

PC850

INSTRUCTION FOR USE



ABOUT THIS MANUAL

READ THIS OPERATING MANUAL BEFORE ATTEMPTING TO USE THE INSTRUMENT.

This manual is valid for the PC850 (applies from serial number 24164 and Audibase version 5.5 onwards).

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1. INTRODUCTION

1.1. THANK YOU

Thank you for purchasing the Amplivox PC850 audiometer, an air-conduction screening audiometer that is designed for use by audiologists and occupational health practitioners. Its primary use is as an automatic audiometer (interfacing to and launched from the Amplivox Audibase PC software). However it may also be used as a “standalone” manual audiometer that can save the results of up to 12 tests. These tests may then be transferred to Audibase at a later stage.

This operating manual applies to the PC850 in combination with Audibase Software Version 5.5. Audibase 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.

The audiometer is not intended for use to determine the full extent and scope of a patient’s hearing deficiency.

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			
PC850 Audiometer	8510385	Patient Response Switch	8011155
Audiometric headset & leads (DD45)	8509615	Approved mains adapter UES12LCP	8512734
HBA audiometric headband	8010882	Cable USB A to USB B (2.0 m)	8011241
USB stick with Software and Operating Manuals	8510705 and 8510707 (OSHA)	Carrying case	8004674
Calibration certificate			

OPTIONAL COMPONENTS

Audiogram Cards

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. When done with the air conduction, the bone conduction is being assessed.

In cases of unsymmetrical hearing, it might be required to mask the air and bone conduction in order to prevent hearing the test tone on the opposite ear. This phenomenon is called 'crossover' and occurs more often while testing bone conduction than air conduction.

2.3. AUDIOMETRY PREPARATION

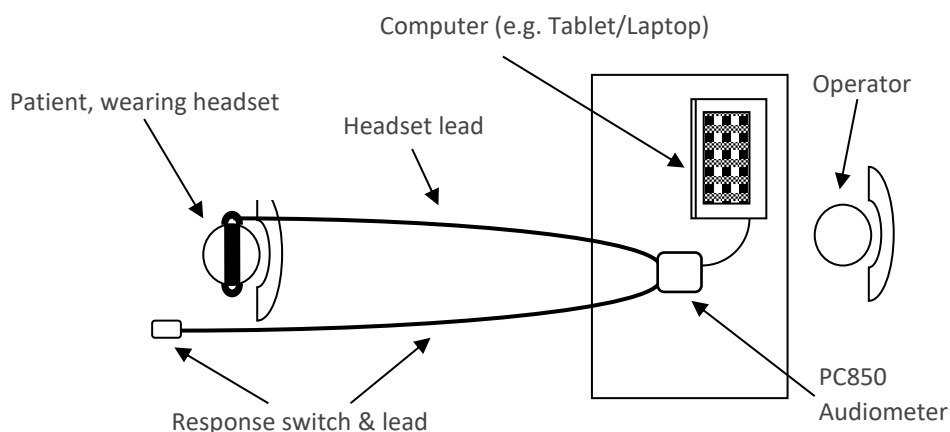
Refer to the various audiometric standards and other relevant publications for guidance on audiometric testing.

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”.

- In the case of Manual or Computer testing – “As soon as you hear the tone, press and release the response switch”
- In the case of Bekesy testing – “press and hold the response switch when a series of pulses are heard, and release when the pulses are no longer 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.







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.
	Identifies the control by means of which the instrument is switched on from (or returned to) a standby condition. A long press to turn enter standby. A short press to wake the device from standby.

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 PC850 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



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 PC850. Only accessories which have been stated by Amplivox Ltd. to be compatible are allowed to be connected to the device or cradle.

To comply with the standards IEC 60601-1 for safety and IEC 60601-1-2 for electromagnetic compatibility (EMC) the audiometer is designed to be used only with the medically-approved mains adapter supplied, which is specified as part of the equipment. **Do not use any other type of mains adapter with this instrument.**

The output from the mains adapter is fitted with electronic circuit protection. In case of overload the adapter will shut down and the indicator will be extinguished. When the fault is cleared the adapter will operate as normal.

The input to the mains adapter is protected with a non-replaceable fuse. If this fails the adapter will not operate.

The mains adapter is the mains disconnect device and therefore the audiometer should be positioned such that easy access to the mains adapter is possible.

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 PC850 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.

Do not use any additional multiple socket-outlet or extension cord. **Use only UES12LCP Power Supply.**

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 PC850 in a highly oxygen-enriched environment, such as a hyperbaric chamber, oxygen tent, etc.

3.3.7. MEASURING SECURITY

To guarantee that the PC850 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 PC850 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 wheellie-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.

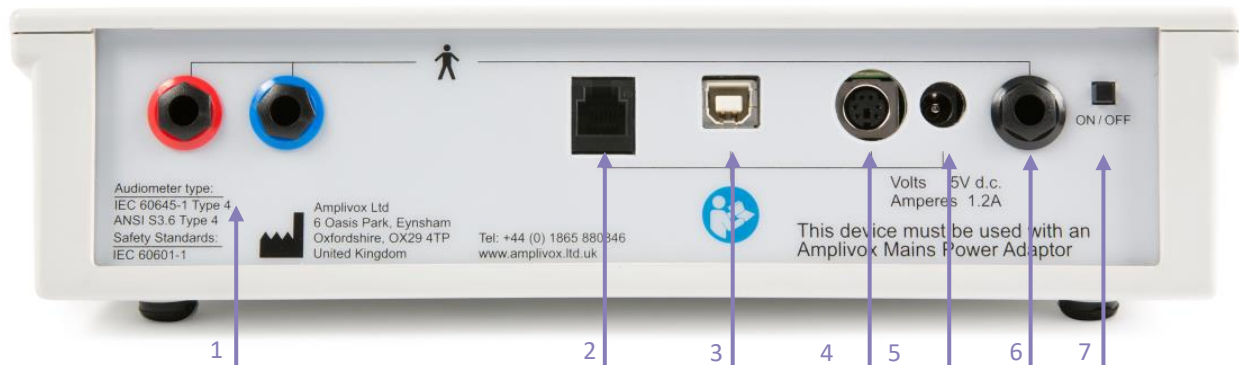
Outside the European Union, local regulations should be followed when disposing of the product after its end of life.

