WARRANTY

Etymotic Research, Inc. warrants each insert earphone it manufactures to be free of defects in material and workmanship for a period of one year from the date of sale to the original purchaser. Etymotic Research’s obligation under this warranty is fulfilled, at ERI’s option, by replacing the product in kind without charge to the original purchaser, repairing the part, or crediting the original purchaser with the purchase price of the returned defective part. For a part to be covered by the warranty it must be returned to Etymotic Research, postage prepaid, within the warranty period, and the part must not show evidence of misuse, neglect, incorrect wiring by others, or improper installation.

DISPOSAL

Within the European Union it is illegal to dispose of electrical and electronic waste as unsorted municipal waste. Electrical and electronic waste may contain hazardous substances and therefore have to be disposed of separately. Such products will be marked with the crossed-out wheelie-bin image shown below. User cooperation is important in order to ensure a high level of reuse and recycling of electrical and electronic waste. Failure to recycle such waste products in an appropriate way may endanger the environment and consequently the health of human beings. Outside the European Union, local regulations should be followed when disposing of the product after its useful life.

Manufacturer

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EC REP

EU Authorized Representative
Medical Device Safety Service (MDSS) GmbH
Schiffgraben 41
D-30175 Hannover
Germany
INTRODUCTION AND INTENDED USE

ER-3C™ earphones are the next generation of insert earphones by Etymotic Research, designed to replace Etymotic's ER-3A® Tubephone earphones, which have been the worldwide standard for audiometric insert earphones since 1985.

ER-3 Series earphones are intended for use with audiometric equipment used in hearing testing in audiology clinics, auditory research and screening in industrial and educational settings. They are well suited for unfavorable test environments that may have high ambient noise levels. The frequency response and performance characteristics of ER-3C earphones are virtually identical to the original ER3-A earphones at all audiometric frequencies and approximate those of Telephonics® TDH 39, 49 and 50 supra-aural earphones.

Advantages of ER-3C earphones:
- Incorporates “touch-proof” electrical connection for safety
- Duplicates ER-3A smooth frequency response
- 30+ dB external noise exclusion – equivalent to a single-wall booth when used with deeply-sealed foam eartips
- 70+ dB isolation (interaural attenuation) between ears; reduces the need for masking
- Reduces test/retest variability compared to supra-aural earphones
- Eliminates test errors due to collapsed ear canals
- Simplifies RECD (Real-Ear-to-Coupler-Difference) measurements
- May be calibrated in a 2-cc coupler, occluded ear simulator, or 0.4-cc coupler

SYSTEM INCLUDES
- ER-3C earphones (10 Ohm or 50 Ohm)
- 7’ cable with dual-mono 6.33 mm (1/4”) plugs
- 20 foam eartips (regular, 13 mm)
- 20 foam eartips (small, 10 mm)
- 2 foam eartips (large, 18 mm)
- Hook-and-loop neckstrap

WARNINGs
- Do not use insert earphones when medically contraindicated, e.g., draining ear, infection, ear canal laceration or other otologic condition where use of insert earphones could potentially exacerbate a medical condition.
- ER-3 Series earphones can produce high sound pressure levels. Use caution when selecting presentation level and duration.
- Reliable test results can be obtained with ER-3C earphones only when the audiometric equipment they are used with is calibrated before initial use and at subsequent intervals as specified by the audiometric equipment manufacturer, in compliance with national and international standards and regulations.
- ER-3C earphones are available in 10-Ohm and 50-Ohm impedance. It is essential that the correct impedance be used in accordance with the specifications of the audiometric equipment. Labels on the earphones identify the earphone impedance.
- Use of accessories or replacement parts other than those supplied by Etymotic Research or its authorized distributors may result in inaccurate results.
- Modification or alteration of any parts may invalidate test results. Example: The sound delivery tube should not be cut. A change of 10 mm in the length of the sound delivery tube will change the frequency response by 0.5 dB at some frequencies.
- Do not use in or near strong magnetic fields (e.g., MRI).
- Do not reuse eartips. All eartips, regardless of material or construction are for single-person use only. Replace eartips for each test session.

EARTIPS
- Foam eartips are recommended for most uses. They are available in three sizes: standard 8-13 mm (ER3-14A), small 6-9 mm (ER3-14B) and large 10-14 mm (ER3-14C).
- Infant eartips are available in two sizes: (ER3-14D 3.5 mm and ER3-14E 4 mm). See page 10.
- Multiple sizes of Single-Use Eartips™ 3 mm-16 mm (ER10D-T series) commonly used in immittance and otoacoustic emissions testing can be used with single-use eartip adapters (ER3-06X).

