AudiTest
Manual for use

1 Description of the device

The AudiTest uses air conduction to screen for hearing loss. The tone is presented through speakers in the headphones worn by the patient.
The operator can set the frequency, the hearing level, the stimulus mode and the left or right-side for tone delivering.
This standalone portable device runs with two 1,5V battery sticks.
It is a pure-tone air conduction, type 4 audiometer.

2 Package contents

The device is delivered into a kit containing:

- ✓ The audiometer electronic box
- ✓ A headset (with 3 meters cord)
- ✓ Two 1.5V batteries

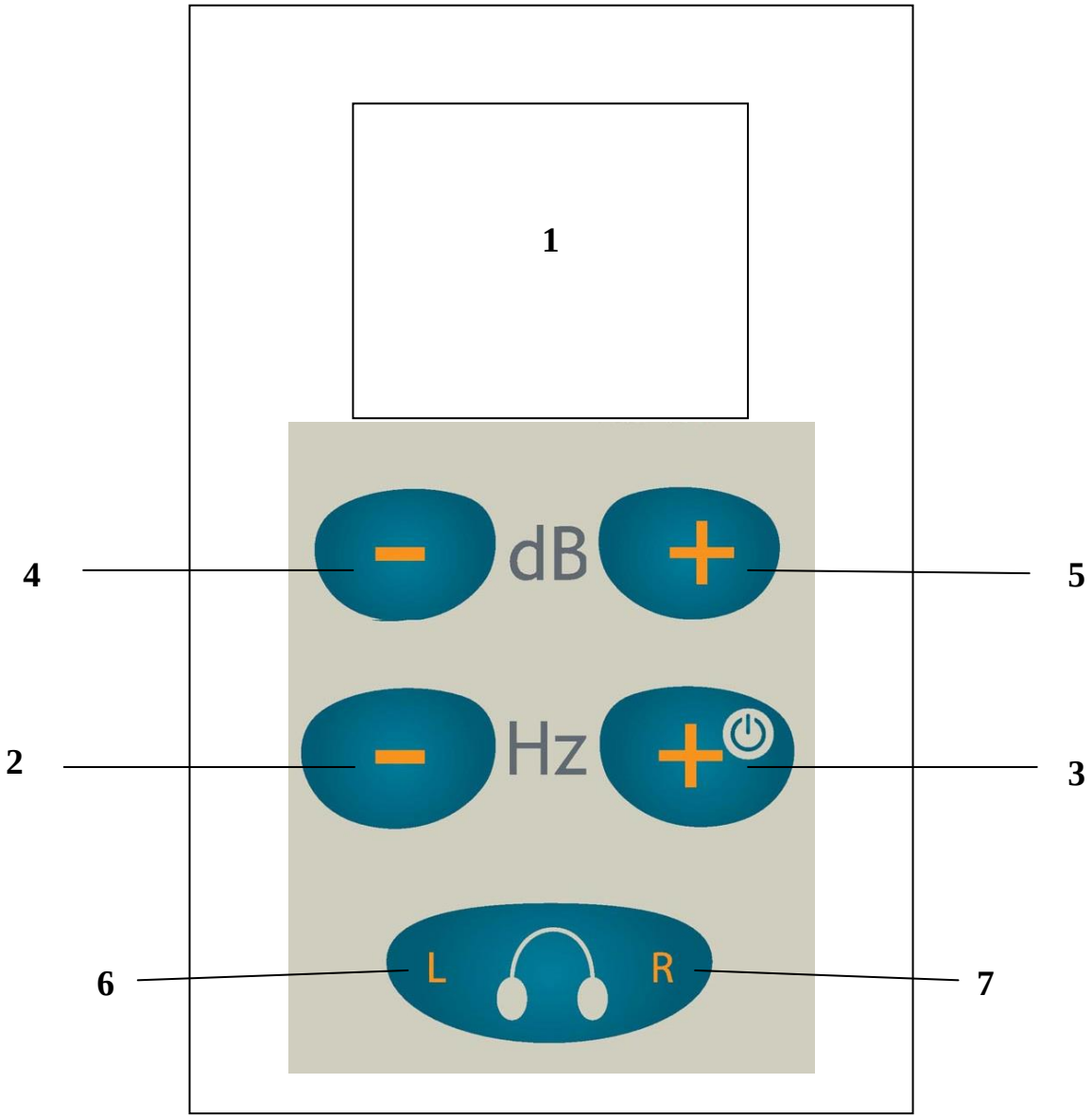
The instructions for use and maintenance is attached to the equipment.

