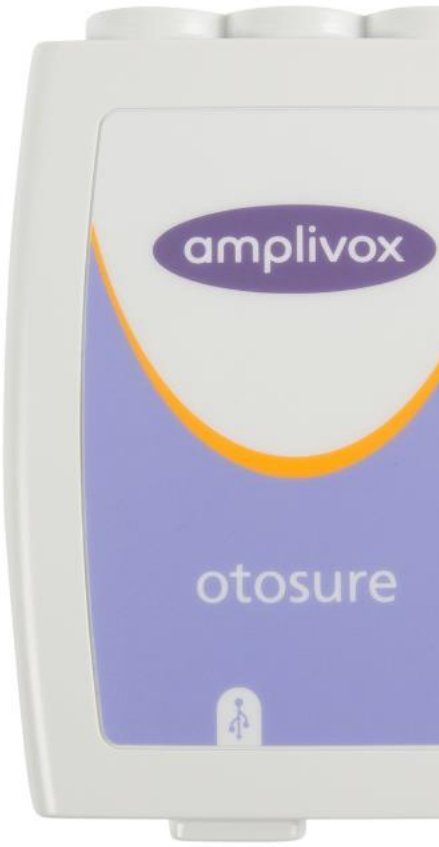
Otosure

INSTRUCTION FOR USE



D-0116492-E

ABOUT THIS MANUAL

READ THIS OPERATING MANUAL BEFORE ATTEMPTING TO USE THE INSTRUMENT.

This manual is valid for the Otosure (applies from serial number 58000 and Audibase version 5.5 onwards).

This product is manufactured by:
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CE 0123

TABLE OF CONTENTS

1. INTRODUCTION

1.1. THANK YOU

Thank you for purchasing an Amplivox audiometer. The Otosure is a compact, automatic air-conduction screening audiometer, driven and controlled by a computer (PC). It provides a cost-effective solution for today's health care environment.

The Otosure is used with the Amplivox Audibase software, which allows electronic storage of audiometric test records on a PC, application of audiogram categorisation schemes, printing of audiograms and data exchange with other PC applications.

This operator's manual enables you to take full and safe advantage of the features offered by the Otosure audiometer. Therefore, PLEASE READ IT THOROUGHLY before using the audiometer.

1.2. INTENDED APPLICATIONS

This instrument is designed for use by trained personnel only, such as audiologists, ENT surgeons, doctors, general practitioners, hearing aid dispensers, child health professionals and hearing healthcare professionals with a similar level of education. It is not recommended to utilize the equipment without the necessary knowledge and training.

1.3. CONTRADICTIONS

Always visually inspect the outer ear and the external auditory canal for abnormalities before testing. Testing should not be performed on patients in the following items is applicable.

1. The presence of other sensitivity to loud sounds may contraindicate testing when high intensity stimuli are used.
2. Recent outer ear surgery.

1.4. STANDARD AND OPTIONAL COMPONENTS

Shipping documentation will reference the stock number quoted above, and images of the parts alongside the relevant stock number are available on the Amplivox website (www.amplivox.com). The required fitting instructions are supplied with each part.

STANDARD COMPONENTS			
Otosure audiometer	8508019	Audiometric headset (DD45)	8509615
Patient response switch	8011155	HBA audiometric headband	8010882
Cable USB A to USB B (2.0 m)	8011241	Carrying case	8004651
Calibration certificate		USB with Audibase Software and manuals	8510705 and 8510707 (OSHA)

OTHER COMPONENTS TO REORDER			
Audiocups (noise reducing earphone enclosures)	8010855	Headband (standard headphone)	8010840
Audiocup ear cushion	8010835	Earphone cushion	8010857
Audiocup headband	8507381	Earphones DD45 *	8010876
Audiocup headband cover	8010834	Headset lead	8010822
Booth Leads	851095		

Accessories marked * require calibration with the specific audiometer to be used. Do not attempt to use these accessories until the audiometer has been calibrated to match their characteristics.

Shipping documentation will reference the stock number quoted above, and images of the parts alongside the relevant stock number are available on the Amplivox website (www.amplivox.com). The required fitting instructions are supplied with each part.

1.5. 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. PRINCIPLES OF OPERATION

2.1. OTOSCOPIC EXAMINATION

A suitably-qualified health care professional should perform a thorough otoscopic examination to establish that the condition of the ear is suitable for the test options selected and that no contraindications are present. The latter would include obstruction of the external ear canal due to excessive wax and/or hairs, both of which would need to be removed. This is required to ensure that the probe tone delivered by the probe are able to reach the ear drum and are not reflected by cerumen or debris and thereby alter the test result.

2.2. PRINCIPALS OF PURE TONE AUDIOMETRY

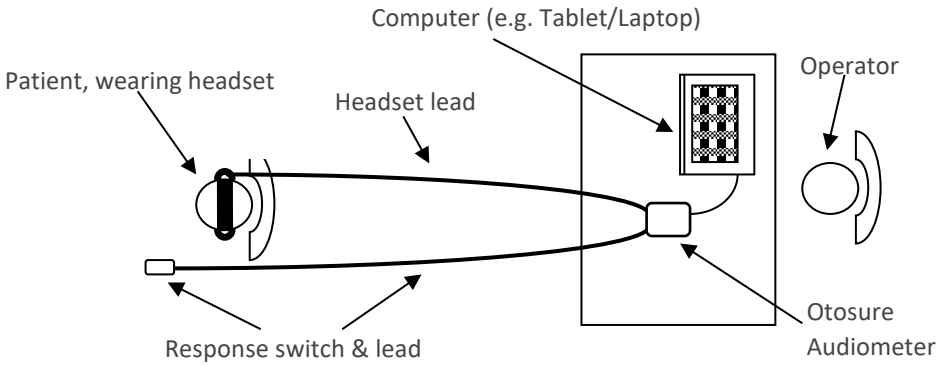
Ideally, hearing tests are conducted in a soundproof room. The purpose of pure tone audiometry is to measure the patient's hearing threshold which is then compared to the hearing threshold of an average normal hearing person. The examination starts with air conduction on the ear with better hearing, or if not specified differently, on the right ear. The BSA (British Society of Audiology) recommends starting the test at 1000 Hz to then next measure the higher frequencies. When done with the high frequencies 1000 Hz shall be retested and to then continue with the lower frequencies.

2.3. AUDIOMETRY PREPARATION

Refer to the various audiometric standards and other relevant publications for guidance on audiometric testing.

Ambient Conditions
Audiometric testing should always be performed in quiet conditions (e.g. a quiet room or an acoustic booth). The optional Audiocups can provide an additional level of isolation from ambient noise. For further explanation on permissible ambient noise levels, please refer to the audiometry standard ISO 6189.

Test System Arrangement
The schematic diagram below shows a typical example of the use of audiometric test equipment. The audiometer is located on the desk of a seated operator as shown.