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:



1	Right	Air conduction headset *	6.3mm jack
	Left		6.3mm jack
2	N/A	Reserved port; Amplivox diagnostic use only	6 pin mini DIN
3	USB	Computer (via USB port)	USB Connector, Type B
4	N/A	Reserved port; Amplivox diagnostic use only	6 pin mini DIN
5	Power	Mains AC/DC Adapter	2.5mm power jack
6	Response	Patient Response Switch *	6.3mm jack
7	Power Switch	On / Off Switch	

For connected parts marked * 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 PC850 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. For other sockets refer to Appendix 2.



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 PC850 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.

4. USING THE PC850 (COMPUTER CONTROLLED)

4.1. GENERAL



Please note: Before the PC850 can be used as an automatic audiometer, the operating software and the Audibase application must be installed and registered on the connected PC. Refer to the relevant section of the Audibase operating manual for details of this operation.

On start-up the display will show the following default setting:



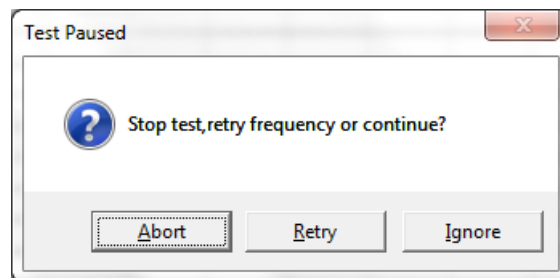
This indicates that the audiometer is now ready to be used for automatic testing which is initiated by Audibase and controlled by the PC850 software.

4.2. SWITCHING THE AUDIOMETER ON AND OFF

Press and briefly hold the switch marked (located on the back panel). No warm-up time is required. The display will briefly show the model and the type of headphone currently in use. To switch off, press the switch marked again, or press and hold the MENU key followed by the YES (RIGHT) key and then release both.

4.3. USING THE TALKOVER FUNCTION

If the TALKOVER key is pressed while an automatic test is in progress the test will be paused with a dialogue box displayed as below.



After any necessary instruction is given to the patient and the TALKOVER key is released, the operator can choose to stop the test ("Abort"), retry the frequency that was being tested when the TALKOVER key was pressed ("Retry"), or skip the frequency that was being tested and move on to the next frequency ("Ignore").

4.4. STARTING THE SOFTWARE



Please note: Before starting an automatic test it is important to clear any current test readings from the audiometer (typically these would be retained thresholds from a previous manual test). If this is not done then dealing with any error conditions could become problematic.

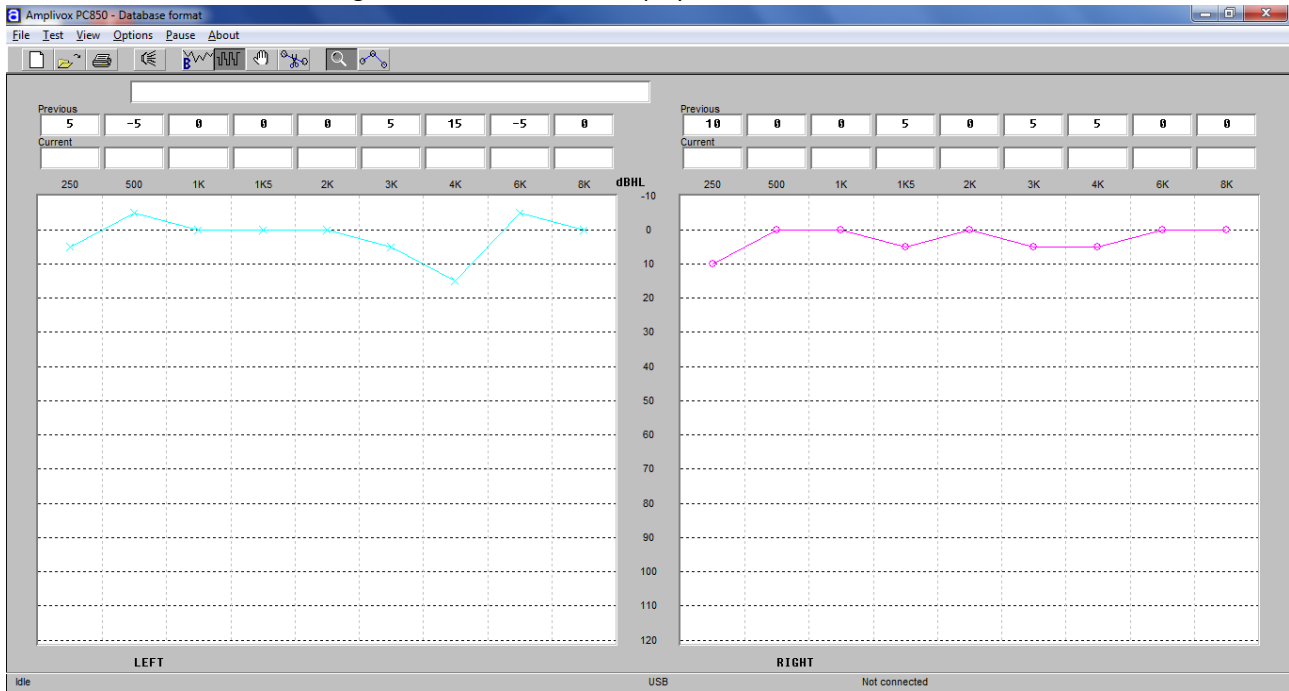
Start the Audibase application, and with reference to the user manual either establish a new a patient, or access and display details of an existing patient.



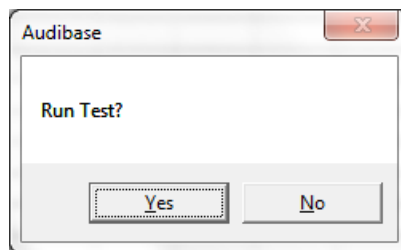
Use the left mouse button to click on the Launch Test icon in the Audibase toolbar.

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

A new window will open for the PC850 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 PC850 window.