3 Checking condition and content of the package

When receiving the equipment, state and content of the kit have to be checked and make sure the AudiTest and its accessories are in good working order.
In case of problem, the assembly should be returned to the seller. Keep the original packaging in view to protect the goods during shipping.

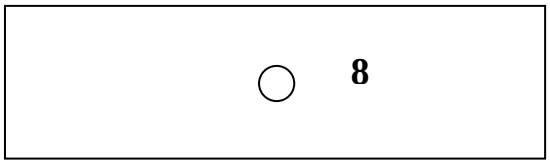
4 Functional features

4.1 Front board



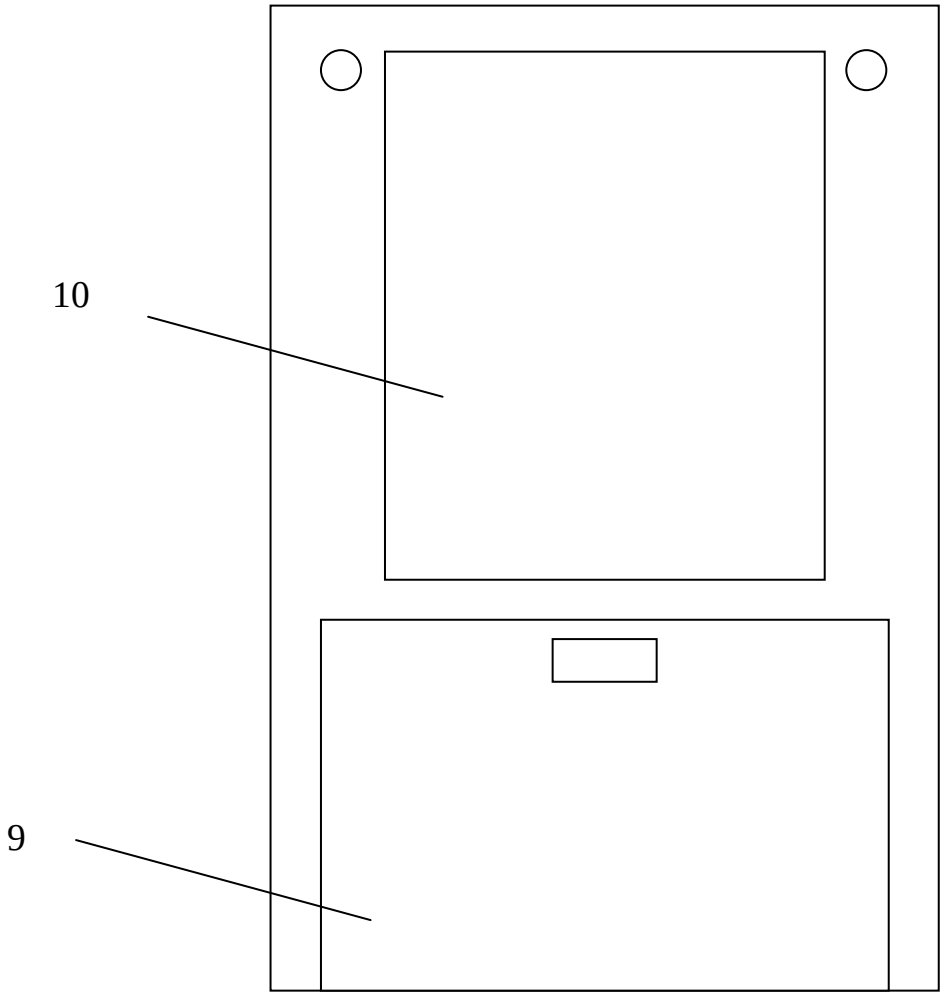
1 : LCD screen
2: Frequency decrement key
3: Frequency increment key and start key
4: Hearing level decrement key
5: Hearing level increment key
6: Left-side sound delivery key
7: Right-side sound delivery key