The patient is seated in front of the desk facing away from the operator. The patient wears a headset (see below) and responds to test stimuli by use of a hand-held switch which is also connected to the instrument.

Headset
The headset must be fitted by a qualified person to ensure a proper seal and comfortable fit. The leads from the headset are connected to the instrument and the headset is then fitted to the patient.

Patient Instructions
The patient is given the following instructions: “Press and then release the response switch when a tone is heard”.

3. UNPACKING AND INSTALLATION

3.1. GENERAL

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

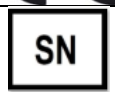
Please retain the carton and packaging as the instrument will need calibrating on an annual basis and should be returned to Amplivox in its original shipping carton.

CAUTION

For supply in US only: Federal Law restricts this device to sale by or on the order of a licensed medical professional.

3.2. MARKINGS

The following markings can be found:

Symbol	Explanation
	Type B applied parts. According to IEC 60601-1. Patient applied parts that are not conductive and can be immediately released from the patient.
	Refer to instruction manual.
	WEEE (EU-directive) This symbol indicates that when the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling. Failing to do so may endanger the environment.
	The CE-mark indicates that Amplivox Ltd. meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. TÜV Product Service, Identification No. 0123, has approved the quality system.
	Serial number.
	Date of manufacture.
	Manufacturer.
	Keep dry.
	Transport and storage humidity range.

	Transport and storage temperature range.
	Medical Device.
	Logo.

3.3. SAFETY INSTRUCTIONS

3.3.1. GENERAL

The following safety precautions must be observed at all times. General safety precautions must be followed when operating electrical equipment. Failure to observe these precautions could result in damage to the equipment and injury to the operator or patient.

The employer should instruct each employee in the recognition and avoidance of unsafe conditions and the regulations applicable to his or her work environment to control or eliminate any hazards or other exposure to illness or injury.

Amplivox Ltd. is aware that safety rules within individual organizations vary. If a conflict exists between the instructions in this manual and the rules of the organization using this instrument, the more stringent rules should take precedence.

The Otosure is intended to be used by hearing healthcare professionals (i.e. ENT doctors, audiologists), nurses or technicians who have been trained in the proper use of the device.

3.3.2. CAUTIONS – GENERAL


CAUTION

If the system is not functioning properly, do not operate it until all necessary repairs are made and the unit is tested and calibrated for proper functioning in accordance with Amplivox's specifications.

Do not drop or in any other way cause undue impact to this device. If the instrument is damaged, return it to the manufacturer for repair and/or calibration. Do not use the instrument if any damage is suspected.

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 secured properly. Parts which may be broken or missing or are visibly worn, distorted, or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from Amplivox Ltd.

Equipment is not user repairable. Repairs must be performed by an authorized service representative only. No modifications of the equipment are allowed by anyone other than a qualified Amplivox Ltd. representative. Modification of the equipment could be hazardous.

Amplivox Ltd. will make available on request circuit diagrams, component part lists, descriptions, calibrations instructions, or other information that will assist authorized service personnel to repair those parts of this instrument that are designated by Amplivox Ltd. as repairable by service personnel.

No parts of the equipment can be serviced or maintained while in use with the patient.

Connect only accessories purchased from Amplivox Ltd. to the Otosure. Only accessories which have been stated by Amplivox Ltd. to be compatible are allowed to be connected to the device or cradle.

3.3.3. ENVIRONMENTAL FACTORS

CAUTION

Use and store the instrument indoors only. It is recommended that the instrument be operated within an ambient temperature range of 15 °C / 59 °F to 35 °C / 95 °F and in relative humidity between 30 % and 90 % (non-condensing).

Do not use the device 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 an authorized service technician.

3.3.4. ELECTRICAL AND ELECTROSTATIC SAFETY

CAUTION

Before performing any service to the insert earphones you must uncouple the Otosure transducers from the patient.

WARNING

Do not touch the contacts on the back of the instrument and the patient at the same time. The consequence could be a too high leakage current to the patient.

Do not open the case of the instrument. Refer servicing to qualified personnel.

This equipment is intended to be connected to other equipment thus forming a Medical Electrical System. External equipment intended for connection to signal input, signal output or other connectors must comply with the relevant product standard e.g. IEC 60950-1 for IT equipment and the IEC 60601-series for medical electrical equipment. In addition, all such combinations – Medical Electrical Systems – must comply with the safety requirements stated in the general standard IEC 60601-1, (edition 3.1), clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 must be kept outside the patient environment i.e. at least 1.5m from the patient support or must be supplied via a separation transformer to reduce the leakage currents. Any person who connects external equipment to signal input, signal output or other connectors has formed a Medical Electrical System and is therefore responsible for the system to comply with these requirements. If in doubt, contact a qualified medical technician or your local representative. When the instrument is connected to a PC, or other similar items, beware of not touching the PC and patient simultaneously.

A Separation Device (isolation device) is needed to isolate the equipment located outside the patient environment from the equipment located inside the patient environment. In particular such a Separation Device is required when a network connection is made. The requirement for the Separation Device is defined in IEC 60601-1 clause 16.

3.3.5. ELECTROMAGNETIC COMPATIBILITY (EMC)

CAUTION

Although the instrument fulfills the relevant EMC requirements, precautions should be taken to avoid unnecessary exposure to electromagnetic fields, e.g., from mobile phones, etc. If the device is used adjacent to other equipment it must be observed that no mutual disturbance appears. Please also refer to the appendix regarding EMC.

3.3.6. EXPLOSION HAZARDS

WARNING

Risk of explosion.

Do not use in the presence of flammable anesthetics or other gases.

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.

Do NOT use the Otosure in a highly oxygen-enriched environment, such as a hyperbaric chamber, oxygen tent, etc.

3.3.7. MEASURING SECURITY

To guarantee that the Otosure works properly, the instrument should be checked and calibrated at least once a year. The transducers supplied with the audiometer are specifically calibrated with it; if these transducers are changed recalibration will be required.

The service and calibration must be performed by an authorized service technician. If these checks are not performed, EU Medical Device Directive (MDD) and other regulations may be violated and warranties may be void.

The use of non-calibrated devices can lead to incorrect test results and is not advisable.

3.3.8. MISCELLANEOUS

Please note: DO NOT connect the Otosure hardware to the computer before the software has been installed!

Storage in temperatures below 0°C /32°F and above 50°C /122°F may cause permanent damage to the instrument and its accessories.

Do not place the instrument next to a heat source of any kind.

Great care should be exercised when handling transducers, as rough handling, for example dropping onto a hard surface may break or damage the parts.

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 to the left. 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 end of life.

