Audiometer 9910

1. Description of the device

The audiometer 9910 uses air conduction to screen for hearing loss. The tone is presented through speakers in the headphones worn by the patient.
The operators can set the frequency, hearing level, and left or right-side tone delivery. A patient feedback lead (accessory, as an option) can be used. It gives signal to the audiometer and by the same to the operator who knows if the sound has been detected or not (lead fitted with a pushbutton).
The device is AC-powered (or from an integrated rechargeable battery, as an option), with a circumaural headphones so called "standard"(or with a high noise attenuation circumaural headphones, as an option).
It is a pure-tone air-conduction type-4 audiometer (Standard: EN 60645-1).

2. Package contents

The device is delivered in a shock-proof briefcase containing:

- ✓ The audiometer electronic box 9910
- ✓ A headphones(cable: about 3 meters)
- ✓ A power adapter (cable:1,70 meters)
- ✓ An audiogram card
- ✓ The user manual
- ✓ Patient feedback lead (accessory as an option) (cable: about 1,20 meters)

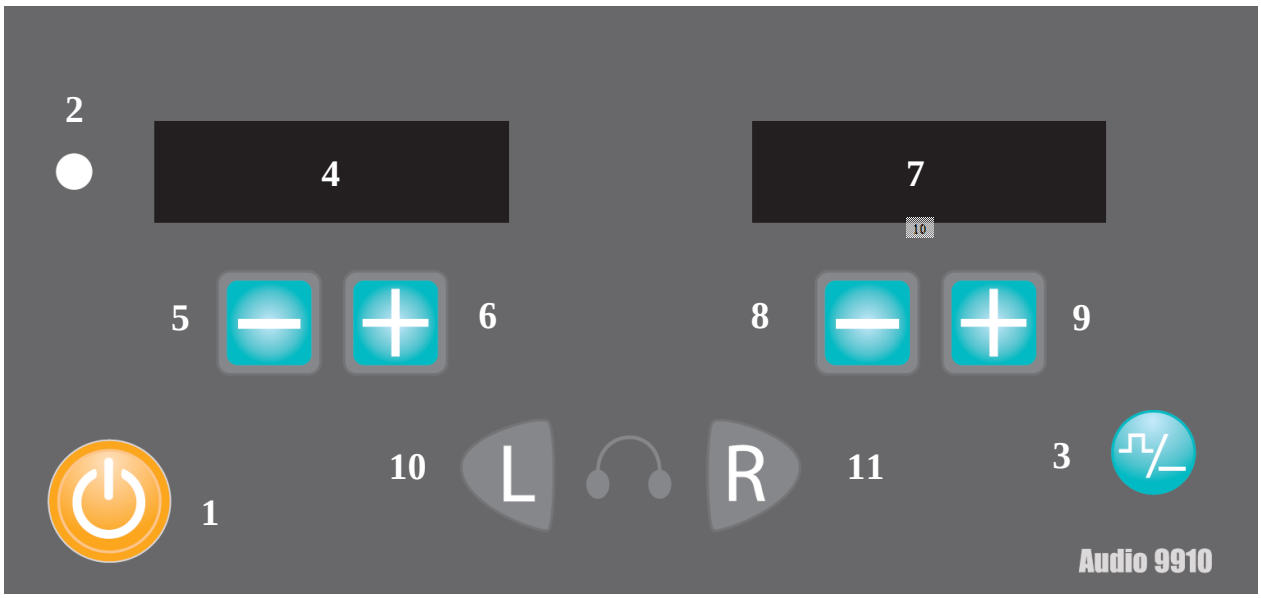
3. Checking condition and contents of the package

When receiving the equipment, state and contents of the briefcase have to be checked and make sure the audiometer 9910 and its accessories are in good working order.

If there is any problem, the assembly should be returned to the retailer. Keep the original packaging, which is designed to protect the goods during shipping.

4. Functional features

4.1. Front board



1: Power on/off key.
2: Power signal
3: Sound output - pulsed or continuous
4: Hearing level display screen.
5: Hearing level decrements key.
6: Hearing level increments key.
7: Frequency display screen.
8: Frequency decrements key.
9: Frequency increments key.
10: Left-side sound delivery key.
11: Right-side sound delivery key.

The key "1" enables to start or to stop the equipment. The LED "2" indicates the operating status. When switched-off stopped, the unit doesn't consume any current except when the option is installed the energy required to recharge the battery.

The button "3" enables, by successive pushes, to select the sound mode.

- The pulsed sound mode enables the generation of an intermittent sound (sound: 150 ms – silence: 250 ms - approximately). The symbol on the display reminds that the pulsed mode has been selected.
- The continuous sound mode generates a continuous tone, without interruption. No icon is displayed on the frequency display.

