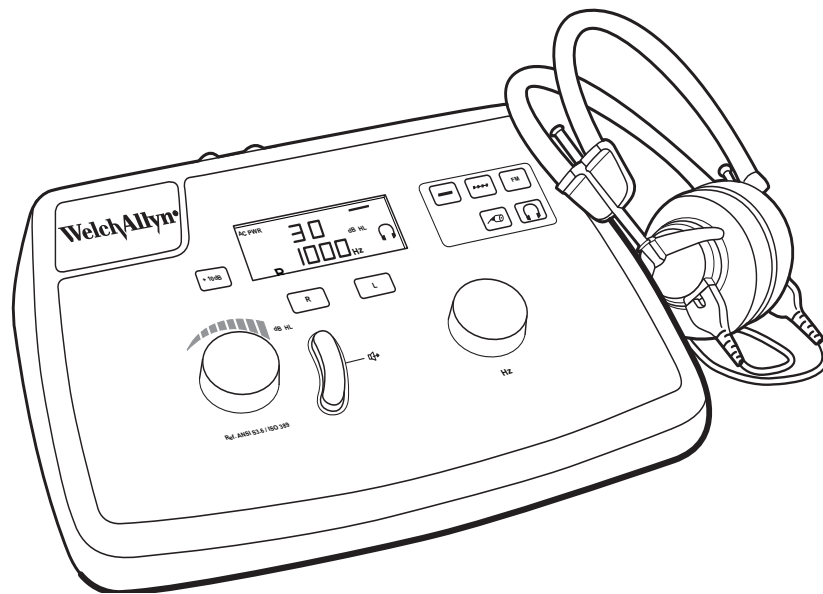


Welch Allyn AM282 Audiometer



Directions for use

Part Number 28204 Rev. E

WelchAllyn[®]

Advancing Frontline Care[™]

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Compliance

The CE0344 mark identifies compliance with the Medical Device Directive 93/42/EEC. Grason-Stadler is an ISO 13485-certified corporation.



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Introduction

The AM282 Audiometer is a single-channel, pure tone, air conduction, portable instrument designed to provide basic audiometric screening capability for physicians' offices and industry. The lightweight design allows easy transport to a variety of testing locations. The clearly labeled front panel controls and full frequency range make accurate, reliable testing a simple matter for any user.

The AM282 Audiometer is a precisely designed and calibrated instrument. With proper care it will deliver accurate sound-pressure levels to subjects' ears for hearing screening programs

Note The AM282 Audiometer should be calibrated yearly (or sooner if a problem develops) by a Welch Allyn certified technician. See Chapter 3.

Indications for use

The Welch Allyn AM282 Audiometer is intended to be used for the identification and etiology of hearing loss in patients of any age. It is intended to be used by an audiologist, ENT, hearing healthcare professional, or trained technician in a hospital, clinic, healthcare facility or other suitable quiet environment. There are no contraindications for the Welch Allyn AM282 Audiometer.

Unpacking and inspection

Although this AM282 Audiometer was carefully tested, inspected and packed for shipping, it is good practice after receiving the instrument to immediately examine the exterior of the container for any signs of damage. Notify the carrier if any damage is noted.

Carefully remove the AM282 Audiometer from its shipping container. If the instrument appears to have suffered mechanical damage, notify the carrier immediately so that a proper claim can be made. Be certain to save all packing materials so that the claim adjuster can inspect it as well. As soon as the carrier has completed the inspection, notify a Welch Allyn representative.

If the instrument must be returned, repack it carefully (in the original AM282 Audiometer container if possible) and return it prepaid to Welch Allyn for necessary adjustments.

Supplied Accessories

Check that all accessories itemized in Accessories supplied below are received in good condition. If any accessories are missing, contact Welch Allyn immediately. See “Accessories” on page 25 for the catalog numbers of accessories and also for a listing of optional accessories.

Welch Allyn Part Number	Welch Allyn Description
28203	DD45 Audiometry Headset External
28208	AM282 Audiogram Forms (1 pad of 50)
28204	AM282 Directions for Use Manual (printed, English only)
28202	AM282 Carry Case
28601	Power supply (UES24LCP-070300SPA)
28206	Threshold Audiometry Card

Optional Accessories

23220	Audiometry Patient Response Switch
23221	Audiometry Single Patch Cord, 2-Conductor
23222	Audiometry Audiocups



WARNING To ensure patient safety and optimal product performance, use only Welch Allyn recommended accessories and supplies

Recycling / disposal



Caution Many local laws and regulations require special procedures to recycle or dispose of electric equipment-related waste including batteries, printed circuit boards, electronic components, wiring and other elements of electronic devices. Follow all of your respective local laws and regulations for the proper disposal of batteries and any other parts of your system.

Safety Summary

Before using the AM282 Audiometer, familiarize yourself with the sections of this directions for use that pertain to your use of the AM282 Audiometer.

- Failure to understand and observe any warning statement in this manual could lead to patient injury, illness, or death.
- Failure to understand and observe any caution statement in this manual could lead to damage to the device or other property, or loss of patient data.



WARNING Warnings indicate conditions or practices that could lead to illness, injury, or death.



Caution Cautions indicate conditions or practices that could damage the equipment or other property.

Note Notes help you identify areas of possible confusion and avoid potential problems during system operation

Safety Notes



WARNING The AM282 is designed for compliance to IEC and UL 60601-1 when used in the patient vicinity. To achieve this compliance, use of hospital grade plug and receptacles are required. For patient and operator safety, the AM282 must be used with properly grounded plug and receptacles at all times. The AM282 is equipped with a specific power transformer (UE100503HKKK3-P, reorder number 28201), which should not be interchanged with any other transformer or supply.