3.3.9. USE OF EQUIPMENT AFTER TRANSPORT AND STORAGE

Please make sure that the instrument is functioning correctly before use. If the instrument has been stored in a cold environment (even for short period of time), please allow the instrument to become acclimatized. This can take long time depending on the conditions (such as environmental humidity). You can reduce the condensation by storing the instrument in its original packaging. If the instrument is stored under warmer conditions than the actual use conditions no special precaution is required before use. Always ensure proper operation of the instrument by following routine check procedures for audiometric equipment.

3.4. CONNECTIONS

The accessory terminals and connections are labelled to ensure correct identification and connection as follows:

SOCKET TYPE	COLOUR CODE	CONNECTED PART
6.3mm jack	Blue	Air conduction headset (Left) *
6.3mm jack	Red	Air conduction headset (Right) *
6.3mm jack	Black	Patient response Switch *
USB Connector	N/a	Computer (via USB port)

Please note: Only connect the accessories supplied with the instrument or supplied by Amplivox or an Amplivox distributor. These parts have been tested for use with the Amplivox Otosure audiometer for compliance with the standards IEC 60601-1 and IEC 60601-1-2. The use of accessories other than those specified may compromise compliance with these standards.

3.5. HARDWARE INSTALLATION

Refer to Section 11 for important information regarding the connection of non-medical electrical equipment to medical electrical equipment.

The audiometer is powered and controlled by a computer (PC) using software supplied for this purpose. This software must be installed before the audiometer is connected to the PC.

All other connections should be made before connecting the audiometer to the PC.

A USB cable is provided to connect the Otosure to a PC. The connected port on the PC must be to USB specification 1.0 or 2.0. Connect the headset and the patient response switch to the Otosure and then make the connection from the Otosure to the PC. No specific warm-up time is required although the device registration to the PC might take a short time to complete.

Please note: Please refer to Section 4 for instructions on how to install the software and drivers, how to carry out the first-time connection to a PC, and how to undertake a basic operational check to ensure the audiometer is functioning correctly.

4. INSTALLING SOFTWARE & OPERATIONAL CHECK

4.1. GENERAL

This section describes the procedure for installing the Otosure operating software & associated device drivers, undertaking the first-time connection of the Otosure audiometer and performing a basic operational check to ensure that the instrument is working.

4.2. INSTALLATION

Installation is a two-stage process (please ensure both are completed):

1. Install the Otosure software on the PC
2. Install the device drivers to enable USB communication between the PC and the Otosure audiometer

Step 1: Install the Amplivox Otosure Software

The installation of the Otosure software is seamless and is installed as part of Audibase. Please refer to the Audibase5.x user guide for step by step installation instructions.

Step 2: Install the USB Device Drivers

Please refer to “D-0115682” Guide to Installing Amplivox USB Drivers

4.3. UNINSTALLING THE OTOSURE PROGRAM

Uninstalling the Otosure program is achieved simply by navigating to the location where the software was originally installed and deleting the file named “Otosure.exe”. There is no need to use the “Add or Remove Programs” utility.

This will leave Audibase installed.

Please note: If more information about the uninstallation of the Audibase are required, please refer to the Audibase5.x user guide.

4.4. OPERATIONAL CHECK

Connect the headphones and patient response switch to the Otosure audiometer, and connect the Otosure audiometer to the PC via a USB cable. Start the Audibase application on the PC and enter new patient details (refer to the Audibase user manual).

Start a test using the Launch Test button in the Audibase toolbar

Close any dialogue boxes in the Otosure window and select the Manual Test option:

Move the mouse pointer over the “Present” icon in the Otosure window and ensure a tone is heard from an earphone. Use the arrow keys on the PC keyboard to change the level and frequency of the tone. Use the “L” and “R” keys on the PC keyboard to switch between earphones.

Press the patient response switch and ensure that the “Response” icon in the Otosure window changes colour to light green and returns to dark green when the switch is released.

The above will demonstrate the basic functionality of the audiometer. When closing the Otosure window remember to use the “Edit > Cancel Insert/Edit” option or cancel toolbar button in Audibase to cancel the test operation.

5. USING THE OTOSURE

5.1. EQUIPMENT PREPARATION

Connect the headset and the patient response switch to the Otosure and then make the connection from the Otosure to the PC. No specific warm-up time is required although the device registration to the PC might take a short time to complete.

5.2. STARTING THE SOFTWARE

Start the Audibase application, and with reference to the user manual either establish a new a patient, or access and display details of an existing patient.

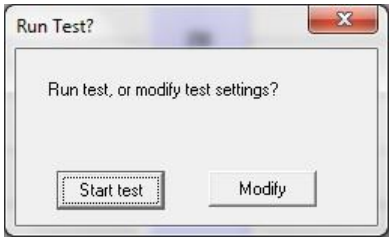
Use the left mouse button to click on the Launch Test icon in the Audibase toolbar.

Alternatively use the “Test > Launch Test” drop-down menu selection at the top of the Audibase window.

A new window will open for the Otosure software. If the patient has more than one set of audiometric results stored in Audibase the most recent audiogram is transferred and displayed in the Otosure window.

The serial number and calibration date of the connected Otosure audiometer is shown at the bottom right of the Otosure window along with the test type currently selected.

The test type last used is remembered; if this was a manual test the procedures may be followed; if this was an automatic test the following dialogue box will be displayed:



To run the same automatic test using the same options (as last used) simply click the “Start test” button and the test will commence.

If a manual test is required, or if the test options are to be modified, click the “Modify” button which will close the dialogue box.

5.3. AVAILABLE TEST MODES

5.3.1. MANUAL TESTING

This allows the operator to use the Otosure to record hearing level thresholds using the computer’s keyboard and mouse. The resulting audiometric data may then be transferred to the Audibase application.

5.3.2. COMPUTER TESTING

This is a method of automatic audiometry based on the Hughson and Westlake method and undertaken automatically by the instrument. The level is increased in 5dB steps until a response is obtained from the patient and decreased in 10 dB steps until no response occurs. The process is repeated until, depending upon the criteria selected for recording a threshold, the instrument will record a threshold at that particular frequency. The Otosure then continues to the next test frequency and so on to complete the test on both ears.

The Otosure provides the facility to run this test at specified single frequencies and add the results into the overall audiogram result. This feature is useful for situations where one particular frequency has proved problematic.

5.3.3. MIXED TESTING

This is typically used when the automatic test has been unable to yield a threshold at one or more frequencies. It is possible to perform a manual test (normally at just a few selected frequencies) to complete an audiogram by adding thresholds to those already established.

5.4. INITIATING A TEST

Start the Audibase application, and with reference to the user manual either establish a new a patient, or access and display details of an existing patient.

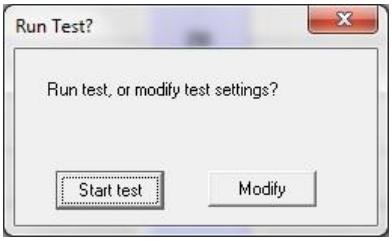
Use the left mouse button to click on the Launch Test icon in the Audibase toolbar.

