

amplivox

ER75 Electro-Acoustic Ear Simulator

Operating Manual



ABOUT THIS MANUAL

READ THIS OPERATING MANUAL BEFORE ATTEMPTING TO USE THE INSTRUMENT.

This manual is valid for the ER75 Electro-Acoustic Ear Simulator.

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For supply in US only

Caution: Federal Law restricts this device to sale by or on the order of a licenced medical professional.

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1. INTRODUCTION

1.1. THANK YOU

Thank you for purchasing an Amplivox ER75 Electro-acoustic ear simulator. This product will give many years of reliable service if treated with care.

1.1. INTENDED APPLICATIONS

The intended application of the ER75 is to perform an objective performance check of the pure tone air conduction output of an audiometer as part of the routine checking regime specified in Clause 12 of ISO 8253-1:2010. It is not a calibration unit and does not replace the need for regular factory calibration of an audiometer.

1.2. UNPACKING

Please check the contents of the shipping carton against the contents listed below to make sure that all items ordered have been included. If anything is missing, please contact the distributor who supplied the product or Amplivox if purchased directly.

1.3. STANDARD CONTENTS AND OPTIONAL ACCESSORIES

STANDARD COMPONENTS

| | | | |
|---------------------------------------|--|---------------------------------------|--|
| ER75 | | 2 off 1.5V 'AA' batteries | |
| Patient response interconnecting lead | | Patient response interconnecting lead | |
| Operating manual | | | |

1.4. WARRANTY CARD (UK CUSTOMERS ONLY)

Please complete the enclosed warranty registration card and return it to Amplivox. This will enable us to register your purchase, help with your enquiries and provide technical support.

1.5. GUARANTEE

All Amplivox instruments are guaranteed against faulty materials and manufacture. The instrument will be repaired free of charge for a period of two years from the date of despatch if returned, carriage paid, to the Amplivox service department. Return carriage is free of charge for customers in the UK and chargeable for overseas customers.

1.6. WARNINGS

Throughout this manual, the following meanings of warnings and cautions apply:



WARNING

The WARNING label identifies conditions or practices that may present danger to the patient and/or user.



CAUTION

The CAUTION label identifies conditions or practices that could result in damage to the equipment.



2. IMPORTANT SAFETY INSTRUCTIONS



WARNING

The Amplivox ER75 is not intended for, or capable of, the calibration of an audiometer. Such a calibration must always be performed using the appropriate specialist equipment and qualified personnel.

2.1. PRECAUTIONS

READ THIS OPERATING MANUAL BEFORE ATTEMPTING TO USE THE INSTRUMENT

The ER75 is for indoor use only and should be used only as described in this manual.

The ER75 should be used in similar conditions to those used for audiometry (e.g. a quiet room or an acoustic booth). Ambient noise and/or vibrations through the test bench/table can affect the results.

2.2. ELECTROMAGNETIC COMPATIBILITY (EMC) CONSIDERATIONS

The ER75 meets the appropriate standards for EMC. However portable and mobile radio-frequency (RF) communications equipment can affect medical electrical equipment and the ER75 should not be used adjacent to or stacked with other electronic equipment.



3. USING THE ER75

3.1. INSTALLING & REPLACING BATTERIES

The ER75 is designed for continuous operation and is powered by batteries.

To fit the batteries, remove the 2 screws in the base of the ER75 and remove the base & back-panel cover by carefully sliding it down. Fit 2 x 1.5V 'AA' alkaline batteries according to the indications on the battery holder. Replace the cover and refit the screws.

If the instrument is not likely to be used for three months or longer, please remove the batteries from the instrument.



WARNING

Batteries should only be changed outside the patient environment. The operator should not touch the battery connectors and the patient simultaneously.

