ASRA Curve Audiometer

User Guide

Version 9

CE 2797

CONTENTS

Asra Curve Audiometer User Guide

Warranty

This warranty is extended to the original purchaser of the audiometer by GM Instruments Ltd, through approved Distributors or through GM Instruments Ltd, and covers defects in materials of workmanship for a period of 1 year from the date of delivery to the original purchaser.

Defects will be corrected at no cost to the purchaser within the first year, except for shipping charges to and from the point of service. This warranty does not apply to those parts that are subject to normal wear and tear, such as cords, ear cushions and headbands. Replaceable parts which may deteriorate with use will be supplied at a reasonable cost.

The manufacturers warranty is void if the audiometer is repaired by persons other than GM Instruments Ltd or an approved Distributor.

The terms of this warranty do not affect your statutory rights.

1. ASRA Curve Audiometer Important Safety Information

Read this Operating Manual before attempting to use the Instrument.

Warnings

This Instrument is for indoor use only and it should only be used as described in this manual.

The system must not be used in the presence of flammable gases or in an environment, which is susceptible to explosions. (Beware of oxygen, dust, and anaesthetic gases)

This unit is powered by the mains adaptor supplied and is specified as part of the equipment. It is advisable not to touch the patient while using the equipment.

The equipment should be positioned in such a way that it can be easily disconnected from the mains supply. The operation of the system can be safely terminated by switching off or removing the mains plug.

If your desktop PC or printer does not have a power supply approved for a patient environment, then an isolation transformer, which is in compliance with BS EN 60601, should be used to power the PC, printer, and the ASRA Curve. You must use the isolation transformer to ensure that the ASRA Curve is in compliance with BS EN 60601.

Applied Parts. The Applied Parts are the headset and the response button.

CAUTIONS

Federal (USA) law restricts this device to sale by or on the order of a physician.

The use of the ASRA Curve near to sources of electromagnetic radiation, such as mobile phones, radio transmitters, x-ray equipment etc, may prevent it from functioning correctly. Appendix 1 provides guidance on the Electromagnetic environment in which to operate the instrument.

This is a medical instrument, which has an electrical classification of Class 2 Type B and a Medical Device Directive classification of Class IIa.

A Class II Type B device categorisation is used to describe an instrument which: -

a) Electrical 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 and

b) Applied parts offer protection to the subject against electrical shock and in the event of a single fault condition arising, leakage current will be limited to less than 0.5 mA.

Any incident, which results in actual or potential injury or death to a subject while using the ASRA Curve should be immediately communicated to GM Instruments at the address below.

The ASRA Curve should only be connected to other mains powered devices such as computers and printers, which comply with EN 60950-1 and we also advise the use of a separating transformer. Unless computers and printers built to EN 60950 are used, patient safety might be compromised.

Non-medical equipment such as computers and printers should be kept out of reach of subjects being tested as such equipment does not comply with medical safety standards. Refer to clause 16 of EN 60601-1:2006 to ensure compliance.

If the PC is allowed to go in to sleep mode, the USB interface is powered down. When brought out of sleep mode, the PC does not re-initialise the USB interface, and it is effectively not present. A solution is to remove the USB connection at the PC or instrument side then reconnect. That may be sufficient, but if not, save any results, close down the instrument software, and restart it

Servicing can only be carried out by GMI approved and authorised personnel. No modifications are allowed.

2. Technical Specification

Factory-trained personnel or engineers familiar with the standard EN 60601 can only undertake servicing of the ASRA Curve Audiometer. Circuit diagrams will be made available to competent persons on request.

Medical CE Mark	The CE mark indicates that the device meets the requirement of Annex V & VII of the Medical Device Directive 94/42/EEC. Approval of the Quality System is made by BSi whose notified body number is 2797	
Standards	Safety	BS EN 60601-1 Class 2 Type B applied parts
	EMC	BS EN 60601-1-2
	Audiometer	BS EN 60645 -1, Type 4
	Categorisation	UK & Ireland H&SE
Operation Environment	Temperature	15°C to 35°C
	Relative Humidity	30% to 90%
	Ambient Pressure	98kPa to 104kPa
	Warm up time	5 Minutes
Transport & Storage	Storage &Transport	-40°C to +60°C
	Relative Humidity	30% to 90%
Supply Power	Supplied PSU	Use only specified PSU **VEP15US09 ***
	Line Voltage	100V to 240 V at 50-60 Hz
	Consumption	12.6W
Tone Type	Tone switching -Tone Presentation -Tone Interruption	Automatic Mode

	Tone Switching -pulsed	Manual Mode
	Response	Required during TONE or as set by the user from the Options menu
Frequency Range	Discrete Frequencies and Maximum Outputs	125Hz (75dB),250Hz (90dB),500Hz (120dB), 750Hz (120dB),1KHz(120dB),1.5KHz(120dB),2KHz(120dB), 3KHz(120dB),4kHz(120dB), 6KHz(110db),8KHz(110dB),
	Accuracy	± 0.1 %
	Total Harmonic	± 1.0 %
Test Type	Auto Threshold	Hughson Westlake
Intensity	Range	-10 dB to +120dB
	Accuracy	± 1.0 %
	Rate of Change	40 m secs
	Duty Cycle	Continuous
	Intensity Limit	To have tones presented at 100dB or above then a positive response from the operator is required
Headset	Earphones, Cushions & Audio	**TDH39P *** (10 Ohm impedance) with MX41/AR Cushions and Amplivox AO22Audio cups
Mechanical	Dimensions	22x 23 x 4 cm
	Weight	1 Kg
Calibration	Frequency	Annual calibration required by Manufacturer or Manufacturer approved provider
	Method	ISO 8253-1 Calibration undertaken using Referenced Transducers and Acoustic Coupler – see calibration certificate
EMC	Effects	Please refer to pages 34 to 38 of this manual (Appendix 1)
Service Life	Safety and Performance	The service life of the ASRA Curve has been evaluated to be 10 years from the date of manufacture.

Additional Technical Information (relative to EN 60601-1:2006) is also provided in Appendix 2

3. Table of symbols used

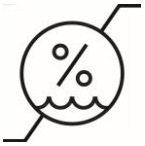
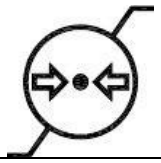
The following symbols appear on the ASRA Curve or the mains adaptor

Symbol	Meaning	Socket Type	Location	Connected Part
	Refer to Instruction Manual ISO 7010-M002	USB Type B	Instrument Back Panel	Computer (Via USB Port)
		2.5mm DC Jack Socket	Instrument Back Panel	Mains AC/DC Adaptor VEP15US09*
	Type B Applied Parts IEC 60417- 5840	Jack Plug	Instrument Back Panel	Right and Left Input Socket Response Button *
	Direct Current IEC 60417 - 5931	_	Mains Adaptor AC/DC	VEP15US09 *

For connected parts marked * only connect the accessories supplied with the instrument. These parts have been tested for use with the instrument for compliance to standards IEC 60601-1 and IEC 60601-1-2.

Symbols used on labelling and packaging

Symbol	Meaning	Location
	Manufacturer ISO 7000-3082	Instrument Label
SN	Serial Number ISO 7000-2498	Instrument Label
	Consult Instructions for Use ISO 7000-1641	Instrument Label
CE 0000	Council Decision 93/465/EC. Annex B(d)	Instrument Label
ZZZZ	Date of Manufacture Where ZZZZ: Date of Manufacture ISO7000-2497	Instrument Label

	Temperature Limit ISO7000-0632	Instrument Shipper Packaging
	Humidity Limitation ISO7000-2620	Instrument Shipper Packaging
	Atmospheric Pressure limitation ISO7000-2621	Instrument Shipper Packaging
	Mandatory Action Sign ISO 7010- M001	Operating Manual
EC REP	Authorized Representative in the European Community	Instrument Shipper Packing & User Manual

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4. Introduction

The ASRA Curve Audiometer is a medical device used to screen subjects for noise induced hearing loss.

It is intended that the ASRA Curve will be used as part of a hearing screening program in industrial and corporate environments. The hearing screening will measure the hearing threshold of a test subject and indicate the need for further clinical analysis and treatment. The ASRA Curve is a stand-alone product and is not intended to be used with other medical devices.

The operator of the ASRA Curve is expected, as a minimum, to be a competent person. Competent persons have completed courses with syllabi determined by the British Society of Audiology. These courses familiarise them with audiology, the methods of performing hearing testing and how to operate and maintain audiometers. Other users may be more skilled experts in audiology, such as Occupational Health nurses and audiologists.

The subject, upon whom the hearing testing is performed, is expected to be an employee working in high-noise environments being screened in line with the Health and Safety Executive's regulations on noise at work or being routinely screened as a part of a workplace health programme. Subsequently, they come from all walks of life and are of working age.

The ASRA Curve audiometer is expected to be used in an environment suitable for the conduction of hearing testing. Most likely a quiet office or a room fitted out with a hearing test booth.

