pressing "TO PC" when the audiometer archive window is open, the tests of all patients in the archive will be sent to the computer, each associated with the index number of the relative patient. When exiting the Maestro module, in this instance, if no patients were previously selected from Daisy, the user will be prompted to associate each test downloaded with a patient listed in the Daisy archive.

With downloading complete, the tests can be displayed and if necessary discarded with the "Delete current test" button; it is also possible to associate a description with each test, which will be included when the report is printed out.
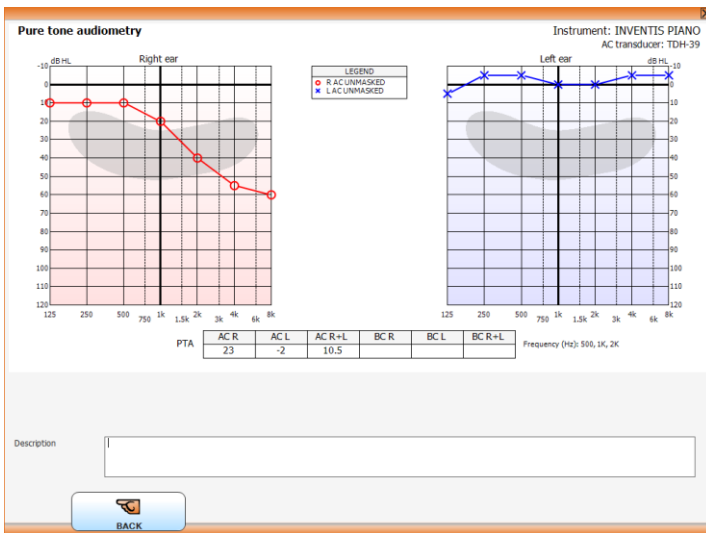
Clicking the "Archive" button at the bottom left of the screen, all the tests downloaded will be saved in the medical record of the selected patient; if no patient was selected before opening the Maestro module, Daisy will prompt the user to indicate which patient in the archive the tests are to be associated with.

HYTECH FUNCTION

The *Hytech* function of the Maestro module allows the user to fully control the audiometry directly from his computer using the mouse, keyboard or a touch panel. This function is available only for pure-tone and speech audiometry tests.

To access the Hytech function, first open the Maestro module by clicking the "Maestro" button located at the bottom of the Daisy archive window. With the module open, the user can select the instrument with which the interface is to be established (should there happen to be more than one Inventis audiometer connected), using the relative button located on the left panel of the screen.

⚠️ *The audiometer must be plugged into the PC before opening the Maestro module, otherwise the connection will not be established.*

The following illustration shows the Hytech function window that will appear in the case of a pure-tone audiometry session.
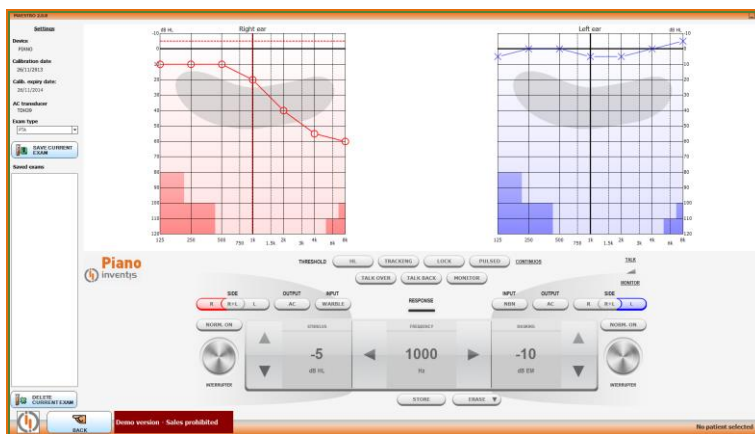
In this instance, the user may find all the common controls needed for a pure tone audiometry straight on the screen. Some of those are:

- Side (R/L), Transducer, Stimuli signal, Stimuli intensity and frequency
- Talk over, Talk back and Built-in monitor speaker levels
- Threshold type, Tracking and Lock functions

All settings can be changed by clicking on the relative button or by pressing the dedicated keyboard shortcut.

Stimuli can be sent by positioning the cursor on the INTERRUPTER area, by right-clicking on the graph area or by pressing the dedicated key.

If a patient has been selected in Daisy before opening the Maestro module, the pure-tone audiometry test currently in progress can be shown together with the audiometric test conducted during a previous visit; this is done simply by checking the box located on the left panel. Selecting this option, the user can then select the date of the second test to be displayed (the *default* setting is the date of the most recent test).