The frequency display "7" allows viewing the selected frequency, sequentially from the decrease button «8» and the increase button "9".
The possible frequency range is as follows:
125 Hz 250 Hz 500 Hz 750 Hz 1 kHz 1.5 kHz 2 kHz 3 kHz 4 kHz 6 kHz 8 kHz

The sound level display "4" allows viewing the selected level of sound, sequentially from decrease key "5" and increase key "6", by steps of 5 dB, from -10 dB to 100 dB (the upper limit depends on the frequency).

When pressing:

- Key "10", the audiometer sends the selected sound (frequency, level, continuous / pulsed) on the patient's left ear.
- Key "11", the audiometer sends the selected sound (frequency, level, continuous / pulsed) on the patient's right ear.

The sound lasts as long as key is pressed, unless the hand switch patient response has been pressed. In this case, the display indicates the patient's response time (in seconds) between the sound sending time and the time at what the patient pushes on the hand switch. This information remains visible up to one of the keys "10" or "11" is still pushed on.

4.2. Back panel

12: Headphone jack connector.
13: Connector for cabling up the patient feedback lead.
14: Power adaptor connector.

4.3. How to use the audiometer

✓ With AC-powered

- Plug the headphones into jack connector “12”.
- Plug the patient feedback lead into “13” (accessory as an option).
- Connect the power adapter into “14”.
- Plug as well the power adapter into the mains power socket.
- Press”1” - the green indicator light “2” comes on. The display screens “4” and “7” will briefly show type of device and the version of the embedded software, and then display screen “7” will read “1000 Hz” while display screen “4” will read “0 dB”.
- Use keys “8” and “9” to set the frequency.
- Use keys “5” and “6” 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).
- Select the operating mode by pressing key"3". When the pulse mode is selected, a symbol such as ⎍⎍ appears on the frequency display.
- Use keys “10” and “11” to deliver the tone to the patient.
- Press “1” to switch the device off.

✓ With the battery option

- Plug the headphones into jack connector “12”.
- Plug the patient feedback lead into “13” (accessory as an option).
- Press “1” to switch the device on. The display screens “4” and “7” will briefly show type of device and the version of the embedded software, and then display screen “7” will read “1000 Hz” while display screen “4” will read “0 dB”. If the battery is undercharged, display screens “4” and “7” will blink, displaying “Battery” when attempting to press a key. The device is still operational, but at this point it should be connected to the mains power via “14” to power the audiometer and charge up the battery. The indicator light “2” comes on to signal only when the power adapter is plugged into the mains. It lights up orange while the battery is charging and green when the battery is fully charged. The battery can be charged up without pressing “1”. If the batteries have discharged too much, the audiometer will not have enough power to run and will have to be connected to the mains power source.
- From here on, the audiometer runs in exactly the same way as when this one is AC-powered.

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.
It is advisable to check that the device shows no signs of impacts or any other damages liable to cause malfunctions.

5.1. Environmental performance conditions

To give optimal performance, the patient must be seated in a very 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, or by pressing the pushbutton on the feedback lead, accessory as an option, (run a preliminary test using the pushbutton to check it is working properly).
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 units 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 mode.
Silent pushbutton controlled left/right side delivery.

7.3. Sound output

6.35 mm stereo jack(1/4 inch).

7.4. Patient feedback (Accessory as an option)

Via a pushbutton, which is connected via a 1.2 meter lead to a 3.5 mm jack

7.5. Power supply

Standard: external power adapter supplied with the device (100-250 V~/15V - 500 mA ⎓ minimum, EN60601-1). Only use the custom power adapter contained into the carry-case.
Optional feature: NiMh battery cell.
- operating life of over 10 hours under normal conditions of use.
- battery cell requiring no specific handling other than charge-up.
- recharge time: 4½ hours maximum (if the battery is completely discharged).
-Lifetime: The battery can be charged up 1000 times approximately.
-The voltage threshold indicating that the battery must be rechargeable, is 8V.If the battery is discharged, display screens “4” and “7” are flashing, displaying “Battery” when attempting to press a key.

7.6. Calibration

Via air conduction according to standard ISO 389-1

7.7. Environmental performance conditions

Storage temperature: -10° to 60°C
Working temperature: 15° to 35°C
Relative humidity: between 30% and 90%
Air pressure: 98kPa to 104 kPa

7.8. CE Marking

Electronica Technologies is certified with the medical CE marking by the notify body LNE / G-MED (France)

CE
0459

7.9. Dimensions

Audiometer 9910:
L= 210 x W=130 x H=30/60 mm (8,27 x 5,12 x 1,18/2,36 in)
Weight: 500 g (1,1 lb) - Power adapter : 150 g (0,33 lb)
Full equipped carry-case:
L= 310 x W=280 x H=100 mm (12,20 x 11,02 x 3,94 in)
Total weight: 1.5 kg (3,30 lb)

7.10. Warm up

Use (sending sound to the patient): minimum 3 seconds after switching on.

