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CA850 Series 5

Automatic Audiometer
Operating Manual

ABOUT THIS MANUAL

READ THIS OPERATING MANUAL BEFORE ATTEMPTING TO USE THE INSTRUMENT.

This manual is valid for the CA850 Series 5 (applies from firmware version 0V56 onwards - see Setup screen).

This product is manufactured by:
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1 INTRODUCTION

Thank you for purchasing the Amplivox CA850 Audiometer, an automatic screening instrument that incorporates a number of innovative features making it an ideal instrument for use in today's health care environment. It will give many years of reliable service if treated with care.

1.1 INTENDED APPLICATIONS

The CA850 Audiometer is designed for use by audiologists, general practitioners, hearing aid dispensers and child health professionals.

Capable of undertaking automatic tests based on the Hughson and Westlake method ("Computer Test") or the Bekesy method ("Bekesy Test"), it can also be used for manual audiometry, but it is not intended for use to determine the full extent and scope of a patient's hearing deficiency.

Audiometric and patient data may be printed using a connected printer, stored in the internal database, exported directly to a computer for use in applications such as the Amplivox Audibase database software, or stored on a USB memory device (e.g. USB memory stick) with the option of encrypted data, for later transfer to a computer.

Entering a patient's previous test details (e.g. from paper records) and then conducting a new test followed by printing and/or saving the results may be accomplished easily.

1.2 UNPACKING INSTRUCTIONS

Open the shipping carton and carefully remove all the equipment. Check against the delivery note that all the accessories ordered have been included with your audiometer. If anything is missing, please contact Amplivox Customer Support on +44(0)1865 880846, email: sales@amplivox.ltd.uk. If you have purchased from a distributor you should contact them directly.

Please retain the shipping carton and packing materials as the audiometer will need calibrating on an annual basis and should be returned in its original shipping carton.

1.3 WARRANTY CARD (UK CUSTOMERS ONLY)

Please complete the enclosed warranty registration card and return it to Amplivox Ltd to register your purchase. This will help us to deal with your enquires, and we will also be able to send you details of updates to your product and of new products and services.

1.4 STANDARD CONTENTS

CA850 audiometer	Carrying case
Audiometric headset	Audiogram paper (250 sheets)
Patient response switch	Operating manual
Mains AC adapter (see Section 2.3)	Calibration certificate
USB memory stick	

1.5 OPTIONAL ACCESSORIES

Audibase audiogram software	Booth leads
Audiocups (noise reducing headset)	ER75 Electro Acoustic Ear Simulator
Designated Printer (including USB cable)	Additional audiogram paper
USB cable (to connect to PC)	

(See Section 17 for details of part numbers etc)

2 IMPORTANT SAFETY INSTRUCTIONS

The CA850 instrument must be used only by practitioners qualified to perform audiometric tests. It is intended for use as a screening tool.

2.1 PRECAUTIONS

READ THIS OPERATING MANUAL BEFORE ATTEMPTING TO USE THE INSTRUMENT.

To comply with the standards IEC 60601-1 for safety and IEC 60601-1-2 for 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. Refer to Section 17 for the stock number of the adapter.**

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

The transducers supplied with the audiometer are specifically calibrated with it; if these transducers are changed calibration will be required.

Do not immerse the unit in any fluids. See Section 16 of this manual for the proper cleaning procedure for the instrument and its accessories.

Do not use the instrument in an oxygen-rich environment or in the presence of a flammable anaesthetic mixture or other flammable agents.

Do not drop or otherwise impact this instrument. If the instrument is dropped or damaged, return it to the manufacturer for repair and/or calibration. Do not use the instrument if any damage is suspected.

The instrument must be stored and used within the specified temperature, pressure and humidity ranges (see Section 13).

Do not attempt to open, modify or service the instrument. Return the instrument to the manufacturer or distributor for all repair and servicing requirements. Opening the instrument will void the warranty.

2.2 ELECTROMAGNETIC COMPATIBILITY (EMC) CONSIDERATIONS

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information in Appendix 2. This provides guidance on the electromagnetic environment in which to operate the instrument.

Portable and mobile radio-frequency (RF) communications equipment can affect medical electrical equipment. The instrument should not be used adjacent to or stacked with other equipment; if this is unavoidable the instrument should be observed to verify normal operation.

2.3 MAINS SUPPLY OPERATION

The audiometer is designed for continuous operation and is powered by a mains adapter which is supplied, and specified as part of the equipment. If a replacement is required, please contact Amplivox or your Amplivox distributor.

All other connections must be made **before** connecting the output lead from the adapter into the POWER input socket on the back of the audiometer. Switch on the mains supply - the indicator on the adapter and the POWER indicator on the audiometer will both illuminate green, showing that the instrument is ready for use.

The output from 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.

2.4 AUDIOMETER CONNECTIONS

The rear panel layout is shown below.
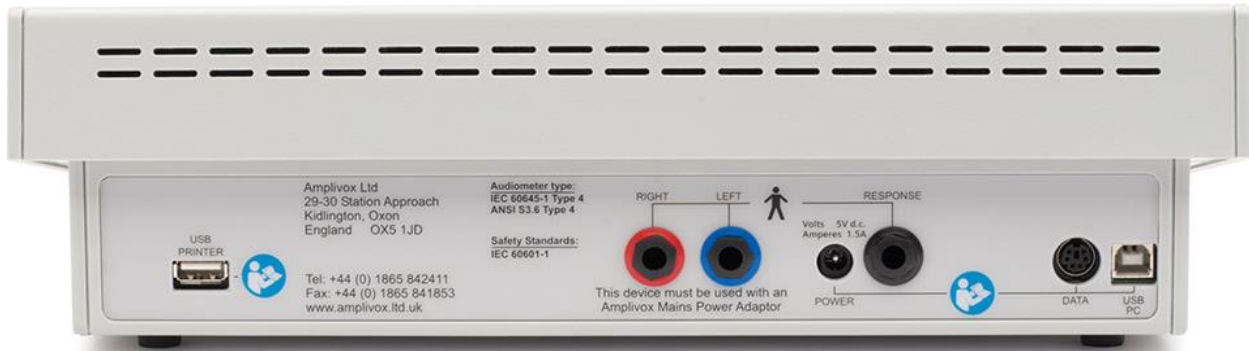
All the relevant accessory terminals and connections are labelled to ensure correct identification and connection as follows:

Socket Label	Socket Type	Colour Code	Connected Part	Notes
USB PRINTER	USB Connector Type A (Master)		Printer or USB Stick *	See 2.5
RIGHT	6.3mm jack	Red	Headset (right ear) *	
LEFT	6.3mm jack	Blue	Headset (left ear) *	
POWER	2.5mm power jack		Mains AC/DC Adapter *	
RESP	6.3mm jack	Black	Patient Response Switch *	
DATA	6 pin mini DIN		Reserved port; Amplivox diagnostic use only	No user access permitted
USB PC	USB Connector Type B (Slave)		Computer (via USB port)	See 2.6

The relevant part numbers are indicated in Section 17

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 CA850 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 3.

2.5 DATA TRANSFER TO A PRINTER OR USB DEVICE

Please refer to Appendix 3 for important information regarding the connection of non-medical electrical equipment to medical electrical equipment

The audiometer can be used with a designated printer (see Section 17) to provide a hard copy of the audiometric test data. The USB PRINTER socket is used for this function. See Sections 9.4.3 and 10.4.3 for further details.

Additionally, a USB memory device may be connected to the USB PRINTER socket to enable transfer of the entire patient database (e.g. for backup or importing into the Audibase application). See Section 10.4.7 for further information.

2.6   DATA TRANSFER TO A COMPUTER

Please refer to Appendix 3 for important information regarding the connection of non-medical electrical equipment to medical electrical equipment

The audiometer can be used with a PC to transfer patient data directly to the Audibase application. The USB PC socket is used for this function. You must use the designated USB cable which is available from Amplivox (see Section 12). See Section 9.4.2 for further details.

2.7   DISPOSAL INFORMATION

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

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

For any waste electrical units purchased from Amplivox that either:

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

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

B2B Compliance

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

Email: operations@b2bcompliance.org.uk

3 USING THE AUDIOMETER (OVERVIEW)

3.1 FRONT PANEL LAYOUT

The front panel layout is shown below.
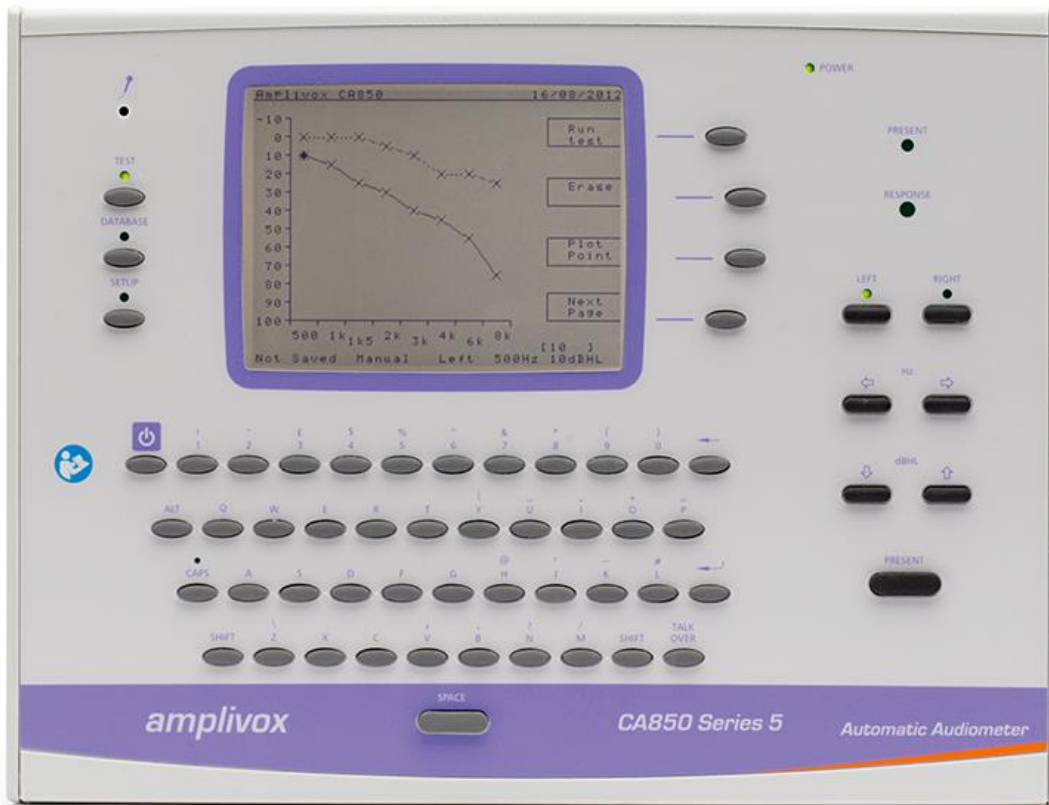
A full-size keyboard is available for data entry. Use the SHIFT or CAPS keys to type capital letters, and the ALT key to type the secondary symbols above the keys (£, $, # etc)

Four "softkeys" are provided to the right of the display, with functions as indicated adjacently on the display.

3.2 SWITCHING THE AUDIOMETER ON AND OFF

Press the ⏻ key (see front panel layout). No warm-up time is required, but the instrument will load and run a diagnostic check, which will take a few seconds to perform.

To switch off, press the ⏻ key again and then the 'Switch off' softkey to confirm. To cancel switch-off press the 'Cancel' softkey.

Note: This instrument is equipped with a real-time clock. Before use, ensure that the date & time are set to local values in order that test data and calibration status are correctly identified. Refer to Sections 11.2.13 & 11.2.14 for further details.

The clock is powered by an internal lithium cell battery which requires no maintenance but should be disposed of according to local regulations at the end of life of the instrument (see Section 2.7).

3.3   TESTING THE PATIENT RESPONSE SWITCH

Press the patient response switch and the indicator labelled RESPONSE (to the right of the display) will illuminate green.

3.4   USING THE TALKOVER FUNCTION

The CA850 is equipped with a Talkover function using the built in microphone to the left of the display. Press and hold the TALK OVER button to interrupt the test and route the operator's voice to the patient headset.

Adjust the volume level using the ⇧ and ⇩ keys while the button is pressed. The Talkover function is indicated at the top of the display along with the volume level while the TALK OVER button is held down.

Release the button when Talkover has been completed, and use the indicated softkeys to repeat the frequency that was being tested, move to the next frequency or cancel the test.

3.5   TEST TYPES AVAILABLE

Refer to Sections 4 & 5 for details of a typical test arrangement and a suggested test procedure with operational sequence. Refer also to the appropriate audiometric standards.

3.5.1 Manual Test

Hearing thresholds may be recorded manually using the Plot point function. When used this will record a threshold for the currently selected ear at the frequency and sound level indicated on the display (see Section 9.3.3).

3.5.2 Computer Test

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 11.2.9), the instrument will record a threshold at that particular frequency. The next test frequency is then used in the same way, and so on to complete the test.

3.5.3 Bekesy Test

This is 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 audiometer will calculate an average to the nearest dB and display this as the hearing threshold at that particular frequency. The next test frequency is then used in the same way, and so on to complete the test.

3.5.4 Single Frequency Test

The CA850 provides the facility to repeat an automatic 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.

3.5.5 Mixed Test

This is typically used when one of the automatic tests has been unable to yield a threshold at one or more frequencies. It is possible to use the alternative automatic test or a manual test (normally at just a few selected frequencies) to complete an audiogram by adding thresholds to those already established automatically. The resulting audiogram will be labelled as a 'Mixed' test.

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3.6   USING AUDIOMETRIC DATA

3.6.1 Viewing test results

Once a test has been completed the results are available to view graphically, on the Audiogram page (Section 9.3) or numerically, on the Test details page (Section 9.4). Note that hearing thresholds may be entered directly on the test details page if required. This is particularly useful for entering details of a previous test (e.g. from paper records) before performing a new test (see Section 9.5 for an example).

3.6.2 Saving test results

Audiometric and patient data may be saved in the internal database (Section 9.4.1). This is referenced by a patient number which should be uniquely assigned to each patient.

3.6.3 Exporting test results

Audiometric and patient data may be transferred to a computer running the Amplivox Audibase database software, or similar application (Section 9.4.2).

3.6.4 Printing test results

If required it is possible to print audiograms using an optional designated printer. Pre-printed audiogram paper is available for this purpose (Section 9.4.3).

3.6.5 Copying the database

The entire database may be copied on to a USB memory device with the option of data encryption for enhanced security. This is vital for data backup purposes, but it is also possible to quickly transfer the data to computer for use in Audibase (or similar application) by this means. Data may be transferred to the audiometer in the same way (e.g. for restoring data) again with the option of data encryption. See Section 10.4.7.

4 AUDIOMETRY PREPARATION

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

4.1 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 ISO6189.

4.2 TEST SYSTEM ARRANGEMENT
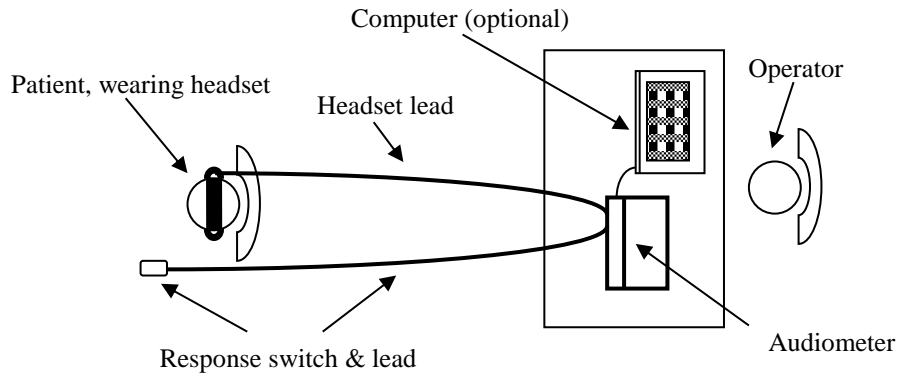
The schematic diagram above shows a typical example of the use of audiometric test equipment. The audiometer is located on the desk of a seated operator as shown.

The patient is seated in front of the desk facing away from the operator. The patient wears a headset (see Section 4.3) and responds to test stimuli by use of a hand-held switch which is also connected to the instrument.

4.3 HEADSET

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

4.4 PATIENT INSTRUCTIONS

The patient should be given the following instructions using the TALKOVER function:

- In the case of "Manual" or "Computer" testing, to press and release the response switch when a tone is heard
- In the case of "Bekesy" testing, to press the response switch when a series of pulses are heard and to release when the pulses are no longer heard

5   SEQUENCE OF OPERATION AND SUGGESTED TEST PROCEDURE

5.1   PATIENT DATA ENTRY

Press the TEST button and then the 'New Person' softkey to clear any existing patient data. Enter the required data as described in Section 9.2. The first line of data to be input is the patient number. As this is the reference number for all other data (including audiometric test results) **it is essential to use a unique patient number for each patient**.

Press the 'Next page' softkey to advance to the Audiogram page.

5.2   MANUAL TESTING

The following notes are for guidance only – refer also to ISO 8253.

Use the 'Erase' softkey and then the 'This test' softkey to clear any existing test data.

Use LEFT/RIGHT keys to select the ear to be tested – an indicator above the selected key will illuminate green. Use the ⇦ and ⇨ keys to change the frequency and the ⇧ and ⇩ keys to change the tone level. The values are indicated on the bottom line of the display. Press the PRESENT key to present a tone to the patient – an indicator above this key will illuminate green.

If the patient indicates that the tone has been heard, the level is decreased in 10dB steps until the patient cannot hear the tone. Then increase the level by 5dB until the tone has been heard. Repeat the process until there are 3 responses at the same level in 5 ascending series. Continue to the next frequency to be tested.

Press the 'Plot point' softkey to record the threshold, and then repeat the above steps at each required frequency for both ears.

5.3   BEKESY AND COMPUTER TESTING

If necessary, switch between these test methods as described in Section 11.2.3.

Press the 'Run Test' softkey and then press a softkey to specify a test on both ears, the currently selected ear or a single test using the currently selected ear & frequency combination.

For a both-ear or a single-ear test the option of running a familiarisation routine prior to the test is provided. The message "Do you want to familiarise?" will appear at the top of the display. (Familiarisation is not available for a single frequency test.)

a)   Press 'Yes' to run the familiarisation routine prior to the test, or

b)   Press 'No' to run the test without familiarisation, or

c)   Press 'Left ear' to run the test with familiarisation only in the left ear (this option is only available for a both-ear test).

After successful completion of the familiarisation routine the test will start automatically and will be performed according to the test criteria and options selected (Section 11.2).

While the test is in progress the option to pause the test is available - press the 'Pause' softkey. The Talkover function may then be used if required and the test may be resumed by using the indicated softkeys to repeat the frequency that was being tested, move to the next frequency or cancel the test.

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.

In Computer mode the time 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.

At the end of the test a status message is shown at the top of the display. This will indicate a successful test, or that an error had occurred, for example if a threshold could not be determined at a particular frequency.