The process follows the British Society of Audiology approved procedures for the determination of Pure Tone thresholds, using the Hughson Westlake technique. The headphones rest on the outside of the head of the test subject and shall transfer sound energy to the subject by air conduction. The subject holds the remote switch and presses it when tones are heard.

Once thresholds have been determined for both ears on selected frequencies, and the age and gender of the subject being tested has been input, the audiogram is categorised according to the Health & Safety Executive categorisation scheme.

5. Installation

5.1 ASRA Curve Program Installation

NB: Do not connect Asra to the PC until all program software and USB driver software installation has been completed.

SOFTWARE (Windows 10 and earlier)

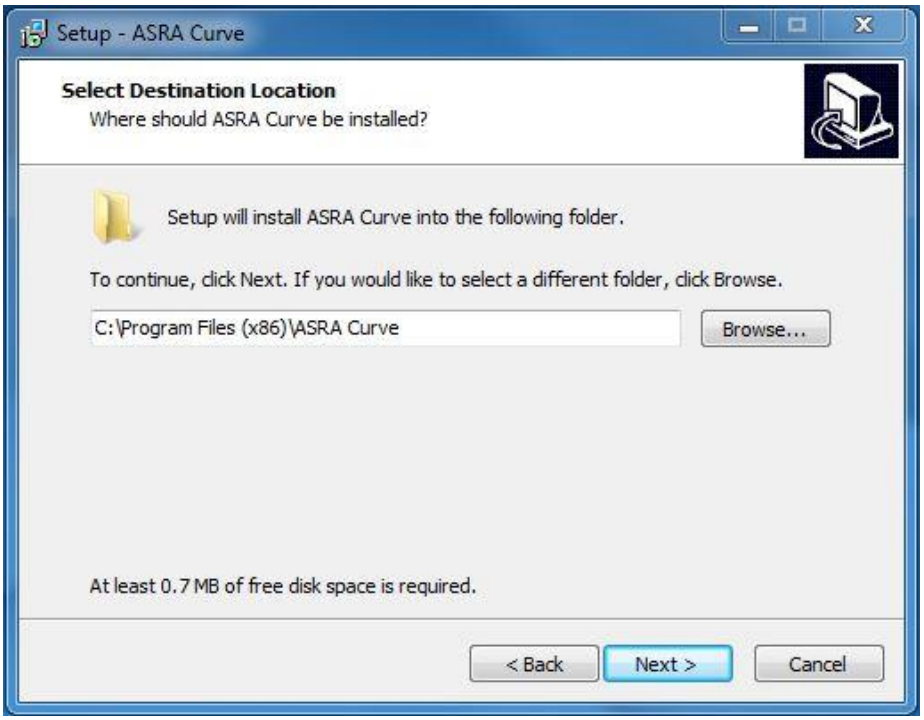
If your PC is password protected and/or network connected, you should log on with administrator rights prior to loading the software.

The Asra software and USB drivers are supplied on a USB drive and can be installed by inserting the USB drive into the computer, navigating to it, and right clicking on the file ***Asra.EXE***, and ***Run as administrator***.

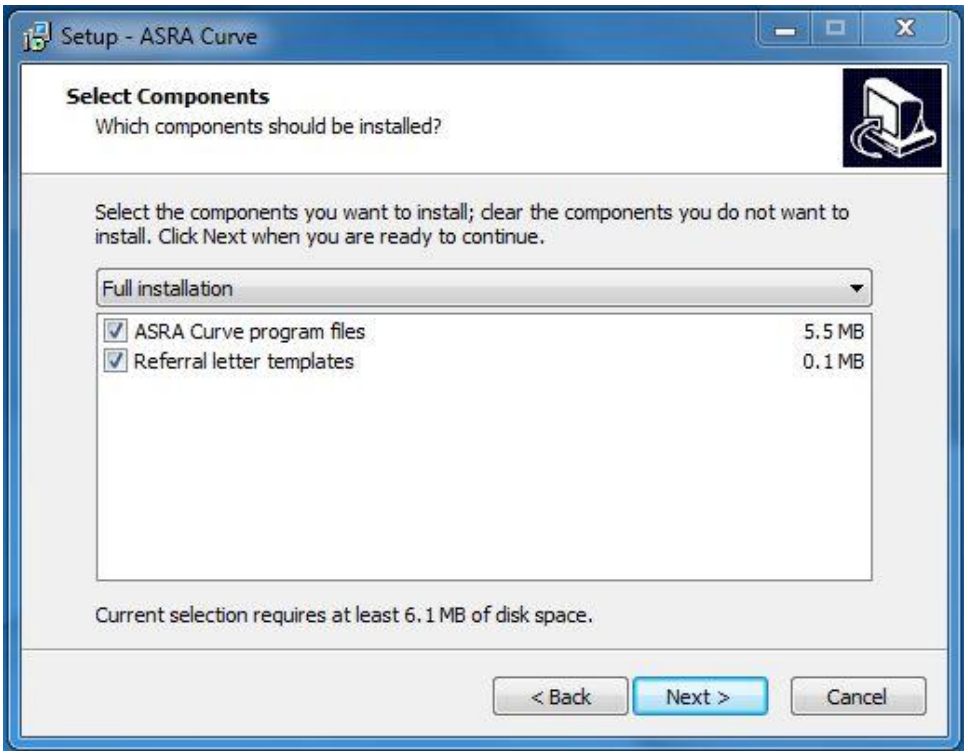
The Asra files will be unpacked and installed on the C drive in a folder called ASRA Curve.
If necessary, the files can be transferred to a network drive.
Care should be taken in installations where a number of users have their own login, to ensure that the two Asra programs are available to all who may need to use them.

When prompted "Do you want to allow the following program from an unknown publisher to make changes to this computer?", click yes and continue.

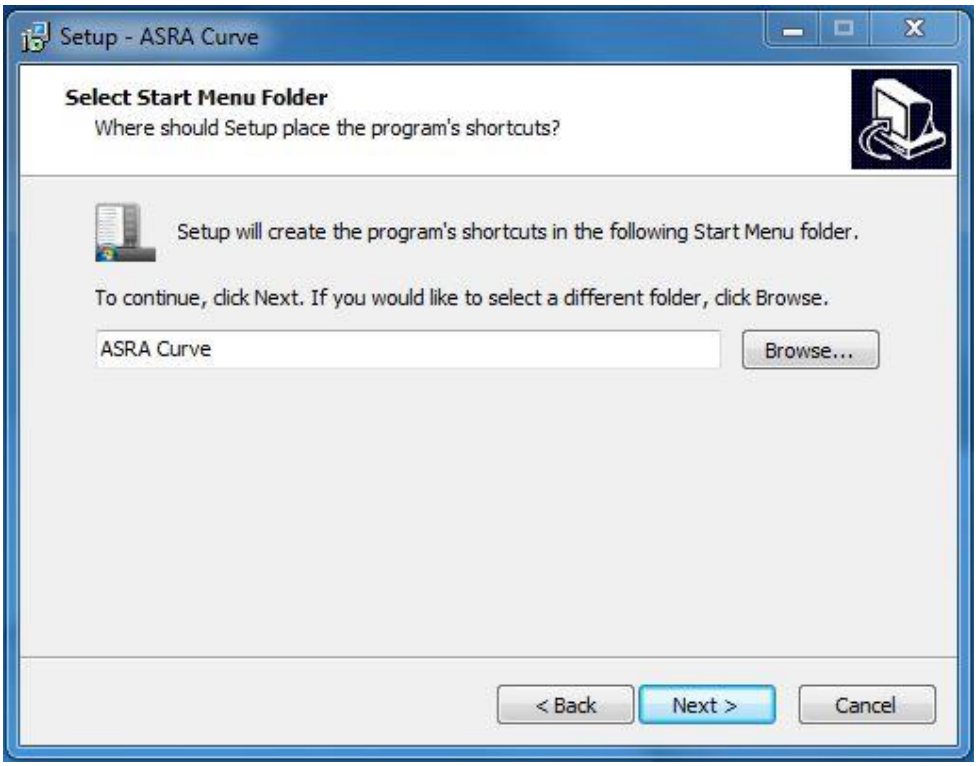
In the set-up window, follow the instructions on screen to the next step.
The default directory for the program is in C:\Program files (x86)\ASRA Curve, check and click next to proceed to the next step.
<u>For correct operation, the drivers should be installed before connecting the audiometer to the computer.</u>