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:



4.5. AVAILABLE TEST MODES

4.5.1. MANUAL TEST

While not strictly an “automatic” test, this allows the operator to use the PC850 software to transfer to Audibase the results of a previous manual test. These could be either the “retained thresholds” (see Section 5.3) or the thresholds stored in one of the internal memory locations of the audiometer (see Section 5.4). The audiometric data is transferred to Audibase in the same way as that for an automatic test.

4.5.2. 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 (see Section 4.4), the instrument will record a threshold at that particular frequency. The PC850 then continues to the next test frequency and so on to complete the test on both ears. When completed the test data is transferred to Audibase.

4.5.3. BÉKÉSKY TEST

This is a method of automatic audiometry devised by Von Bekesy (1947) using pure tone stimuli to track auditory thresholds.

This application is known as discrete frequency Bekesy testing and the principle behind the test is that the patient adjusts the presented level according to his hearing threshold. The decibel level decreases when the patient presses the response switch upon hearing the presented tone. Conversely when the patient can no longer hear the presented tone, he will release the response switch therefore allowing the level to increase until the presented tone is heard again. The level changes are in 2.5dB steps.

When a number of these "peaks" and "valleys" have been consistently performed, the PC850 will calculate an average to the nearest dB and display this as the hearing threshold for that particular frequency. The PC850 then continues to the next test frequency and so on to complete the test on both ears.

4.5.4. SINGLE FREQUENCY TEST

The PC850 provides the facility to repeat a test at a specified single frequency and add the results into the overall audiogram result. This feature is useful for situations where one particular frequency has proved problematic.

4.5.5. MIXED TESTING

This allows manual testing of any frequencies when an automatic test has been unable to determine a threshold. The combined results are then transferred to Audibase.

4.6. INITIATING A TEST VIA COMPUTER

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.

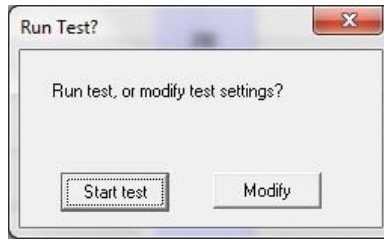
Use the left mouse button to click on the Launch Test icon  in the Audibase toolbar.

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

A new window will open for the PC850 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 PC850 window.

The serial number and calibration date of the connected PC850 audiometer is shown at the bottom right of the PC850 window along with the test type currently selected.


The test type last used is remembered; if this was a manual test the procedures described in Section 4.4 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 (refer to Section 4.5).

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. Refer to Sections 4.4 to 4.7 and Section 5 as appropriate for additional guidance.

4.7. RUNNING A PREVIOUS TEST TYPE

To run the same type of test with the same options as previously used simply click “Yes” and the test will commence as previously run (refer to Sections 4.3.5 to 4.3.9). The “Run selected test” icon will change the following icon: 

Assuming that an automatic test is in use, the serial number of the connected audiometer is shown at the bottom right of the PC850 window and the status message “Running test” is displayed at the bottom left. Additionally, the message “Linked” is shown on the display of the audiometer.

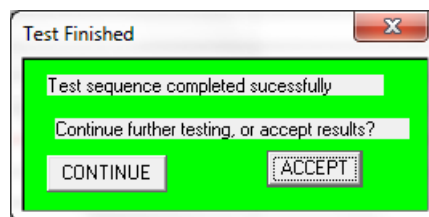
To view the traces of the presented tones select the “Show test detail” icon .

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

To view the audiogram thresholds select the “Show Audiogram” icon .

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

If thresholds are established at all of the selected test frequencies, the automatic test will finish with the following dialogue box displayed:




Click “CONTINUE” to keep the PC850 program window open; this allows the user to perform further testing if required - for example to repeat a threshold at a particular frequency.

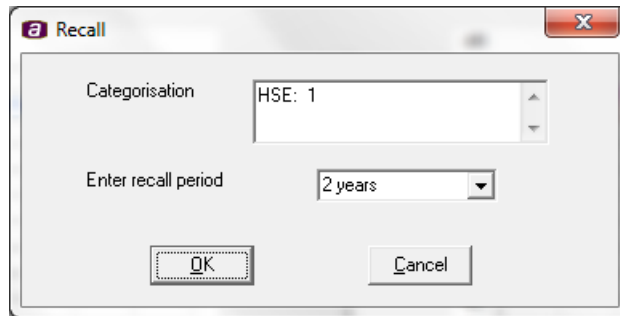
Click “ACCEPT” to exit the PC850 program and transfer the complete test thresholds to Audibase.



Please note: When transferring thresholds to Audibase, remember to “save” the data in Audibase to store it in the database (refer to the Audibase operating manual). If the data is not to be stored then the “Edit > Cancel Insert/Edit”

menu option in Audibase is used to discard it, or click the cancel insert/edit button on the Audibase toolbar .

When data is saved in Audibase a further dialogue box appears similar to that shown below. This displays the hearing level categorisation and provides an opportunity for the operator to enter a recall period for the patient.




Enter the appropriate recall period from the drop-down options and click on “OK” to confirm saving of the data. Clicking on “Cancel” will cancel the save operation and discard the data.


Users should remain aware that it is possible to modify audiometric test results transferred into Audibase as long as they have not been saved. Refer to the Audibase manual for details.

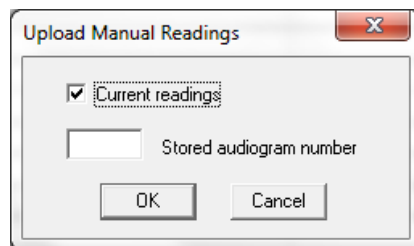
4.8. MANUAL TESTING

This assumes that a set of audiometric thresholds has already been established by using the audiometer in manual test mode.

Click the “Select upload manual test” icon (the icon will then be highlighted) .

Alternatively use the “Test > Manual” drop-down menu selection at the top of the PC850 window.

To transfer a set of manual thresholds to Audibase click the “Run selected test” icon  and confirm the operation by clicking “Yes” in the Run Test dialogue box. A further dialogue box will open.



This allows either the “Current readings” (i.e. the retained thresholds) or the thresholds stored in one of the audiometer’s internal memory locations to be transferred to Audibase. To select an internal memory location un-check the “Current readings” box and enter the required memory location (numbers 1 to 12).