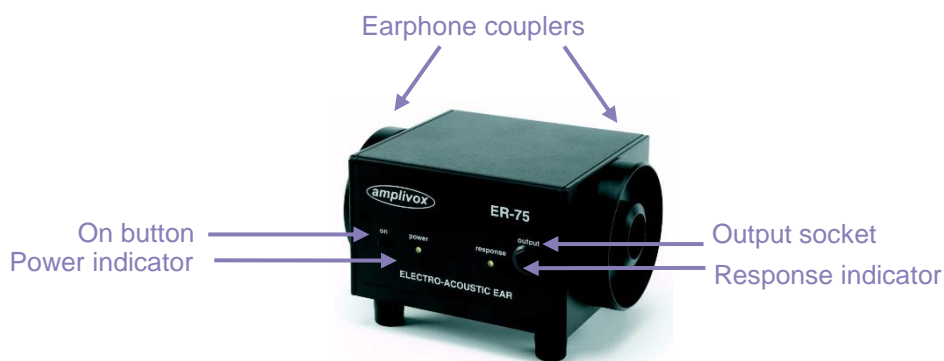
Note that local regulations are likely to cover disposal of used batteries.

3.2. LOW BATTERY INDICATION

If the power indicator flashes (approximately 3 times per second) when the “on” button is held the batteries need to be changed.

Place the audiometric headset earphones over the earphone couplers located on the sides of the ER75 such that there is a secure and consistent fit. Connect the supplied interconnecting lead between the socket on the ER75 marked “output” and the socket marked “RESPONSE” or “RESP” which is normally located on the back panel of an audiometer.

If using the ER75 within an acoustic booth, the interconnecting lead should be inserted into the patient response socket inside the booth in place of the patient response switch.



3.3. SERVICE INDICATION

If the power indicator flashes slowly (approximately once every two seconds) when the “on” button is held the unit needs to be serviced and the performance verified.

3.4. SWITCHING ON AND OFF

To switch the ER75 on, Press and hold the “on” button until the power indicator illuminates green. The instrument will automatically power down approximately 2 minutes after last response was made.



3.5. TESTING THE RESPONSE INDICATOR

Present an audiometer tone (1kHz, 80dBHL) and check that the indicators on the ER75 and the audiometer labelled "response" illuminate green.

3.6. SEQUENCE OF OPERATION AND SUGGESTED TEST PROCEDURE

3.6.1. GENERAL

In use the ER75 simulates the actions of a patient responding to an audible stimulus. If a tone level greater than approximately 75dBHL is provided via the audiometric headset a response signal is output to the audiometer.

The ER75 can detect tones at a range of audiometric frequencies and may be used with Amplivox audiometers operating in both manual and automatic modes.

3.6.2. PRE-TEST

- (1) Set the audiometer up as normal with the exception of the patient response switch which should remain unconnected
- (2) Place the earphones over the earphone couplers on the ER75
- (3) Connect the patient response interconnecting lead, supplied with the ER75, between the audiometer and the ER75
- (4) Switch the ER75 and the audiometer on.

3.6.3. TEST PROCEDURE FOR MANUAL AUDIOMETERS

- (1) Set the audiometer step size to 2.5dB if this facility is available
- (2) Present the first test tone at 65dBHL at 1kHz to the left headphone
- (3) If the ER75 responds by illuminating the response indicator on the audiometer **return the ER75 for service & verification**; if there is no response, move to step 4
- (4) Increase the signal level in steps until the ER75 responds - this should occur at approximately 75dBHL; record this signal level on an audiogram form
- (5) Select the next test frequency
- (6) Repeat steps 2 to 5, testing the frequencies in the following order: 1kHz, 1.5kHz, 2kHz, 3kHz, 4kHz, 6kHz, 8kHz, 250Hz and 500Hz.
- (7) Repeat steps 2 to 6 for the right headphone

3.6.4. TEST PROCEDURE FOR AUTOMATIC AUDIOMETERS

- (1) Run the automatic test sequence (using the 'Bekesy' test mode if this is available)
- (2) Print a copy of the results
- (3) If responses are made at any frequency at levels of 65dBHL or less **return the ER75 for service & verification**

3.6.5. ACTION FOLLOWING TEST PROCEDURE

Compare the results with the response levels supplied originally with the ER75, or with the most recent response levels if the ER75 has been re-calibrated. The audiometer should be returned for service & verification either to Amplivox or to the designated distributor if the two sets of results differ by more than that specified in the routine checking regime that has been established by the user organization (see ISO 8253-1:2010).