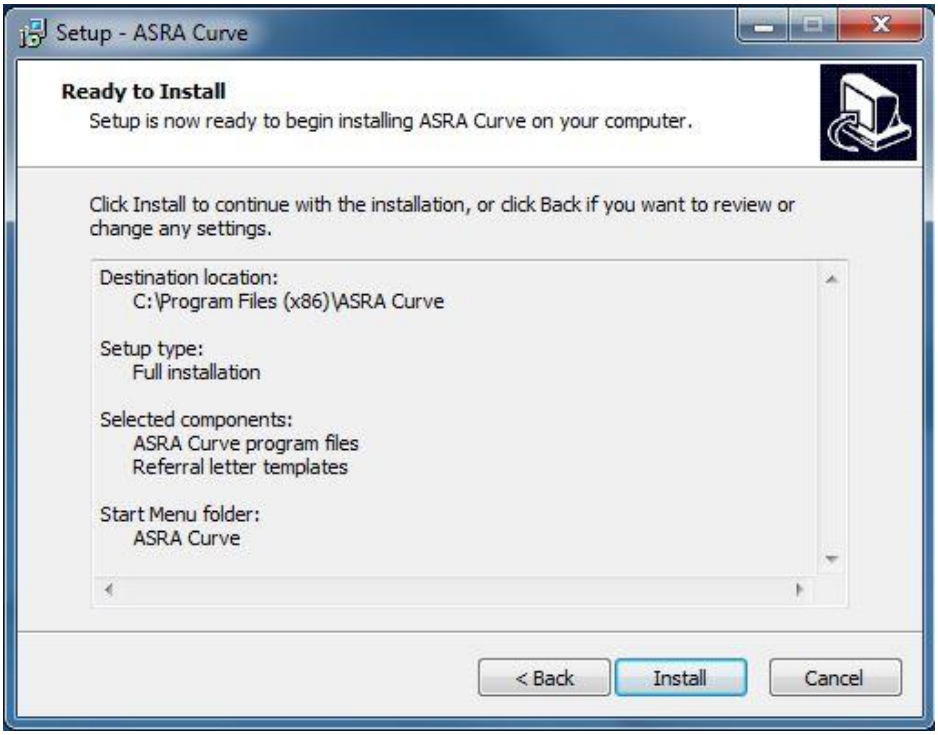
The next stage allows selection of the components to be installed with the ASRA software, all components should be selected for installation before proceeding.



The next stage will prompt to create a shortcut to the Asra Curve program in the Start Menu folder, press Next to confirm.



At the next stage, review the setting before clicking next and continuing with the installation.



Click on Finish to complete the installation.

The installation of the ASRA software is now complete. If it is necessary to change the default save and passive directory locations, this can be within the main program and then using Exit to save as the new default.

It is recommended that icons for ASRA Curve (ASRA Curve testing program) and Batch Processing Utility (ASRA batch utility program) be made available on each person's desktop. To do this open the start menu and open the folder named ASRA Curve. Next, right-click on the ASRA Curve program icon and select 'More' followed by 'Open File Location'. Click and drag the shortcut icon that comes

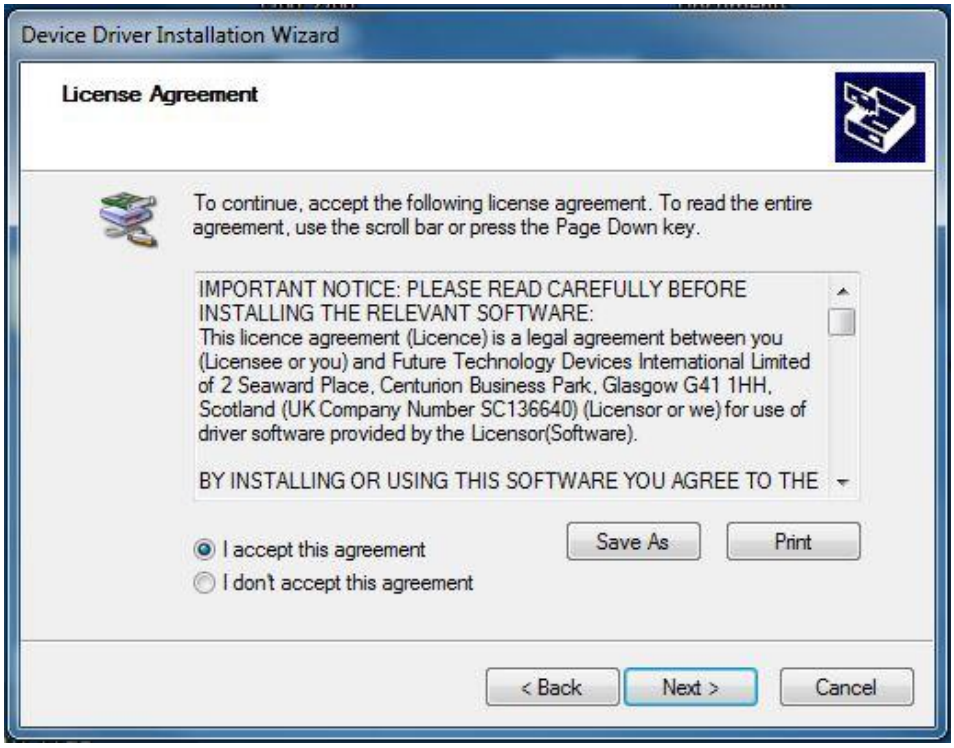
up onto the desktop. Repeat the process for a folder called ASRA Osicus Batch_Utility to put the Batch_Utility shortcut onto the desktop.

5.2 ASRA Driver Installation

To install the Asra Curve drivers, right click ***CDM21228_Setup.exe*** and select ***Run as Administrator***.

In the setup window, follow the instructions by click next to start the installation

In the following window, select acceptance and then next to confirm the License Agreement and continue.



Once the installation has completed click on '***Finish***', then **close down and restart your computer**.

5.3 Installing the Hardware

Operation of the ASRA audiometer is controlled by software running on a Windows based PC.

The link between PC and Asra Curve is by means of a standard USB cable.

The other connections on the back of Asra Curve, which are essential for its correct operation are:-

- Power supply cable – check the LED on the front of Asra Curve to show that it is lit when mains power is switched on.

- Right (red) earphone plug - **if a booth is used**, link the socket marked right on the back of Asra to the red socket on the booth and connect the red earphone plug to the corresponding red socket inside the booth. **If no booth is available**, connect the red plug directly into the socket marked right.

- Left (blue) earphone plug - **if a booth is used**, link the socket marked left on the back of Asra to the blue socket on the booth and connect the blue earphone plug to the corresponding blue socket inside the booth. **If no booth is available**, connect the blue plug directly into the socket marked left.

- Response button plug – **if a booth is used**, link the socket marked response on the back of Asra Curve to the black socket on the booth and connect the response button plug to the corresponding black socket inside the booth. **If no booth is available**, connect the response button plug directly into the socket marked response.

  Operation can be confirmed by pressing the button and checking the response LED lights.

5.4 To Check Installation

- Close down PC and log on as an ordinary user

- Check the two Asra icons are on the desktop

- Double-click on each icon in turn to check that both programs run

- In the Asra Curve testing program select ***New Test*** and confirm that the headphone serial numbers match with the headset plugged into the Asra Curve

- From the dropdown menu labelled ***Test***, select ***Manual***, and, put on the earphones and click the ***Tone*** button to present a tone

  The Tone On light should illuminate and a tone should sound.

  If the response button is pressed while the tone is sounding the small cursor on the screen should become large to show that the response has been accepted, the Tone On

light should go out and the Response light should turn on and the message “RESPONSE” appears in the bottom righthand corner of the program window.

Click on ***Stop*** to return to normal operation.

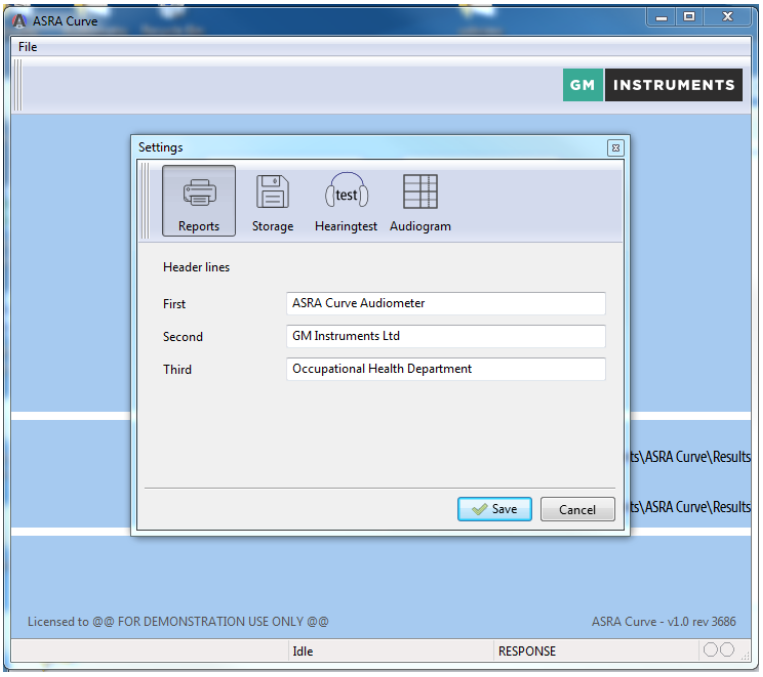
- Click on print to check the operation of the printer.