Click on OK, and the selected data will be transferred to Audibase when the PC850 window is closed. Remember to “save” the data in Audibase to retain it in the database (refer to the Audibase operating manual).

Note that the manual test method described above will transfer only thresholds stored in the audiometer. The results of any (partial) automatic test will be discarded. Thus, if an automatic test has been completed but with errors, the “Mixed Test” mode should be used to insert manual readings into the incomplete automatic test.

4.9. 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 PC850 window. A screen similar to that shown 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 PC850 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:

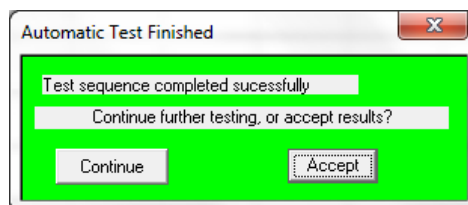


Alternatively use the “View > Audiogram” drop-down menu option.

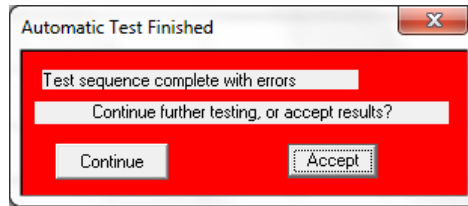
The order of frequencies tested, assuming that all frequencies are selected, are 1kHz, 1.5kHz, 2kHz, 3kHz, 4kHz, 6kHz, 8kHz, 500Hz and 250Hz.

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 PC850 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.

4.10. BÉKÉSKY TEST

Use the audiometer controls to clear any current test readings (retained thresholds).

Click the “Bekesy” test icon (the icon will then be highlighted) .

Alternatively use the “Test > Bekesy” drop-down menu selection at the top of the PC850 window.

To run a Bekesy test click the “Run selected test” icon  and confirm the operation by clicking “Yes” in the Run Test dialogue box.

The Bekesy test will run according to the test options selected with the test status indicated at the bottom left of the PC850 window.

The time available for the patient to respond in Bekesy mode is from the point the tone is presented until the point when the next tone in the sequence is presented.

The test will proceed and conclude as described. Remember to “save” the data in Audibase to retain it in the database or “Cancel Insert/Edit” if the data is to be discarded (refer to the Audibase operating manual).

4.11. SINGLE-FREQUENCY TESTING

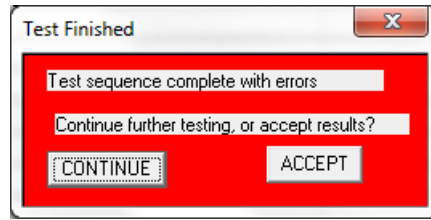
This option allows an automatic test at a single frequency to be repeated, for example if the full automatic test has been unable to record a threshold.

Use the “Test > One freq. test” drop-down menu selection at the top of the PC850 window to select the single frequency from those available for testing.

An automatic test at that frequency will be performed and the test will proceed. Remember to “save” the data in Audibase to retain it in the database or “Cancel Insert/Edit” if the data is to be discarded (refer to the Audibase operating manual).


4.12. MIXED-MODE TESTING

This allows manual readings to be inserted at frequencies at which an automatic test has been unable to establish a threshold. In these circumstances the automatic test would finish with the following dialogue box displayed:




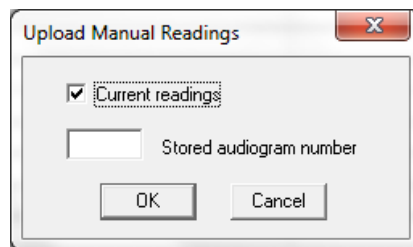
Click “CONTINUE” and note the frequencies at which thresholds were not established. Only click “ACCEPT” if you wish to exit the PC850 program and transfer the incomplete test to Audibase.

Return to the audiometer and use it to manually determine thresholds at these frequencies (refer to Section 5). It will be easier to do this if any previous displayed results (the “retained thresholds”) have been cleared.

When the required manual test results have been established on the audiometer click the “Select insert manual readings” icon (the icon will then be highlighted) .

Alternatively use the “Test > Mixed” drop-down menu selection at the top of the PC850 window.

To transfer the combined thresholds to Audibase click the “Run selected test” icon  and confirm the operation by clicking “Yes” in the Run Test dialogue box. A further dialogue box will open.



In this case leave “Current readings” selected, click on OK, and the combined data will be transferred to Audibase when the PC850 window is closed. Remember to “save” the data in Audibase to retain it in the database (refer to the Audibase operating manual).

Note that any automatic test thresholds recorded will always be transferred, even if a threshold has been manually entered on the audiometer at that frequency. Only manual thresholds entered at frequencies where there is no automatic test threshold are transferred to Audibase.



Note also that if the previous test results on the audiometer (the “retained thresholds”) were not cleared then any retained thresholds at frequencies where an automatic test was not carried out (e.g. for frequencies that were deselected for an automatic test) would also be transferred into Audibase. This is why it is essential to clear the retained thresholds before carrying out an automatic test.

5. USING THE PC850 STAND-ALONE

5.1. GENERAL

Manual testing with the audiometer in “standalone” mode may be carried out with or without the connection to the PC. If an automatic test has been launched by Audibase then manual testing is not possible until this has concluded.

5.2. SWITCHING THE AUDIOMETER ON AND OFF

Press and briefly hold the switch marked  (located on the back panel). No warm-up time is required. The display will briefly show the model and the type of headphone currently in use. To switch off, press the switch marked  again, or press and hold the MENU key followed by the YES (RIGHT) key and then release both.

5.3. AUDIOMETER DISPLAY

On start-up the display will show the following default setting:-

SIGNAL dBHL



FREQUENCY Hz

30dB	1kHz
< >	< >



This indicates that when the PRESENT key is pressed, a tone will be presented at 30dBHL at a frequency of 1kHz to the indicated ear. On start up the audiometer defaults to the left ear.







5.4. AUDIOMETER CONTROLS

5.4.1. MULTIFUNCTION KEYS

Several keys on the audiometer have different functions depending on the actual mode of operation. These are MENU (OFF), LEFT (NO), RIGHT (YES) and FREQUENCY   (MENU SELECT). The use of these keys is described below.