Alternatively use the “Test > Launch Test” drop-down menu selection at the top of the Audibase window.

A new window will open for the Otosure software. If the patient has more than one set of audiometric results stored in Audibase the most recent audiogram is transferred and displayed in the Otosure window.

The serial number and calibration date of the connected Otosure audiometer is shown at the bottom right of the Otosure window along with the test type currently selected.

The test type last used is remembered; if this was a manual test the procedures may be followed; if this was an automatic test the following dialogue box will be displayed:



To run the same automatic test using the same options (as last used) simply click the “Start test” button and the test will commence.

If a manual test is required, or if the test options are to be modified, click the “Modify” button which will close the dialogue box.

5.5. CONTROL BUTTONS

starts the selected automatic test

selects Computer test type

selects Manual test mode

selects test detail display

selects audiogram display

Sounds a test tone in Manual test mode when the mouse pointer is moved over this icon; there is **no need** to click the mouse button.

The icon changes to this format while a tone is being presented

Please note: The present icon will also be displayed during automatic testing, although use of the mouse as described above will have no effect when automatic testing is performed.

Patient response indicator, displayed like this when the patient has not made a response.

The icon changes to this format when a response is made.

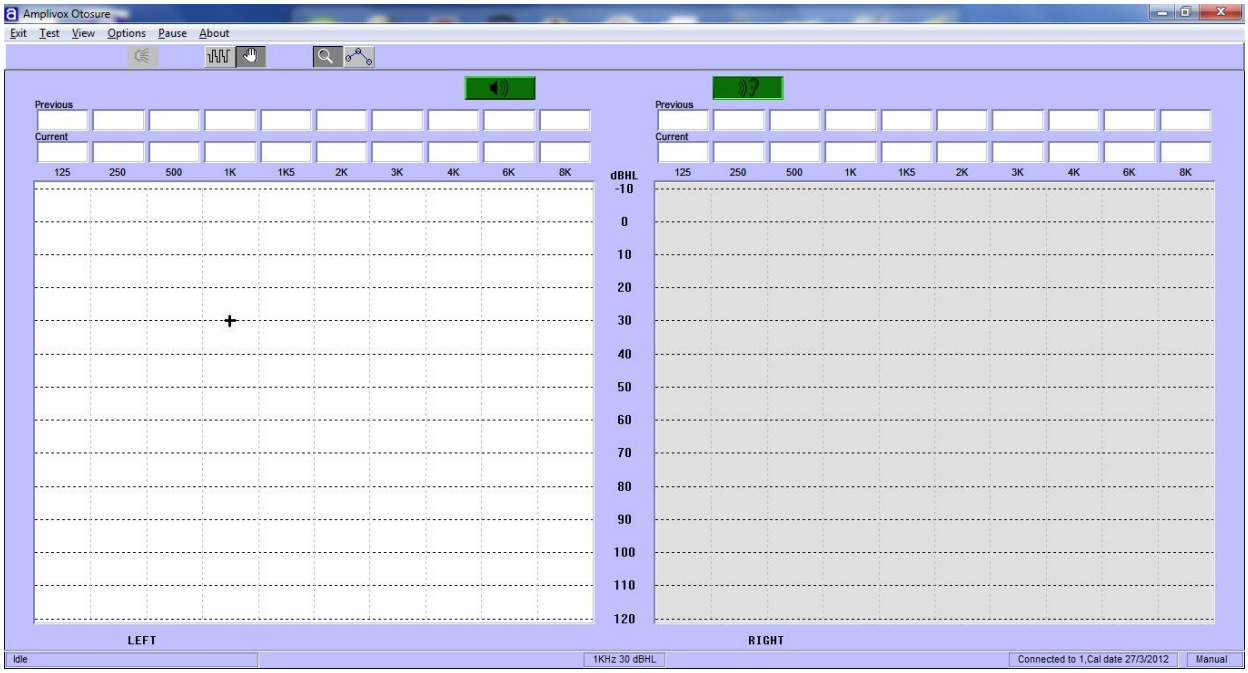
5.6. CONTROL - PC KEYBOARD AND MOUSE

Keyboard, "L" key: selects left ear in Manual test mode
Keyboard, "R" key: selects right ear in Manual test mode
Keyboard, ↑ key: increases the sound level in Manual test mode
Keyboard, ↓ key: decreases the sound level in Manual test mode
Keyboard, ← key: selects a lower tone frequency in Manual test mode
Keyboard, → key: selects a higher tone frequency in Manual test mode
Mouse, pointer: sounds the test tone when positioned over the present icon in Manual test mode
Mouse, left button: selects Windows-based options as normal
Mouse, right button: in manual test mode only, plots a threshold

5.7. MANUAL TESTING

Click the Manual test button  (the button will then be highlighted)

Alternatively use the “Test > Manual” drop-down menu selection at the top of the Otosure window. The following screen is displayed:



Note the cursor positioned in left ear audiogram area indicating the current frequency and dBHL value (also displayed at the bottom centre of the Otosure window).

Moving the mouse over the “Present” icon  will sound the prescribed tone at this level and frequency from the left earphone, and the “Present” icon will change to  .

If the patient presses the response switch the “Response” icon will change from a dark green colour  to a light green colour  .

To change the level of the presented tone, use the ↑ and ↓ arrow keys on the PC keyboard.

When confident that a consistent response has been elicited at a particular level the threshold may be plotted on the screen by clicking the right mouse button. The numerical value of the threshold is added to the appropriate text box above the audiogram. If an error has been made, simply plotting a different threshold at the selected frequency will override any previous threshold.

To clear all thresholds from the audiogram use the “Test > Clear readings …” drop-down menu selection and select the appropriate items to clear.

To change the frequency of the presented tone, use the ← and → arrow keys on the PC keyboard. Continue plotting thresholds until all desired frequencies have been tested.

To select the right ear use the “R” key on the PC keyboard, and to return to the left ear use the “L” key.

Use the controls described above to build up a complete audiogram for the patient. Once satisfactorily completed, click on “Exit” at the top of the Otosure window and confirm to exit Otosure. The Otosure window will close and the Audibase window will display the test results. Refer to the Audibase user manual for additional options, but it should be noted that the results must be saved in Audibase to be retained in the database.

5.8. COMPUTER TESTING

Click the Computer test button (the button will then be highlighted)

Alternatively use the “Test > Computer” drop-down menu selection at the top of the Otosure window. A screen is displayed but with the “Present” icon and cursor removed.

To run a full Computer test on both ears simply click the “Run selected test” button.

Alternatively use the “Test” drop-down menu option to select either a full test or a restricted test (for example, limited to a single ear).