4. ROUTINE MAINTENANCE

The ER75 is a precision instrument. Handle it carefully in order to ensure its continued accuracy and service.

When cleaning the instrument use a soft cloth and mild detergent to clean the instrument surfaces and the earphone couplers. Do not allow any moisture to enter the microphones in the centre of the circular earphone couplers.

5. VERIFICATION AND REPAIR OF THE INSTRUMENT

Amplivox recommend that the performance of this instrument should be verified on an annual basis. Please contact Amplivox or the designated distributor for details of verification & calibration services.

The instrument should be returned to the manufacturer for service & repair. There are no user-serviceable parts within it.

When packing the instrument for shipping, please use the original shipping carton and packing materials.

6. TECHNICAL SPECIFICATION

6.1. PERFORMANCE

| | |
|--|--|
| Audiometry | |
| Audiometric frequencies | 250Hz, 500Hz, 750Hz, 1kHz, 1.5kHz detected: 2kHz, 3kHz, 4kHz, 6kHz & 8kHz |
| Frequency detection range | ±5% of nominal value |
| Level to trigger a response | 75 dBHL |
| Response signal duration | 1 second (minimum) |
| Physical | |
| Power (battery) | 2 x 1.5V AA cell batteries |
| Power consumption | 120mW operating, 40µW standby |
| Construction | Plastic |
| Dimensions | 150mm (w) x 110mm (d) x 95mm (h) |
| Weight (without batteries) | 360g |
| Environmental | |
| Operating temperature range | +15°C to +35°C |
| Storage & Transportation temperature range | -20°C to +70°C |
| Storage & Transportation humidity range | 10% to 90% (non-condensing) |
| Storage & Transportation atmospheric pressure range | 500 hPa to 1060 hPa |
| Standards conformance | |
| Degree of protection against ingress of water | Not protected |
| Mode of operation | Continuous operation |
| Equipment mobility | Portable |
| The ER75 is CE marked to EMC directive and meets the requirements of the following standards | <ul style="list-style-type: none"> • EN 61000-6-1:2007 • EN 61000-6-3:2007 |



7. ORDERING CONSUMABLES AND ACCESSORIES

To order parts, please contact Amplivox Ltd for current prices and delivery charges. The items available are listed below:

| STOCK NO. | DESCRIPTION |
|-----------|---------------------------------------|
| A074 | Patient response interconnection lead |
| MANER75 | ER75 Operating Manual |

8. DISPOSAL INFORMATION



Amplivox Limited is fully compliant with the WEEE (Waste Electrical and Electronic Equipment) Regulations. Our PRN (Producer Registration Number) is WEE/GA0116XU and we are registered with the approved WEEE Compliance Scheme, B2B Compliance, approval number WEE/MP3338PT/SCH.

The main purpose of the WEEE Regulations is to encourage the segregation of waste electrical items from the general waste stream and into reuse, recovery and recycling routes.

Therefore for any waste electrical units purchased from Amplivox that either:

- bear the crossed out wheeled bin symbol with black bar underneath, or
- have been replaced with new Amplivox products on a like-for-like basis

please contact our WEEE Compliance Scheme, B2B Compliance, using the details below. B2B Compliance will be able to provide further information on how to recycle your waste electrical units and answer any queries you may have.

B2B Compliance

Tel: +44 (0) 1691 676 124 (Option 2)

Email: operations@b2bcompliance.org.uk



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