The system is now ready for use!

6. Initial Setup

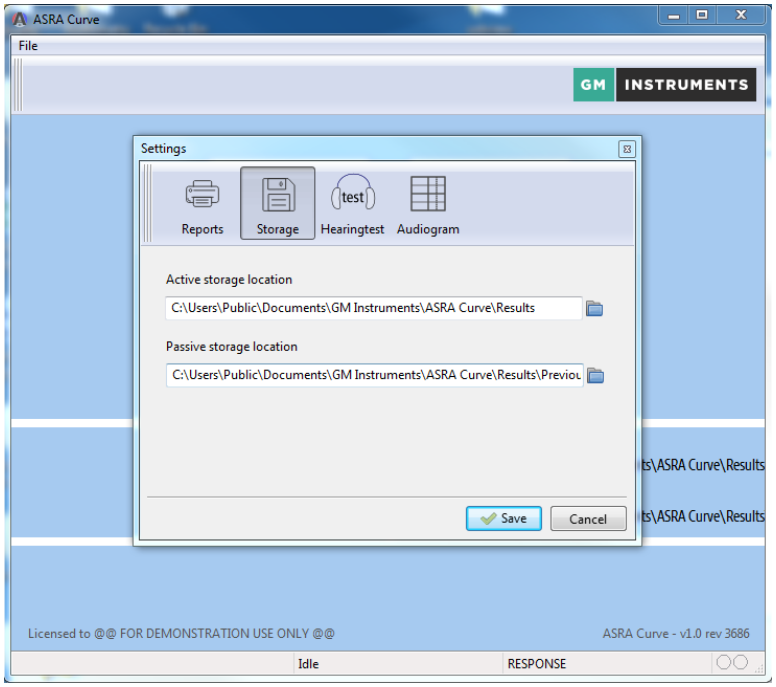
6.1 Printouts & Reports

The headers on the audiogram printouts can also be customised by clicking the ***Reports*** tab within the settings window and editing as required and then clicking the ***Save*** button.



6.2 Save & Storage Locations

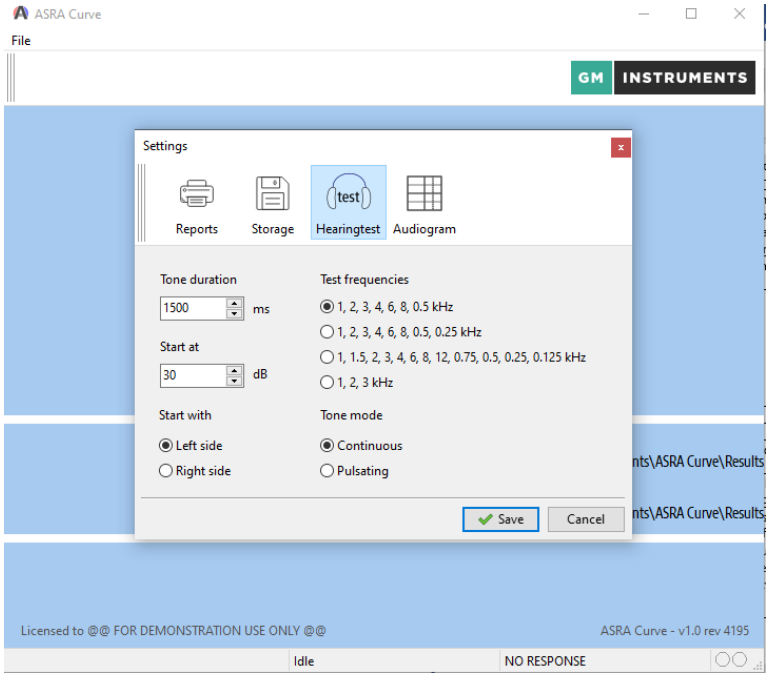
The default Active save, and Passive storage locations are set in the program on installation. These can be edited to any location on the PC or a network location defined by the User. This can be changed by selecting the ***Settings*** tab on the home screen and then ***Storage*** in the new window.



The location can be changed by click the blue folder icon, and navigation to the desired location using the ***Browse For Folder*** window. To select, press ***OK*** and the ***Save*** when finished to make the new destinations default in future.

6.3 Hearing Test Settings

The default settings for the hearing test are shown when the Hearing Test tab is selected and are shown below.



The menu allows the test frequencies, tone duration, starting intensity and side, and either continuous or pulsed tones to be selected.

The default settings are:

- Tone duration – 1.5 seconds
- Starting Intensity - 40dB
- Starting Side - Left
- Test Frequencies – 1, 2, 3, 4, 6, 8, 0.5 kHz
- Tone mode – Continuous

Once changes have been made, select ***Save*** to confirm and set as default for testing.

7. Making and Recording Measurements

The Asra can be used by any "**competent person**", technician, nurse, or doctor, who has been certified as having satisfactorily completed a competent person's audiology course.

Having become familiar with the hardware and software you are now ready to record measurements.

7.1 Calibration check

It is recommended that a calibration check is carried out at the beginning of the day prior to patient testing to confirm Asra Curve performs as expected.
To do a calibration check, switch on the Asra Curve, start the software and move to the testing screen. Enter Patient ID details if you want to save the calibration check.

Then either put the headset on an "artificial ear", with the response cable replacing the response button unit or ask someone whose hearing level is known to put on the headset (remove glasses and earrings if they interfere with the fit of the headset). Advise them to press and release the button as soon as they hear the tone.

The red audio cup goes on the right ear and the blue audio cup on the left ear. Click on the ***Test*** button to start the test.

On completion compare the audiogram with the previously recorded audiogram for that "artificial ear" or test person.

It is always possible for any threshold point to move up or down by 5 dB, but if almost all points are further down the audiogram from previous results, the jack connections inside the booth and outside the booth (if a booth is being used), plus the jack connections at the back of the Asra should be cleaned with an alcohol wipe and swiped in and out 10 to 20 times to clean them.

The test should then be repeated. If this does not restore the thresholds, then a cable problem might exist on the ear in question.

7.2 Patient Preparation

The patient should be prepared, prior to testing, by having them in a quiet stable environment for 5 to 10 minutes. This is a suitable time to take their history, complete your pre-test questionnaire and examine the ears for wax.

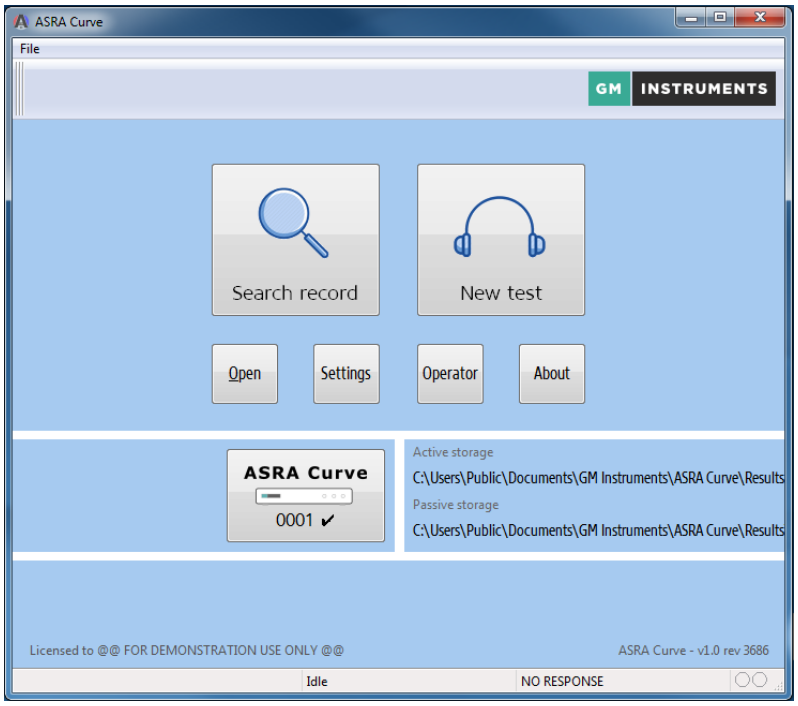
If they have recently been exposed to excessive noise, or have a cold prior to this appointment, a note to this effect can be made in the comments section of the program.

7.3 Introduction

The ASRA audiometer software if based on the Hughson-Westlake testing routine recommended by the British Society of Audiology. It has a number of additional features which combine to make Asra Curve a unique instrument, while still complying with the recommended procedures of the British Society of Audiology and the Health and Safety Executive. This section describes, among other things, the default settings in the program and the recommended steps in normal usage. It also gives a more detailed description of all the menu facilities which are provided in the program.

7.4 The Home Screen

The Home screen is the central point where the functions of the audiometer can be accessed. Clicking on the Home icon at any time will return you to the Home screen. From the Home screen, you can create New records, Search records, Run Tests and Exit the program, all by clicking on the associated icon.