The Computer test will run according to the test options selected with the test status indicated at the bottom left of the Otosure window. The “Present” icon will re-appear and indicate when tones are presented, and the “Response” icon will change to light green when a patient response is made.

To view the traces of the presented tones select the “Show test detail” button:

Alternatively use the “View > Detail” drop-down menu option.

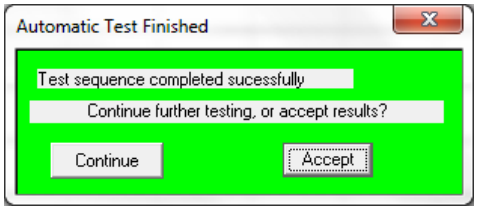
To view the audiogram thresholds select the “Show Audiogram” button:

Alternatively use the “View > Audiogram” drop-down menu option.

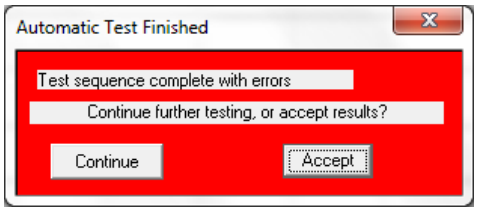
The order of frequencies tested, assuming that all frequencies are selected, are 1kHz, 1.5kHz, 2kHz, 3kHz, 4kHz, 6kHz, 8kHz, 500Hz, 250Hz and 125Hz.

The time available for the patient to respond is from the point the tone is presented to the beginning of the next presented tone (approximately 2.3 seconds maximum). If a response is made within this time period a random delay is then added to the time until the next tone is presented.

Once the test has been completed successfully the following dialogue box will be displayed:



If the test has not been completed successfully the following dialogue box will be displayed:



To accept the results and transfer them to Audibase click on the “Accept” button. The Otosure window will close and the Audibase window will be displayed. Refer to the Audibase user manual for additional options, but it should be noted that the results must be saved in Audibase to be retained in the database.

To continue testing click on the “Continue” option. The dialogue box will close and the operator may continue testing as described in these sub-sections.

5.9. SINGLE-FREQUENCY TESTING

In Computer test mode it is possible to run a test at a single frequency. For example, the operator might have noticed that the patient response at a particular frequency was erratic, or the automatic test was unable to establish a response at a particular frequency.

The “Test > One freq. test” drop-down menu option may be used to select a single frequency for a particular ear. Clicking on the required option for frequency and ear initiates a test which will override any audiometric data already established for that frequency. At the end of the test the option to “Continue” or “Accept” is presented.

5.10. MIXED-MODE TESTING

This allows an audiogram to be completed by performing tests (typically at a few selected frequencies) using an alternative test type. For example, this facility could be used to perform a manual test if the automatic test option was unable to establish a threshold at a particular frequency).

The legend “Mixed” is displayed at the bottom right of the Otosure window.

6. OPTIONS AVAILABLE TO SET-UP

6.1. GENERAL

The Otosure software stores the most recent test configuration and will initially use this to run any subsequent tests. However, there are a number of options available for setting up, modifying and controlling a test. These are summarised below - please refer to the operating window of the Otosure Software.

6.2. MENU COMMANDS

Exit: this closes the Otosure window and transfers any audiometric thresholds found plus other test detail to Audibase, if the user acknowledges the confirmation.

Test: this provides access to a number of controls as follows:

- Run full test (tests each ear in turn using the current automatic test type)
- Left test (tests the left ear only using the current automatic test type)
- Right test (tests the right ear only using the current automatic test type)
- One freq. test (tests the selected ear & frequency combination using the current automatic test type)
- Stop test (displays a further option to confirm or cancel the 'Stop test' command; the test continues until a response is made; if 'Stop test' is confirmed any thresholds found are retained)
- Clear readings (clears all audiogram & threshold data, or only the data for the left or right ear)
- Computer (sets Computer to be the current automatic test type)
- Manual (sets the audiometer into the manual test mode)

View: this allows either test "Detail" (graphical representation of presented tones and patient responses), or "Audiogram" (plots of thresholds found) to be selected

Options: this opens a dialogue box, which provides access to the following options:

Video available on how to use different test settings.

- Frequencies – include or exclude 125Hz, 250Hz, 1.5kHz or 8kHz to/from the test regime
- Computer test - controls to allow:
    - the selection of either 2 out of 3, or 3 out of 5 consistent responses to generate a valid threshold
    - a retest of the 1kHz frequency to be omitted (including this function can prove useful in correlating test results)
- Tone response - controls to determine the action to be taken on error:
    - the number of times a frequency is repeated (0, 1, 2 or 3 times) if an error in testing occurs (for example, if there is an erratic response from the patient)
    - and then the action to be taken if the error continues (skip the frequency or pause the test)
- Start level - specify a start level of either 20dBHL, 30 dBHL or 40 dBHL for a test, and for all frequencies 1kHz and lower for a Computer test
- Start with familiarisation - a familiarisation at 1kHz prior to the test
- Beep on finish - produces an audible tone to alert the operator that the test has finished

Pause: immediately pauses the test and displays furthers options to abort the test, retry the current frequency being tested or ignore the current frequency and skip to the next one (skip not for a manual test); if the test is aborted any thresholds found are retained

About: displays the version of the Otosure software installed on the PC and the support email address

7. TROUBLESHOOTING

7.1. GENERAL

The Otosure is straightforward to use with an intuitive user interface, and if the instructions are followed the testing process should be performed easily. The product has been designed to detect and report a number of errors that could be encountered while performing audiometric testing and these are described below.

7.2. NO INSTRUMENT FOUND

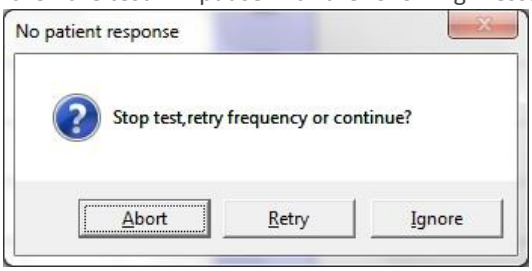
If the audiometer has not been connected when a test is requested from Audibase the Otosure software will not start and the following warning dialogue box will be displayed:

Clicking OK will return to Audibase.

Use the “Edit > Cancel Insert/Edit” option or cancel toolbar button to cancel the insert operation. The Otosure may then be connected and Audibase operations continued.

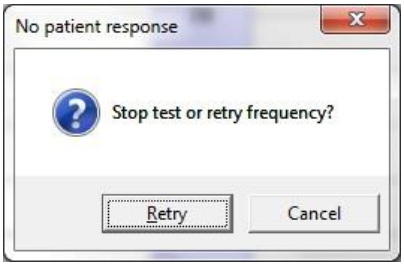
7.3. NO RESPONSE FROM PATIENT

If the audiometer detects that no response to the test tone is made by the patient during an automatic test the tone level will increase to maximum and then the test will pause with the following message displayed on the PC screen:



Depending on circumstances the operator may choose to abort the test, retry the frequency, or ignore the error (and proceed to testing of the next frequency).