The left and right hand traces can be shown on two separate graphs, or one above the other on a single audiogram; this option, together with other display options, can be changed from the Daisy settings panel (see Daisy manual for further details).

Pressing the "SAVE CURRENT EXAM" button will store the exam into the box on the left panel and, when exiting from the module, into the patient folder. When an exam is stored, a description can be added to it.

The following illustration shows the Hytech function window that will appear in the case of a speech audiometry session.
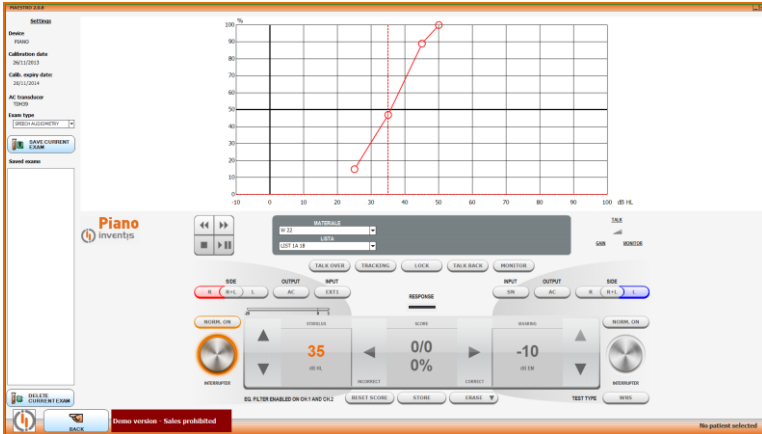
In this instance, the user may find all the common controls needed for a speech audiometry straight on the screen. Some of those are:

- Side (R/L), Score (%), Transducer, Stimuli source and intensity
- Talk over, Talk back and Built-in monitor speaker levels
- Exam type, Tracking and Lock functions

SETTINGS

All the Maestro settings can be accessed by entering the module and clicking the "Settings" label on the left panel.
Above all, the user may choose between the monitor or hytech function for the module.

The following illustration shows the settings window.
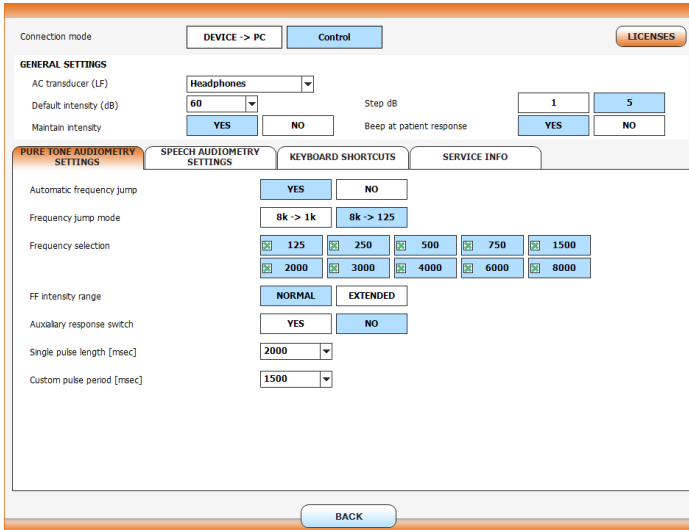
For any detail on the settings available, please refer to next chapter where the instruments' are described, most are identical.

THE NOAH MAESTRO MODULE

The Noah Maestro module allows to store in the Noah database pure tone and speech exams done with Bell, Harp and Piano audiometers. It requires the same software license of Daisy Maestro to store or print new exams. The module installation is straightforward, just double click on the setup file located in the folder "NoahModules\Maestro" of the "Daisy-Noah module CD", and follow the instructions that will appear.
To acquire new exams, click on the Inventis icon located on the acquisition tab of the module selection window (Noah 3.7) or on the upper part of the main window (Noah 4).

Same as for Daisy Maestro, Noah Maestro module allow the user to choose between the monitor or the hytech functions. For further instruction, please refer to the previous paragraphs, information are suitable for both.