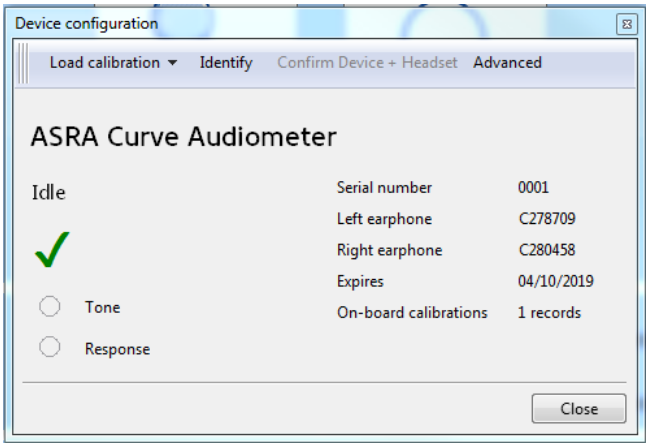


Home Screen

Additionally, you can prepare the audiometer for use by using the 3 set-up buttons – Select Audiometer – Settings – Tester Settings. The following chapter takes you through these functions.

7.5 Selecting Audiometer

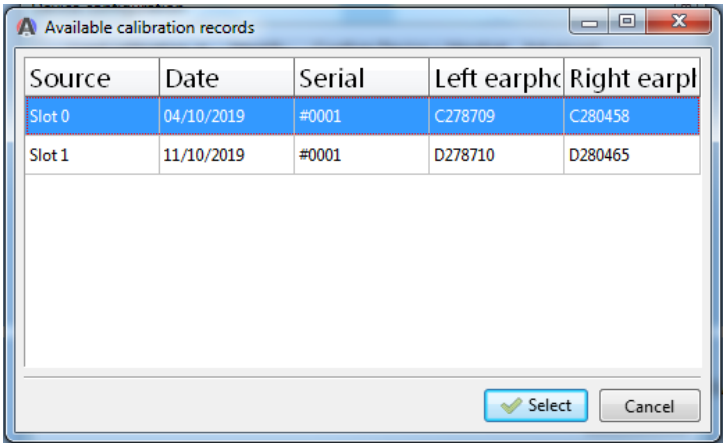
Selecting the Device using the ASRA Curve button will open the device configuration window below and allows you to check that you are using the correct audiometer/earphone combination and that the calibration file is up to date.



An audiometer is calibrated with one set of headphones. The audiometer number and matching headphone numbers are stored during audiometer setup. The audiometer should only be used with the headphones used during calibration.

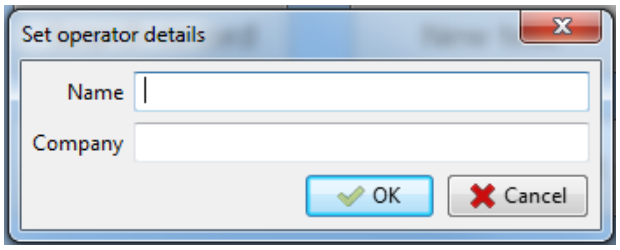
If the audiometer or headset serial number is incorrect, click on the ***Load Calibration*** button, then select the correct audiometer or headset from the list either by loading from a valid calibration file or from the onboard device memory. If the audiometer is not listed, then its details must be added by loading in a new calibration file. Now click on ***Confirm Device + Headset***. Use the ***Identify*** button to confirm that the audiometer is connected and functioning.
Click ***close*** to then return to the next screen.

Where a second headset has been calibrated to the audiometer, the calibration will be saved onto the device memory and loaded by selecting the correct headphone serial numbers as above from either ***Slot 0*** or ***Slot 1***



To guarantee accuracy, each audiometer must be calibrated at least once each year and receive an exhaustive calibration every two years. The date of last calibration is displayed with the audiometer details.
After calibration, you will be supplied with a file containing calibration information. To update the calibration information, press the Change button, browse to this file and click on Ok.

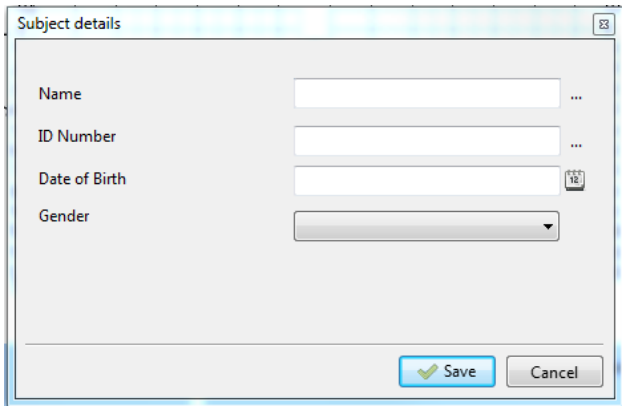
7.6 Tester Information



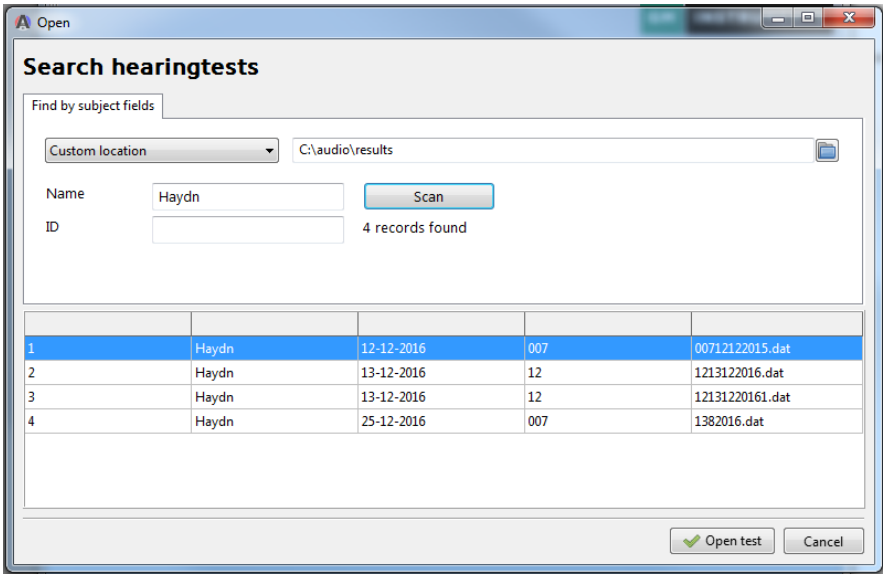
Enter the name of the person who will be doing the tests, and the company they represent.

7.7 Patient Details

For **New Patients**, click the ***New Test*** button to enter the test screen. Under the details section, clicking the pencil symbol will open a window to enter the patients details as below. In this you can enter the patients name, employment ID number, date of birth and gender. The date of birth and gender must be entered correctly for the effective categorisation of resultant audiograms

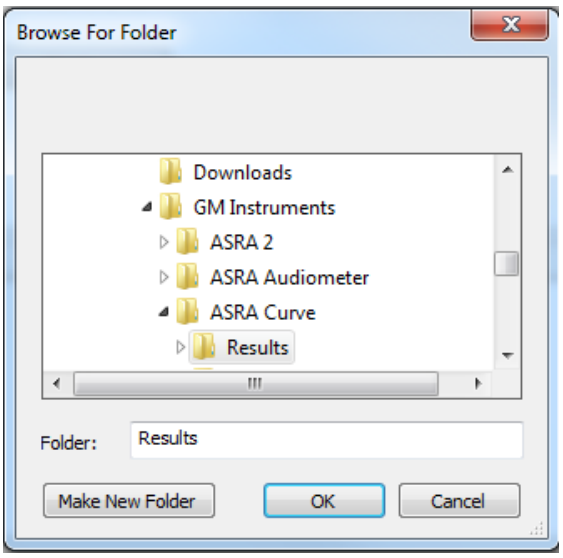


7.8 Find Patient



If a patient has previously been tested then by using the ***Search Record*** function on the **Home Screen** then previous records can be searched by entering either the patients name or ID number.