For a single frequency test, the tone level will also increase to maximum and then the test will pause with the following message displayed on the PC screen:

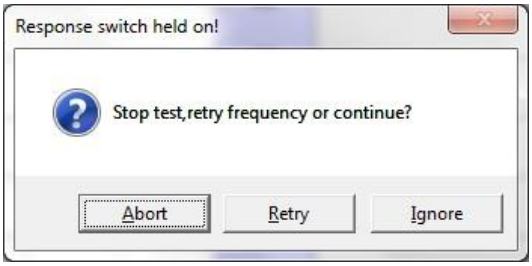


Depending on circumstances the operator may choose to retry the single frequency, or cancel the single frequency test.

Check that the patient fully understands the instructions previously given regarding use of the response switch. Check also that the response switch is connected and operating and that tones are being output from the headphones.

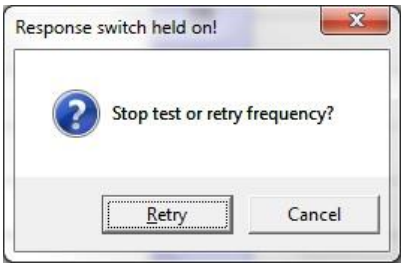
7.4. RESPONSE SWITCH HELD ON

If the audiometer detects that the response switch is not released by the patient during an automatic test the tone level will decrease to minimum and then the test will pause with the following message displayed on the PC screen:



Depending on circumstances the operator may choose to abort the test, retry the frequency, or ignore the error (and proceed to testing of the next frequency).

For a single frequency test, the tone level will decrease to minimum and then the test will pause with the following message displayed on the PC screen:

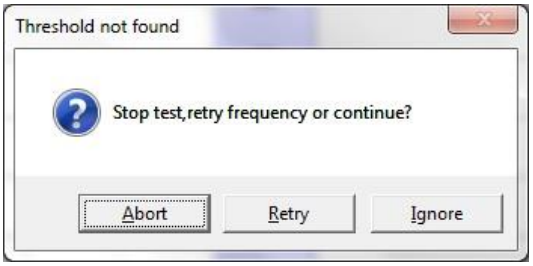


Depending on circumstances the operator may choose to retry the single frequency, or cancel the single frequency test.

Check that the patient fully understands the instructions previously given regarding use of the response switch. Check also that the response switch is connected and operating and that tones are being output from the headphones.

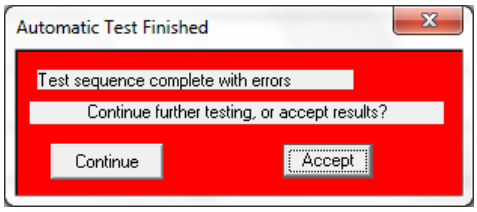
7.5. ERRATIC PATIENT RESPONSE

If the patient is not consistent in making responses during an automatic test it will not be possible for a threshold to be established. In these circumstances, and depending on the test options selected the test may be paused or the next test frequency may be presented. If pause is selected, the test will pause with the following message displayed on the PC screen:



Please note: This message will not be displayed for a single frequency test, but rather the test will complete but with errors (see below).

If the audiometer manages to establish some but not all thresholds during an automatic test the following dialogue box will be displayed at the end of the testing process:



This alerts the operator to the fact that errors in testing have occurred, and allows either:

- further testing to be continued or
- the thresholds that were established to be accepted and transferred to Audibase

7.6. EXIT OTOSURE WITH NO RESULTS

If the Otosure Software is closed without obtaining any test results the following warning will be displayed in Audibase:

Click OK and then use the “Edit > Cancel Insert/Edit” option or cancel toolbar button to cancel the operation.

7.7. USB LEAD DISCONNECTED

If the USB cable connecting the Otosure becomes disconnected any automatic test running will immediately cease, and the following message will be displayed:

Once the message has been acknowledged, it will be possible to select control buttons and menu options in the Otosure window on the PC but these will have no effect. If the Otosure cable becomes disconnected, the recommended course of action is for the operator to close the Otosure window and return to Audibase. Then use the "Edit > Cancel Insert/Edit" option or cancel toolbar button to remove any data, and close Audibase. The Otosure may then be reconnected and Audibase started as usual.

When the Otosure window is closed any thresholds found or plotted will be transferred into Audibase and care should therefore be taken with the use of this data.

Please also refer to Section 11 for important information regarding the connection of non-medical electrical equipment to medical electrical equipment.

8. ROUTINE MAINTENANCE

8.1. GENERAL MAINTENANCE PROCEDURES

The performance and safety of the instrument will be maintained if the following recommendations for care and maintenance are observed:

1. It is recommended that the instrument go through at least one annual service, to ensure that the acoustical, electrical and mechanical properties are correct. This should be carried out by an authorized repairer in order to guarantee proper service and repair.
2. Observe that no damage is present to the insulation of the mains cable or the connectors and that it is not exposed to any kind of mechanical load that could involve damage.
3. To ensure that the reliability of the instrument is maintained, we recommend that the operator at short intervals, for instance once a day, performs a test on a person with known data. This person could be the operator.
4. If the surface of the instrument or parts of it is contaminated, it can be cleaned using a soft cloth moistened with a mild solution of water and detergent or similar. Always disconnect the mains power adaptor during the cleaning process and be careful that no fluid enters the inside of the instrument or accessories.
5. After each patient examination, ensure that there has been no contamination to the parts touching the patient. General precautions must be observed in order to avoid cross-contamination of disease from one patient to another. Water should be used for frequent cleaning, but in the case of severe contamination it may be necessary to use a disinfectant.

CAUTION

- Before cleaning always switch off and disconnect from the power supply
- Use a soft cloth lightly dampened with cleaning solution to clean all exposed surfaces
- Do not allow liquid to come in contact with the metal parts inside the earphones/headphones
- Do not autoclave, sterilize or immerse the instrument or accessory in any fluid
- Do not use hard or pointed objects to clean any part of the instrument or accessory
- Do not let parts that have been in contact with fluids dry before cleaning
- Rubber ear-tips or foam ear-tips are single use components

Recommended cleaning and disinfection solutions:

- Warm water with mild, nonabrasive cleaning solution (soap)
- 70% isopropyl alcohol only on hard cover surfaces

8.2. AUDIOMETER MAINTENANCE

The Otosure audiometer is a precision instrument. Handle it carefully in order to ensure its continued accuracy and service. When cleaning the instrument, use a soft damp cloth and mild detergent to clean the instrument panel. Refer to ISO 8253-1 for additional guidance.