During monitor function, once the audiometric examination is finished, press the "TO PC" button on the device to send the exam to the computer. After doing it, the exam will be displayed as shown below.
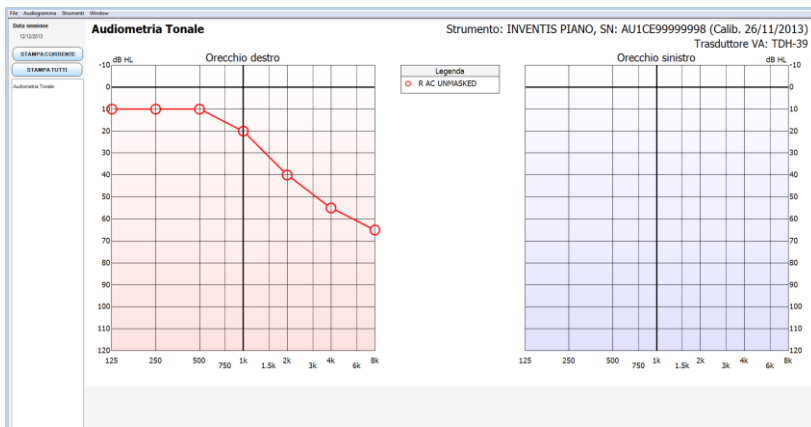
Note that at this point the exam has not been saved in the Noah database yet. To do so press the "Store in Noah database" button on the left bottom part of the screen.

To view an exam stored in the Noah Database click on the corresponding icon in the Noah session browser or select it from the Audiogram menu of the Noah Maestro window, as shown below.
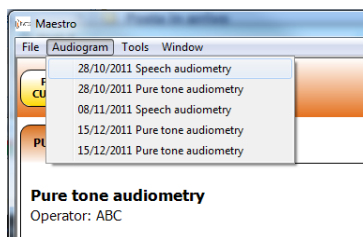
With Noah Maestro is also possible to print the acquired exams. By pressing the "Print Current" button, only the visible exam will be printed, whereas the "print all" button will print all the patient's exams taken during the same session.

It's possible to customize the printout header by selecting Tools -> Preferences -> Print. A screenshot of the print windows is shown below.
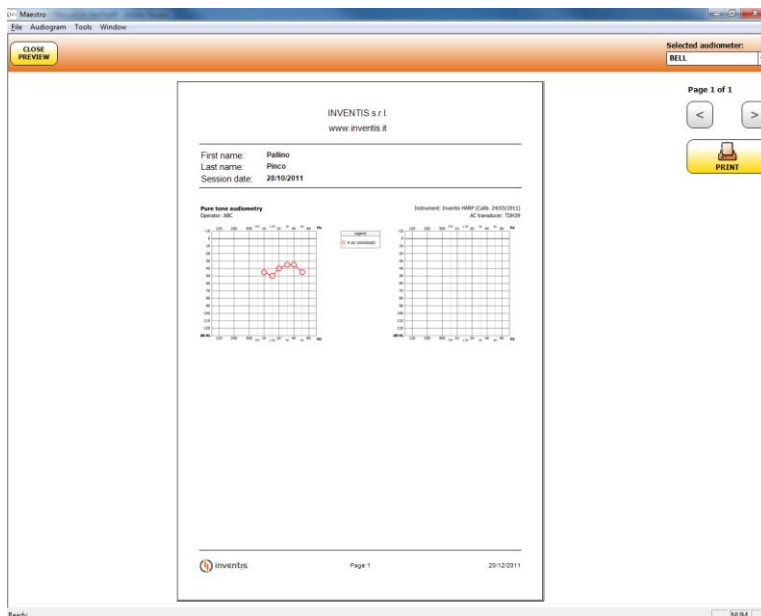
ENABLE LICENSES

You can enable the available licences for your instrument (i.e. optional tests) directly from the device or through the Maestro module. In both cases, the activated licenses are stored into the instrument memory.

In order to access to the licences management window, launch the Maestro module, enter the settings window and press the LICENCES button.

This button opens a window listing all the available licences for the device model connected to computer. To enable a test, press on the corresponding ENABLE button and digit the licence code. You can obtain the licence code contacting your reference technical service and providing the serial number of the device on which activates the licence.

The following illustration shows the licences management window.
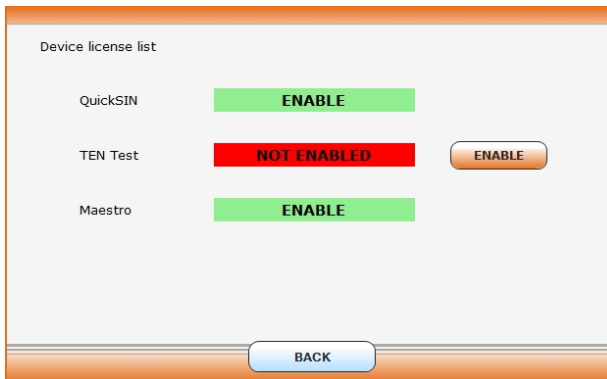
In addition, on devices that you can control from computer, it is possible to enable a test directly selecting it from the tests list, placed on the left part of the Maestro module window.

CHAPTER 10:

Settings

Bell and Harp audiometers have a number of configuration parameters that can be changed in the settings window. This chapter describes the parameters available, and how to change them.