5.4.2. MENU

Press and hold MENU to access the following options. Use the MENU SELECT keys to step through the available options and then the NO, YES or SIGNAL   keys to select an action or modify a setting. Release of the MENU key then initiates the action or saves the modified setting and returns to the default display.

<u>Menu Option</u>	<u>Description</u>
Switch off?:	Press Power Button.
Clear test?:	Press YES and release MENU to clear the Threshold Retention Function results from the previous test
Save audiogram to (1):	Use the SIGNAL   keys to select the required storage location and press the YES key to save the audiogram; then release MENU
Load audiogram no (1):	Use the SIGNAL   keys to select the required storage location and press the YES key to load the audiogram; then release MENU
Contrast:	Adjust contrast using the SIGNAL   keys; then release MENU

5.4.3. DESCRIPTION OF FUNCTION OF OTHER KEYS

+20dB	This enables tone levels to be presented with up to 20dB higher output in manual test mode; press the key and then use SIGNAL ↑ to access the extra 20dB in 5dB steps; an indicator above the key illuminates green to show that the function is active
TALK OVER	Hold this key to interrupt the test and route the operator’s voice from the front panel microphone to the headset; the level is adjusted with the SIGNAL ↓↑ keys
LEFT	Press once to select the left ear (the indicator above the key illuminates green); if the left ear is already selected, press again to store the displayed signal value as a threshold (see Section 5.3)
RIGHT	Press once to select the right ear (the indicator above the key illuminates green); if the right ear is already selected, press again to store the displayed signal value as a threshold (see Section 5.3)
SIGNAL	Press the ↓↑ keys to decrease or increase the level of the tone presented in 5dB steps; to scroll through the range keep the key pressed
FREQUENCY	Press the ⇐ key to select a lower frequency and the ⇒ key to select a higher frequency
PRESENT	Press to present the displayed test signal to the patient. The “PRESENT” indicator above the display will be illuminated green during tone presentation

5.5. THRESHOLD RETENTION FUNCTION

This function allows the thresholds determined for each ear and each frequency to be stored and displayed for reference.

The operator can then review the results at the end of the test and record them on an audiogram card, transfer them into the internal memory or transfer the results into the Amplivox Audibase application.

Once a threshold has been determined press the “selected” ear key once again and the level will be stored and displayed in a similar way to that shown below.

To review the retained thresholds, use the FREQUENCY ⇐ ⇒ keys to select the required frequency. The threshold values for the left and right ears are shown on the lower line of the display as illustrated below.

SIGNAL dBHL	FREQUENCY Hz	
30dB	4kHz	This display shows thresholds at 4kHz
20 10		
Thresholds retained		Left ear 20dBHL
		Right ear 10dBHL

To clear the Threshold Retention memory, press and hold the MENU key, use the FREQUENCY ⇐ ⇒ keys to select “Clear test? No”. Press YES and then release the MENU key.

5.6. SAVING AUDIOGRAMS IN INTERNAL MEMORY

The user may save up to 12 audiograms, referenced by number, in the internal memory of the audiometer. To save the current set of audiogram thresholds press and hold the MENU key, and then press MENU SELECT repeatedly until "Save Audiogram to 1" appears on screen. Use the SIGNAL ↓↑ keys to select a location numbered 1-12, and then press the YES key. Release the MENU key once confirmation appears on the display. Note that the Save process will overwrite any records that exist in the selected memory location.

5.7. LOADING AUDIOGRAMS FROM INTERNAL MEMORY

Press and hold the MENU key, and then press MENU SELECT repeatedly until "Load Audiogram No 1" appears on screen. Use the SIGNAL ↓↑ keys to select a location numbered 1-12, and then press the YES key. Release the MENU key once confirmation appears on the display.

5.8. DATA TRANSFER TO AMPLIVOX AUDIBASE

Refer to the Audibase operating manual to transfer test results to a PC with the Amplivox Audibase software installed.

5.9. SUGGESTED SEQUENCE OF OPERATION AND TEST PROCEDURE

The following notes are for guidance only. Refer also to ISO 8253 (Audiometric Test Methods) for further guidance.

5.9.1. PRE-TEST

- (1) Switch the audiometer on
- (2) Perform a listening check
- (3) Decide whether to use the Threshold Retention Function and/or an audiogram card to record the thresholds
- (4) Prepare the test environment & patient
- (5) If the patient response switch is not being used give instructions to the patient to acknowledge any tone presented by raising or lowering the finger
- (6) If the patient response switch is in use give instructions to the patient to acknowledge any tone presented as follows:
"As soon as you hear the tone, press the switch. When you no longer hear the tone, release the switch".
- (7) Fit the headset to the patient. Select the better hearing ear (according to the patient) by pressing either the LEFT or RIGHT key and start the familiarisation session.

5.9.2. FAMILIARISATION

- (1) Present the tone 30dB at 1kHz for between 1 and 2 seconds. If there is no response at 30dB, increase the attenuation level in 10dB steps until the patient responds
- (2) When the patient responds, wait for 1 to 2 seconds and present the tone again at the same level; however, if the patient does respond at 30dB, reduce the signal level in 10dB steps, repeating the presentation until there is no response, then increase the signal level in 5dB steps until the patient responds; wait 1 to 2 seconds and present the tone again at the same level
- (3) If the responses are consistent with the pattern of tone presentation, start measuring the patient's hearing thresholds; if not, repeat the familiarisation

5.9.3. TEST

- (1) Use the Clear test option to clear any thresholds
- (2) Present the first test tone at 30dB at 1kHz

- (3) If the patient responds, reduce the signal level in 10dB steps repeating the presentation until there is no response; then increase the signal level in 5dB steps until the patient responds
- (4) If the patient does not respond, increase the signal level in 5dB steps until there is a response and then continue with step 5.
- (5) Repeat the test by reducing the signal level in 10dB steps until the patient no longer responds. Then increase the signal level in 5dB steps until a response occurs and note this level.
- (6) Repeat step 5 until the patient responds three out of a maximum of five times at the same signal level. This indicates the patient's hearing threshold level for that frequency. Either mark the threshold on an audiogram card or press the appropriate ear key once to activate the Threshold Retention Function and save the threshold level on screen.
- (7) Proceed to the next test frequency. It is common practice to test the frequencies in the following order: 1k, 2k, 3k, 4k, 6k, 8k and 500 Hz.
- (8) Repeat steps 2 to 7 for the other ear.