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- Multiple sizes of Single-Use Eartips™ 3 mm-16 mm (ER10D-T series) commonly used in immittance and otoacoustic emissions testing can be used with single-use eartip adapters (ER3-06X). No data are available on the interaural attenuation or noise exclusion of immittance eartips.

All eartips, regardless of material or construction are for single person use only. Replace eartips for each test session. Do not reuse eartips.
EARTIP COUPLING
Foam eartips developed for ER-3C Series insert earphones have dimensions that ensure proper calibration and test accuracy.

1. The length of black tubing from the end of the sound tube adapter through the foam eartip is 26 mm. Do not cut the black tubing that connects the foam eartip to the sound tube.

2. To obtain the noise exclusion and interaural attenuation shown on pages 6-7, insertion depth should be 14-15 mm into the ear canal. This depth is achieved when the outside edge of the foam eartip is 2-3 mm inside the entrance to the ear canal.

Notes
• Do not cut the sound delivery tube. A change of 10 mm in the length of the sound tube will change the frequency response by 0.5 dB at some frequencies.
• Replace the sound delivery tubes (ER3-21) if they crack or harden.
• When using single-use eartip adapters, calibration will be maintained if the eartip is seated on the adapter so that the opening of the eartip is flush with the tip of the adapter.

INSTRUCTIONS FOR USE
1. Refer to the audiometer manual for instructions on properly connecting the earphones.
2. Examine the ear canal for obstruction or excessive cerumen.
3. Visually determine for each ear canal if a different size eartip other than the standard foam eartip is required.
4. Make sure the sound delivery tube is not blocked.
5. Insert the black tubing of an ER3 foam eartip completely onto the adapter of the sound delivery tube.

6. To facilitate proper placement, firmly roll the foam eartip into the smallest diameter possible.

7. Insert the eartip into the ear canal.
   • The purpose of deeply inserted eartips is to maximize interaural attenuation and noise exclusion.
   • There is usually less than a 3-dB difference in eardrum pressure between shallow and deeply-sealed eartips. The accuracy of threshold is less dependent on insertion depth.
8. Correct insertion depth: When the outside edge of the eartip is 2-3 mm inside the entrance of the ear canal.
9. Allow foam to expand to acoustically seal the ear canal.
   • Hold/press the eartip in place until it expands.
   • If correct insertion depth cannot be achieved, try rolling the foam into a smaller diameter before insertion. If unsuccessful, use a different size eartip.
   • If the seal is inadequate, try another eartip.
10. Discard eartips after each person use.
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EXTERNAL NOISE EXCLUSION

ER-3 Series insert earphones provide greater than 30-dB exclusion of background noise. As insertion depth increases, the amount of attenuation increases. Deeply-inserted ER3 foam eartips can provide noise exclusion equivalent to a single-wall booth. Testing to audiometric zero can be done reliably whenever the SPL of the background noise is less than 45 dBA. The graph below shows the attenuation of two audiometric earphones. ER-3 Series insert earphones have significantly greater attenuation than traditional supra-aural earphones and circumaural earphones.

INTERAURAL ATTENUATION AND MASKING

A comparison of the interaural attenuation of a TDH-39 and ER-3 Series insert earphone is shown in the above graph. High interaural attenuation values reduce the need for masking air conduction thresholds when using insert earphones. In cases of severe bilateral conductive hearing loss, a masking dilemma (overmasking) occurs when a high level of masking in the non-test ear reaches the opposite (test ear) cochlea via bone conduction and elevates threshold in the test ear. Interaural attenuation is significantly higher with insert earphones, making it possible to use lower masking levels in the non-test ear.

Interaural attenuation of ER-3 Series earphones increases with insertion depth. The graph below illustrates the importance of deep eartip insertion when maximum interaural attenuation is desired.
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Interaural attenuation of ER-3 Series earphones increases with insertion depth. The graph below illustrates the importance of deep eartip insertion when maximum interaural attenuation is desired.
Allowable A-weighted Room Noise During Audiometric Testing

The current ANSI Standard “Maximum Permissible Ambient Noise Levels (MPANLs) For Audiometric Test Rooms” [ANSI S3.1-1999 (R2013)] includes octave band and one-third octave band permissible noise levels for both supra-aural and ER-3 Series insert earphones. See the ER-3 Series Calibration Manual for more information.