4.2 Top-side plate



8 : Headphone jack connector

4.3 Back panel



9 : Battery compartment cover
10: Identification label

4.4 How to use the audiometer

- Plug the headphones into jack connector '8'.
- Press '3'. The display screen '1' will indicate “1000 Hz” and “20 dB” on which the audiometer is setting by default.
- Use keys '2' and '3' to set the frequency.
- Use keys '4' and '5' to set the hearing level. (When the audiometer reaches 100 dB, the display indicates “! +100 dB” to alert the fact that a high sound output could cause patient discomfort).
- Deliver sound to the patient using keys '6' or '7'. As the key is being pressed, a pictogram appears on LCD screen and indicates which side the tone is being presented to.
- To switch from continuous sound to pulsed sound and reverse, press and maintain simultaneously the keys '2', '3' and '4'. In the mode “pulsed”, a special pictogram appears on LCD screen.
- If the device is left idle for a 1,5 minute period, it will shut down automatically to save on battery life.
- If batteries are discharged, a pictogram appears on the top and right of the screen. It means that they must be replaced.
- For that, open the rear-side battery compartment cover. Take care to observe the polarities marked in the compartment. A good quality 1,5V alkaline batteries is required.

5 Operating procedures

The operator has to be an health contributor who knows the basics necessary to operate and to interpret the test results.
Otherwise, it is preferable to contact the Distributor of the audiometer or a training center in view to go thoroughly into the knowledge of audiometry.

5.1 Environmental performance conditions

To give optimal performance, the patient must be seated in a room where there is very little environmental noise (i.e. below 20 dB).
The headset shall be adjusted to fit the patients head as flushly as possible. Make sure the headset is fitted with the left (L) and right (R) earphones correctly placed.
Patients who wear glasses should remove them for the test.

5.2 Method for determining hearing thresholds

Only the operator shall be able to use the audiometer controls.
He must start by explaining how the patient is to reply, i.e. by raising the hand on the side they can hear through.
Optimal threshold determination hinges on the patient first being familiar with the audiometer tone.

Procedure:

- Deliver a 40 dB tone (starting at 1000 Hz)
- Decrease the tone in steps until the patient can no longer hear the tone, and read-off this value.
- If 40 dB is too low for a start point, increase the tone in 10 dB steps until the patient can hear the tone.
- Drop the sound level back down to find the familiarization threshold, and read-off this value.

Determination of the hearing threshold:

- Deliver a tone that is 10 dB below the level identified during the familiarization step. If the patient cannot hear the tone, increase in 5 dB steps until the patient picks up the sound.
- Repeat this sequence several times (2 or 3 times) to pinpoint the patient's hearing threshold.

6 Acoustic scales

In 1937, internationally-recognized acoustics standards established the sound pressure measurement scale as a logarithmic unit expressed in dB (decibell). The 0 dB reference measure was concomitantly set at 20 µPascal at 1000 Hz, which falls just below the absolute threshold of human hearing. This scale, called the SPL (Sound Pressure Level), is used in acoustics and sonometry, and it is also widely popular in North American audiology centers.

However, one of the specificities of the human ear, which is an extremely sensitive sensor, is that it is selectively better at pinpointing tones within the 1000 to 3000 Hz range that at 125 Hz or 8000 Hz.

A statistical study led on a sample population of subjects with “healthy hearing sensitivity” defined and characterized perception thresholds, as summarized in the table below:

Frequencies emitted, in **Hz**	125	250	500	750	1K	1.5K	2K	3K	4K	6K	8K
Threshold of hearing, in **dB**	45	27	13,5	10	7,5	7,5	9	11,5	12	16	15,5

The scale has therefore been adjusted to correct for this factor, using the same unit but with different reference levels created for each frequency. It is called as HL, for Hearing Level, although it is sometimes termed compensated curve. This is the unit used by the vast majority of Western-European audiometry centers. It is easier to apply, as the sensitivity threshold is always indexed to 0 dB whatever the frequency.