5.9.4. POST-TEST

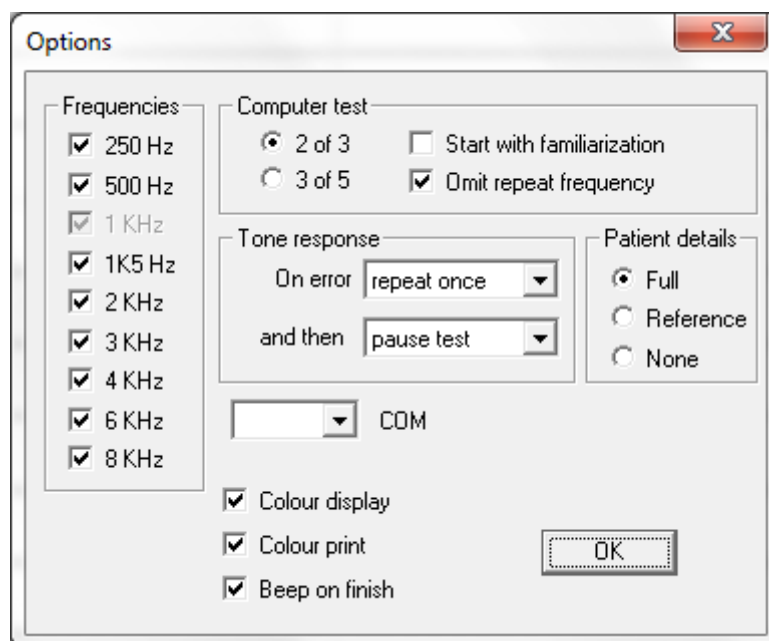
- (1) Use the Threshold Retention Function to review the results
- (2) If required do one or more of the following:
 - Record the results on an audiogram card, or
 - Save the results to the internal memory, or
 - Transfer the results to a computer

6. OPTIONS AVAILABLE TO SET-UP

6.1. GENERAL

The PC850 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 PC850 Software.

The “Options” menu selection at the top of the PC850 window opens a dialogue box, which provides access to a number of options as follows:

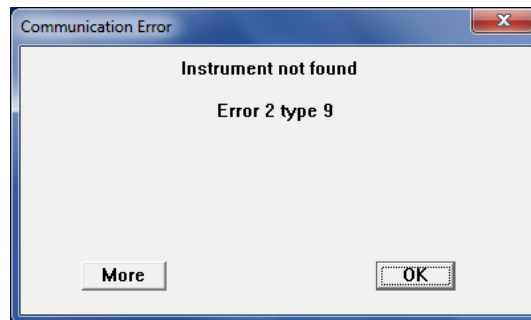


- Frequencies, which allows the operator to add or delete specific frequencies to or from the test regime; note that 1kHz is always included
- Computer test, which provides controls to allow:
 - the selection of either 2 out of 3, or 3 out of 5 consistent responses to generate a valid threshold
 - a familiarisation run prior to the test
 - a retest of the first frequency to be omitted (including this function can prove useful in correlating test results)
- Tone response, which provides 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 no response from the patient)
 - and then the action to be taken if the error continues (skip the frequency, stop the test or pause the test)
- Patient details, which may be ignored when used with Audibase
- COM, which may be ignored for instruments with serial numbers covered by this user guide
- Colour display, which may be selected to display the audiogram in colour
- Colour print, which may be ignored when used with Audibase
- Beep on finish, which sounds an audible warning on the PC at the end of the test

7. TROUBLESHOOTING

7.1. NO INSTRUMENT CONNECTED

If no audiometer has been connected when a test is requested from Audibase a dialogue box similar to that shown below will be displayed:



Check:

- That the PC850 audiometer is switched on
- That the PC850 audiometer is connected to the computer
- That the PC850 software has been installed correctly

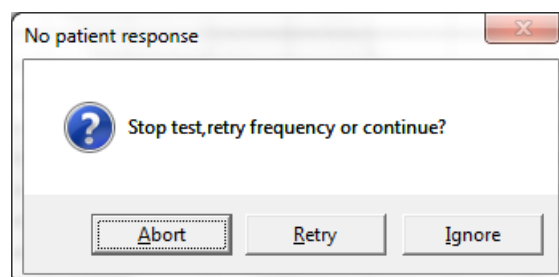
Click OK to close the box and then use the “Edit > Cancel Insert/Edit” option to cancel the operation. Audibase functions may then be continued.

7.2. WRONG PASSWORD

If this error message is seen the audiometer is being used with a version of Audibase older than Version 5.5. Please refer to the documentation supplied with the previous version.

7.3. NO RESPONSE FROM PATIENT

If the patient does not operate the response switch and the maximum output level is reached the following dialogue box will be displayed:



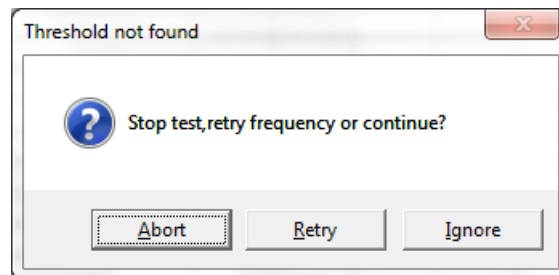
Check:

- That the earphones and response button are correctly plugged in
- That the audiometer is presenting a tone
- That the Patient Response Switch is working correctly
- That the patient understands the test and that they understand how to respond to the tones presented

The operator can choose to stop the test (“Abort”), retry the frequency (“Retry”) or skip the frequency that was being tested and move on to the next frequency (“Ignore”).

7.4. CONTINUAL RESPONSE FROM PATIENT

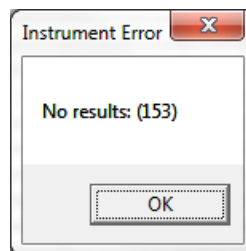
If the patient holds the response switch on continuously it will not be possible to record a hearing threshold and the following dialogue box will be displayed:



The operator can choose to stop the test (“Abort”), retry the frequency (“Retry”) or skip the frequency that was being tested and move on to the next frequency (“Ignore”).