Refer to Section 6 for information about errors that may occur during testing.

5.4   MIXED MODE TESTING

To add a test threshold to an audiogram (for example if an automatic test at a particular frequency has been unsuccessful) the alternative type of automatic test at a single frequency or the manual test mode as described in Sections 5.2 & 5.3 may be used. The audiometer display will change to "Mixed".

In Bekesy & Computer test modes, if the manual test keys are operated the audiometer will assume a "mixed" test mode has been entered and will adjust the display accordingly.

To ensure exit from the "mixed" mode of testing, use "Erase > This test" prior to starting a new Computer/Bekesy test (see Section 9.3.2).

5.5   REVIEW RESULTS

Press the 'Next page' softkey to advance to the Test details page. The hearing thresholds and other associated data may be reviewed and modified if necessary, and then saved in the internal database, printed or exported to a computer (see Section 9.4).

5.6   OPERATIONAL DIAGRAM

The above operational steps are presented in a summary chart (see Section 7).

5.7   OPTIONS FOR DATABASE MANAGEMENT AND CONTROLLING THE TEST

For details for these functions refer to Sections 10 & 11.

5.8   ENTERING PREVIOUS DATA AND PERFORMING A NEW TEST

As this is a very common requirement, an example of performing this task quickly and easily using the CA850 Audiometer is provided in Section 9.5.

6 ERROR HANDLING & TROUBLESHOOTING

6.1 NO RESPONSE FROM PATIENT

If the patient does not operate the response switch and the maximum output level is reached, the test at that particular frequency will be repeated according to the 'Retries' setting (see Section 11.2.4).

If a response is still not made then the message "No response!" is displayed at the top of the screen. The test will then be paused with options to retry the same frequency, skip to the next frequency or cancel the test. If the test is cancelled then any thresholds that have been established will be retained.

6.2 CONTINUAL RESPONSE FROM PATIENT

If the patient holds the response switch on continuously and the minimum output level is reached, the test at that particular frequency will be repeated according to the 'Retries' setting (see Section 11.2.4).

If the response switch is still held then the message "Response not released!" is displayed at the top of the screen. The test will then be paused with options to retry the same frequency, skip to the next frequency or cancel the test. If the test is cancelled then any thresholds that have been established will be retained.

6.3 INCONSISTENT RESPONSE FROM PATIENT

If the patient does not respond in a consistent manner and a hearing threshold cannot be established, the test at that particular frequency will be repeated according to the 'Retries' setting (see Section 11.2.4).

If the response is still inconsistent then the message "Test failed!" (Bekesy test) or "Frequency failed!" (Computer test) is displayed at the top of the screen. The test will then be paused with options to retry the same frequency, skip to the next frequency or cancel the test.

If the test is cancelled then any thresholds that have been established will be retained.

If the next frequency is chosen the test will continue, but at the end of the test the message "Test completed with errors" is displayed at the top of the screen.

6.4 ERRORS IN TEST SEQUENCE

If one or more thresholds cannot be recorded for other reasons the message "Test completed with errors" is displayed at the top of the screen.

The operator may then re-test the patient at specific frequencies that were problematic using the Mixed test mode if appropriate (Section 5.4).

7 OPERATIONAL DIAGRAM

Amplivox CA850 Series 5 Audiometer Operating Guide

Power on

TEST button

Patient details

PATIENT DETAILS
Patient number
Surname
Forename
Position
Department
Company
Date of birth
Sex (M/F)
Address

Next page

Auto test   **Manual test**

Erase   Run test   Plot point(s)

What do you want to test?

- This point
- This ear
- This test
- Cancel

- Both ears
- Single ear
- Single frequency
- Cancel

Familiarise

Familiarise before test?

- Yes
- No
- Left Ear
- Cancel

Next page

Results

- Save test
- Data Export
- Print test

Next page

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8 AUDIOMETER OPERATING MODES

The CA850 Audiometer has three operating modes, TEST, DATABASE and SETUP. Select one of these modes by pressing the appropriate key at the left hand side of the display. The indicator above the key will illuminate green. In order to perform an audiometric test, the CA850 Audiometer must be in the TEST mode.

When first powered-up the audiometer enters TEST mode and displays the Audiogram page (see Section 9.3). This is to allow the operator to perform the checks necessary to confirm that the audiometer is operating correctly prior to carrying out tests on a patient.

When TEST mode is selected at any subsequent time the Patient details page (see Section 9.2) is displayed in anticipation of the requirement to enter patient-specific data prior to performing a test on that patient.

The following sections describe these operating modes and the function of controls.

9 TEST MODE

9.1 OVERVIEW

There are three pages available in the TEST mode which may be selected in turn by pressing the 'Next Page' softkey.

Note: As entering previous patient data and then immediately running a new test is a very common requirement, examples of performing this task quickly and easily using the CA850 Audiometer are provided in Sections 9.5 & 10.5.

9.2 PATIENT DETAILS PAGE

To enter information about a patient the patient details page is used (see below).

```
Amplivox CA850                    02/08/2012
Patient No 12345
Surname     Bloggs              ┌─────────┐
Forename    Frederic            │ New     │
Position    Engineer            │ Person  │
Department  Development         └─────────┘
Company     Amplivox
Birth Date  01/01/1970
Sex (M/F)   M

Address 1   Units 29-30
Address 2   Station Approach
Address 3   Kidlington
Address 4   Oxford
Address 5   Oxfordshire
Address 6   [OX5 1JD_           ]
                                ┌─────────┐
                                │ Next    │
                                │ Page..  │
                                └─────────┘

Patient has 1 Records
```

Patient details are added or modified by using the ⇧ and ⇩ keys to select the required line and then using the keyboard to enter the details. The back-arrow key will delete characters. A mixture of letters and numbers is allowed in the data but **please note that it is essential to use a unique patient number for each patient**.

SOFTKEY OPTIONS

9.2.1 New person

To enter the details of a new patient the 'New person' softkey <u>must</u> be selected to ensure all details of the previous patient are erased.
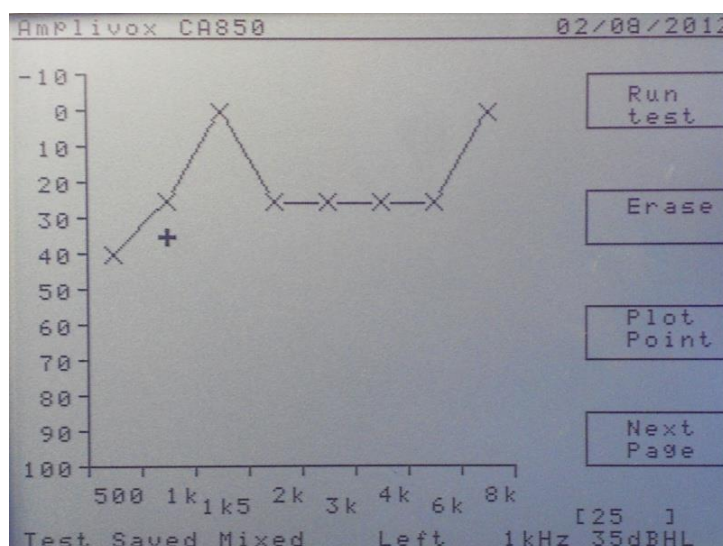
9.2.2 Next Page

Press the 'Next Page' softkey to access the following page within the TEST mode.

9.3   AUDIOGRAM PAGE

To perform an audiometric test the audiogram page is used (see below).

SOFTKEY OPTIONS

9.3.1 Run Test

Press the 'Run test' softkey to initiate a test sequence. Two further options require selection – the selection of the ear(s) to test and familiarisation (if required)

9.3.1.1 Both ears

Press the 'Both ears' softkey to ensure that both the left and right ears will be tested.

9.3.1.2 This ear

Press the 'This ear' softkey to perform the test on the specified ear (the indicator above the LEFT or RIGHT key will illuminate).

9.3.1.3 Single frequency

Press the 'Single freq' softkey to perform the test at the specified frequency (as indicated on the display) on the specified ear (the indicator above the LEFT or RIGHT key will illuminate).

9.3.1.4 Cancel

Pressing the 'Cancel' softkey will cancel the 'Run Test' function.

9.3.1.5 Familiarise?

When the test selection has been made the option to run a familiarisation routine is presented. This allows the patient to make responses to the test stimuli prior to the actual test with the operator monitoring these responses to ensure consistency. For a test on both ears the option to use just the left ear for familiarisation is available.

9.3.2 Erase

Press the 'Erase' softkey to delete the specified data as defined below. (Note that this function applies to current hearing thresholds only and does not affect the patient details entered or any data held within the internal database.)

9.3.2.1 This point

Press the 'This point' softkey to erase the hearing threshold at the indicated frequency.

9.3.2.2 This ear

Press the 'This ear' softkey to delete all hearing thresholds for the selected ear.

9.3.2.3 This test

Press the 'This test' softkey to delete hearing thresholds.

9.3.2.4 Cancel

Press the 'Cancel' softkey to cancel the erase selection and return to the audiogram page.

9.3.3 Plot point

Pressing the 'Plot point' softkey will plot a hearing threshold for the specified ear, frequency and sound level. This feature is used when performing manual audiometry in conjunction with the ⇦ and ⇨ keys (to change frequency) and the ⇧ and ⇩ keys (to change level).

9.3.4 Next Page

Press the 'Next Page' softkey to access the following page within the TEST mode.