WARNING Any program aimed at obtaining reliable records of hearing thresholds should be staffed and supervised by appropriately-trained individuals.

Latex is not used anywhere in the manufacturing process.

The base material for the earphone cushions is made from natural and synthetic rubber.



WARNING This symbol ▼ indicates the location of a service adjustment part and is intended for service personnel only. The AM282 is a specifically calibrated audiometer and the periodic service and adjustments for the instrument that may be required should be done only by an authorized service technician

WARNING Please read the entire manual prior to using the AM282 to become familiar with the test functions and proper accessory connections.

WARNING Accessory equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (IEC950 for data processing or IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Everyone who connects additional equipment to the signal input or signal output port configures a medical system, and is therefore responsible that the system complies with the requirements of the system standard IEC60601-1-1. If in doubt, consult the technical service department or a local Welch Allyn representative.

Customer Responsibility



WARNING This product and its components will perform reliably only when operated and maintained in accordance with the instructions contained in this manual, accompanying labels, and/or inserts. A defective product should not be used. Make sure all connections to external accessories are snug and secured properly. Parts which may be broken or missing or are plainly worn, distorted or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from Welch Allyn.

WARNING This product should not be used in the presence of fluid that can come into contact with any of the electronic components or wiring. Should the user suspect fluids have contacted the system components or accessories, the unit should not be used until deemed safe by a Welch Allyn certified service technician.



WARNING Do NOT use in the presence of flammable gaseous mixtures. Users should consider the possibility of explosions or fire when using this device in close proximity to flammable anesthetic gases.

WARNING Periodically, have a service technician perform electrical safety checks on the unit in order to show continued compliance to IEC and UL 60601-1.

Warranty

We, Welch Allyn, warrant that this product is free from defects in material and workmanship, and when properly installed and used, will perform in accordance with applicable specifications. If within one year after original shipment it is found not to meet this standard, it will be repaired, or at our option, replaced at no charge except for transportation costs, when returned to an authorized product service facility.

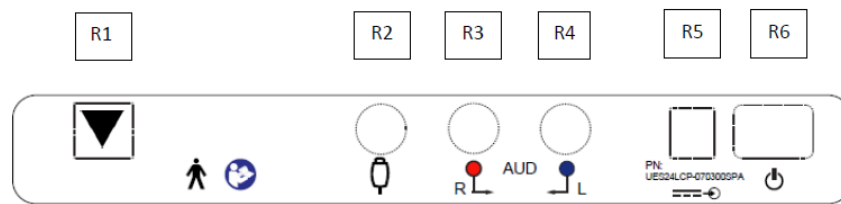
Note Changes in the product not approved in writing by Welch Allyn shall void this warranty. Welch Allyn shall not be liable for any indirect, special or consequential damages, even if notice has been given in advance of the possibility of such damages.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OF FITNESS FOR A PARTICULAR PURPOSE.

Installation

1. Plug the power cord into the appropriate jack (R5) on the rear panel.
2. Plug the power cord from the Power Module into a line power (mains) outlet.
3. Plug the earphones into the earphone jacks on the rear panel. R3 is for the right and R4 is for the left earphone/insert phone.
4. Turn the power switch to ON (R6).










Rear panel connectors




R1	Covered by a sticker and intended for service personnel only.
R2	Patient Hand Switch input jack (standard phone jack).
R3	Right ear phone output jacks (standard phone plug). Insert either the External Headset or Internal Earphone jacks.
R4	Left earphone output jacks (standard phone jack). Insert either external headset or Internal Earphone plugs.
R5	Power Input jack (2.1 mm pin).
R6	Power switch.

Symbols on the AM282 Audiometer

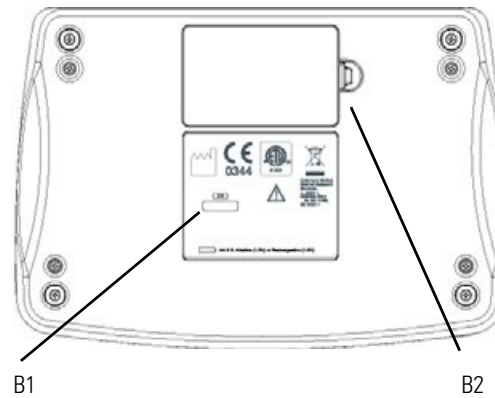
Symbol	Description
	Attention, consult accompanying documents
	Mandatory - Consult Directions for Use
	Date of manufacture
	Manufacturer
	CE Marked in accordance with the European Council Directive 93/42/EEC concerning medical devices.
	Medical device listing mark for U.S. and Canada by Intertek Testing Service.

Symbol	Description
	Special Recycling Required. Do not dispose in landfill.
	Type B equipment
REF	Symbol for "CATALOG NUMBER"
	Serial number.
Rx ONLY	Prescription only or "For Use by or on the order of a licensed medical professional"
	China RoHs
	Stand-by
	Right Ear
	Left Ear
	Patient Response Button
	AC Power

 **WARNING** Do not turn on/off system power while a patient is wearing the headsets or internal earphones.

WARNING Use only the provided power supply. The AM282 Audiometer provided power supply should only be connected to a power source meeting the following range: 90-246VAC, 47-63Hz. In North America, the power source should be a maximum of 120VAC.