8.3. HEADSET MAINTENANCE

Before use check the headset cables and connectors for signs of wear and/or damage. If you find any, please replace the item immediately by contacting Amplivox or your Amplivox distributor, requesting the relevant part number.

Handle the audiometric headset (and audiocups) with care. For these parts that are in direct contact with the patient it is recommended that they are subjected to a standard disinfecting procedure between patients.

This includes physically cleaning and use of a recognised disinfectant. The specific manufacturer's instructions should be followed for use of this disinfecting agent to provide an appropriate level of cleanliness.

Clean the ear cushions (including those on the Audiocups, if used) with a recognised disinfectant, e.g. a “Mediswab”.

Please note: During the cleaning process do not allow moisture to enter the earphone.

8.4. ACCESSORIES/REPLACEMENT PARTS

Some reusable components are subject to wear with use over time. We recommend that you keep theses replacement parts available.

8.5. REPAIR

Amplivox Ltd.is only considered to be responsible for the validity of the CE marking, effects on safety, reliability and performance of the equipment if:

- assembly operations, extensions, readjustments, modifications or repairs are carried out by authorized persons
- a 1 year service interval is maintained
- the electrical installation of the relevant room complies with the appropriate requirements, and
- the equipment is used by authorized personnel in accordance with the documentation supplied by Amplivox Ltd.

It is important that the customer (distributor) fills out the RETURN REPORT every time a problem arises and sends it to

Amplivox Limited
3800 Parkside, Solihull Parkway,
Birmingham Business Park,
Birmingham, West Midlands,
B37 7YG
United Kingdom
hello@amplivox.com

This should also be done every time an instrument is returned to Amplivox Ltd. (This of course also applies in the unlikely worst case scenario of death or serious injury to a patient or user).

When packing the instrument for shipping, please use the original shipping carton and packing materials. Place the instrument parts in plastic bags before packing.

8.6. WARRANTY

Amplivox therefore gives the purchaser the following Warranty;

If within twenty-four months from the date of dispatch, any defect in respect of material or workmanship within our control is discovered, we will make good the defect without charge, subject to the following conditions;

- Notice of the fault is given to Amplivox within the Warranty period.
- The instrument is forwarded, carriage paid, to Amplivox Limited at the above address or as otherwise directed.
- The responsibility of Amplivox under this Warranty is strictly limited to making good the defect in the instrument itself.
- No attempt has been made to effect a repair or adjust the calibration or alter the instrument from the original build standard.
- Defects caused by abnormal conditions of use, accident or neglect are expressly excluded.

If any product requires service during the applicable warranty period, the purchaser should communicate directly with the local Amplivox Ltd. service center to determine the appropriate repair facility. Repair or replacement will be carried out at Amplivox's expense, subject to the terms of this warranty. The product requiring service should be returned promptly, properly packed, and postage prepaid. Loss or damage in return shipment to Amplivox Ltd. shall be at purchaser's risk.

In no event shall Amplivox Ltd. be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any Amplivox Ltd. product.

This shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner or holder of the product. Furthermore, this warranty shall not apply to, and Amplivox Ltd. shall not be responsible for, any loss arising in connection with the purchase or use of any Amplivox Ltd. product that has been:

- repaired by anyone other than an authorized Amplivox Ltd. service representative;
- altered in any way so as, in Amplivox Ltd. opinion, to affect its stability or reliability;
- subject to misuse or negligence or accident, or that has had the serial or lot number altered; defaced or removed; or
- improperly maintained or used in any manner other than in accordance with the instructions provided by Amplivox Ltd.

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of Amplivox Ltd. Amplivox Ltd. does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of Amplivox Ltd. any other liability in connection with the sale of Amplivox Ltd. products.

AMPLIVOX LTD. DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FOR FUNCTION OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.

8.7. CALIBRATION AND RETURN OF THE INSTRUMENT

Amplivox recommends that the Otosure is calibrated annually.

Please contact Amplivox or the designated distributor for details of calibration services.

8.8. GUARANTEE

All Amplivox instruments are guaranteed against faulty materials and manufacture. The instrument will be repaired or replaced free of charge for a period of three 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.

Please note: The following exceptions apply:
The earphones may go out of calibration due to rough handling or impact (dropping). The life of the leads is also dependent upon conditions of use. These parts are only guaranteed against faulty materials or manufacture.

9. TECHNICAL SPECIFICATIONS

9.1. STANDARDS AND REGULATORY

The Otosure Audiometer complies with the relevant parts of following standards:

- BS/EN/IEC 60601-1: Medical Electrical Equipment – General requirements for basic safety and essential performance
- BS/EN/IEC 60601-1-2: Medical Electrical Equipment – Electromagnetic Compatibility: Requirements and Tests
- BS/EN/IEC 60645-1: Electroacoustics – Audiological Equipment – Part1: Pure-tone Audiometers

Degree of protection against electric shock:	Type B applied part
Degree of protection against ingress of water:	Not protected
Mode of operation:	Continuous operation
Equipment mobility:	Portable

The Otosure audiometer is classified as a Class IIa device under Annex IX of the Medical Devices Directive. It is intended for transient use as a screening hearing test instrument.

9.2. INPUT/OUTPUT

Connection to PC:	USB (version 1.0 or 2.0); type B connector
Left and Right Outputs:	6.3mm Jack Socket
Patient Response Switch:	6.3mm Jack Socket
Maximum voltage at any output:	5V peak

9.3. AUDIOMETRIC

Audiometer type:	Type 4 (IEC 60645-1:2001 & ANSI S3.6:2004)
Frequencies:	125Hz, 250Hz, 500Hz, 1kHz, 1.5kHz, 2kHz, 3kHz, 4kHz, 6kHz, 8kHz
Frequency accuracy:	<1%
Distortion:	<2%
Output level range:	-10dB to 100dBHL (80dBHL at 125Hz)
Output level steps:	5dB
Output level accuracy:	Within 3dB
Headset static force:	4.5N

9.4. EARPHONE SOUND ATTENUATION CHARACTERISTICS

Frequency, Hz	125	250	500	1000	2000	4000	8000
Attenuation, dB	2	5	7	15	25	31	23

9.5. PHYSICAL & ENVIRONMENTAL

Audiometer Dimensions:	120mm (L) x 85mm (W) x 30mm (H)
Audiometer Weight:	150gm
Operating temperature:	+15°C to +35°C
Storage/transport temperature:	-20°C to +70°C

Humidity (operating):	30% to 90% (non-condensing)
Humidity storage/transport):	10% to 90% (non-condensing)
Atmospheric Pressure (operating):	700hPa to 1060hPa
Atmospheric Pressure (storage/transport):	500hPa to 1060hPa

10. EMC GUIDANCE & MANUFACTURER'S DECLARATION

CAUTION

- This instrument 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 instrument 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
- 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. The list of accessories, transducers and cables can be found in this appendix.
- 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 this instrument, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result

NOTICE

- ESSENTIAL PERFORMANCE for this instrument is defined by the manufacturer as:
  This instrument 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 There are no deviations from the collateral standard and allowances uses
- This instrument is in compliance with IEC60601-1-2:2014, emission class B group 1
  NOTICE: There are no deviations from the collateral standard and allowances uses
  NOTICE: 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.