9.4   TEST DETAILS PAGE

The Test Details page is normally used to view test details numerically. However it is possible to enter data directly on this page, for example the examiner, threshold values and the test date. Use the ⇧ and ⇩ keys to select the required data field and enter data from the keyboard. Thresholds are always entered in the 'Current' columns (use 'ALT' 'I' to enter a negative value). If specific frequencies have been omitted from the test (see Section 11.2.6) the ↵ key may be used to skip over these data fields.

Refer to Section 9.5 for details of how to enter patient details and previous data, and then immediately perform a new test.

SOFTKEY OPTIONS

9.4.1 Save test

Press the 'Save test' softkey to save the test record within the internal database. If a record with the same patient number and date already exists, the operator will be prompted either to create a new record or overwrite the existing one. If required, the database functions may be used to confirm the save operation (see Section 10).

9.4.2 Data export

Press the 'Data export' softkey to transfer the displayed test record to Audibase (or other computer-based application). Note that the CA850 needs to be connected to a computer with Audibase correctly configured to allow this (refer to the Audibase documentation). Data is transferred via the 'USB PC' socket.

9.4.3 Print

Press the 'Print' softkey to print the audiogram on a printer connected to 'USB PRINTER' socket. Pre-printed audiogram paper is available for this purpose. **Note: Printer initiation can take several seconds - do not press the 'Print' softkey again until the printout has been generated.**

9.4.4 Next Page

Press the 'Next Page' softkey to access the following page within the TEST mode.

9.5 EXAMPLE – ENTERING PREVIOUS PATIENT & AUDIOGRAM DETAILS AND RE-TESTING

The procedure below outlines the steps needed to enter the details of a new patient and a previous test (e.g. from paper records) and then immediately perform a new test.

a) Press the TEST button to enter TEST mode

b) Erase details of the current patient (press the 'New Person' softkey)

c) Enter the patient details manually on the Patient Details page ensuring that a unique patient number is assigned (refer to Section 9.2 if necessary)

d) Press the 'Next page' softkey to advance to the Audiogram page

e) Erase details of any current test (press the 'Erase' and then 'This test' softkeys)

f) Press the 'Next page' softkey to advance to the Test Details page

g) Enter the examiner (if necessary), and then the threshold values from the previous test (refer to Section 9.4 if necessary); **these are entered in the "Current" columns**

Please pay particular attention to the following steps

h) Once the final threshold has been entered (for example Right ear, 8kHz) pressing ⇩ or ↵ will move the cursor into the 'Test date' field (see below)

i) Enter the date of the previous test with care; if a mistake is made use ← to correct it, or if the cursor has been moved away from this field use the ⇧ and ⇩ keys to reposition it in the 'Test date' field and re-enter the date of the previous test

j) Carefully check that all of the information displayed is correct and then press the 'Save test' softkey; the following will then occur:

  • The record will be saved in the internal database with the previous test date as entered - for example this might be considered 'baseline' data; the message 'Test Saved' will be displayed briefly before reverting to 'Not saved'

- The threshold values will be moved into the 'Previous' columns (see below) and also displayed as previous data on the Audiogram page

- The patient details will be retained in the audiometer

- The Test date will be set to today's data in anticipation of an immediate re-test

k) The audiometer may then be used to carry out a new test using the same patient details while retaining the previous threshold values, e.g. for categorisation purposes (Section 5)

l) The new test would then normally be saved in the internal database as a new record for that patient (use the 'Save test' softkey)

Notes

- If the today's date is entered at step i) the record will be simply saved in the database as a new record with today's date and the data will NOT transfer to the Previous column

- If incorrect data has been entered at step g) then the record may be erased using the database functions (see Section 10.4.8) and the above steps may be repeated

- The re-test at step k) may be carried out as described in Section 5, and all modes of testing may be used (Computer, Bekesy, Mixed, Manual, or Single Frequency). The test may be cancelled or repeated as necessary, but do not use the 'Erase' softkey before saving the re-test (unless the re-test data is not required).

- The previous data saved at step j) is always retained in the database, so if any difficulties occur with the re-test process as described above the previous data may be loaded and a re-test carried out as described below in Section 10.5.

10 DATABASE MODE

10.1 DATABASE OVERVIEW

The CA850 has an internal database which is capable of storing up to 2000 patient records (consisting of the patient details plus audiometric test data). The data is held in non-volatile memory and is thus retained when the audiometer is powered down.

However, as with all computer-based systems of this nature it is vital that the database is regularly backed up for security. Refer to Section 10.4.7 for details of how to perform this operation.

For additional security, access to the database is possible only by entering a five-digit security passcode which is unique to each audiometer.

10.2 DATABASE SECURITY PAGE

The Database is accessed by pressing the DATABASE button on the keyboard. The database security page is then displayed as shown below.
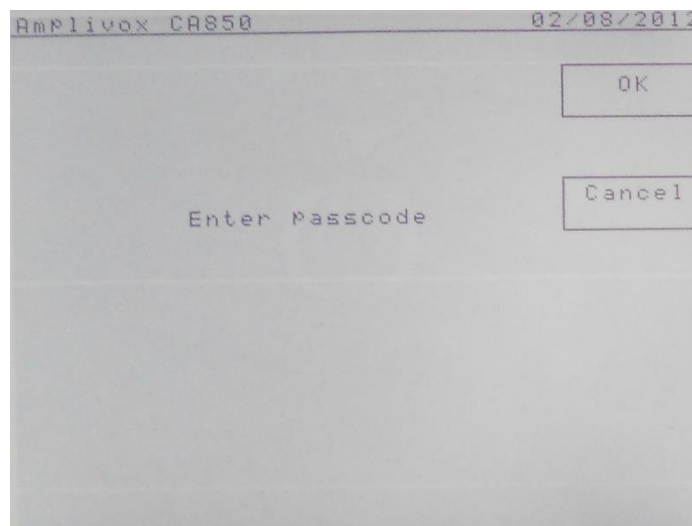
Use the keyboard to enter the passcode supplied with the audiometer and Press the 'OK' softkey. Note: For security the passcode is displayed as a series of asterisks (*).

If an incorrect passcode has been entered the security page is displayed again.

Alternatively press the 'Cancel' softkey to return to TEST mode.

10.3 DATABASE INITIAL PAGE

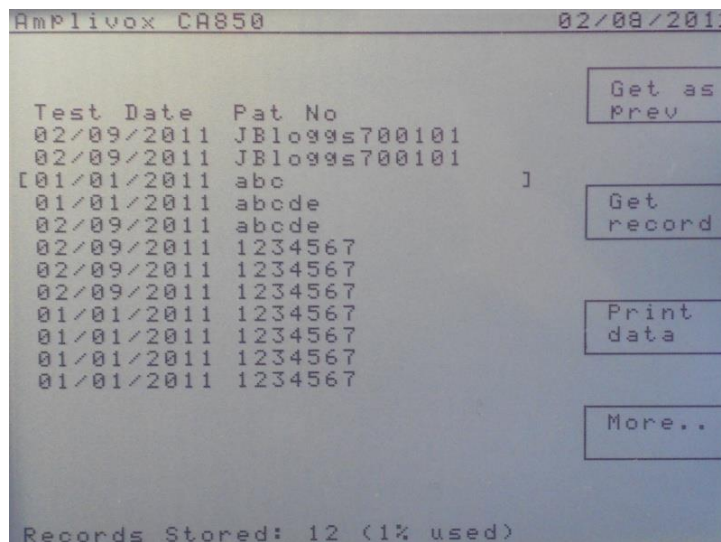When the correct passcode has been entered the database initial page is displayed as shown below. A cursor consisting of square brackets identifies a particular patient record, and this may be moved through the database using the ⇧ and ⇩ keys.

10.4 SOFTKEY OPTIONS

There are three pages available in the DATABASE mode which may be selected in turn by pressing the 'More..' softkey. The menu options are arranged over these three pages and are described below.

10.4.1   Get as prev

If it is required to compare a new test with a previous test this may be carried out by moving the cursor to the required "previous" test record and pressing the 'Get as prev' softkey. This will retrieve the previous record from the internal database and return operation to TEST mode, allowing a new test to be carried out without having to re-enter the patient details. This feature is of use when performing serial audiometry as it allows print out of both the new and previous tests on a single audiogram. (See also the example in Section 10.5)

The original record in the internal database is not changed in any way.

10.4.2   Get record

Having moved the cursor to the required test record, pressing the 'Get record' softkey will retrieve the record from the internal database and return operation to TEST mode. This feature is of use if it is required to examine a particular patient record, print the associated audiogram or transfer the data to a computer.

The original record in the internal database is not affected in any way.

10.4.3   Print data

Pressing the 'Print data' softkey will allow printing of test data in one of the formats described below. A brief message is displayed when requesting a print function. **Note: Printer initiation can take several seconds - do not press the 'Print data' softkey again until the printout has been generated.**

10.4.3.1 Print Summary

This function will print a summary list of records according to the selected filter requirements (see Section 10.4.4). Plain A4 paper should be used for this function.

10.4.3.2 Print details

This function will print extended details of records according to the selected filter requirements. Plain A4 paper should be used for this function.

10.4.3.3 Print record

This function will print an audiogram of a test record - use the ⇧ and ⇩ keys to make the selection. Pre-printed audiogram paper is available for this purpose.

10.4.3.4 Cancel

This function returns control to the database overview page.

10.4.4   Edit filter

The edit filter function enables the user to specify the particular parameters that are used to display data records.

In general, the filter function enables the user to retrieve record(s) according to specific search requirements. The database fields, which facilitate a filter search, are as follows:-

> Patient number
>
> Surname
>
> Forename
>
> Position
>
> Department
>
> Company
>
> Test date before
>
> Test date after

The user can select any of the above database fields with the use of the ⇦ and ⇨ keys and the apply filter key and then edit the specified filter such that only the record(s) within the internal database which match the search criteria are identified.