Bottom panel

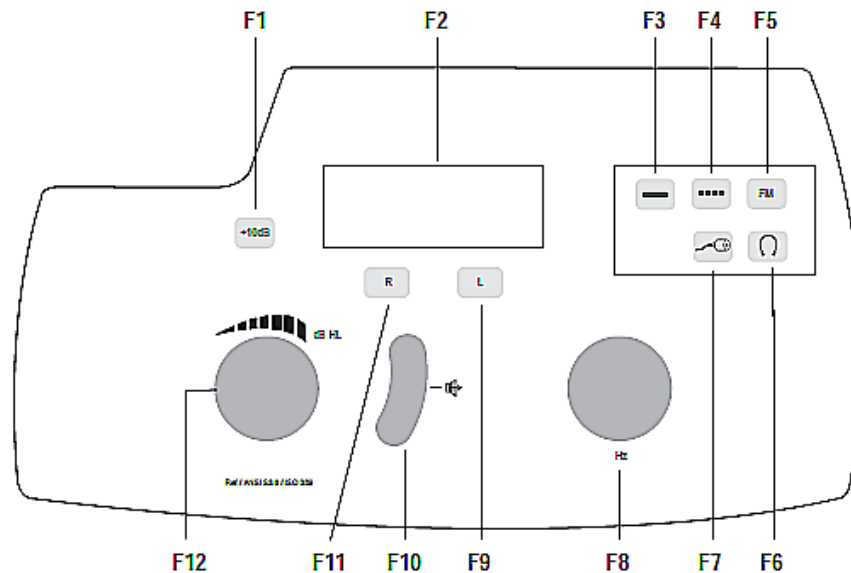


B1 Serial number of system

B2 Battery compartment


See [“Replacing the batteries”](#) on page 10 for detailed instructions.









Controls and indicators




F1 Range extension pushbutton allows you to increase the stimulus intensity 10 dB above the standard maximum HL at any frequency. When in use, a “+” appears on the LCD.

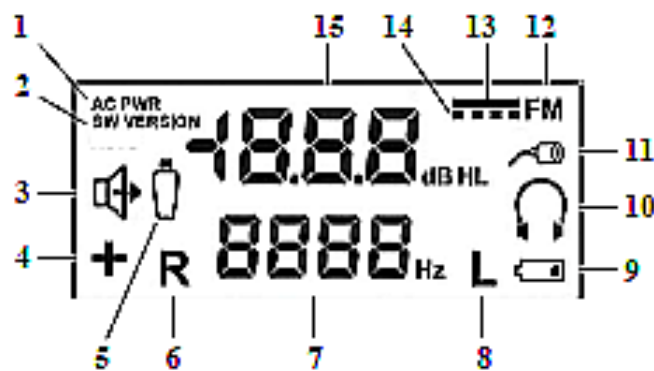
F2 Liquid Crystal Display (LCD).



F3 Selects steady stimulus tone type. The symbol  is shown in the upper right hand corner of the display when selected.







- F1** Range extension pushbutton allows you to increase the stimulus intensity 10 dB above the standard maximum HL at any frequency. When in use, a "+" appears on the LCD.
- F4** Selects pulsed stimulus tone type. The symbol  is shown in the upper right hand corner of the display when selected.
- F5** Selects frequency modulated stimulus tone type. **FM** is shown in the upper right hand corner of the display when selected.
- F6** Selects the calibration file for external headset transducers. When the  button is pressed, the display will flash. Press the  button again to engage the external headset transducer. The symbol  is shown on the right side of the display when selected.
- F7** Selects internal earphone calibration file for transducers. When the button  is pressed, the display will flash. Press the  button again to engage the internal earphone transducers. The symbol  is shown on the right side of the display when selected.
- F8** Control for setting the stimulus frequency. Frequency is indicated in the bottom center of the display.
- F9** Select to present the stimulus to the Left ear. An "L" will appear in the lower right side of the display to indicate the stimulus is being routed to the left ear.
- F10** Present bar for stimulus presentation. The symbol  appears on the left side of the display when the stimulus is being presented.
- F11** Select to present the stimulus to the Right ear. An "R" will appear in the lower left side of the display to indicate the stimulus is being routed to the right ear.
- F12** Hearing Level knob for setting the stimulus intensity level. Level is indicated on the center top of the display.

Note The  symbol is located on the rear panel of the AM282 Audiometer and denotes a Type B applied part.

LCD display



Legend	Icons/LEDs	Description
1	AC PWR	Indicates power is on.
2	SW VERSION	Indicates the current software version.
3		When displayed, the stimulus is being presented.
4		When displayed, an additional 10dB is available at the test frequency.

Legend	Icons/LEDs	Description
5		When displayed, indicates the Patient Response button is being pressed.
6	R	Stimulus is being presented to the right ear.
7	8888 Hz	Stimulus frequency indicator.
8	L	Stimulus is being presented to the left ear.
9		Indicates the battery is low.
10		The headset calibration file is applied to the stimulus and Headphones should be used. Press this button twice to activate the calibration file.
11		The insert phone calibration file is applied to the stimulus and Insert phones should be used as the transducer. Press this button twice to activate the calibration file.
12	FM	The stimulus is a Frequency Modulated (FM) tone.
13		The stimulus is a continuous tone.
14		The stimulus is a pulsed tone.
15	-18.88 dB HL or OFF	Stimulus presentation level. Not enough power from the batteries to operate the system.

AC power

An AC power supply can be purchased to use with the AM282 Audiometer.



WARNING Use only the Welch Allyn provided power supply. The AM282 Audiometer provided power supply should only be connected to a power source meeting the following range: 90-246VAC 47-63Hz. In North America, the power source should be a maximum 120VAC.