Simple Rule

A room noise below 50 dBA should provide accurate audiometric testing to 0 dB HL. A room noise of 70 dBA should provide accurate screening to 20 dB HL.

Both of those guidelines depend on use of a foam eartip properly inserted as described on page 4, which provides an average external noise exclusion of approximately 40 dB, with a minimum of 36 dB at 2 kHz.

Background

Botsford (1973) analyzed a wide variety of typical background noise spectra, and chose five prototype noises whose spectra covered the range of most noises.

ANSI S3.1-1977 Criteria for Permissible Ambient Noise During Audiometric Testing gave the maximum octave-band levels that would limit the masking in that band to produce less than a “1-dB increase in threshold above the accepted reference hearing threshold levels.” Tables that applied to “ears open” and “TDH-39/MX41 AR” earphones were provided.

Killion and Studebaker (1978) later converted each of Botsford’s five noise spectra to octave-band levels and adjusted each curve graphically to the highest level that would not exceed, at any frequency, the S3.1-1977 allowable levels. Surprisingly enough, for the ears-open condition, the corresponding A-weighted level for all five of those adjusted noises fell within a 2.5 dB range: 14 dBA to 16.5 dBA. The authors concluded that “Subtracting 15 dB from the A-weighted noise level in a room provides a rough estimate of the maximum threshold elevation produced by that noise.”

Thus a conservative rule of thumb is that room noise below 50 dBA should provide accurate test results to audiometric zero (50-36-14 = 0). For screening to 20 dB HL, room noise of 70 dBA should be allowable.

CALIBRATION

• Before calibration, confirm that the impedance of the earphones matches the requirements of the audiometric equipment. The labels on the earphones identify the impedance. Unless the audiometer was purchased with ER-3 Series earphones precalibrated by the audiometric equipment manufacturer, the Reference Equivalent Threshold Sound Pressure Levels (RETSPL) values and procedure cited in the current version of the ANSI S3.6 or IEC 60645-1 Standard must be used to calibrate the equipment prior to initial use. Re-calibration should subsequently be performed at intervals specified by the audiometric equipment manufacturer, in compliance with national and international standards and regulations.

• Correction factors can be applied where it is necessary to alternate between insert earphones and a supra-aural earphone with audiometers that do not provide a dual-calibration option.

RELIABILITY

Traditional supra-aural earphones have limitations. Among them are:

1. Poor noise exclusion at low frequencies, which invalidates tests done outside a sound booth.
2. Low interaural attenuation.
3. Erroneous high-frequency thresholds resulting from collapsed ear canals when using traditional MX-41AR earphone cushions.

Insert earphones eliminate all three of these problems. Wilber et al. also found less variability, on average, across subjects using insert earphones.
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![TEST RELIABILITY](image-url)
CARE AND CLEANING

- Use a damp cloth to wipe down any parts that become soiled during normal use.
  - Antimicrobials (glutaraldehyde) are safe for external surfaces.
  - Any other agents must be tested before using to prevent damage.
- Do not submerge earphones in any liquid or allow liquid into the sound delivery tubes.
- Do not use alcohol or other strong chemicals or solvents to clean earphones or any parts, including cables, sound delivery tubes and eartips.

ACCESSORIES AND REPLACEMENT PARTS

Accessories and replacement parts are available from Etymotic Research and its authorized distributors.

CABLE ATTACHMENT AND REPLACEMENT

Firmly insert the cable connector in the corresponding transducer housing socket until fully seated. Replacement cables are available through Etymotic Research and its authorized representatives.

Re-calibration of audiometric equipment is not required with cable replacement.

SPECIFICATIONS

- Impedance: 10 Ohms or 50 Ohms
- Sensitivity: 102.5 dB SPL in HA-2 coupler at 0.1 Vrms (10 Ohms)
  - 102.5 dB SPL in HA-2 coupler at 0.2 Vrms (50 Ohms)
- Temperature: 15-35 °C
- Relative Humidity: 30-90% (non-condensing)
- Ambient Pressure: 98-104 kPa
- Output: Meets or exceeds 110 dB HL at standard audiometric frequencies
  - between 0.5 and 4 kHz

Safe Operating Limits: Maximum continuous sine wave drive: 2.5 Vrms (10 Ohms), 5 Vrms (50 Ohms)

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