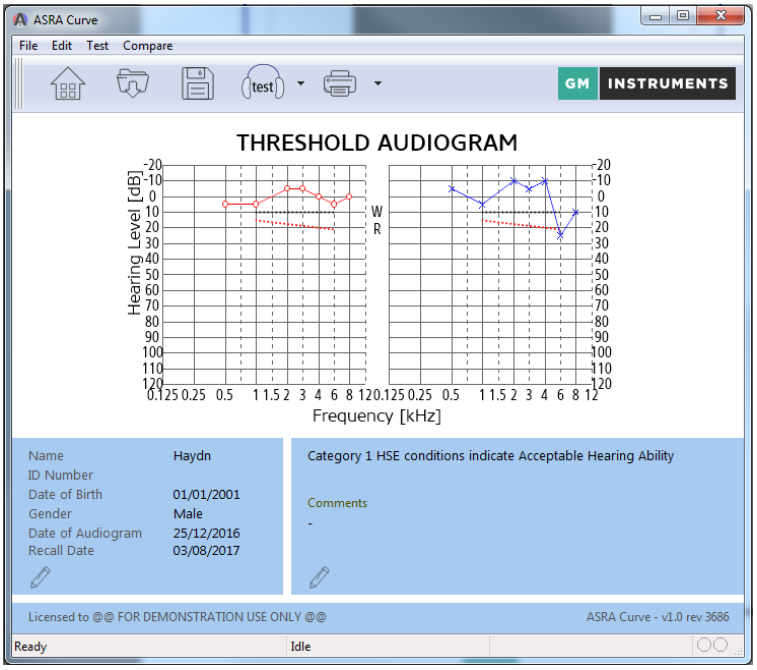
The search can be based on the content of a particular folder/directory such as the **Active storage** or **Passive storage**, or a custom location using the drop-down menu. When **Custom location** is selected, clicking the  button will allow you to browse for or create the relevant folder in the window as below.



Having found the person you want, highlight the entry and click on ***Open test***.
The screen will then become available and you have the option of using the Details/Tests/Audiograms tabs to view the previously generated data.

The ***Search Records*** tab will show all of the stored audiograms for the selected person. If you want to view a particular audiogram, select it and click on ***Open Test***.

An example of a completed audiogram, brought back from saved records is shown below.



7.9 Comparison of Audiograms

To compare the selected audiogram with another, click the Compare Audiograms tab at the top of the testing window. A further window will open to allow you to select the audiogram to be compared with the previously selected one. Highlight the one you want and then click on the Select button. Both will then be shown superimposed. And can be toggled on/off using the tick box at the side of the test window.

8. Running Hearing Tests

Having previously either entered details for a new person or selected someone who has been tested before, click on Run Test from the home screen. Before testing, you should ensure that the subject's ears are not blocked, the audiometer is connected and has been tested and the headphones are correctly in place.

8.1 Automatic Operation

To use automatic testing, simply click the Test button 

in the testing window and monitor the test as it runs. If different test settings are required for a particular patient, ie pulsed tones if a patient suffers from tinnitus, then this should be selected in the ***Hearing Test Settings*** in through the **Home Screen.**

During the hearing test the subject will hear tones in one ear at each frequency and then again in the other ear.
Each tone will increase in intensity until the subject confirms that they have heard the tone by pressing the response switch. The system will run through 3 times for each tone to ensure a consistent response, with a response of the best 2 out of 3 being taken as the threshold. If there is no consistent response you will be notified by a message appearing on screen. As the test proceeds, the results will be plotted on the audiogram.

If at any point the test must be paused or stopped, use the buttons provided on the interface. Pressing Stop will stop the test but retain all results up to that point.

8.2 Manual Operation

To switch to manual operation, click the drop-down arrow on the **Test** button 

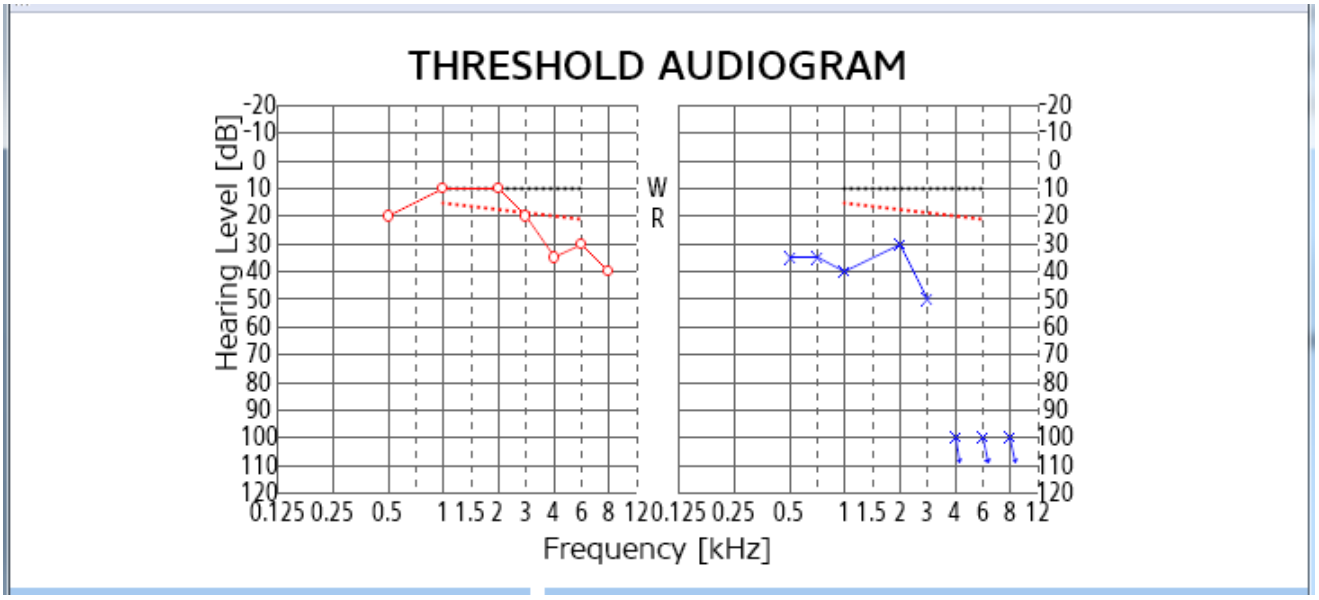
and select **Manual.** The test screen will then change to show buttons for presenting ***Tone***, ***Set Threshold*** and ***Set Overpower Flag***.

To change Frequency, use the Left ← and Right → arrows on the keyboard.
To change Hearing Level, use the Up ↑ and Down ↓ arrows on the keyboard to increase and decrease the intensity.
To present the tone to the patient, clicking the ***Tone*** button will do so at the selected frequency and hearing level.
When a response is registered this is plotted and recorded on the audiogram by using the ***Set Threshold*** button.

To exit Manual mode, click the **Stop** button.

8.3 Audiograms and HSE Categories

Audiograms are the recognised method of displaying hearing test data. They are graphs showing the level at which the subject responded for each tone. Each ear is graphed separately.

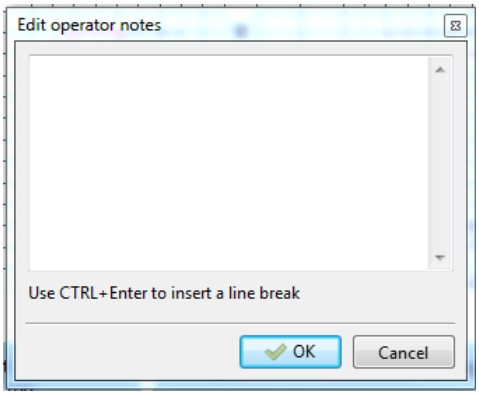


As the test proceeds, points are plotted on the audiogram, representing the test subject's results. The above shows an example of audiograms for the left and right ears.
The left ear audiogram is blue and points are plotted using crosses (**X**).
The right ear audiogram is red with points plotted using circles (**O**).

No response to a frequency is plotted at 100 dB HL (maximum amplitude without operator intervention) and the symbol includes an arrow pointing down. This is shown above at 4, 6 and 8 kHz on the left ear.

At the end of the test, the HSE categories are automatically calculated and displayed in the Categorisation section at the bottom of the testing window along with and comments from analysis of the audiogram.

The operator can also add comments and notes to this section using the pencil button  to open the dialogue box as shown below.



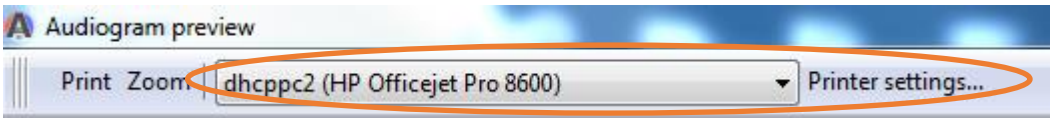
These can relate to any observations during the test and will be printed on the audiograms.

Depending on the circumstances caution is recommended in discussing audiogram results and HSE Categories with subjects.

The results must be saved to the database before exiting the test window. Results can be saved by pressing the Save button. The audiograms and related information can be printed as a report by pressing the Print button.