Connecting the AC power

1. Ensure the system is turned off while connecting the AC Power.
2. Plug the AC power supply into the power supply receptacle located next to the power switch on the rear panel.
3. Connect the power cord to the Power Supply brick.
4. Plug the Power cord into the wall socket.
5. Turn the power ON.

When the power supply is plugged into the unit, the power from the batteries will be switched off automatically to preserve battery life.

Disconnecting the AC power

1. Turn the system OFF.
2. Disconnect the power supply from the wall outlet.
3. Remove the power supply from the rear panel.

Battery operation

The AM282 Audiometer requires 5 x 1.5V AA alkaline batteries. It can also use 5 x 1.2V AA NiMH or NiCad batteries if rechargeable batteries are desired. The AM282 Audiometer does not have a built-in charger, rechargeable batteries should be purchased with the recommended charger for those batteries. Welch Allyn recommends the purchase of extra rechargeable batteries to ensure a fully charged supply of batteries will be available. The system was designed to operate for 10 hours on rechargeable batteries. Alkaline batteries may last longer than 10 hours.




Caution Remove the batteries from the AM282 Audiometer if it is not going to be used for an extended time.

Sleep mode

When using battery power, the AM282 Audiometer will enter a power saving mode (this is called sleep mode and is indicated by dashes on the LCD display) if the buttons on the Front Panel have not been pressed for 5 minutes. To exit the sleep mode, press the **Presentation** button.

Low battery indicator

When there is approximately 1 hour of battery time left, the  icon will be displayed on the screen.

When the battery can no longer provide enough power to operate the AM282 Audiometer, the word **OFF** will be displayed on the LCD and the system will no longer function. At that point, replace the batteries (with new or fully charged batteries) or use the AC Power Module to continue testing.

Replacing the batteries



WARNING Do not touch the patient and the battery terminals at the same time. The battery cover is to be closed at all times except when replacing the batteries.

Batteries are to be replaced only by qualified personnel. Always turn off the system before replacing the batteries.

Always inspect batteries for leakage and do not use if the batteries show any signs of damage. The batteries should be the same type. When replacing batteries, replace all of the batteries at the same time for optimal battery life.

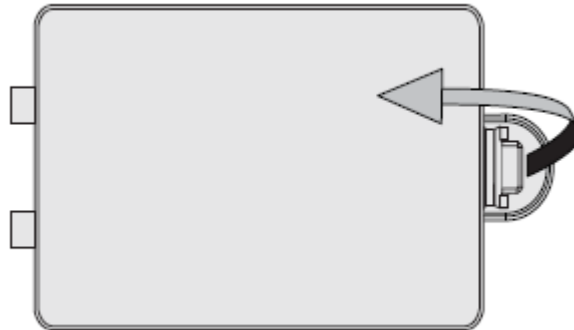
The AM282 Audiometer requires 5 x 1.5V AA alkaline batteries. It can also use 5 x 1.2V AA NiMH or NiCad batteries if rechargeable batteries are desired.

Removing the batteries

The battery compartment on the AM282 Audiometer is located on the bottom of the base unit.

To open the battery compartment,

1. Gently squeeze the tab toward the door and away from the concave half circle and lift the door upward.

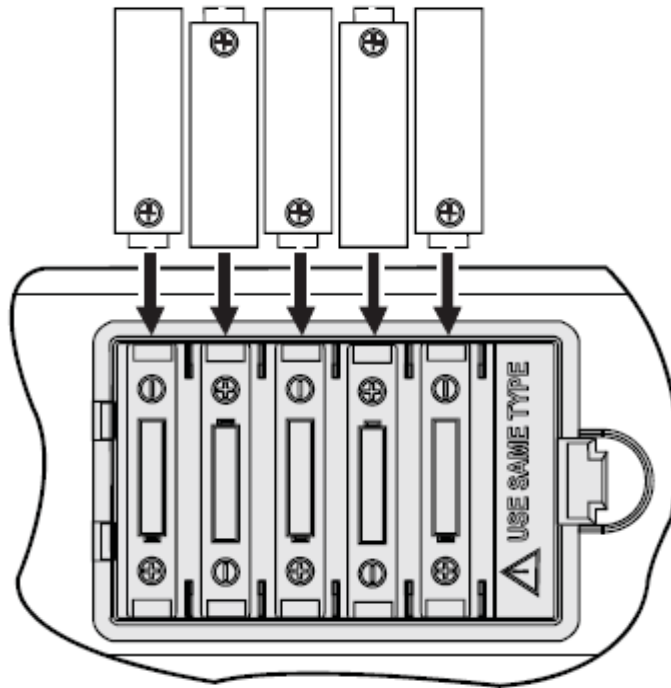


2. Reach into the compartment through the empty battery slot and gently force the battery up until it is free from the silver battery contacts.
3. Repeat for all 5 batteries. Do not simultaneously touch both sides of the battery contacts at any time.

Inserting new batteries

Before inserting new batteries in the battery compartment, always inspect batteries for leakage and do not use batteries that show any signs of damage.

1. Insert the batteries starting with the battery slot farthest from the slot that is not used. Be sure to match the + side of the battery with the marked + side for each battery slot.



2. Place the + side of the battery in at an angle and then push down on the - side of the battery until the battery fits securely.
3. Replace the battery compartment cover by inserting the square pegs into the slots and gently pushing down until the tab snaps into place and the compartment door is flush with the bottom of the AM282 Audiometer.

2 Operation

Preliminary check

Throughout this chapter are references to front panel (**F**) and rear panel (**R**) connectors, controls and indicators. Please refer to “[Rear panel connectors](#)” on page 5, “[Controls and indicators](#)” on page 7 and “[LCD display](#)” on page 8 of this manual for specific descriptions and locations.