For example to select all the patient records identified with surname "Smith", with the filter keys shown on the database page, use the ⇦ and ⇨ keys until the required database field (surname) is displayed adjacent to the test date heading. Press 'Apply filter' followed by 'Edit filter'. The database field and the filter required parameter should now be displayed at the top of the screen. Enter/amend the parameter within the brackets so that that the parameter matches the requirement, i.e. SMITH. Press the 'OK' softkey. The records within the internal database that are identified as Smith would now be listed.

10.4.5   Apply filter

The Apply filter function allows the user to specify which database field is to be used as the filter. To select a database field use the ⇦ and ⇨ keys until the required field is displayed adjacent to the test date on the database display and press the 'Apply filter' softkey. The selected filter field will now be displayed at the top of the display.

10.4.6   Remove filter

This function enables the user to clear the filter and list all records within the internal database.

10.4.7   Import/ Export

This function allows the transfer of test records between the internal database and an external computer via a USB memory device.

For enhanced security it is possible to encrypt the data. A user-selectable 16-digit password is used for this encryption, and this same password must be used to decrypt the data on the computer or to import encrypted data into the audiometer. Thus a note must be made of the user-selectable password which should be stored securely.

If the user-selectable password is lost then the data will no longer be accessible. But it is, of course, possible to import or export data <u>without</u> encryption.

Refer to Appendix 1 for more details of software that may be used on a computer to encrypt or decrypt data files.

The following controls are used for the import/export functions.

10.4.7.1 USB Import

This function will transfer test records to the database from a USB memory device (connected to the 'USB PRINTER' socket). Please allow the USB memory device to initialise prior to selecting this command (up to 20 seconds is suggested) and ensure that the activity light on the USB memory device is extinguished before removing it.

There must be a single database file on the USB memory device and this file must be named 'exportdata.csv' (or 'exportdata.cry' if encryption is used). If an encrypted data file is being imported and the password is incorrect then the message "0 records read" will be displayed briefly.

10.4.7.2 USB Export

This function will transfer test records from the database to a USB memory device (connected to the 'USB PRINTER' socket). Please allow the USB memory device to initialise prior to selecting this command (up to 20 seconds is suggested) and ensure that the activity light on the USB memory device is extinguished before removing it.

An exported database will be named 'exportdata.csv' (or 'exportdata.cry' if encryption is used). This filename may be changed to something more meaningful, (for example 'JSmithLtdPatients13thMarch2007.csv') but if it is to be imported back to the audiometer (for example if it was a backup that needs to be restored) then the filename must be changed back to that specified above.

10.4.7.3 Set Password

This function is used to enter a 16-character alphanumeric password to enable USB encryption for both import and export functionality. Press the 'OK' softkey when complete.

If a 16-character password is entered and USB Export is then performed, the exported database will **always** be named 'exportdata.cry' and will be associated with this password.

Similarly if a 16-character password is entered, USB import will **always** search for a file named 'exportdata.cry' and attempt to decrypt it using this password.

Once set, the password remains valid and will be used to create an encrypted file for export to the USB memory device. This file can then be decrypted on a PC into CSV format, for example by using the freeware application available from Amplivox (see Appendix 1) and entering the 16-digit password that was used to encrypt the file.

If a data file that was encrypted on a computer (for example by using the freeware application) is to be imported, the 16-digit password that was used for encryption must be entered into the CA850 before the import is performed. The CA 850 will then decrypt the database during import. This password will then remain valid until changed or deleted.

The password may be changed at any time simply by deleting the characters, entering a new password and pressing the 'OK' softkey. The password may be deleted (thus removing the encryption function) by deleting all 16 characters and then pressing the 'OK' softkey.

The password must have 16-characters for the encryption programme to operate. If fewer than 16-characters are used then USB Export will generate random data and USB Import will be unable to read the data file.

If the user-selectable password is lost then the data will no longer be accessible.

10.4.7.4 Cancel

Pressing this softkey returns to the previous page.

10.4.8   Erase

Pressing the 'Erase' softkey will allow one or more data records to be deleted as described below.

10.4.8.1 This record

Pressing this softkey will delete the selected test record (use the ⇧ and ⇩ keys).

10.4.8.2 Filter items

Pressing this softkey will delete the filtered test records. Further confirmation is required.

10.4.8.3 All items

Pressing this softkey will **erase the entire internal database**. Further confirmation is required.

10.4.7.4 Cancel

Pressing this softkey returns to the previous page.

10.5 EXAMPLE – LOADING A RECORD FROM THE DATABASE AS A PREVIOUS TEST FOR RE-TESTING

The procedure below outlines the steps needed to load an existing record from the database into the audiometer to use as a baseline audiogram for a new test

a) In TEST mode erase details of the current patient (from the Patient Details page press 'New Person')

b) In TEST mode erase details of any current test (from the Audiogram page press 'Erase' and then 'This test')

c) In DATABASE mode select the required previous record of the patient using the ⇧ and ⇩ keys (refer to Section 10.3 if necessary)

d) Press 'Get as prev' to retrieve the patient's previous record and load it into the Test pages as previous data (refer to Section 10.4.1 if necessary)

e) Carry out a new test as described in Section 5 (the new thresholds will be displayed as 'Current' values on the Test Details page)

f) The new test would then normally be saved in the internal database as a new record for that patient (use the 'Save test' softkey)

11 SETUP MODE

11.1 OVERVIEW

SETUP mode allows options to be set that control an automatic test and other settings to be made. Press the SETUP button on the keyboard and the following page is displayed.
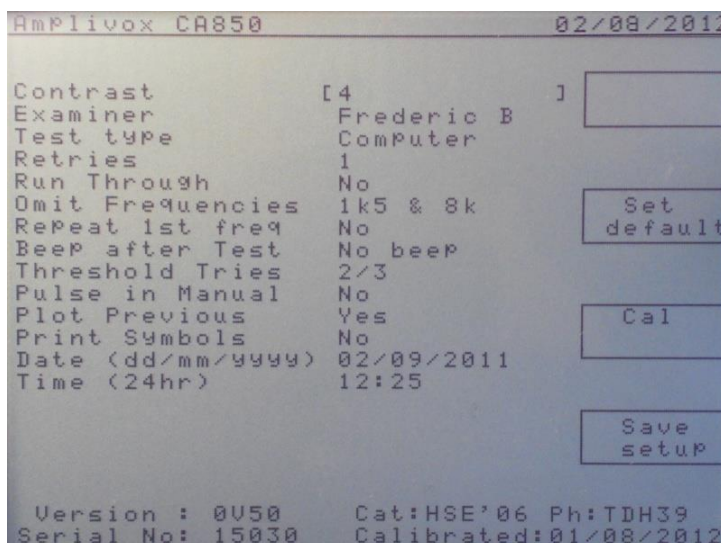
11.2 SETUP OPTIONS

A cursor consisting of square brackets identifies a particular setup item, and this may be moved through the items using the ⇧ and ⇩ keys. The ⇦ and ⇨ keys are then used to cycle through the available options (except where noted below).

11.2.1 Contrast

This function adjusts the display contrast.

11.2.2 Examiner

For purposes of good record keeping, the examiner's name is stored with each record in the database, and also printed with the audiogram. Use the keyboard to enter the examiner's name.

11.2.3 Test Type

This command allows the user to switch between Bekesy and Computer test as the default automatic test routine.

11.2.4 Retries

If a hearing threshold level is not established in Bekesy or Computer test mode this option will enable an automatic retest at the failed frequency prior to the continuation of the audiometric test. Select 0 to 3 retries.

11.2.5 Run Through

If Run Through is set to 'Yes', the Bekesy and Computer tests will proceed from start to finish whether or not a threshold level has been established for a particular frequency.

If Run Through is set to 'No' and the patient does not establish a threshold, the operator will be alerted. At this stage the operator may wish to further instruct the patient using the Talkover facility before retesting that particular frequency.

11.2.6 Omit 1.5kHz and/or 8kHz

Select the option to suit specific screening requirements. Note: to aid data entry in the Test details page, use the ↵ key to skip over the omitted fields. To enter values in the omitted fields if required use the ⇧ and ⇩ keys. See Section 9.4.

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11.2.7 Repeat 1st frequency

This function enables an automatic retest of the first test frequency (1kHz) when running a Computer test. This may be used for correlation of patient responses.

11.2.8 Beep after Test

If this option is set to 'Beep', a short audible tone is generated to alert the operator that the test has finished. If this option is set to 'Long beep', the audible tone continues for approximately 10 seconds. Any key (apart from ALT, CAPS and SHIFT) will cancel the tone.

11.2.9 Threshold Tries

When Computer test mode is used, this option allows the threshold pass criteria at any particular frequency to be set at either 2 out of 3 or 3 out of 5 consistent responses.

11.2.10 Pulse in Manual

This option is used in manual operation. When set to 'Yes' a series of tone pulses is presented when the PRESENT key is pressed; when set to 'No' the tone is continuous.

11.2.11 Plot Previous

When set to 'Yes', the results of any previous test are plotted on the Audiogram page; when set to 'No', these results are not plotted, although they are still presented on the Test Details page.

11.2.12 Print Symbols

This function allows the operator to choose the style of the audiogram printout when 'Print' is selected in the Test Details page. When set to 'No' a graphical trace is printed which shows all tone presents, patient responses and thresholds; when set to 'Yes' the thresholds only are printed ("-x-" for a left ear threshold and "-o-" for a right ear threshold).

11.2.13 Date

If incorrect enter the current date using the keyboard.

11.2.14 Time

If incorrect enter the current time using the keyboard.