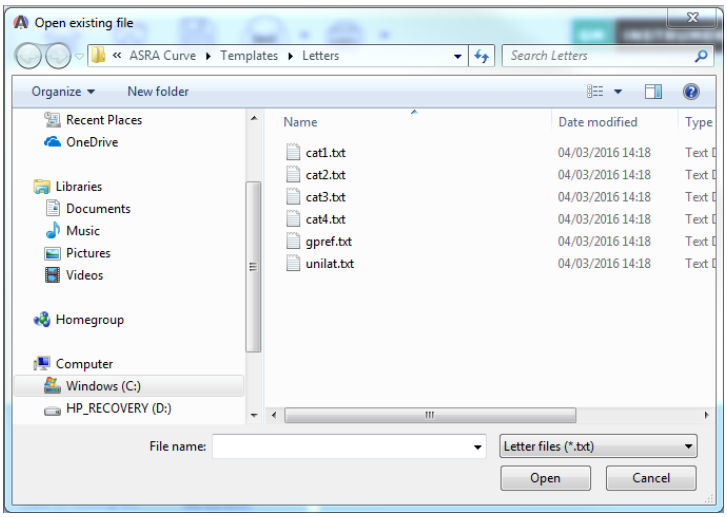
8.4 Printing Audiograms

When you choose to print audiograms, click the ***Printer*** icon  at the top of the window and a new window will open with a print preview of the report including any related personnel and test data. From this window you can choose to print the document to a selected printer, save the document to file such as a PDF if a PDF printing utility is installed, or zoom in and out of the document.



8.5 Printing Referral Letters

Supplied with the Asra Curve audiometer are letter templates based on HSE recommendations, explaining the resultant audiogram based on the category achieved. These can be printed by selecting the arrow next to the print icon and selecting ***Referral Letter***.



The relevant letter template related to the patients result can then be selected and printed, with the details populated automatically from the details section of the test.

9. Categorisation of Results

The ASRA program controls the acquisition of an audiogram, along with the employee's details, stores them in a file and displays them in the Results box on the audiogram screen and on the printout. It is therefore appropriate and easier that the program should also determine the Health and Safety Executive (H&SE) categorisations for the current audiogram and display them in a similar way.

The Asra Curve testing program uses the categorisation scheme which was introduced in the year 2006 by the H&SE, and this implementation is described here.
The H&SE have done extensive analyses of the prevalence of Industrial Hearing Loss and its relationship to the threshold levels in an employee's audiogram. Based on the results of these analyses, the H&SE have drawn up tables of threshold levels above which Warnings or Referrals should be made.
These tables are used in the ASRA program to perform HSE Categorisation on an audiogram produced from hearing tests.

Sum of hearing levels 1, 2, 3, 4 and 6 kHz				
Age	Males		Females	
	Warning Level	Referral Level	Warning Level	Referral Level
18-24	51	95	46	78
25-29	67	113	55	91
30-34	82	132	63	105
35-39	100	154	71	119
40-44	121	183	80	134
45-49	142	211	93	153
50-54	165	240	111	176
55-59	190	269	131	204
60-64	217	296	157	235
65+	235	311	175	255

Classification of hearing levels into warning and referral levels.

Referrals to a General Practitioner or to a hospital audiology clinic are made in cases of poor hearing, when the thresholds are above the levels indicated in the Referral table below.

Warnings are given to the employee when the thresholds indicate mild hearing impairment, as indicated in the H&SE Warning table below. These levels indicate that the employee's hearing is not as good as might be expected at his/her age. The warnings state that greater care should be taken to use appropriate protective devices when working in a noisy environment.

For further guidance to the operator and as a further explanation to the employee, two dotted lines are drawn on each of the audiogram grids, both on the screen and on the printout. These indicate the approximate level for Referral and for Warning.

The H&SE recommend that each audiogram should be put into one of four categories, based on the threshold levels in the audiogram, and the age and sex of the employee. The frequencies normally used for this assessment are 1, 2, 3, 4 and 6kHz.

These recommendations are followed in the Asra Curve program, where the four categories, as they are described on the screen, are as follows.

Category	Calculation	Action
1 Acceptable Hearing Ability Hearing within normal limits.	Sum of hearing levels at 1, 2, 3, 4 and 6 kHz.	None
2 Mild Hearing Impairment Hearing within 20th percentile, i.e. hearing level normally experienced by 1 person in 5. May indicate developing NIHL.	Sum of hearing levels at 1, 2, 3, 4 and 6 kHz. Compare value with figure given for appropriate age band and gender in Table A1.	Warning
3 Poor Hearing Hearing within 5th percentile, i.e. hearing level normally experienced by 1 person in 20. Suggests significant NIHL.	Sum of hearing levels at 1, 2, 3, 4 and 6 kHz. Compare value with figure given for appropriate age band and gender in Table A1.	Referral
4 Rapid Hearing Loss Reduction in hearing level of 30dB or more, within 3 years or less. Such a change could be caused by noise exposure or disease.	Sum of hearing levels at 3, 4 and 6 kHz.	Referral
Unilateral Hearing Loss Suggesting a problem due to disease or infection	Sum of hearing levels at 1, 2, 3 and 4kHz for both ears. **If the difference between the ears is greater than 40dB the individual should be advised of the findings.**	Referral

The HSE Categorisation Scheme

1. NIHL: Noise Induced Hearing Loss
2. Reference: HSE Controlling Noise at Work. The Control of Noise at Work Regulations 2005, pg 118 & 119.

10.. Troubleshooting and Error Messages

No audiometry hardware detected

The computer does not recognise the audiometer. A number of things to check that could cause this:

1. Is the Asra curve plugged in and getting power? The green power LED on the front panel will indicate whether it is powered up or not
2. Is the USB cable from the computer plugged into the back of the Asra Curve?
    a. If not, close the program window down and plug in then restart the program.
3. Have the drivers been installed?
    a. This can be checked in Device Manager in Windows. It should display and USB Serial Port (COM X) under Ports and USB Serial Converter under Universal Serial Bus controllers headings.
    b. If the drivers have not been installed, close the program down, unplug the USB from the back of the Asra Curve. The follow the instructions in the Installation section of this manual.

File Not Saved!

The audiogram has not been saved ---Is the folder and the path to it (if saving over a network to a server) valid and does the user currently logged on, have permissions to save to it?

File already exists, Ok to overwrite?

You are attempting to overwrite an existing file with this one

No calibration data has been found

The program attempted to load a file called cal.cal from the folder which contains the program, but it has not been found. If you proceed the system will not be correctly calibrated.

11.. Factors which affect absolute accuracy

Measurement accuracy and repeatability will depend on the following:-

Calibration:	Please refer Technical Specification given on page
Temperature:	Use equipment in controlled conditions, please refer to Technical Specification given on page
External noise	Use equipment in an environment which limits external noise to the minimum. The basic headset provides very little attenuation of external noise. Audiocups fitted to the headset improves the situation, particularly for higher frequencies and a booth also improves attenuation but particularly for low frequencies. Refer to BS EN ISO 8253-1:2010 for details on acceptable test environments.
Headset positioning	Remove glasses, ear rings etc. Place the headset so it sits comfortably on the head, with the headband adjusted for best fit.
Patient cooperation:	Advise the patient to press and release the button as soon as they hear the tone. A familiarisation facility is available when using the “Single” test button.

12.Maintenance / Technical Information

The Asra audiometer should have its calibration checked each day using a bio-simulator box (artificial ear) or by testing someone whose hearing levels are known, on at least 3 frequencies on each ear. In addition to this the cables should be inspected regularly for signs of damage, in particular in the region of the response button and where the cables approach the headset.

13.Calibration

Annual calibration should be performed by an approved supplier, who has access to the ASRA Curve calibration software and whose equipment has been calibrated to traceable standards.

14. Cleaning

14.1 Instrument Enclosure

Unplug instrument from the PC and the supplied PSU prior to cleaning.

Should the enclosure require cleaning for any reason, unplug it from the PC and wipe it with a damp cloth, or a cloth soaked in a mild alcohol- based solution or cleaning wipes. **Do not allow liquid to run into the enclosure.**

14.2 Patient Contact Parts

Must be cleaned with a Non-Alcoholic wipe and care taken to prevent liquid build up.

The Earphone Cushions, Audiocup cushions and the Response Button must be cleaned with a non- alcoholic wipe. Care should be taken to prevent the build-up of liquid on the earphone.
Note: The use of an alcohol-based wipe has the effect of spreading, and therefore changing the profile of, the earphone cushions.

15. Supplied Parts

The following parts are supplied with the Instrument

Instrument
Power Supply Unit – VEP15US09
Response Button
Headset with Audiocup Sound Reduction Headset
USB link to PC
User Manual
Software USB or Disk
Calibration certificate

16. Spare Parts and Consumables

Additional consumables or spare parts can be ordered against the codes below

Item	Part No
Response Button Unit	ASRA/OSICUS P R BUT
Microphone	ASRA MICROPHONE
Earphone cable	ASRA/OSICUS CORD
Earphone Cushion (Pair)	EARPHONE CUSHIONS
Audiocup Cushion	AUDIOCUP CUSHIONS
Earphones (TDH39)	EARPHONE
Audiocup Background Noise Reduction Headset	ASRA/OSICUS/SR/HEAD
Carry Case	ASRA TRANSIT
Power Supply Unit	ASRA CURVE PSU
EARS BOX – Electroacoustic Auto Response Unit	AUTOTEST BOX

Appendix 1: Guidance on the Electromagnetic environment in which to operate the instrument.