7 Technical data

7.1 Tone frequency and output capacities

Hz	125	250	500	750	1K	1.5K	2K	3K	4K	6K	8K
Min (HLdB)	-10										
Max (HLdB)	70	90	100						90		

The sound levels are expressed in HLdB, i.e. Hearing Level in decibels. This is what is known as a compensated curve, where “0 dB” for each of the frequencies corresponds to the minimum hearing threshold of an otologically healthy subject (definition according to standard EN 60645-1). The sound levels can be adjusted in 5dB steps.

7.2 Tone presentation

Digitally controlled pure sine tone, continuous or pulsed.
Selection of left/right side chanel by silent keys.

7.3 Sound output

3.5 mm stereo jack.

7.4 Power supply

Battery type : 2 alkaline batteries of 1,5V – AA/LR6 type.
Autonomy : around 10 hours for professional-standard alkaline batteries and under normal conditions of use.
If the audiometer is scheduled not to be used for any extended period, remove the batteries.
Pictogram display "low battery" below 2,38V.

7.5 Calibration

Only via air conduction according to ISO 389-1 standard.

7.6 Other features

Robust, non deforming touchpad.
Switched on with a key on front board.
Use (sending sound to the patient): minimum 3 seconds after switching on.
Automatic switch off after 1,5 minutes without use.

7.7 Environmemental performance conditions

Storage temperature: -10° to 60°C (14° to 140° F)
Operating temperature: 15° to 35°C (59° to 95° F)
Relative humidity: between 30 % and 90%
Air pressure : 98kPa to 104 kPa

7.8 Standards compliance

Electronica Technologies has been certified for CE medical marking by the Organism LNE/G-MED (France).

CE
0459

7.9 Dimensions

Audiometric box :

L= 122 x W=79 x H=33 mm (4,80 x 3,11 x 1,30 in)

Weight : 150g (0,33 lb)

Complete kit :

Weight : 600g (1,32 lb)

7.10 Product origin

Device designed and built in France by:
ELECTRONICA Technologies, ZA de la Tour, 03200 Abrest
First CE 0459 marking obtained in 2014.

7.11 Classification

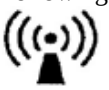
Type 4 pure tone audiometer.
Electrical safety: internal electricity source via 2 x 1,5V alkaline batteries.

Type B. 

7.12 Electromagnetic compatibility

Guidance and manufacture´s declaration – electromagnetic emission		
The Audiometer AudiTest is intended for use in the electromagnetic environment specified below. The customer or the user of the Audiometer AudiTest should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The audiometers AudiTest use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The audiometers AudiTest are suitable to be used in all establishments, different than the domestic promises and those directly connected with the public low voltage power supply network, feeding domestic use buildings.
Harmonic emissions IEC 61000-3-2	Not Applicable	
fluctuations/flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and manufacture´s declaration – electromagnetic emission			
The Audiometer AudiTest is intended for use in the electromagnetic environment specified below. The customer or the user of the Audiometer AudiTest should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-5	± 2 kV for power supply lines ± 1 kV for input/output lines	Not Applicable ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 sec	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of audiometers Audi Test requires continued operation during power mains interruptions, it is recommended that the audiometers AudiTest be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment
NOTE : U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture´s declaration – electromagnetic immunity			
The Audiometer AudiTest is intended for use in the electromagnetic environment specified below. The customer or the user of the Audiometer AudiTest should assure that it is used in such an environment.			
Immunity test	**IEC60601 Test level**	**Compliance level**	**Electromagnetic environment –guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the audiometers AudiTest, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter
Conducted RF IEC 61000-4-6	3 Veff 150kHz to 80 MHz	3 Veff 150kHz to 80 MHz	**Recommended separation distance** $d = 0{,}35\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 0{,}35\sqrt{P}$ 80 Mhz to 800 MHz $d = 0{,}7\sqrt{P}$ 800 Mhz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range b Interference may occur in the vicinity of equipment marked with the following symbol:: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a]	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Audiometer AudiTest is used exceeds the applicable RF compliance level above, the Audiometer AudiTest should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Audiometer AudiTest.		
[b]	Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m		

8 Routine maintenance

Never open up the device. There is no reason for anyone other than a manufacturer-approved technician to attempt to conduct repairs. It must not be modified, neither utilized for other purposes than those stated in this manual.