11.3 SOFTKEY OPTIONS

11.3.1 Set defaults

Pressing this softkey will reconfigure the set up options to factory settings.

11.3.2 Cal

This softkey is used when calibrating the audiometer. There is no access for the operator.

11.3.3 Save Set-up

Pressing this softkey will save the changes made in SETUP mode such that all subsequent tests are performed in accordance with the new settings.

12 HEARING CATEGORISATION

Only suitably qualified practitioners should undertake the assessment of audiometric data produced by this instrument.

As an aid to this assessment the audiometer produces hearing categorisations once hearing thresholds (based on Manual, Computer or Bekesy testing) and other patient data are established.

Such hearing categorisations include those derived from the UK Health & Safety Executive (HSE) scheme incorporated into the UK Control of Noise at Work Regulations 2005 (L108). These regulations define 5 categories of hearing as follows:

- Category 1 - acceptable hearing ability

- Category 2 - mild hearing impairment

- Category 3 - poor hearing

- Category 4 - rapid hearing loss (based on a previous test within 3 years)

- Category U - unilateral hearing loss (based on a comparison of left & right ears)

Each ear of a patient is placed into one (or more) of the above categories based on the hearing threshold results at a number of frequencies and the age and sex of the patient. Based on the resulting categorisation, a patient may be warned about hearing ability or referred for further medical advice. For detail of the derivation and application of these categories the user/operator is referred to the regulations.

As long as the required data is available (e.g. hearing thresholds have been established at the required frequencies) the CA850 audiometer will perform this calculation and present the hearing categorisation results. These are displayed at the bottom of the Test Details page (see Section 9.4) and are saved, printed or transferred to computer with other data.

The category identifier (1, 2, 3, 4 and 'U') will be followed by an associated coding which shows which part of the audiogram data caused the category identifier to be assigned. These codings are:

- L (left)
- R (right)
- B (both)
- no data (previous test data is not available)
- Age < 18 (HSE tables do not cover this age range)
- Data incomplete (required threshold data not available)

Examples of categorisations presented on the CA850 audiometer:

- 1
- 1 4-no data U Age < 18
- 2R 3L 4R U
- 2B 4R U
- 3B 4-no data U
- 2R 3L 4L Age < 18
- 2R 3L 4-no data U Age < 18
- Data incomplete
- No sex chosen
- No sex chosen Age under 18
- Invalid patient age (e.g. if date of birth age was not provided or is inconsistent)

As shown above, to differentiate each part of the categorisation, there is a space between category identifiers.

13 TECHNICAL SPECIFICATION

13.1 INPUT/OUTPUT

a) Power Input   5V DC, 1.5Amp; 2.5mm barrel-type socket
b) Left and Right Earphone   6.3mm Jack Socket
c) Patient Response Switch   6.3mm Jack Socket
d) Serial Interfaces   industry-standard USB
e) Diagnostic Interface (Data)   reserved port (no user access permitted)
f) Maximum Voltage at any output 12V peak

13.2 AUDIOMETRIC

a) Audiometer type   Type 4 (IEC 60645-1)
b) Frequencies (air conduction)   500 (Hz), 1, 1.5, 2, 3, 4, 6 & 8 (kHz)
c) Frequency Accuracy   <1%
d) Distortion: <2%
e) Output Level Range   -10dBHL to 95dBHL (all frequencies)
f) Manual test Output Level Steps 5dB
g) Bekesy test Output Level Steps 2.5dB
h) Computer test Output Level Steps 5dB
i) Output Level Accuracy   Within 3dB
j) Rate of change of SPL   Approx 5 dB/sec in Bekesy test mode
k) Output transducer & ref. level DD45: ISO 389-1, Table 2
l) Tone present   single, pulsed in manual mode
m) Headset static force   4.5N

13.3 EARPHONE SOUND ATTENUATION CHARACTERISTICS

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

13.4 OTHER FEATURES

a) Keyboard   Standard layout for data entry
b) Communication   Talkover via integral microphone
c) Built-in Graphics LCD Display 115mm wide x 86mm high display area
d) Real Time Clock   Battery backed
e) Internal Database   2,000 records including name and address.

13.5 PHYSICAL & ENVIRONMENTAL

a) Dimensions (Main Unit)   330mm wide, 250mm deep, 98mm high
b) Weight   1.6kg
c) Operating Temp/Humidity   +15°C to +35°C; 30% to 90% (non-condensing)
d) Transport/Storage Temp/Humidity -20°C to +70°C; 10% to 90% (non-condensing)
e) Pressure (Operating)   700hPa to 1060hPa
f) Pressure (Transport/Storage) 500hPa to 1060hPa
g) Power Requirement   100-240V, 50/60Hz, 0.25A (via mains adapter)
h) Paper Requirement   Pre-printed single sheets (A5), plain (A4)

13.6 EQUIPMENT CLASSIFICATION

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 CA850 audiometer is classified as a Class IIa device under Annex IX of the EU Medical Devices Directive. It is intended for transient use as a screening audiometer instrument.

14 PERFORMANCE STANDARDS

The CA850 Audiometer complies with the relevant parts of following standards:

a) IEC 60601-1 (plus UL, CSA & EN deviations): (Safety and Essential Performance)

b) IEC 60601-1-2: (Electromagnetic Compatibility)

c) BS/EN/IEC 60645-1: (Pure-tone Audiometers)

15 SYMBOLS

The following symbols appear on the audiometer or mains adapter:

Definition: Refer to instruction manual (mandatory)

Definition: Type B applied part – an applied part providing protection against electric shock, particularly regarding allowable patient leakage current and patient auxiliary current.

Definition: The output from the Mains AC adaptor is Direct Current
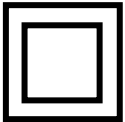
The applied parts are the left & right earphones, patient response switch and the associated cables.

Definition: Class II equipment – equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions.

16 ROUTINE MAINTENANCE

16.1 AUDIOMETER MAINTENANCE

The CA850 audiometer is a precision instrument. Handle it carefully in order to ensure its continued accuracy and service. When cleaning the instrument, first disconnect it from the mains supply. Use a soft cloth and mild detergent to clean the instrument panel when required. Refer to ISO 8253-1 for additional guidance.

16.2 TRANSDUCER MAINTENANCE

Before use check the transducer 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 (see Section 17).

Handle the audiometric headset and other accessories with care. For parts that are in direct contact with the patient it is recommended that the parts 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".

During the cleaning process do not allow moisture to enter the earphone or other parts of the instrument.

16.3 MAINS ADAPTER MAINTENANCE

Before use check the mains AC adaptor for signs of wear and/or damage. If any is found replace the adapter immediately by contacting Amplivox or your Amplivox distributor. Refer to Section 17 for approved part numbers.

DO NOT USE ANY OTHER MAINS ADAPTOR WITH THIS INSTRUMENT

16.4 CALIBRATION AND REPAIR OF THE INSTRUMENT

Amplivox recommend that this audiometer should be calibrated on an annual basis. Please contact Amplivox or the designated distributor for details of calibration services. Refer to ISO 8253-1 for additional guidance.

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

the instrument for shipping, please use the original shipping carton and packing materials. Please also ensure that the headset leads are not wrapped around the headband of the headset.

16.5 GUARANTEE

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

Important Note:

The following exceptions apply:

Earphones and other transducers may go out of calibration owing to rough handling or impact (dropping). The life of leads is also dependent upon conditions of use. These parts are only guaranteed against faulty materials or manufacture.

16.6 DISPOSAL OF INTERNAL BATTERY

At the end of the life of a CA 850 audiometer, the internal battery needs to be removed and disposed of separately.

This operation must be carried out by a competent technician.

We recommend that you contact your Local Government Authority for advice on how to dispose of the rest of the CA850 separately through a route for the recycling of electronic components. Within the EU refer to Section 2.7.

17 ORDERING CONSUMABLES, PARTS AND ACCESSORIES

To order consumables, additional accessories and to replace detachable parts that have been damaged, please contact Amplivox Ltd for current prices and delivery charges. The items available are listed below:

Stock No.	Description
A022	Audiocups (noise reducing earphone enclosures)
AC1042	Audiocup ear cushion
AC1047	Audiocup headband
AC1048	Audiocup headband cover
A023	Headband (standard headphone)
A026	Earphone cushion
A032	Earphones DD45 *
A030	Headset lead
BC0004	Carrying case
A091-7	Approved mains adapter (see Section 2.3)
A085	Patient response switch
C017	Audiogram paper (pack of 250)
A073	Booth Leads
HP200	Hewlett Packard OfficeJet 200 printer (USB cable not included)
HP200-BK	Ink cartridge (black) for OfficeJet 200 printer
HP200-CO	Ink cartridge (colour) for OfficeJet 200 printer
F06-A	USB memory stick
AUD06	Amplivox Audibase 5.5 (including USB cable)
F07	USB Cable, 1.8m

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. The required fitting instructions are supplied with each part.

APPENDIX 1 – AMPLIVOX 'ENCRYPTION' FOR ENCRYPTION & DECRYPTION

A1.1   Introduction

A number of software applications are readily available for the encryption and decryption of .cry files. A web search should provide suitable options.

As an alternative, 'encryption' is freeware software available from Amplivox which can be used to encrypt and decrypt .cry files for use with the CA850 audiometer and Audibase.

The freeware is supplied as a file named 'Amplivox encryption.exe' and may be obtained directly from Amplivox by emailing sales@amplivox.ltd.uk with a request for the 'encryption' freeware. To bypass firewalls it may be necessary for the file extension to be renamed prior to emailing. After saving the attachment, rename the file extension back to 'exe'.