1. Prior to testing, ensure that the power cord or the batteries are in place and earphone cords are plugged in securely.
2. Turn the audiometer on.
3. Select the desired tone type (steady, pulsed or FM).
4. Make whatever notations your procedure requires on the audiogram form.



Caution Always handle earphones with care. Neither drop them nor permit them to be squeezed together. Severe mechanical shock may change their operating characteristics and require their replacement.

Note Always clean and maintain earphone cushions for hygiene purposes. Check periodically for cracking or signs of wear. Cleanse cushions daily or after each use (depending upon population being tested). Use a solution of diluted alcohol or mild soap and water. Do not allow any of the cleaning solution to enter into the earphone speaker. Use earphones only when completely dry. Insert the earphone cords between the earphone cushions during storage to prevent damage from mechanical shock.

Pretest noise recovery period

Note The generic term “subject” used in this manual is used to identify the person whose hearing is being evaluated.

Two prerequisites are of particular importance to the procurement of reliable audiograms:

- Prior to testing, allow enough time for the subject to recover from the effects of noise exposure. Exposure to high levels of sound (unmuffled lawn mowers, power tools, loud music, gunfire, etc.) tends to create a temporary threshold shift (TTS), which diminishes with time after exposure. If a subject is tested too soon after noise exposure, a hearing test may indicate a hearing loss that does not reflect the subjects true hearing. It is recommended that the testing procedure prescribe some time interval - usually at least 16 hours – between the last exposure to high-level sound and the administration of any hearing test.

- Tests should be performed in a quiet area.



WARNING Any program aimed at obtaining reliable records of hearing thresholds should be staffed and supervised by appropriately-trained individuals. Training courses leading to certification are available for audiometric technicians in most urban areas.

Test environment

Excessive noise in the test environment can reduce test validity by masking test tones. The test site should be away from conversation, printers, hallway traffic, outside auto traffic, and other noise producing environments. An acoustically tested room may be required if room noise at the subject's ears reaches objectionable levels. Audiocups are available from Welch Allyn as an optional accessory for use with the external headset headphones. Insert earphones are another option in noisy test environments. They provide greater than 30 dB reduction of external noises. If the test subject is in the same room as the audiometer, it is recommended that the subject be seated about 1 meter (approximately 3 feet) away from the instrument.

Maximum permissible test environment sound-pressure levels are specified by American National Standard Criteria for Permissible Background Noise during Audiometric Testing, S3.1-1977 (revised). The table below shows the maximum background levels that can be present inside the room while a valid hearing test is being conducted. For more comprehensive information about hearing testing and hearing conservation, refer to the Bibliography.

Test Tone Frequency (Hz)	125	250	500	750	1000	1500	2000	3000	4000	6000	8000
*Test Room- Maximum dB SPL	34.5	23.0	21.5	22.5	29.5	29.0	34.5	39.0	42.0	41.0	45.0

*Ears covered with earphone mounted in MX-41/AR cushion.

Providing patient instructions

Put the subject as much at ease as possible before the test begins. In addition, help the subject understand how the test is to be conducted and what the subject will hear. Uniform and unvarying instructions should be given to each subject in order to achieve consistent and reliable test results. The following is an example of standard instructions:

"I am going to place these earphones over your ears. You will hear tones or beeping sounds which may be loud or soft. Whenever you hear, or think you hear one of these tones, raise your hand. Lower your hand when you no longer hear the sound. Remember, raise your hand when you hear the tone and lower your hand when you do not."

Modify the instructions accordingly if the optional response handswitch is to be used.

Placing the earphones

Proper placement of the earphones on the ears is essential to achieve reliable test results.

- a. Eliminate all obstruction between earphone and subject (hair, eyeglasses, earrings, hearing aids, etc.).
- b. Adjust the headband so the earphone cushions are centered over the ears and head. The earphone cushions will put firm pressure on both ears.

Response handswitch

If the optional response handswitch is used ensure that the plugs and jacks are properly connected.

Welch Allyn Audiogram Form

The Welch Allyn Audiogram Form consists of three distinct parts:

- Space for entering personal information about the subject to be tested.
- A convenient chart for manually plotting test data.
- Space for entering comments about the subject or the test.

AUDIOGRAM

Name _____ No. _____

Age _____ Gender _____ Date _____ Time _____

Audiometer Model No. _____

Serial No. _____

Job Location _____

Examiner _____

Signature _____

Symbols

Ear - Phone	Response	No Response	
Left - Blue	X	X	Earphone <input type="checkbox"/>
Right - Red	○	○	Insert phone <input type="checkbox"/>

Comments

ISO 389-1 (1989) ANSI S3.1 (2004)
 IEC 60645-1 (2001)




Part No : 28208 Rev B




Welch Allyn, Inc
 4341 State Street Road, Skaneateles Falls, 153-0220 USA
 Tel: 800 535 6663 Web: www.welchallyn.com

Routine test administration

Transducer selection

The AM282 Audiometer provides options for either headset or insert transducers.

Selecting  the will apply the calibration values for the headset. Selecting the  will apply the calibration values for the insert earphones. To make the selection for the headset, press the  button and the headset icon will flash on the LCD.

To confirm the selection push the  button again. To make the selection for insert earphones, press the  button and the insert earphone icon will flash on the LCD. To confirm the selection push the  button again.

See “[Appendix A](#)” on page A for applied reference threshold values (RETSPL) for both the external headset and the internal earphones.

