

ER 3C™

INSERT EARPHONES



User Guide



INTRODUCTION AND INTENDED USE

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

ER-3C 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 ER-3A earphones at all audiometric frequencies and approximate the frequency response of the supra-aural or circumaural headphones commonly used for audiometry.

Advantages of ER-3C earphones:

- Incorporates "touch-proof" electrical connection for safety
- Duplicates the 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 or circumaural 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, 50 Ohm, or 300 Ohm)
- 7' cable with dual-mono 6.3 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-3C 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, 50-Ohm, and 300-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.
- 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-subject 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).

No data are available on the interaural attenuation or noise exclusion of immittance eartips.

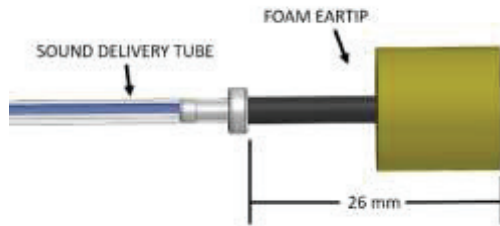


All eartips, regardless of material or construction are for single-subject use only. Replace eartips for each test session. Do not reuse eartips.

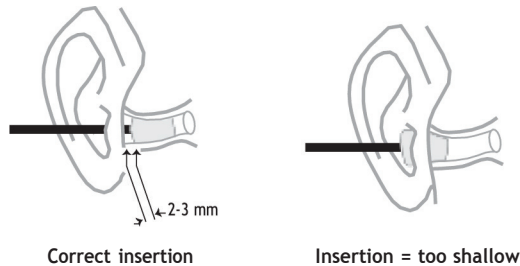
EARTIP COUPLING

Foam eartips developed for ER-3C 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.

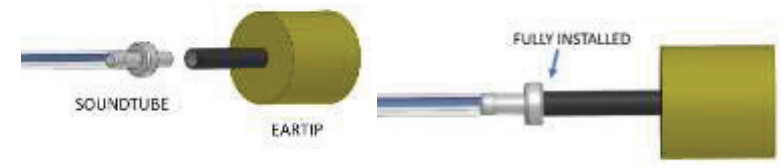


Notes

- 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.
- Calibration is maintained when using single-use eartip adapters.

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 evaluate each ear canal to determine the appropriate size eartip.
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.
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 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.
10. If the seal is inadequate, try another eartip
11. Discard eartips after each use.

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-3C Calibration Manual for more information.

Room noise below 45 dBA should provide accurate audiometric testing to 0 dB HL. A room noise of 65 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.

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-3C earphones pre-calibrated 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.

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

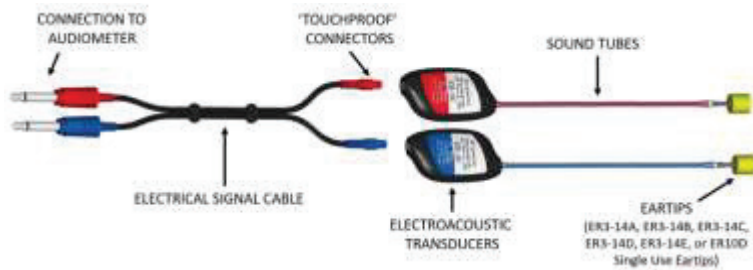
Accessories and replacement parts are available from Etymotic Research and its authorized distributors



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 or 300 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)
102.5 dB SPL in HA-2 coupler at 0.49 Vrms (300 Ohms)

Temperature: 15-35 °C

Relative Humidity: 30-90% (non-condensing)

Ambient Pressure: 98-104 kPa

Maximum Output: Meets or exceeds 110 dB HL at standard audiometric frequencies between 0.5 and 4kHz

Safe Operating Limits: Maximum continuous sine wave drive: 2.5 Vrms (10 Ohms)
5 Vrms (50 Ohms) 13.75 Vrms (300 Ohms)

REFERENCES

1. American National Standards Institute. ANSI S3.7-1995 (R2008). Methods for Coupler Calibration of Earphones.
2. American National Standards Institute. ANSI S3.1-1999 (R2013). Maximum Permissible Ambient Noise Level for Audiometric Test Rooms.
3. American National Standards Institute. ANSI S3.6-2010. Specifications for Audiometers
4. Botsford JH (1973). How to estimate dBA reduction reduction of ear protectors. Sound Vib 7(1):32-33.
5. International Electrotechnical Commission. IEC 60601-1:2005. Medical Electrical Equipment-Part 1: General Requirements for Safety and Essential Performance.
6. International Electrotechnical Commission. IEC 60645-1:2012. Electroacoustics-Audiometric Equipment-Part 1: Equipment for Pure Tone Audiometry
7. International Organization for Standardization. ISO 389-2 (1996). Acoustics – Reference zero for the calibration of audiometric equipment. Part 2 – Reference equivalent threshold sound pressure levels for pure tones and insert earphones
8. Organization for Standardization. ISO 389-5 (2006). Acoustics – Reference zero for the calibration of audiometric equipment. Part 5 – Reference equivalent threshold sound pressure levels for pure tones in the frequency range 8 kHz to 16kHz.
9. Killion MC (1978) Revised estimate of minimum audible pressure. Where is the missing 6dB? J. Acoust Soc. Am, 63 (5), 1501-1508

SYMBOL DEFINITIONS:



Indicates the entity importing the medical device into the locale



Indicates the medical device Manufacturer



Indicates Date of Manufacture



Identifies the European Union Authorized Representative



MDSS CH GmbH, Laurenzenvorstadt 61, 5000 Aarau, Switzerland



Symbol indicating separate collection for WEEE – Waste of electrical & electronic equipment



Consult instructions for use or consult electronic instructions for use



To indicate that caution is necessary when operating the device or warning of use is needed when operating the device



Indicates Do not reuse



Indicates Medical device



Indicates shock protection



Indicates Non-Sterile medical device



Indicates Prescription required



Indicates Unique device indicator (UDI)



Indicates Serial number



Product reference or part number

WARRANTY

Etymotic Research, Inc. (ERI) 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 must be disposed of separately. Such products will be marked with the WEEE symbol as 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.

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