As freeware, Amplivox provides no warranty (implied or otherwise) regarding this software and will not be liable for any aspect or consequences of its copying or use on a 3rd-party computer. By downloading and/or running the application the user accepts these conditions.

No installation is necessary. Simply copy the Amplivox encryption.exe file to a suitable location and run it in the usual way (e.g. by double-clicking on the filename). The file may be renamed if required.

The following sections describe the operation of encryption.

A1.2   Encryption (prior to importing data into the CA850)

Run 'Amplivox encryption.exe' and the following window will open.
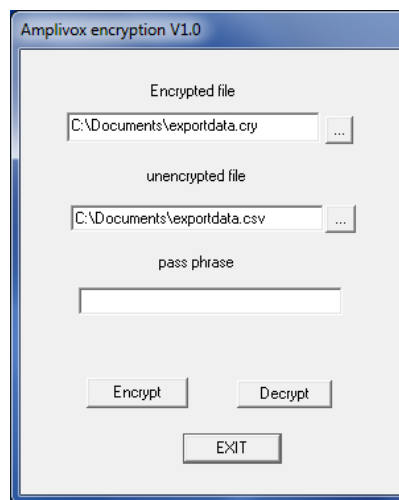
To locate a file to encrypt, click the [...] button next to the 'unencrypted file' field and browse to find the required file in the usual way. Select the file to encrypt and click on the 'Open' button. Note that 'exportdata.csv' is the default CA850 audiometer filename for importing and exporting data without encryption). This is illustrated in the window below.
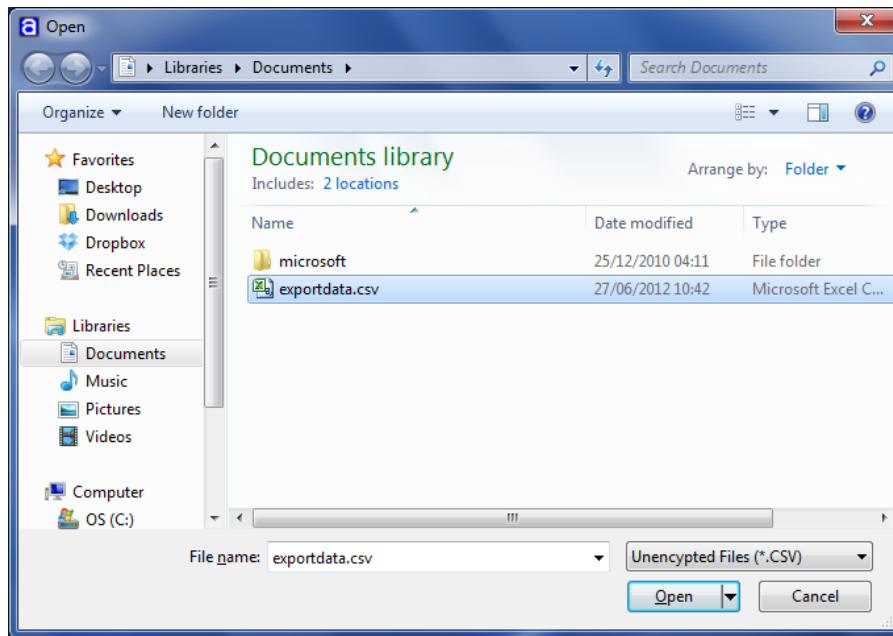
Next specify the name and location for the encrypted file. Click the [...] button next to the 'Encrypted file' field and browse to select the required location and enter the filename in the usual way. Click 'Open' and the window below will be displayed.
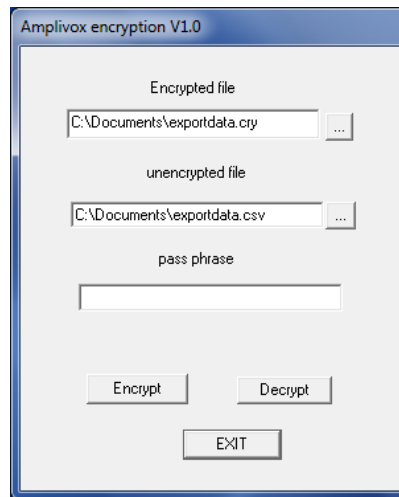
Note: if it is required to import this file immediately into the CA850 audiometer it should be named 'exportdata.cry' (as above). Otherwise the filename can be set as something more meaningful, but it **must be changed to 'exportdata.cry'** before importing to the CA850.

Next enter a 16-character alphanumeric password (pass phrase) which will be used to encrypt the file. This password will be uniquely associated with the encrypted data file, and it must be noted for later use when importing the data into the CA850 audiometer (or decrypting the data file on a computer).

Do not use more than 16 characters. Although the data file will be encrypted, the CA850 will not be able to dycrypt it.

If the password is lost then the data will no longer be accessible. But it is, of course, possible to repeat the above process using the same original data file to produce a new encrypted file.

An example of a suitable alphanumeric password (pass phrase) is shown in the window below.
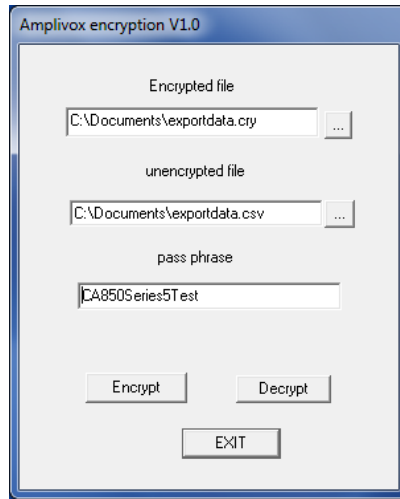
Finally, click the 'Encrypt' button to encrypt the file. The following message will be displayed if the encryption was successful, and the encrypted file will be created in the selected location.


This file may then be copied to a USB memory stick and imported to the CA850 (after renaming to 'exportdata.cry' if necessary). See Section 10.4.7 of this operating manual.

A1.3   Decryption (for example, after exporting data from the CA850)

Encrypted data that has been exported from the CA850 will initially reside on a USB memory stick although it may be copied to any convenient location on a computer. This data will typically be used with the Amplivox 'Audibase' application. Data encrypted on a computer (as described in A3.2) may also be decrypted as described below.

To decrypt the data file, run the file named 'Amplivox encryption.exe' and the following window will open.
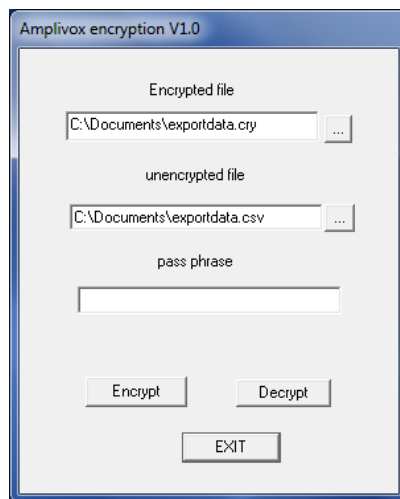
Locate a file to decrypt by clicking the [...] button next to the 'Encrypted file' field and browse to find the required file in the usual way. Select the file to decrypt and click on the 'Open' button. Note that 'exportdata.cry'

is the default CA850 audiometer filename for importing and exporting data <u>with</u> encryption). This is illustrated in the window below.
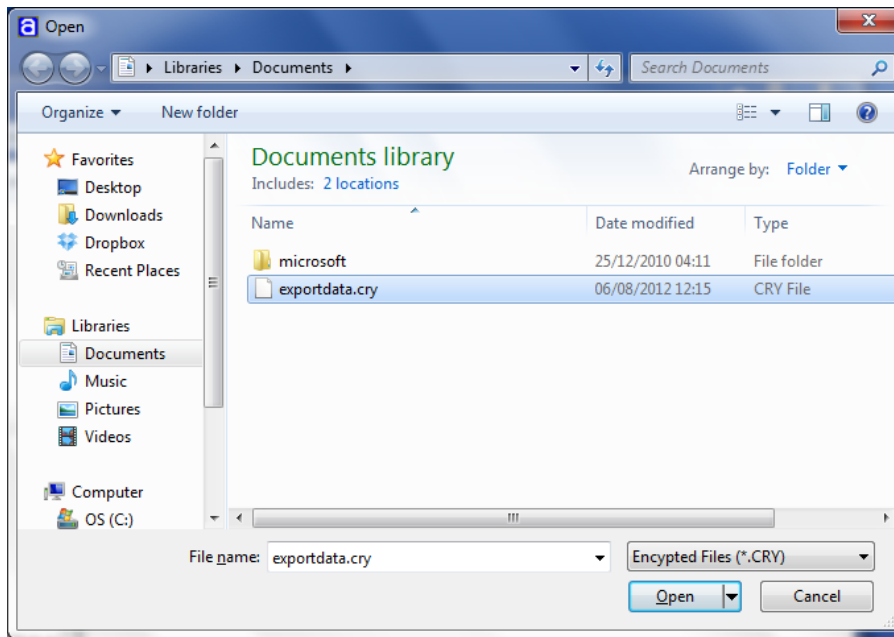
Next specify the name and location for the decrypted file. Click the [...] button next to the 'unencrypted file' field and browse to select the required location and enter the filename in the usual way. Click 'Open' and the window below is displayed.
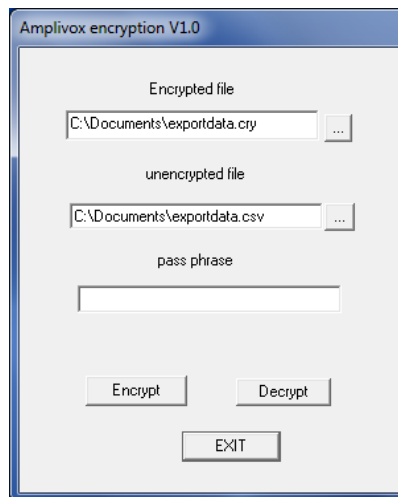

Note: if it is required to use this file with Audibase immediately it should be named 'exportdata.csv' (as above). Otherwise the filename can be set as something more meaningful, but it **must be changed to 'exportdata.csv'** before use with Audibase.