7.11. Product origin

Device designed and built in France by:
ELECTRONICA Technologies, ZA de la Tour, 03200 ABREST, France
First CE 0459 marking awarded in 2008.

7.12. Classification

Type 4 pure tone audiometer.
Electrical safety:

Class II appliance  type B 

7.13. Other features

Robust, fully silent touchpad.
Power indicator light on the front board.
Front board power switch, plus automatic shut-off if the device remains idle (after 30 minutes under mains power or after 5 minutes under battery power).

7.14.Electromagnetic compatibility

<table>
<tr><th colspan="3">Guidance and manufacture´s declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">The Audiometer 9910 is intended for use in the electromagnetic environment specified below. The customer or the user of the Audiometer 9910 should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions

CISPR 11</td><td>Group 1</td><td>The Audiometer 9910 uses 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The Audiometer 9910 is 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.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Not Applicable</td></tr>
<tr><td>fluctuations/flicker emissions
IEC 61000-3-3</td><td>Not Applicable</td></tr>
</table>

Guidance and manufacture´s declaration – electromagnetic emission			
The Audiometer 9910 is intended for use in the electromagnetic environment specified below. The customer or the user of the Audiometer 9910 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	± 2 kV for power supply lines ± 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	± 1 kV differential mode ± 2 kV common mode	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	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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Audiometer 9910 requires continued operation during power mains interruptions, it is recommended that the Audiometer 9910 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 9910 is intended for use in the electromagnetic environment specified below. The customer or the user of the Audiometer 9910 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 Audiometer 9910, 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	10 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 9910 is used exceeds the applicable RF compliance level above, the Audiometer 9910 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Audiometer 9910.
[b]	Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

8. Precautions for use

The audiometer 9910 is fully associated with the headphones delivered into the briefcase. Using any other headphones may distort the measurements. The headphone and the audiometer share exactly the same last four digits in the serial number.

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

Only use the power adapter as well as the optional patient feedback lead delivered in the original carry-case; any attempt to use a power adapter or an optional patient feedback lead made by another manufacturer could damage the device. Do not attempt to replace or uninstall the optional battery unit.

The audiometer electronic box has to be set on a stable surface, not only to prevent it being dropped, which could damage the device or hurt the patient, but also to make it easier to use the controls and displays. It is recommended not to use the device if installed too much close others electronic equipments. If it is really not possible, the good running of the audiometer must be checked first under such conditions.
Similarly, the use of wireless communication equipments may interfere with the good working of the audiometer. Concerning minimal distances to be respected, would you please refer to the chapter ”electromagnetic compatibility”.

The operator must simultaneously avoid touching the patient and the pins on the power connector (Rep.14).

Before testing a different patient, double-check the surface interface between headset and patient to make sure there is no asperity capable of causing injury. This surface area should also be cleaned between patients to avoid spreading contamination. Recommended cleaning agents include: Linget’Anios, Biohit Proline Biocontrol, or any other similar product).

The other parts of the device can be cleaned with a soft cloth that you may dampen in soapy water, making sure no liquids are allowed to get into the device.

The audiometer 9910 must only be used in a warm, dry environment. No liquids should be allowed to penetrate the accessories (electronic box, headset, power adapter, patient feedback lead option if delivered).

When the audiometer 9910 has reached the end of its useful life, do not throw it in the bin. It should be returned to the retailer to be disposed of.

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.

9. Operating incidents

The audiometer does not power up:
Check that the mains power adapter is properly connected to the audiometer electronic box, and that it is plugged into a working 230V mains socket.
If you choose to use the device under battery power, keep charging the batteries until the indicator light turns green. If, after 4½ hours of charging, the indicator lights still does not go green, the batteries should be considered defective, in which case you will need to get them replaced by the manufacturer.

No tone in the headphones:
Check that the headset is properly plugged into the audiometer electronic box and that the sound level is loud enough to be heard.
If it is not case, return the full set of equipment back to the retailer in its carry-case.

Inconsistent headphone tone (sound too strong, erratic, etc.) :
Return the full set of equipment back to the retailer in its custom carry-case.

The surface interface between headset and patient is damaged, or the headphones cushioning shows signs of wear:
Return the full set of equipment back to the retailer in its custom carry-case.

Displays largely illegible (no backlighting or damaged screen) :
Return the full set of equipment back to the retailer in its custom carry-case.

Keypad not working properly:
Return the full set of equipment back to the retailer in its custom carry-case.