SETTINGS WINDOW

To access the settings window, simply press the SETUP function button shown on the main screen of the instrument.

Once the settings window appears, the left hand knob can be used to scroll through the available items, whereas to change the value of the selected item, either rotate the right hand knob or press the CHANGE button. Certain items, such as setting of the date and time, require access to a specific window if changes are to be made; in these cases, press the SELECT button to access the changes window.

The settings window also includes an INFO function button, which opens a window containing certain items of information on the audiometer such as the serial number and the version of the internal software.

When exiting the settings window, if at least one parameter has been changed, the instrument will prompt whether to save the new settings or maintain the previous settings.

USER-SETTABLE PARAMETERS

All configuration parameters that can be set by the user are listed below. A default value is indicated for each parameter. This represents the factory setting. Not all of the items listed are available on every model.

Language

Selection of the interface language used by the instrument.

Default value: English

Viewing mode (Harp only)

Select the viewing mode (numeric or graphical) of the pure tone and speech audiometry exams.

Default value: Graphical

Link BC symbols

Enables / disables the display of lines interconnecting bone conduction symbols in speech audiometry.

Default value: No

Symbol for BC-Right

Selects the symbol for pure tone audiometry using bone conduction, right ear.
The symbols that can be selected are.

a) $<$

b) $>$

Default value: $<$

Symbol for masked BC-Right

Selects the symbol for pure tone BC audiometry with masking (right ear).
The symbols available when selecting the symbol identified by letter *a* for BC right are indicated in the following illustration by the letters *c* and *d*; if the symbol selected for BC right is that identified by letter *b*, then the symbols available are *e* and *f*.

c) ◁   d) ⌐

e) ▷   f) ⌐

Default value: ⌐

Symbol for UCL

Selects the symbol for UCL threshold in the pure tone audiometry, right ear. The symbols that can be selected are:

a)   E

b)   ⫟

c)   ⊔

Default value: E

High contrast display

Enables / disables the display of test screens with a high level of contrast. In particular, the normally grey background of the fields showing channel status information (level, input, output, side, activation) changes to white, in high contrast mode.

Default value: No

AC transducer

Selects the type of transducer used for AC. The options are supra-aural headphone and insert-type earphone.

Default value: supra-aural headphone

⚠ *Make sure that the correct transducer is selected. Different transducers have different calibration values, therefore setting the incorrect transducers will bring to wrong exams results.*

Max frequency with HDA 280 headphones (Bell only)

Sets the maximum frequency available for air-conducted pure tone signals when using HDA 280 headphones.
The value can be set at 8 kHz or 12.5 kHz.

Default value: 8 kHz

FF intensity range (Harp only)

The intensity range for free field pure tone and speech audiometry tests, in other words the maximum output values; can be normal (Norm.) or extended (Ext.). See Appendix A for details of maximum values in the two different configurations.

Default value: Normal

Default intensity (dB)

In pure-tone audiometry, selects the default level for the stimulus on the primary channel, in other words the intensity at which channel 1 is set when changing the stimulation side, the output, the input or the frequency. The initial intensity can be set between 0 and 60.

Default value: 40 dB

Maintain intensity

If enabled, the level of the stimulus on the primary channel in pure-tone audiometry stays the same (i.e. does not revert to the default value) when changing the stimulation side, output, input or frequency.

Default value: No

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.

Beep for automatic tests

Enables or disables the beep generated at the end of automatic test sequences.

Default value: Yes

Beep at patient response

Enables or disables the beep generated when the patient presses the patient response switch.

Default value: No

Patient management

Enables / disables the patient archive of the audiometer.

Default value: Yes

PTA at start-up

If set to Yes, the instrument will go directly to the pure-tone audiometry window when powered up, otherwise the main menu will appear to allow selection of the different test options.

Default value: No

Frequency selection

Access to the frequency selection window.
In this window you can enable / disable the frequencies to be tested in pure-tone audiometry.

Frequency jump mode

Sets the sequence in which frequencies are scanned for pure-tone audiometry, when automatic jump mode is selected.
There are 2 options:
1) 8k → 125: saving the threshold at 8 kHz (or 12.5 kHz if this is the active frequency), the program jumps to 125 Hz, followed by each of the higher frequencies.
2) 8k → 1k: saving the threshold at 8 kHz (or 12.5 kHz if this is the active frequency), the program jumps to 1 kHz, then moves sequentially through the lower frequencies, down to 125 Hz. This is the frequency scanning method prescribed by standard EN ISO 8253-1.