Use of portable telephones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation

- The ASRA Curve has been tested to EN60601-1-2:2015, regarding its ability to operate in an environment containing other electrical/electronic equipment (including other medical devices).

- The purpose of this testing is to ensure that the ASRA Curve is not likely to adversely affect the normal operation of other such equipment and that other such equipment is not likely to adversely affect the essential operation of the ASRA Curve.

- Despite the testing of the ASRA Curve that has been undertaken, normal operation can be affected by other electrical/electronic equipment and portable and mobile RF communications equipment.

- As the ASRA Curve is medical equipment, special precautions are needed regarding EMC (electromagnetic compatibility).

- It is important that the ASRA Curve is configured and installed/put into service, in accordance with the instructions/guidance provided herein and is used only in the configuration as supplied.

- Changes or modifications to the ASRA Curve may result in increased emissions or decreased immunity of the instrument in relation to EMC performance.

- The ASRA Curve should be used only with the cables, accessories and transducers provided by GM Instruments. The cables should not be extended by the user. If the cable is extended by the user, this may result in an increased level of emissions or decreased level of immunity, in relation to the ASRA Curve EMC. The use of the cables, accessories and transducers with devices other than the ASRA Curve, may result in an increased level of emissions or decreased level of immunity, in relation to the other device's EMC.

- The ASRA Curve should not be used adjacent to or stacked with other equipment. If adjacent or stacked use with other equipment is necessary, the ASRA Curve and the other equipment should be observed/monitored, to verify normal operation in the configuration in which it will be used.

- For the purposes of EN60601-1-2 the ASRA Curve has an essential performance (The instrument should not produce tones greater than 100dB unless permitted by the user).

Appendix 1: Guidance on the Electromagnetic environment in which to operate the instrument (cont'd)

Guidance and manufacturer's declaration – electromagnetic emissions		
The Asra is intended for use in the electromagnetic environment specified below. The customer or the user of the Asra should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Class B Mode 2	The equipment is suitable for use in a professional healthcare facility environment only.
RF emissions CISPR 11	Class B Mode 2	The equipment is suitable for use in a professional healthcare facility environment only.
Harmonic emissions IEC61000-3-2	Class A Mode 2	
Voltage fluctuations / flicker emissions IEC61000-3-3	Plt Pst Dmax Mode 2	

Appendix 1: Guidance on the Electromagnetic environment in which to operate the instrument (cont'd)

Guidance and manufacturer's declaration – electromagnetic immunity			
The Asra is intended for use in the electromagnetic environment specified below. The customer or the user of the Asra should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC61000-4-2:2009	± 2, 4, 6, 8 kV contact ± 2, 4, 8, 15 kV air	± 2, 4, 6, 8 kV contact ± 2, 4, 8, 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
Electrical fast transient / burst IEC61000-4-4	± 2 kV for power supply lines N/A: No DC Port ± 1 kV for input / output lines N/A: No Signal Port >3m 100kHz repetition frequency	± 2 kV for power supply lines N/A: No DC Port ± 1 kV for input / output lines N/A: No Signal Port >3m 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC610 00-4-5	± 0.5 kV and ± 1 kV line(s) to line(s) ± 0.5 kV, ± 1 kV and ± 2 kV line(s) to earth N/A: No DC Port	± 0.5 kV and ± 1 kV line(s) to line(s) ± 0.5 kV, ± 1 kV and ± 2 kV line(s) to earth N/A: No DC Port	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 IEC61000-4-11	0% U_T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0%; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0° 0% U_T; 250/300 cycle Mode 1	0% U_T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0%; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0° 0% U_T; 250/300 cycle Mode 1	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Asra requires continued operation during power mains interruptions, it is recommended that the Asra be powered from an uninterruptable power supply or a battery.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Appendix 1: Guidance on the Electromagnetic environment in which to operate the instrument (cont'd)

Guidance and manufacturer's declaration – electromagnetic immunity			
The Asra is intended for use in the electromagnetic environment specified below. The customer or the user of the Asra should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Power frequency (50/60Hz) Magnetic field IEC61000-4-8	30 A/m Mode 1	30 A/m Mode 1	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			
Conducted RF IEC61000-4-6 Radiated RF IEC61000-4-3	3 Vrms 0.15 MHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz	3 Vrms 0.15 MHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the Asra, including any cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance (*d*)** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz 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).
Proximity fields from RF wireless communications IEC61000-4-3	Frequency - Test Level 385MHz - 27 V/m 450MHz - 28 V/m 710MHz – 9V/m 745MHz – 9V/m 780MHz – 9V/m 810MHz - 28 V/m 870MHz - 28 V/m 930MHz - 28 V/m 1.72GHz - 28 V/m 1.845GHz - 28 V/m 1.97GHz - 28 V/m 2.45 GHz - 28 V/m 5.24GHz – 9V/m 5.50GHz – 9V/m 5.875GHz – 9V/m	Frequency - Test Level 385MHz - 27 V/m 450MHz - 28 V/m 710MHz – 9V/m 745MHz – 9V/m 780MHz – 9V/m 810MHz - 28 V/m 870MHz - 28 V/m 930MHz - 28 V/m 1.72GHz - 28 V/m 1.845GHz - 28 V/m 1.97GHz - 28 V/m 2.45 GHz - 28 V/m 5.24GHz – 9V/m 5.50GHz – 9V/m 5.875GHz – 9V/m	Fields 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 80 MHz and 800 MHz, 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 Asra is used exceeds the applicable RF compliance level above, the Asra should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the Asra [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Appendix 2: Technical Information (relative to EN 60601-1:2006+A12:2014)

No modification to this equipment is allowed.

- The ASRA Curve Audiometer is powered by an external universal mains power module. Power can be removed by unplugging the mains plug, or by switching power off at the mains plug.
- It complies with the specification for Class 1 ME equipment, and can be used along with a PC and printer, normally supplied by the customer. NB the warning made earlier about the PC and printer being compliant with EN 60950 and placing these items out of the reach of a subject.
- The Applied Parts comprise, Right and Left Headset and the Response Button, which are classified as type B applied part.
- The enclosure does not provide protection against the ingress of liquids and is therefore classified as IPX0. The supplied PSU enclosure does not provide protection against the ingress of liquids but does have level 2 degree of protection and is rating IP20.
- There are no parts which are supplied sterile or are required to be sterile.
- The ASRA Curve Audiometer is **NOT** suitable for use in an oxygen rich environment.
- The ASRA Curve Audiometer is rated for continuous use.
- The ASRA Curve serial number can be found on the label on the back panel, and the software version number can be viewed on the start-up screen and by clicking on Help, found on the top bar of the software (when fitted)

- Information is given in the Warning and Caution section of this manual, which the user must read prior to operating this instrument. Appropriate labels are fixed to the back panel

- The Headset and Response Button are identified as accessories with part numbers

- The ASRA Curve power supply module is marked VEP15US09. No other external supply can be used, unless supplied by GM Instruments as a replacement.

- The ASRA Curve power supply module, provides DC voltages of 9 volts dc from an input which can range from 100 to 240 volts, AC at 50 to 60 Hz.

- The rating input of the ASRA Curve is detailed on the supplied PSU VEP15US09

- Environmental conditions for transport and storage with no additional special measures
    - Temperature: -40 °C to +60 °C
    - Humidity: 30 to 90% RH

- The ASRA Curve Audiometer can be used by any medically trained technician, nurse, or doctor, who has either read this manual or who has been trained by a competent authority in its use.

- The power module provided with the ASRA Curve Audiometer (VEP15US09) is considered to be part of the ME equipment.

- The Headset and Response Button are considered to be the applied parts.

- The equipment should be positioned to enable it to be disconnected from the mains supply quickly and easily.

- Error Messages --- see Troubleshooting section 10

- The ASRA Curve software can be closed by clicking on FILE and EXIT. The ASRA Curve hardware can be switched off by either of the following:
    - Removing the MAINS PLUG
    - By switching off the MAINS PLUG at the socket
    - By disconnecting it from the PC USB socket
    - Powering down the PC if fitted

- There are no parts which need routine maintenance or servicing other than general “housekeeping”, such as keeping the equipment clean and cables free of twisting.

- The EXPECTED SERVICE LIFE of the ASRA Curve has been evaluated and determined to be 10 years from the date of manufacture. After this time, the ASRA Curve and the accessories, Headset, Response Button and supplied PSU, can be returned to GM

Instruments for dismantling and disposal, while your PC/Printer should be returned to your supplier for dismantling and disposal.

- These parts are subject to the WEEE directive, and should not be disposed of in landfill.

- The only parts which are interchangeable by service personnel are the power module and the mains cable. If these are changed, a Medical Electrical Safety test to the current standard should be made prior to allowing release for use.

- Circuit diagrams, component lists and parts lists are available on request, along with email/telephone advice to service personnel trained and qualified to work on ME devices. Modification of the ASRA Curve Audiometer is not allowed.