No response time display when pressing on the patient back button:
Return the full set of equipment back to the retailer in its custom carry-case.

10. Routine maintenance

Never open up the device. There is no reason for anyone other than a manufacturer-approved technician to attempt to conduct repairs.

Defective batteries can be replaced only by the manufacturer (optional feature).

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

11. Warranty

Thank you for purchasing the audiometer 9910. 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.
-Also covered under this warranty are the audiometer accessories sold with the original package.

- This warranty extends to a 3 years period, starting from the purchasing date of the audiometer. The customs and transportation costs have to be taken into charge by the customer, for both ways.
- This warranty does not cover:
    - the calibration checks and operations.
    - the replacement of parts following normal wear (note that warranty period of integrated battery assembly is limited to 1 year).
    - 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 the user manual.

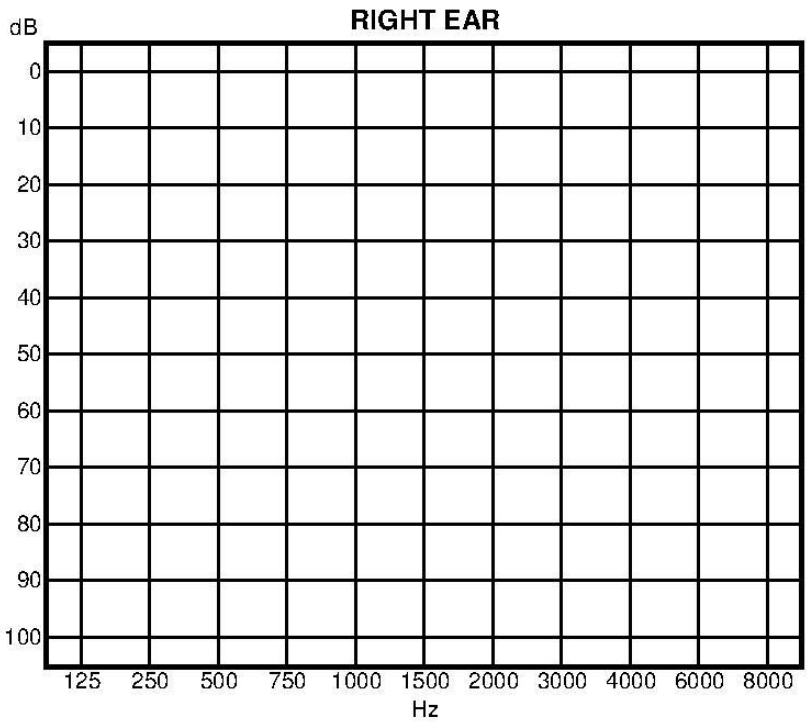
Date : _____

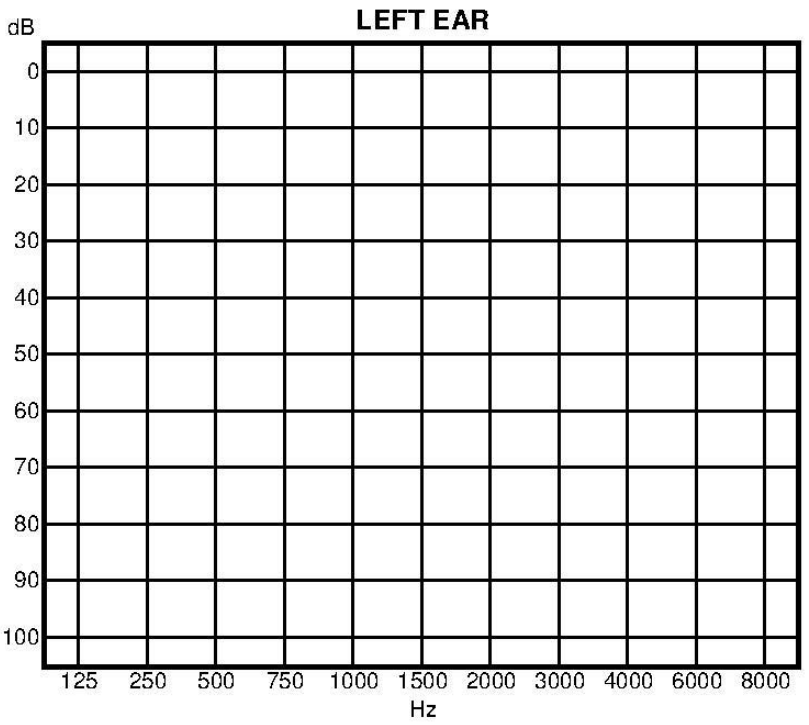
Last name : _____

First name : _____

Birth date : _____

AUDIOGRAM
(AIR CONDUCTION)





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