Default value: 8k → 1k

Automatic frequency jump

In pure-tone audiometry, enables / disables automatic transition to the next frequency after a value has been saved by pressing the STORE button. The order in which frequencies are scanned will depend on the "Frequency jump mode" parameter, described below.

Default value: Yes

Speech score mode (Harp only)

Selects the method of calculating the percentage of correct responses in speech audiometry.

Mode 1: calculates the percentage of correct responses in relation to the total number of responses given. More exactly, indicating the words recognized successfully by the patient as *correct*, and the number of words not recognized by the patient as *incorrect*, the *percentage* is calculated as follows:

$$percentage = 100 * correct / (correct + incorrect)$$

Mode 2: calculates the percentage of correct responses in relation to the *total number of words* in the list. This parameter is configurable from the settings window.
The *percentage* in this instance is calculated as:

$$percentage = 100 * correct / total\ number\ of\ words$$

Default value: Mode 1

Speech words number (Harp)

Sets the total number of words in the lists; this parameter is used only when Mode 2 is selected as the method of calculating the outcome of a speech audiometry test.
The number of words can be set between 1 and 99.

Default value: 10

Pause after each word (Harp)

In speech audiometry test, if set to Yes, the player is automatically paused after playing each word.

Default value: No

Enable WRS single point (Harp)

Option for measuring the Word Recognition Score as a single point instead of using a graph. Furthermore, if enabled, you may select the same input for both channels during the speech audiometry.

Default value: No

Turn off monitor after speech (Harp only)

If enabled, sets the intensity of the monitor signal to zero when the speech audiometry window is closed. When the window reopens, the previous levels will be restored.

Default value: Yes

Enable EQ filter with TDH39 (Harp only)

Enables / disables the equalization filter applied to AC speech audiometry output signals when using TDH-39 headphones.

Default value: No

Print patient data header

Enables / disables printout of the heading with details of the patient.

Default value: Yes

Clinic data menu

Access to a window in which the user can enter details of the clinic, for inclusion in the header of the printed document. The user can also enable or disable printout of the window.

Calibration menu

Access to the calibration window of the audiometer.

Date and time menu

Access to the window in which the date and the time are set.

Service tests

Access to the window from which service tests are run on the instrument. For maintenance purposes only.

CHAPTER 12:

Maintenance

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

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

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

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

PERIODIC CHECKS

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

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

- Before switching on the instrument, check that all the contacts are perfectly connected and that the cables and/or connectors as well as all other elements do not appear to be broken or damaged externally

- Check subjectively that the air conduction and bone conduction output is equal on both channels and all frequencies, in order to do

this 10 or 15 dB, just enough to hear is applied. The person who carries out this check should have good hearing

- Check at a level of 60dB in AC and 40dB in BC that there is no distortion, noise or parasitic signals in any of the frequencies

- Check that the 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

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

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

MAINTENANCE OF TRANSDUCERS

Do not use liquids or sprays to clean the audiometer.

Do not allow dust to collect on the transducers. Also:
- The headphone cushions are made of biocompatible material, but are not sterile: whenever the headphones are to be worn by a new patient, the cushions must be wiped with a hypoallergenic proprietary disinfectant, following the maker's instructions. This will prevent the spread of infection and guarantee the biocompatibility of the material.

- The eartips of ER-3A and ER-5A insert earphones are made of biocompatible material and disposable: use once only and dispose of in accordance with current health and safety regulations.

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

CLEANING

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

All parts not mentioned specifically in the previous section can be cleaned using a soft cloth moistened with ethyl alcohol.

REPLACEABLE PARTS

The transducers and accessories 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 accessories of the audiometer are designed specifically for use with the appliance. Only accessories 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" appendix have been tried.
There are no requirements for the sterilization or disinfection of parts being returned to the manufacturer for repair and servicing (ISO 10940 §6 b).
Should the instrument need to be sent to the Inventis service department or returned to the dealer, it is important that the original packing should be used, and that all accessories and transducers are enclosed.

Technical specifications

Classification

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

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

Harp Basic e Plus
   Type 2 pure tone audiometer (EN 60645-1 / ANSI S3.6)
   Type A or A-E speech audiometer (EN 60645-2 / ANSI S3.6)

AVAILABLE SIGNALS				
Type	*Bell Basic*	*Bell Plus*	*Harp Basic*	*Harp Plus*
Pure tone	●	●	●	●
Warble tone	●	●	●	●
2 external inputs for speech audiometry (EXT1 and EXT2)	-	-	●	●
MIC input for live speech audiometry	-	-	●	●
Internal input (flash memory) for speech audiometry	-	-	-	●
Narrow-band noise (NBN)	●	●	●	●
White noise (WN)	-	●	●	●
Speech noise (SN)	-	-	●	●
Threshold equalizing noise (TEN)	-	-	-	●