It is recommended to achieve some good running tests (refer to standard ISO 8253-1 to know all the test procedures)

- Routine check and subjective tests every weeks
- Every 3 years : calibration, total functional checking, verification of headphones and box status

9 Precautions for use

The AudiTest electronic box is fully associated with the headset delivered into the kit. Using any other headset may distort the measurements. The headset and the electronic box bear exactly the same last four digits in their serial number.

Always make sure that you only test tones at an intensity level that is acceptable for the patient.

The AudiTest is a portable device that does not need to be set on a table. It can be handled with just one hand. Nevertheless, it is preferable to use it with both hands, not only to prevent it to fall down, which could damage the device or hurt the patient, but also to make it easier to use the console controls and to watch at LCD screen.

It's convenient to check that the device don't have any chock mark or other damage which could cause disfunction.

It is preferable as well, not to use the audiometer if this one is too much close to others electronic equipments. If this is impossible, it is suitable to check the good working status of the audiometer in such conditions.

As well, the using of wireless communication equipment may affect the good working of the audiometer. Concerning the minimum distances, refer to chapter “Technical data”.

Before testing a new patient, it is recommended to check the cushion surfaces of the headset and to make sure there is no asperity capable of causing injury. These surfaces should also be cleaned to avoid any contamination. Suggested cleaning agents include: Linget’Anios, Biohit Proline Biocontrol, or any other similar product.

The AudiTest must only be used in a warm, dry environment. No liquid is supposed to penetrate inside components (electronic box, headset).

When the AudiTest has reached the end of its useful life, do not throw it in the bin. It should be returned to the retailer to be eliminated.

Worn batteries should be placed in a special battery recycling point.

This audiometer is a screening tool designed to be used by doctors, nurses or other healthcare operators. Under no circumstances, it may override the medical diagnosis carried out by a specialized physician.

10 Operating incidents

The audiometer does not power up :
Check if the batteries are installed properly; if yes, replace them with new batteries.

Display of the"low battery" pictogram :
Replace batteries with new batteries.

No tone in the headset :
Check that the headset jack connector is properly plugged into the audiometer electronic box and that the sound level is loud enough to be heard.
If these two points are correct, return the full set of equipment back to the retailer in its kit.

Bad headphone tone (sound too strong, erratic, etc.) :
Return the full set of equipment back to the retailer in its kit.

The surface between headset and patient is damaged, or the headphones cushions show signs of wear :
Return the full set of equipment back to the retailer in its kit.

LCD screen is largely illegible (damaged screen) :
Return the full equipment back to the retailer in its kit.

Keypad not working properly :
Return the full set of equipment back to the retailer in its kit.

Box damaged :
Return the total equipment to the seller in its kit.

11 Warranty

Thank you for purchasing the AudiTest. In the event of any claim made under warranty, please check the following terms and conditions:

-Electronica Technologies warrants this equipment to remain free from operating defects throughout the warranty period. If the equipment proves defective at some point during the warranty period, it will be repaired free-of-charge at the place the audiometer was manufactured

- This warranty extends to a 3 years period, starting from the purchasing date of the audiometer. The return shipping cost has to be taken into charge by the customer.
- This warranty does not cover:
    - the calibration checks and operations.
    - the replacement of parts following normal wear.
    - the defects caused by modifications made by the user.
- The warrantied repair service does not cover damages or defects coming from:
    - misuse, excessive use, or any abnormal operations or conditions of audiometer use in contradiction with the terms of the user manual.
    - any repairs performed by anyone who has not been authorized to do so by the audiometer manufacturer.
    - any use of accessory parts that are not compatible with the audiometer.