HL knob

The HL knob increases or decreases the signal intensity in 5 dB increments. Rotating the Control knob clockwise increases the intensity; counterclockwise decreases intensity. When the maximum or minimum available intensity is reached for any frequency, the display will flash.

Range Extension pushbutton

This control allows the operator to present tones of up to 10 dB above the standard maximum HL at any frequency. It will only function when the intensity is set within 10 dB below the maximum standard intensity at any frequency. This feature requires an extra step to access the highest available intensities. It prevents accidental presentation of the highest intensities to normal subjects.

To enable the range extension feature, press the button labeled +10 dB while the intensity is at the maximum for that frequency. Note that a “+” sign appears on the LCD. To disable the feature, either press the button a second time, reduce the intensity (with the HL control knob) to 20 dB below the standard maximum HL or change any other parameter (Frequency or Routing).

Tone Type selector

This control allows you to choose the type of tone presented to the test subject. It can be set on steady, pulsed (2.5 pulses per second) or FM (warble tone).

Pulsed tones and warble tones are often used with difficult to test subjects, such as children and hard of hearing individuals, because they hold the subject’s attention better than the steady tone.

Typical testing session

Pretest review

1. Turn the instrument on.
2. Check that the earphones are operating properly.
3. Seat the subject comfortably in the test area.
4. Explain the test procedure.
5. Place the earphones on the subject.
6. Select the desired tone type.

Familiarization

1. Select the transducers.

2. Select the L or R pushbutton to route the test tone to the selected ear.
3. Demonstrate the 1000 Hz tone at a 50 dB level. The tone duration should be between 1 and 2 seconds.
4. Repeat at 40 dB Hz.

Determining the threshold (Pure Tone)

1. Present the first tone at 50 dB in the subjects better ear, or if no preference, the right ear. Decrease the intensity in 10dB steps until the subject no longer responds. Increase the intensity in 5dB steps until the patient responds.

Note Down 10 dB, Up 5 dB

2. The threshold is considered to be the lowest intensity at which a response has occurred two out of three times. Record this setting on the audiogram form using the appropriate symbol for L (X) or R (O).

Testing procedure

1. A suggested order in which to present frequencies is as follows:

1000 Hz, 500, 250 repeat 1000, 2000, 3000, 4000, 8000 Hz.

An alternative order is as follows:

250 Hz, 500, 1000, 1000 again, 2000, 3000, 4000, 8000 Hz.

2. The 1000 Hz retest is to verify the results of the test to ensure the subject understands the task.

If there is a difference of 20 dB or more between two successive octaves, test the inter-octave responses (i.e., 750, 1500, 3000 Hz). Record this information on the audiogram form.

3. Repeat for the other ear.

3

Routine Maintenance

Preventive maintenance

To maximize the service life of the audiometer and headset, the following is recommended.

1. Turn the instrument off when not in use.
2. Dust the instrument occasionally with a soft, dry cloth.
3. Wipe the headset cords and ear cushions occasionally with a warm damp cloth.
4. Leave the earphones connected to the audiometer permanently to minimize straining the connections. Should it be necessary to remove the headset, always grasp the barrel of the connecting plugs and pull straight out - never pull on the cords.
5. Avoid dropping the earphones or snapping them together as this could affect the calibration accuracy.



WARNING It is recommended that all repairs be performed by a qualified service representative. Any malfunctions resulting from improper maintenance or repair by anyone other than an authorized representative will void all warranties.

Cleaning patient contact reusable devices

To help ensure patient safety, prevent cross infection, and provide effective service, Welch Allyn devices must be properly maintained. Maintenance should include cleaning before each use. The earphone cushions and patient hand switch can be wiped with a slightly damp cloth containing soap and water, isopropyl alcohol, ammonia based cleaners or bleach based cleaners. Gently wipe the earphone cushions with the slightly damp cloth. Prevent moisture from entering the speaker portion of the earphones.

Routine calibration check

The length of time that an audiometer should be operated before re-calibration varies depending upon the use and treatment of the instrument and its headset. It is recommended that the instrument be fully calibrated by a certified Welch Allyn technician annually.

It is recommended that a biologic calibration check is established as soon as the instrument is received.

1. Make several careful tests of the operators hearing and record the results properly on the audiogram cards provided with the instrument.

2. Conduct similar tests with several young adults on whom subsequent retests may be made. Record the results on the audiogram forms.
3. File these audiogram forms where they will be readily available for comparison with future results.

If the AM282 Audiometer is to be used to monitor employee thresholds as part of an industrial Hearing Conservation Program, this “biological listening check” must be done at the beginning of each day the audiometer is to be used (per CFR 1910.95 Occupational Noise Exposure, March 8, 1983).

Since individual thresholds can shift up or down as much as 5 dB from one day to the next, variation within this range may be considered acceptable. Variations that exceed this range, however, are likely to reveal problems that require attention. The routine maintenance checks described in this chapter may suggest the source and solution to the problem. If they do not, the instrument should receive technical service by a certified technician before further use.

Earphone cords

With extended use, earphone cords tend to fray internally at the junctions of both earphone and audiometer connectors. This fraying will ultimately decrease the signal level in the associated earphone or cause signals to be intermittent as the cord is flexed.

To check for either condition:

1. Set the Audiometer frequency control to 1000 or 2000 Hz.
2. Set the HL knob at a comfortable audible level and use a Steady Tone type.
3. Press the Present bar and flex earphone cord next to plug at both ends, listening for intermittent signal, abrupt changes in signal level, or a scratchy sound superimposed over the signal that coincides with the flexing of the cord. The presence of any of these three conditions signifies that the cord should be replaced.