Next enter the 16-character alphanumeric password (pass phrase) that was used when the file was originally encrypted (typically on the CA850 audiometer).

If the password has been lost then the data will no longer be accessible. But it is, of course, possible to export the original data from the CA850 (encrypted if required) and repeat the above process to produce the required decrypted file.

An example of an alphanumeric password (pass phrase) is shown in the window below.
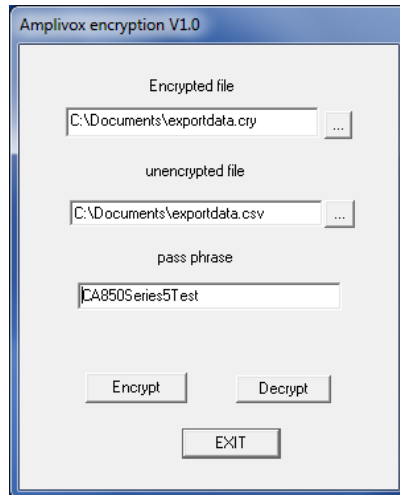
Finally, click the 'Decrypt' button to decrypt the file. The following message will be displayed if the decryption was successful, and the decrypted file will be created in the selected location.

This file may then be imported to Audibase (after renaming to 'exportdata.csv' if necessary) as described in the Audibase operating manual.
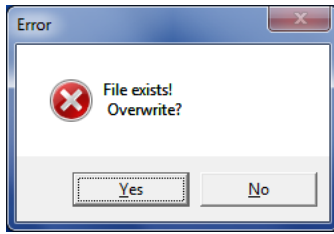
A1.4   Error Conditions

If the password entered is under 16 characters, the following message will be displayed:
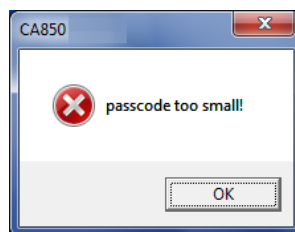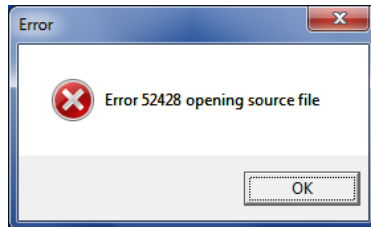

Note: Any password characters entered over 16 characters will be ignored for decryption.

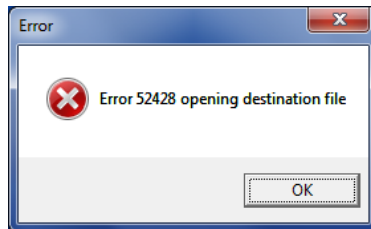If the encrypted or unencrypted file already exists, the following message is displayed:

If the source file cannot be found when either encrypting or decrypting a file, the following message is displayed:

If the destination file is already open or in use, the following message is displayed:

If an incorrect 16-character alphanumeric password is entered then a dycrypted file will be created but will consist of random data.

APPENDIX 2 – EMC GUIDANCE AND MANUFACTURER'S DECLARATION

Guidance and manufacturer's declaration – electromagnetic emissions		
The CA850 Audiometer is intended for use in the electromagnetic environment specified below. The customer or user of the CA850 Audiometer should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The CA850 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 A	The CA850 Audiometer is suitable for use in all establishments other than domestic 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	CLASS A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The CA850 Audiometer is intended for use in the electromagnetic environment specified below. The customer or user of the CA850 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	±6 kV contact ±8 kV air	±6 kV contact ±8 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	±2 kV for power supply lines ±1 kV for input/output lines	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	±1 kV differential mode ±2 kV common mode	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	<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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CA850 Audiometer requires continued operation during power mains interruptions, it is recommended that the CA850 Audiometer be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 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			

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Guidance and manufacturer's declaration – electromagnetic immunity			
The CA850 Audiometer is intended for use in the electromagnetic environment specified below. The customer or user of the CA850 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 2.5GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the CA850 Audiometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz 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 CA850 Audiometer is used exceeds the applicable RF compliance level above, the CA850 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 CA850 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 CA850 Audiometer

THE CA850 AUDIOMETER IS INTENDED FOR USE IN AN ELECTROMAGNETIC ENVIRONMENT IN WHICH RADIATED RF DISTURBANCES ARE CONTROLLED. THE CUSTOMER OR THE USER OF THE CA850 AUDIOMETER CAN HELP PREVENT ELECTROMAGNETIC INTERFERENCE BY MAINTAINING A MINIMUM DISTANCE BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT (TRANSMITTERS) AND THE CA850 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.

APPENDIX 3 – USE WITH NON-MEDICAL 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 CA850 audiometer are specified for user connections and 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 Identification	Socket Type	Socket Function	Typical Connection
USB PRINTER	USB Type A (Master)	USB device connection	▪ Printer ▪ USB Drive
USB PC	USB Type B (Slave)	USB device connection	▪ 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 Section 4 of this operating manual for a typical test arrangement and to Diagrams 1 to 3 below for example configurations of connected peripheral equipment. Refer to Amplivox Limited at the address given on the front of this user manual if advice is required regarding the use of peripheral equipment.

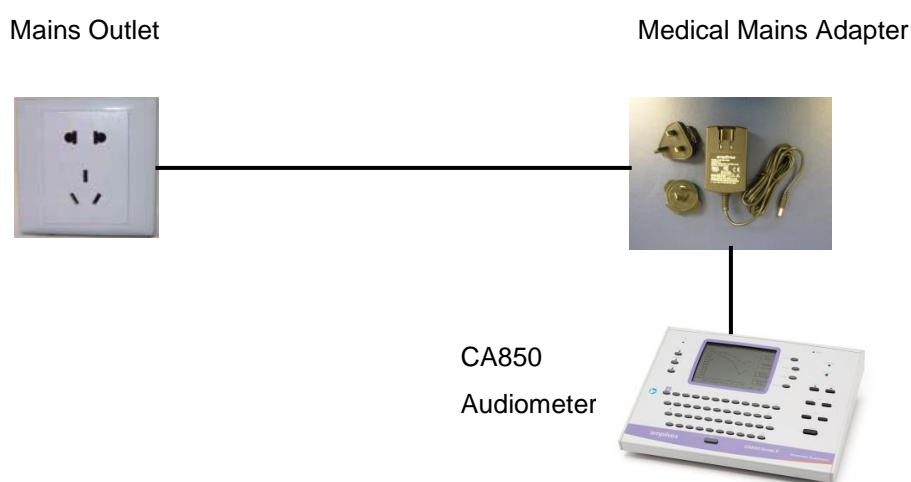Diagram 1: CA850 used with the medically-approved mains adapter

Mains Outlet

Medical Mains Adapter

CA850

Audiometer

Diagram 2: CA850 used with the medically-approved mains adapter and printer

Mains Outlet Medical Mains Adapter CA850 Audiometer

Mains Outlet Printer Power Supply Printer via USB PRINTER Socket
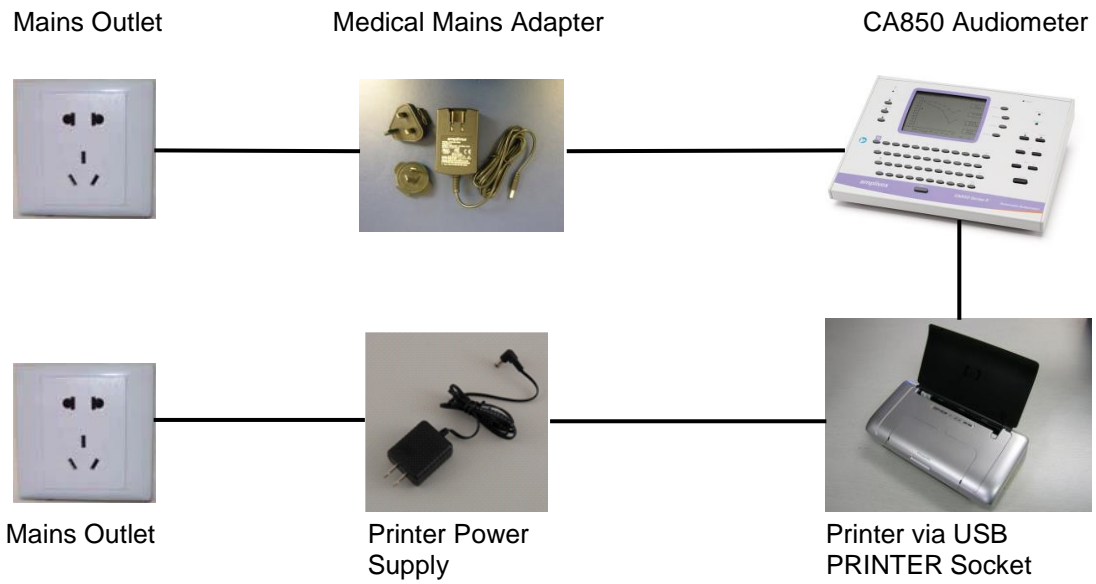
Diagram 3: CA850 used with the medically-approved mains adapter and PC

Mains Outlet Medical Mains Adapter CA850 Audiometer

PC via USB PC Socket

Mains Outlet PC Power Supply

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