Guidance and manufacturer's declaration – electromagnetic emissions

The Otosure Audiometer is intended for use in the electromagnetic environment specified below. The customer or user of the Otosure Audiometer should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Otosure Audiometer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Otosure Audiometer is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Otosure Audiometer is intended for use in the electromagnetic environment specified below. The customer or user of the Otosure Audiometer 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 ±15 kV air	±8 kV contact ±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	Not applicable	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	Not applicable	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	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Otosure Audiometer requires continued operation during power mains interruptions, it is recommended that the Otosure Audiometer be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 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 a.c. mains voltage prior to the application of the test level			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Otosure Audiometer is intended for use in the electromagnetic environment specified below. The customer or user of the Otosure Audiometer should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150kHz to 80MHz 3 V/m 80MHz to 2.7GHz	3 Vrms 150kHz to 80MHz 3 V/m 80MHz to 2.7GHz	Portable and mobile RF communications equipment should be used no closer to any part of the Otosure 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√P d = 1.2√P 80MHz to 800MHz d = 2.3√P 800MHz to 2.7GHz 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 metres (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 80MHz and 800MHz, 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 Otosure Audiometer is used exceeds the applicable RF compliance level above, the Otosure Audiometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Otosure Audiometer. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the Otosure Audiometer

The Otosure Audiometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Otosure Audiometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Otosure 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	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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 80MHz and 800MHz, 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.

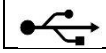
NOTE 3 WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the Otosure audiometer including cables specified by the manufacturer. Otherwise degradation of the performance of this equipment could result.

11. USE WITH NON-MEDICAL ELECTRICAL EQUIPMENT

Any person who connects external equipment to signal input, signal output or other connectors has created a medical electrical system and is therefore responsible for the system complying with the requirements of clause 16 of IEC 60601-1:2005 (*General requirements for basic safety and essential performance*).

If connections are made to standard equipment such as printers and computers, special precautions must be taken in order to maintain medical safety. The following notes are provided for guidance in making such connections to ensure that the general requirements of clause 16 of IEC 60601-1:2005 are met

The following signal inputs and outputs on the Amplivox Otosure audiometer are electrically isolated to the requirements of IEC 60601-1 in order to reduce any potential hazard associated with the use of connected mains-powered equipment:

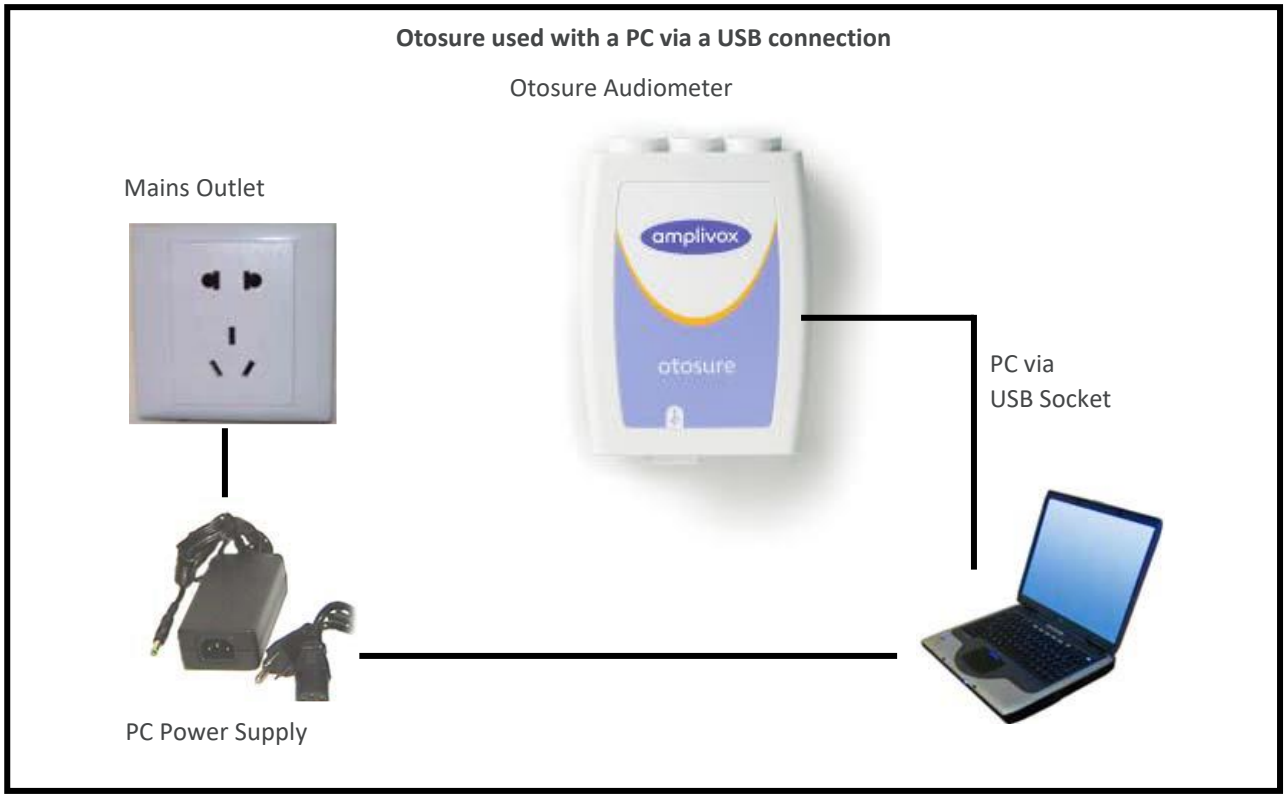
Socket Label	Socket Type	Typical Connection
	USB Connector	Computer

External equipment intended for connection to signal input, signal output or other connectors, shall comply with the relevant IEC or international standards (e.g. IEC 60950, CISPR 22 & CISPR 24 for IT equipment, and the IEC 60601 series for medical electrical equipment).

Equipment not complying with IEC 60601 shall be kept outside the patient environment, as defined in IEC 60601-1 (at least 1.5m from the patient). The operator must not touch the connected equipment and the patient at the same time as this would result in an unacceptable hazard.

Refer to the diagram below for a typical configuration of a connected computer. Refer to Amplivox Ltd at the address given on the front of this user manual if advice is required regarding the use of peripheral equipment.

Otosure used with a PC via a USB connection



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