Hum and random noise

With the instrument set on 1000 Hz, move the HL knob from 0 to 60 dB and listen for low-frequency hum and random noise (hiss or low rushing sound) at all attenuator levels. Some audible random noise at levels above 60 dB is permissible. Below 60 dB, however, only the signal should be audible. Any of these noises can be confused with the signal by naive subjects and affect the accuracy of the audiogram. Schedule the audiometer for immediate service if any audible hum or noise is detected for clarity.

Distortion and frequency shift

This check can be best made by listening to the output of the AM282 Audiometer through the earphones while presenting all 11 frequencies at a loud, but not uncomfortable, level (70 to 80 dB HL for normal ears.)

Listen for rattling, rasping or distortion in the tones presented. Listen also to verify that signal frequencies change appropriately when the frequency selector is moved to a new position. If distortion is heard in one earphone but not in the other, the chances are high that the earphones are at fault and should be replaced. In any case, the audiometer should be scheduled for immediate maintenance.

Special messages

The AM282 Audiometer performs a self-check each time the instrument is turned on (the self-check does not occur when instrument operation resumes from the "sleep mode"). Certain messages will be displayed on the front panel LCD if any error in the instrument operation is detected. These messages are described below.

Cal

When a transducer or frequency is selected that has a calibration error (e.g., right ear selected at 2000 Hz), the word "CAL" will be displayed. The audiometer will not function at this frequency with this ear selected, to prevent invalid results. The word "CAL" will be displayed as long as the erroneous ear and frequency settings are selected. If the calibration error is an isolated situation, changing either the frequency or the ear will restore normal instrument function.

As in the case with any instrument malfunction, a certified service technician should be contacted immediately. Remember to make note of the combination of selected ear and frequency that cause the "CAL" message.

Exx

When an error code consisting of an "E" and a two digit number (xx = number) appears on the audiometer's display, a system error has been detected. The AM282 Audiometer will enter a "lockout" mode which will not permit the instrument to operate. The specific error code will remain on the display for several seconds, then the instrument will shut itself down completely. Should an Exx appear on the LCD, take the following steps:

1. Power down, power up again. This could be only a temporary failure and may never appear again. However, should the Exx message appear again, proceed to the following.
 - a. Write down the numbers displayed on the display.
 - b. Contact a certified Welch Allyn service representative and give them the numbers you recorded.

4

Standards, Specifications, and Accessories

Standards and Compliance

The AM282 meets

ANSI S3.6 (2004)	Specification for Audiometers (Type 4)
IEC 60645-1 (2002)	Electroacoustics - Audiological Equipment - Pure Tone Audiometers (Type 4)
IEC 60601-1 (2003)	Medical Electrical Equipment Part 1 - General Requirements for Safety
UL 60601-1	Medical Electrical Equipment, Part 1 - General Requirements for Safety
CAN/CSA-C22.2 No. 601.1-M90 (2003)	Medical Electrical Equipment - Part 1: General Requirements for Safety
IEC/EN 60601-1-2 (2001)	Medical Electrical Equipment Part 1 - Electromagnetic compatibility requirements

Frequency Range

Discrete Frequencies:	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz
Accuracy:	±2%
Total Harmonic Distortion:	<2.5% measured acoustically at the maximum Hz for frequencies below 5000 Hz and measured electrically above 5000 Hz.

Intensity

Ranges* In increments of 5 dB steps	
125 Hz	-10 to 50 dB HL
500 to 4000 Hz	-10 to 90 dB HL
6000 Hz	-10 to 85 dB HL
250 and 8000 Hz	-10 to 70 dB HL

*The above intensity ranges apply to the external headset earphones.

Note The maximum output values in dB HL are reduced by 10 dB when insert phones are used, except for 6 kHz where the maximum dB HL is reduced by 20 dB.

A "+10" dB button extends the maximum at all frequencies by 10 dB.

Accuracy	125 to 4000 Hz, ± 3 dB 6000 to 8000 Hz, ± 5 dB
Signal to Noise Ratio:	>70 dB

Tone Type

Rise/Fall Time:	20-50 msec
Continuous:	Steady when present bar depressed
Pulsed:	2.5 pulse/sec
FM:	$\pm 5\%$, 5 Hz, Triangular modulation
Capacity:	Minimum of 10 hours of power for either battery type.

Head set

DD45 External Headset Earphones with Type 51 Cushions (10 ohm impedance).

Headband	Exerts a force between 4 and 5 N when the earphones are separated by 145 mm.
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Power

Line Voltage:	The AC-DC adapter is a universal auto-ranging with an input voltage range of 90 - 264V at 47 - 63 Hz.
Consumption:	1.5 Watts
Battery:	Types: 5 each Alkaline AA 1.5V 5 each Rechargeable Nicad or NIMH AA 1.2V

Note

The instrument does not provide a recharging circuit for these batteries.

Capacity:	Minimum of 10 hours of power for either battery type. A <i>Low Battery</i> icon  will display when there is approximately 1 hour of power remaining.
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Environmental

Operating Temperature	59° F to 104° F (15° C to 40° C)
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Note

Warm-up time is required if storage temperature is different from room temperature.