To get the best use of this audiometer, the customer is strongly advised to carefully read this user manual.

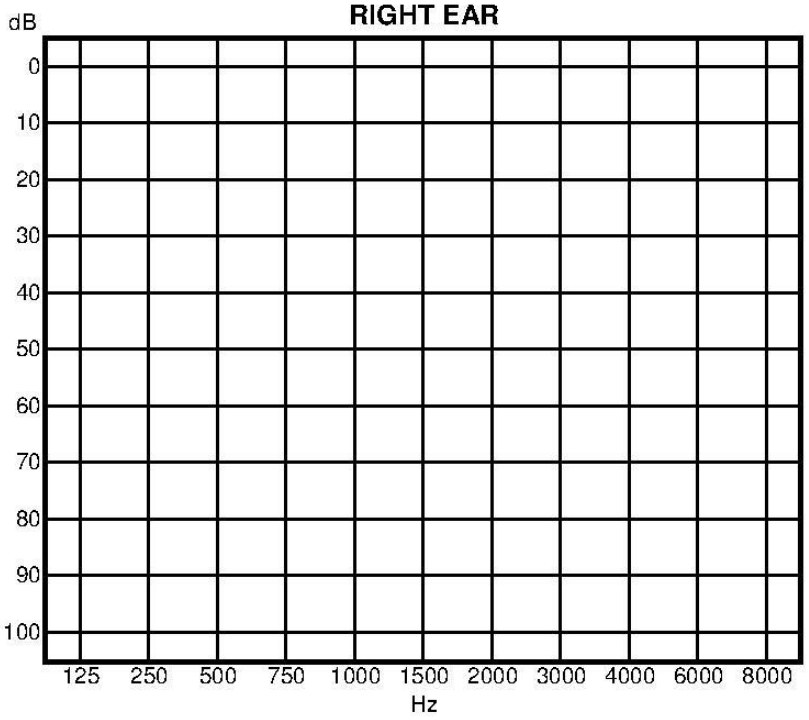
Date : _____

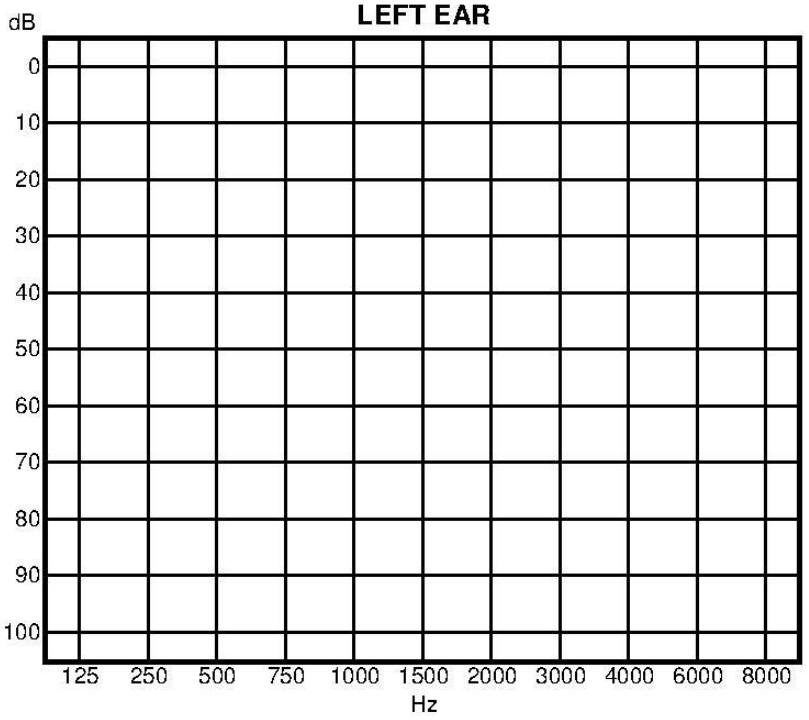
Last name : _____

First name : _____

Birth date : _____

AUDIOGRAM
(AIR CONDUCTION)





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