SIGNALS SPECIFICATIONS	
Attenuators step	Bell: 5 dB Harp: 1 and 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 $f_1 = f / 1.1892$ - upper cut-off frequency $f_u = f \cdot 1.1892$ where f is the centre frequency
WN	Lower cut-off frequency: 100 Hz Upper cut-off frequency: 24 kHz
SN	As specified in EN 60645-2 §13
External signals	EXT1 and EXT2 input: max 3 Vrms
TEN	Lower cut-off frequency: 350 Hz Upper cut-off frequency: 6500 Hz

AVAILABLE OUTPUTS			
Output	Bell Basic	Bell Plus	Harp Basic/Plus
Air conduction			
TDH-39 / DD45 headphones or EARTone 3A / 5A insert earphones	●	●	●
HDA-280 headphones	●	●	-
Bone conduction (B-71 bone vibrator)	-	●	●
Free field	-	-	●
Insert masking earphone	-	●	●

PURE AND WARBLE TONE AVAILABLE FREQUENCIES AND MAXIMUM INTENSITES						
Freq. (Hz)	AC TDH39 DD45 (dB HL)	AC HDA280 (dB HL)	AC EARTone 3A (dB HL)	AC EARTone 5A (dB HL)	BC (dB HL)	FF (*) (dB HL)
125	80	90	90	90	-	75
250	100	100	105	100	45	85
500	110	115	110	110	65	95
750	115	120	115	120	70	95
1.000	120	120	120	120	75	95
1.500	120	120	120	120	80	95
2.000	120	115	120	115	80	95
3.000	120	115	120	115	75	95
4.000	120	115	110	110	75	95
6.000	105	100	95	100	55	90
8.000	95	90	90	90	50	85
12.500	-	80	-	-	-	-

(*) The maximum levels refer to the "normal" intensity range for free field. In case of extended range, add 10 dB to each value (see *Chapter 11: Settings* for switching between the two options).

SPEECH AUDIOMETRY MAXIMUM INTENSITIES				
AC TDH39 DD45 (dB HL)	AC EARTone 3A (dB HL)	AC EARTone 5A (dB HL)	BC (dB HL)	FF (dB HL)
100	100	100	55	Norm.: 75
				Ext.: 85

EXTERNAL SIGNALS LEVEL INDICATOR (only for Harp Basic/Plus)	
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

NARROW BAND NOISE (NBN) AND WHITE NOISE (WN) AVAILABLE FREQUENCIES AND MAXIMUM INTENSITES							
Freq. (Hz)	AC TDH39 DD45 (dB EM)	AC HDA280 (dB EM)	AC EARTone 3A (dB EM)	AC EARTone 5A (dB EM)	BC (dB FL)	Insert earphone (dB EM)	FF (*) (dB HL)
125	60	65	70	65	-	80	75
250	80	85	85	85	105	95	85
500	95	100	95	95	110	105	95
750	100	105	100	100	110	110	95
1.000	105	120	105	100	110	115	95
1.500	105	110	105	100	110	115	95
2.000	105	105	105	100	110	115	95
3.000	105	105	105	100	100	115	95
4.000	105	105	100	100	100	110	95
6.000	100	95	90	95	90	95	90
8.000	90	95	80	80	90	95	85
12.500	-	70	-	-	-	-	-
WN	110 dB SPL	110 dB SPL	100 dB SPL	100 dB SPL	100 dB FL	100 dB SPL	95 dB SPL
WN (speech)	90 dB EM	90 dB EM	80 dB EM	80 dB EM	45 dB EM	80 dB EM	75 dB HL

(*) The maximum levels refer to the "normal" intensity range for free field. In case of extended range, add 10 dB to each value (see *Chapter 11: Settings* for switching between the two options).

SPEECH NOISE (SN) MAXIMUM INTENSITES					
AC TDH39 DD45 (dB EM)	AC EARTone 3A (dB EM)	AC EARTone 5A (dB EM)	BC (dB EM)	Insert earphone (dB EM)	FF (dB HL)
90	80	80	45	80	Norm.: 75
					Ext.: 85

ACOUSTICAL SAFETY OF THE DEVICE	
Alert condition	Tone intensity higher than 100 dB HL (EN 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
(only for Bell) Supra-aural headphones	Sennheiser elec. GmbH	HDA-280
Insert earphones	Etymotic Research Inc.	EARTone 3A
Insert earphones	Etymotic Research Inc.	EARTone 5A
Bone vibrator	Radioear Corp.	B71
Insert earphone for masking	Inventis srl	IME-100