Ambient Pressure:	98 kPa to 104 kPa
Warm-up Time:	10 minutes for instruments stored at room temperature
Storage/Shipping:	-30° F to 149° F (-34° C to 65° C)
Battery Storage:	-4° F to 105° F (-20° C to 40° C)
Humidity:	15% to 95%

Mechanical

Dimensions:	12.59" W x 8.76" D x 3.18" H (32 cm W x 22.3 cm D x 8.1 cm H)
Weight	2.55 lbs (1.16 Kg) with 5 AA batteries

Accessories

Welch Allyn Part Number	Welch Allyn Description
28200	AM282 Manual Audiometer with Case
28601	Power supply (UES24LCP-070300SPA)
28202	AM282 Carry Case
28203	DD45 Audiometry Headset External
28204	AM282 Directions for Use Manual (printed, English only)
28206	Threshold Audiometry Card
28208	AM282 Audiogram Forms (1 pad of 50)
28210	Audiometry Y-Cord Headset 2 Plug Shielded
23220	Audiometry Patient Response Switch
23221	Audiometry Single Patch Cord, 2-Conductor
23222	Audiometry Audiocups

Electromagnetic Compatibility

Portable and mobile RF communications equipment can affect the device. Install and operate the device according to the EMC information presented in this chapter.

The device has been tested for EMC emissions and immunity as a stand-alone device. Do not use the device adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, the user should verify normal operation in the configuration.

The use of accessories, transducers and cables other than those specified, with the exception of servicing parts sold by Welch Allyn as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the device.

Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard.

Cautions regarding EMC



WARNING This device is suitable in hospital environments except for near active HF surgical equipment and RF shielded rooms of systems for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high.

Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this instrument and the other equipment should be observed to verify that they are operating normally.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

ESSENTIAL PERFORMANCE for this device is defined by the manufacturer as:

- This device does not have an ESSENTIAL PERFORMANCE
- Absence or loss of ESSENTIAL PERFORMANCE cannot lead to any unacceptable immediate risk
- Final diagnosis shall always be based on clinical knowledge.

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Guidance and Manufacturer's Declaration Electromagnetic Immunity

The Welch Allyn AM282 Audiometer is intended for use in the electromagnetic environment specified below. The customer or the user of the Welch Allyn AM282 Audiometer should assure that it is used in such an environment.

Guidance and manufacturer's declaration—electromagnetic emissions		
The Welch Allyn AM282 Audiometer is intended for use in the electromagnetic environment specified below. The customer or the user of the Welch Allyn AM282 Audiometer should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment—guidance
RF emissions CISPR 11	Group 1	The Welch Allyn AM282 Audiometer 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.
RF emissions CISPR 11	Class B	The Welch Allyn AM282 Audiometer is suitable for use in all commercial, industrial, business, and residential environments.
Harmonic emissions IEC 61000-3-2	Complies Class A Category	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment

The Welch Allyn AM282 Audiometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Welch Allyn AM282 Audiometer can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Welch Allyn AM282 Audiometer as recommended below, according to the maximum output power of the communications equipment.

Recommended separation distances between portable and mobile RF communications equipment and the Welch Allyn AM282 Audiometer

The Welch Allyn AM282 Audiometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Welch Allyn AM282 Audiometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Welch Allyn AM282 Audiometer as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800 MHz, the separation distance for 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.

Guidance and Manufacturer's Declaration Electromagnetic Immunity

The Welch Allyn AM282 Audiometer is intended for use in the electromagnetic environment specified below. The customer or the user of the Welch Allyn AM282 Audiometer should assure that it is used in such an environment.

Guidance and manufacturer's declaration—electromagnetic immunity			
The Welch Allyn AM282 Audiometer is intended for use in the electromagnetic environment specified below. The customer or the user of the monitor should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 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 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or residential 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 residential 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 residential environment. If the user of the Welch Allyn AM282 Audiometer requires continued operation during power mains interruptions, it is recommended that the Welch Allyn AM282 Audiometer be powered from an uninterruptible power supply or its battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note U_t is the AC mains voltage prior to application of the test level.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Conducted RF IEC 61000-4-6	3 V _{rms} 150 kHz to 80 MHz 2Hz AM	3 V _{rms}	Portable and mobile RF communications equipment should be used no closer to any parts of the Welch Allyn AM282 Audiometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz 2Hz AM	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and d is the recommended separation distance in meters. 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 battery-operated Propaq LT Series monitor is used exceeds the applicable RF compliance level above, the battery-operated Propaq LT Series monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the battery-operated Propaq LT Series monitor.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Note: There are no deviations from the collateral standard and allowances uses.

Note: All necessary instruction for maintaining compliance with regard to EMC can be found in the general maintenance section in this instruction. No further steps required.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. To ensure compliance with the EMC requirements as specified in IEC 60601-1-2, it is essential to use only the following accessories:

Item	Manufacturer	Part number
Complete headset with DD45 Earphones and headband	RadioEar	28203
Audiometry Patient Response Switch	Grason-Stadler	23220

Conformance to the EMC requirements as specified in IEC 60601-1-2 is ensured if the cable types and cable lengths are as specified below:

Description	Length	Screened/unscreened
Complete headset with DD45 Earphones and headband	2 m	Screened
Audiometry Patient Response Switch	2 m	Screened

Note The use of the accessories, transducers and cables with medical equipment/system other than this equipment may result in increased emissions or decreased immunity of the medical equipment/system.

A

Appendix A

DD45 External Headset RETSPL Values for NBS 9A Coupler

Frequency (Hz)	125	250	500	750	1000	1500	2000	3000	4000	6000	8000
R/L (dB)	47.5	27.0	13.0	6.50	6.0	8.0	8.0	8.0	9.0	20.5	12.0

ANSI S3.6 and ISO 389.2 Reference Thresholds for ER3A/ER5A Internal Earphones with Rigid Tube

Frequency (Hz)	125	250	500	750	1000	1500	2000	3000	4000	6000	8000
R/L (dB)	26	14.0	5.5	2.0	0	2.0	3.0	3.5	5.5	2.0	0

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