7.5. NO RESULTS

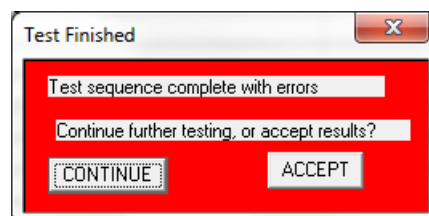
If no results are available to transfer to Audibase the following dialogue box will be displayed:



This could be because the PC850 window was closed before any thresholds could be recorded, the test was aborted or some other problem has occurred with the test sequence. Click OK to close the box and then use the “Edit > Cancel Insert/Edit” option to cancel the operation. A further test may then be launched from Audibase.

7.6. ERRORS IN TEST SEQUENCE

If one or more thresholds cannot be recorded the following dialogue box is displayed at the end of the test:



Click “CONTINUE” to keep the PC850 program window open; this allows the user to perform further testing.

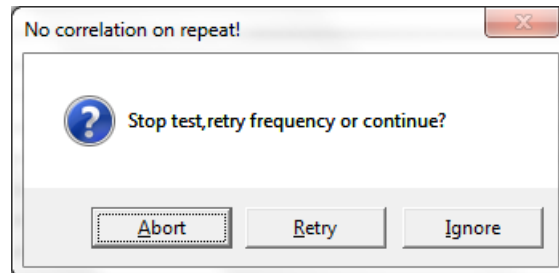
Click “ACCEPT” to exit the PC850 program and transfer the incomplete test thresholds to Audibase.

7.7. INCONSISTENCY IN 1KHZ REPEAT TEST

If the repeat frequency option is enabled for a Computer test an additional test at 1kHz is carried out at the end of the test and compared with the original test result at this frequency.

If the two results differ by 10dB or less then the second result is recorded as the threshold at 1kHz and the test continues.

If the two results differ by more than 10dB the following dialogue box is displayed.

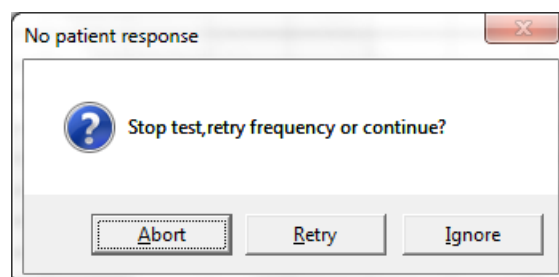


The operator can choose to stop the test ("Abort"), retry the repeat frequency ("Retry") or skip the repeat frequency and continue the test ("Ignore"). If the Ignore option is selected the second result is recorded as the threshold at 1kHz.

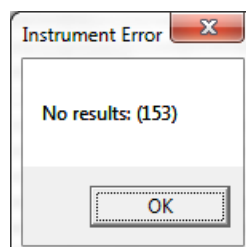
7.8. USB LEAD DISCONNECTED

If the cable connecting the PC850 to the PC becomes disconnected any automatic test running will cease. It may take the audiometer a few moments before the test stops. It may be possible to select control buttons and menu options in the PC850 window on the PC but these will have no effect. Reconnecting the USB lead will also have no effect.

Depending on the task in process when disconnection occurred, one or more error messages may be displayed; for example:



If possible use the "File > Exit" drop-down menu selection at the top of the PC850 window. This should close the PC850 window and return to Audibase. Further error messages may appear, for example:



If possible, use the use the "Edit > Cancel Insert/Edit" option in Audibase to discard any data, and then close Audibase.

Depending on the task in process when disconnection occurred, the audiometer may lock up and not respond to the controls. If possible, attempt to switch off the audiometer. Then remove the power from the audiometer for several seconds. The PC850 may then be reconnected and Audibase started as usual.

7.9. ACCIDENTAL CLOSURE OF PC850 PROGRAM

If the PC850 program is closed while an automatic test is running the test will end and the “No results” message will be displayed in Audibase. It will be necessary to switch the audiometer off and on. Clear any test results and re-start the test.

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 PC850 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 these 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 PC850 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 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

Type of protection against electric shock: Powered via SELV ClassII mains adapter

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 Model PC850 Audiometer is classified as a Class IIa device under Annex IX of the EU Medical Devices Directive. It is intended for use as a screening audiometer instrument.

Audiometer type: Type 4 (IEC 60645-1:2001)

Type 4 (ANSI S3.6:2004)

Types and reference levels: DD45: ISO 389-1, Table 2

Static headband force: Headphones: 4.5N

Sound attenuation characteristics: ISO8253-1, Table 3

9.2. INPUT/OUTPUT DATA

Outputs:	Left & Right earphone
Frequency range:	250Hz-8kHz
Frequency accuracy:	<1%
Distortion:	<2%
Output level range:	-10dBHL min; 100dBHL max (all frequencies)
Output level accuracy:	Within 3dB
Output level step size:	5dB
Output transducer (AC):	DD45 earphones (supplied)
Tone present:	Single tone
Communication:	Integral talk over facility
USB interface:	Interface to PC (PC850 & Audibase software)
Power input:	2.5mm barrel-type socket.
Patient response input:	6.3mm Jack socket
Left & Right outputs:	6.3mm Jack socket
USB:	Type B socket
Maximum voltage at any output:	12V peak

9.3. PHYSICAL DATA

Display:	2 lines of 24 characters
Mains power:	100-240Vac; 50-60Hz; 0.5A
Input Rating:	5Vdc; 1.2A
Dimensions:	270mm (W) x 175mm (D) x 68mm (H)
Weight:	0.7kg (approx)
Safety:	IEC 60601-1 (plus UL, CSA & EN deviations)
EMC:	IEC 60601-1-2
CE mark:	To the EU Medical Device Directive

9.4. EARPHONE SOUND ATTENUATION CHARACTERISTICS

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

9.5. ENVIRONMENTAL

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 used.
- 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 used.
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 PC850 Audiometer is intended for use in the electromagnetic environment specified below. The customer or user of PC850 Audiometer should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The PC850 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. The PC850 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.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity (1)			
The PC850 Audiometer is intended for use in the electromagnetic environment specified below. The customer or user of the PC850 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%

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Voltage dips, short interruptions and voltage variations on power supply input lines (100V/60Hz & 240V/50Hz) IEC 61000-4-11	0% U_T (100% dip in U_T) for 0.5 cycle 0% U_T (100% dip in U_T) for 1 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 500ms 0% U_T (100% dip in U_T) for 5 sec	0% U_T 100% dip in U_T) for 0.5 cycle 0% U_T (100% dip in U_T) for 1 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 500ms 0% U_T (100% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the PC850 Audiometer requires continued operation during power mains interruptions, it is recommended that the PC850 Audiometer be powered from an uninterruptible power supply or a battery
Power frequency (50/60Hz) 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.