PATIENT – OPERATOR COMMUNICATION			
	Bell Basic	*Bell Plus*	*Harp Basic/Plus*
Talk-over through: - Embedded microphone - External microphone (not included).	●	●	●
Talk back through: - Embedded speaker - External speakers (not included) - Patient microphone	-	-	●
Patient response trigger	●	●	●

AVAILABLE TESTS				
	Bell Basic	*Bell Plus*	*Harp Basic*	*Harp Plus*
Pure tone audiometry	●	●	●	●
Autothreshold	●	●	●	●
Speech audiometry	-	-	●	●
ABLB	-	-	●	●
SISI	-	-	-	●
DLI	-	-	-	●
Tone decay	-	-	-	●
Master hearing aid	-	-	-	●
Stenger	-	-	-	●
TEN test	-	-	-	opt.
QuickSIN	-	-	-	opt.

DATA MANAGEMENT		
	Bell	*Harp*
Internal memory capacity	100 patients	100 patients (*)
Integrated thermal printer (paper size: 112 mm)	-	Optional
Communication to the computer	USB	
Management software	Daisy with Maestro module Noah with Maestro module	

(*) Only pure tone audiometry exams can be stored in the internal archive.

DISPLAY	
Type	Graphical colour TFT LCD
Size	diagonal 4,3", 95 mm x 54 mm
Resolution	480 x 272
Available viewing modes	Normal / High contrast

POWER SUPPLY	
Model without printer	
Consumption (max.)	8 Watts
Power supply	6V, 1.67A cont., through an external 100-240 Vac 50/60 Hz power supply (included), compliant to EN 60601-1 standard
Model with printer	
Consumption (max.)	25 Watts
Power supply	6V, 6A cont., through an external 100-240 Vac 50/60 Hz power supply (included), compliant to EN 60601-1 standard

CALIBRATION	
Calibration validity	12 months

ENVIRONMENTAL CONDITIONS	
Use	Temperature: between 15°C (59°F) and 35°C (95°F) Relative humidity: between 30% and 90% (non-condensing) 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

MECHANICS	
Models without the integrated printer	
Size (LxDxH)	32 x 32 x 9 cm / 12.6 x 12.6 x 3.5 in
Weight (device only)	1.8 Kg / 4.0 lbs
Weight (including transducers and package)	4.2 Kg / 9.3 lbs
Model with the integrated printer	
Size (LxDxH)	32 x 39 x 9 cm / 12.6 x 15.4 x 3.5 in
Weight (device only)	2.3 Kg / 5 lbs
Weight (including transducers and package)	4.7 Kg / 10.4 lbs

SOCKETS ON THE REAR PANEL		
Description	*Type*	*Connector*
Power supply	In	DC plug
L and R headphones	Out	2 audio jack, 1/4" mono
Bone vibrator (not in Bell Basic)	Out	Audio jack, 1/4" mono
Insert masking earphone (not in Bell 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 Harp audiometers		
L and R Free Field output	Out	2 RCA
Monitor headset	Out	Audio jack, 3.5 mm stereo
Microphone for live speech tests	In	Audio jack, 1/4" mono
Patient microphone for talk-back	In	Audio jack, 1/4" mono
EXT1 and EXT2	In	2 RCA

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) Impedance: 10KΩ
External input for speech aud.	Sensitivity: 3mV at max volume and 0Vu Impedance: 10K Ω Freq. response: 75-12000Hz +/- 3dB
Microphone	Electret or 200 Ω dynamic microph.
Talk over	Impedance: 47KΩ
Talk back	Freq. response: 100-12KHz +/- 3dB Electret Bias: 2.2V through 2.2KΩ

SPECS OF OUTPUT FACILITIES		
Output	*Available Voltage*	*Nominal Impedance*
TDH 39	8Vpp	10 Ω
DD45	8Vpp	10 Ω
ER 3A	8Vpp	10 Ω
ER 5A	8Vpp	10 Ω
B 71	8Vpp	10 Ω
HDA 280	8Vpp	37 Ω
Free Field (SPKF)	8Vpp	100 Ω
Insert mask	8Vpp	32 Ω
Monitor	1Vrms by 32 Ω load	

SOUND ATTENUATION VALUES		
Freq [Hz]	*TDH 39 / DD45 with MX41\AR or PN 51 cushion* [dB]	*ER 3A ER 5A* [dB]
125	3	33.5
250	5	34.5
500	7	34.5
750	-	-
1000	15	35
1500	-	-
2000	26	33
3000	-	-
4000	32	39.5
6000	-	-
8000	24	43.5

REFERENCE EQUIVALENT THRESHOLD LEVELS

Freq	TDH 39 ISO 389-1 (ANSI S3.6)	DD45 Vendor Tech. Specification	ER 3A ISO 389-2 (ANSI S3.6)	ER 5A ISO 389-2	B71* ISO 389-3 (ANSI S3.6)	HDA 280 Vendor Tech. Specification	FF ISO 389-7 (ANSI S3.6)
[Hz]	[dB re 20 µPa]	[dB re 20 µPa]	[dB re 20 µPa]	[dB re 20 µPa]	[dB re 1 µN]	[dB re 20 µPa]	[dB re 20 µPa]
125	45	47.5	26	26	-	38.5	22.1
250	25.5	27	14	14	67	25	11.4
500	11.5	13	5.5	5.5	58	13	4.4
750	7.5 (8)	6.5	2	2	48.5	9	2.4
1000	7	6	0	0	42.5	7.5	2.4
1500	6.5	8	2	2	36.5	9.5	2.4
2000	9	8	3	3	31	8	1.3
3000	10	8	3.5	3.5	30	6.5	5.8
4000	9.5	9	5.5	5.5	35.5	9.5	5.4
6000	15.5	20.5	2	2	40	19	4.3
8000	13	12	0	0	40	18	12.6
10000	-	-	-	-	-	18.5	13.9
12500	-	-	-	-	-	30.5	12.3

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

The reference norms are ISO 389-1:2000, ISO 389-2:1997, ISO 389-3:1999, ISO 389-5:2007, ISO 389-8:2004, ISO 389-7:2006 and ANSI S3.6:2010.

APPLICABLE STANDARDS			
	Bell Basic	*Bell Plus*	*Harp B/P*
EN 60645-1 / ANSI S3.6	Type 4	Type 3	Type 2
EN 60645-2 / ANSI S3.6	-	-	Type A or A-E (*)
Autothreshold		Modified from EN ISO 8253-1:2000	
Calibration	AC: EN ISO 389-1 (TDH 39), EN ISO 389-2 (EARTone 3A e 5A), technical data from the manufacturer (DD45 and HDA-280) BC: EN ISO 389-3 FF: EN ISO 389-7		
Electrical safety	EN 60601-1 Bell and Harp without printer: Class I Type BF Harp with integrated printer: Class I Type BF		
EMC	EN 60601-1-2		

(*) Type A-E if the AC equalization filter is enable (see *Chapter 11: Settings* for details)

CE CERTIFICATE	
93/42/EEC MDD classification	Class IIa
Classification rule (Annex IX, 93/42/EEC)	10
Notified body	TÜV SÜD Product Service GmbH Ridlerstrasse 65 D-80339 München
Number of the notified body	0123
Number of the Inventis CE certificate	G1 12 09 65346 006

APPENDIX B:

Specifications of the amplifier / speakers for free field

In order to reach the values of the intensities for free filed output specified in the Appendix A (both for "normal" and "extended" range), the amplifier and the loudspeakers (or the active loudspeakers) must meet the following specs.

Characteristics of the dual channel amplifier:

	Normal range	Extended range
Minimum output power	2 x 60 W rms	2 x 200 W rms
Passband	90 Hz – 20 kHz	

Characteristics of the loudspeakers:

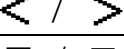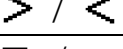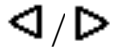|	Normal range	Extended range
Minimum output power	2 x 60 W rms	2 x 200 W rms
Sensitivity (at 1 m for 1 W, 1 kHz)	> 88 dB SPL	> 98 dB SPL
Passband	90 Hz – 20 kHz	
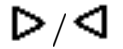
Audiometric symbols

Air Conduction

	Right	Left	Bilateral
HL threshold without masking	○	✕	⊗
HL threshold with masking	△	□	
UCL threshold	E or ⊓ or ⊔	∃ ⊓ ⊔	

Bone Conduction

	Right	Left
HL threshold without masking	< / >	> / <
HL threshold with masking	⊏ / ⊐ or ◁ / ▷	⊐ / ⊏ ▷ / ◁

The direction of the symbols used for BC and the symbol used for masked BC can be selected in the device set-up window (see *Chapter 11: Settings*).

Free Field

	Right	Left	Bilateral
HL threshold	⋈	⋈	⋈

In case of absence of response, a diagonal arrow pointing towards bottom is added in the lower part of the symbol.

APPENDIX D:

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 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)
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 *ATIT* 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.*

APPENDIX E:

Electromagnetic emissions

The Bell and Harp audiometers are Class B instruments according to IEC 60601-1-2.

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

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

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

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

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