Guidance and manufacturer's declaration – electromagnetic immunity (2)			
The PC850 Audiometer is intended for use in the electromagnetic environment specified below. The customer or user of the PC850 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	10 Vrms 150kHz to 80MHz	10 Vrms 150kHz to 80MHz	<p>Portable and mobile RF communications equipment should be used no closer to any part of the PC850 Audiometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \text{ 80MHz to 800MHz}$ $d = 2.3\sqrt{P} \text{ 800MHz to 2.7GHz}$ <p>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).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>
Radiated RF IEC 61000-4-3	10 V/m 80MHz to 2.7GHz	10 V/m 80MHz to 2.7GHz	
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 PC850 Audiometer is used exceeds the applicable RF compliance level above, the PC850 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 PC850 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 PC850 Audiometer			
The PC850 Audiometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PC850 Audiometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PC850 Audiometer as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter	Separation distance according to frequency of transmitter		
	m		
W	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
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 PC850 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 PC850 audiometer are electrically isolated to the requirements of IEC 60601-1 in order to reduce any potential hazard associated with the use of mains-powered equipment connected to these inputs and outputs:

Socket Label	Socket Type	Typical Connection
USB	USB Connector Type B	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 60601-1:2005 (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 Diagrams 1 & 2 below for typical configurations of connected peripheral equipment.

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.

Diagram 1: PC850 used with the medically-approved mains adapter

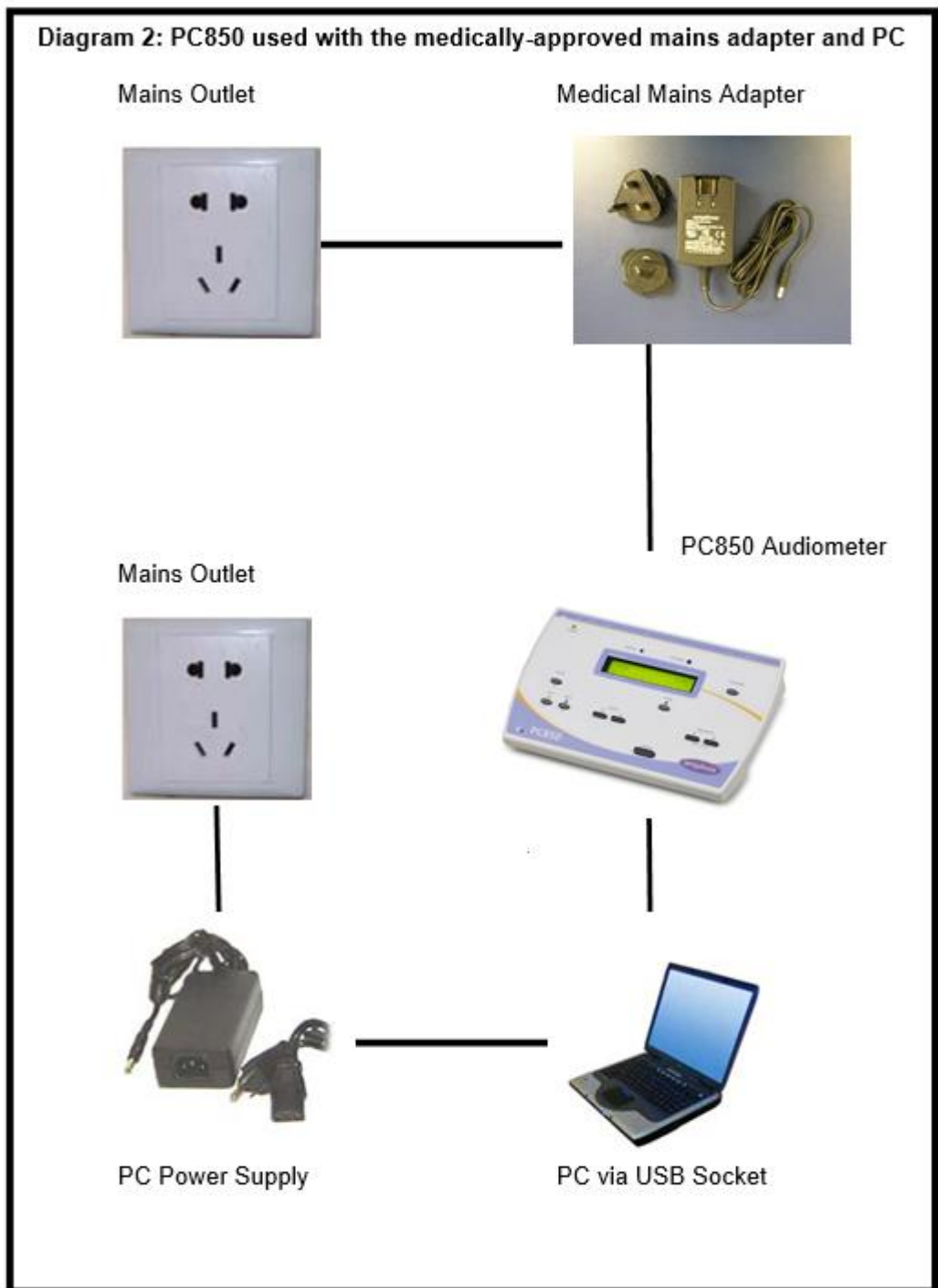
Mains Outlet

Medical Mains Adapter



PC850 Audiorr







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