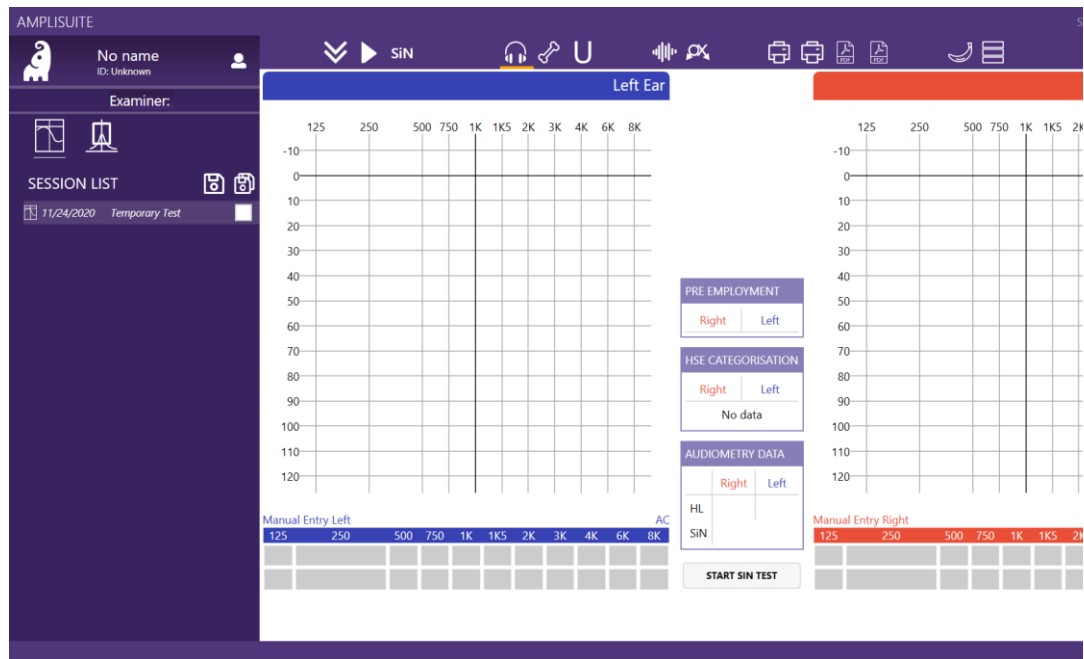


FHAS

Functional Hearing Assessment System

INSTRUCTION FOR USE



ABOUT THIS MANUAL

READ THIS OPERATING MANUAL BEFORE ATTEMPTING TO USE THE INSTRUMENT.

This manual is valid for the FHAS (from amplSuite SiN 1.2.45.20209 onwards).

This product is manufactured by:
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1. INTRODUCTION

1.1. THANK YOU

Thank you for purchasing the Amplivox Functional Hearing Assessment System (FHAS), system including a speech in noise test to identify speech perception disorders in noisy environments. The software is used together with the Model 240 audiometer, as well as the Otosure software, creating the system FHAS, the Functional Hearing Assessment System.

Amplisuite V1.1 and its connected software modules (Otosure.exe and SinTool (1v49).exe) have been tested and work according to calibrated standards.

The software has undergone significant testing to focus on test procedure and gathering the correct data values from the resulting tests.

Some data calculation errors have been identified and therefore Pre-employment, HSE Categorisation, CoP (College of Police) standards and SiN Pass Refer standards should be calculated and verified initially.

1.2. ABOUT AMPLIVOX FHAS

The Amplivox FHAS (functional hearing assessment system) is a combined solution of audiometers (Model 240 and Otosure) and software (ampliSuite SiN). Speech in Noise assessments are conducted using the Model 240 together with the ampliSuite SiN Module.

In addition, pure tone audiograms can be recorded using the audiometer Otosure.

1.3. ABOUT THE SPEECH IN NOISE (SIN) TEST

The Speech in Noise test was created in partnership with the University of Southampton in order to provide an additional diagnostic assessment tool (along with Pure Tone Audiometry) to assess hearing abilities of subjects. This test is a specialised version of the Co-ordinate Response Measure (CRM) developed for the evaluation of hearing abilities on Authorised Firearms officers and other potential safety critical occupations.

The College of Policing (CoP) determines appropriate hearing levels on the sum of low frequency and high frequency thresholds as follows:

Sum of Frequencies	Sum of 500Hz, 1KHz & 2KHz	Sum of 3, 4 & 6KHz
Acceptable Limits	≤ 84dB HL	≤ 123dB HL

Where a subject fails to meet the CoP standard, the Speech in Noise test can be used as an additional tool to help evaluate hearing ability in complex listening environments. This test has been shown to differentiate well between those considered to have a good hearing ability and those without.

At the time of development, there is no agreed international standard as to what constitutes Auditory Fitness For Duty for Authorised Firearms officers and other potential safety critical occupations.

1.4. INTENDED APPLICATIONS

This solution is designed for use by trained personnel only, such as occupational health personal and hearing healthcare professionals with a similar level of education. It is not recommended to use the equipment without the necessary knowledge and training.

The audiometer (Model 240) is capable of undertaking both air conduction tests with the additional features supporting speech audiometry from recorded sources.

The ampliSuite software can display audiology test results from the audiometer Model 240. ampliSuite can show up to 10 test results at once to make test comparison easier. The system calculates results according to HSE Categorisation and also calculates HL (CoP Hearing level sum), SNR 1, SNR 2 values and can compare them with acceptable values. In addition, our software is able to categorise Speech in Noise test result taken from external app (included).

1.5. CONTRAINDICATIONS

Always visually inspect the outer ear and the external auditory canal for abnormalities before testing.

Testing should not be performed on patients if the following conditions are applicable:

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

1.6. STANDARD AND OPTIONAL ACCESSORIES

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

STANDARD ACCESSORIES			
Model 240 Audiometer		Audiogram cards (pack of 50)	8013007
Audiometric headset, Earphones DD45 ¹	8517340	Operating Manual & ampliSuite SiN on USB stick	
Mains adaptor (2x)	8512734	Carrying case	8004673
Patient response switch ¹	8011155	Cable USB – A & B connector	8011241
SiN module		Calibration certificate	8011512
Audiocups add-on (noise reducing earphone enclosures) ¹	8010855		

1.7. GUARANTEE

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

1.8. WARNINGS

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

¹ Applied part according to IEC60601-1



WARNING

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



CAUTION

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

2. UNPACKING AND INSTALLATION OF THE AUDIOMETERS

2.1. GENERAL

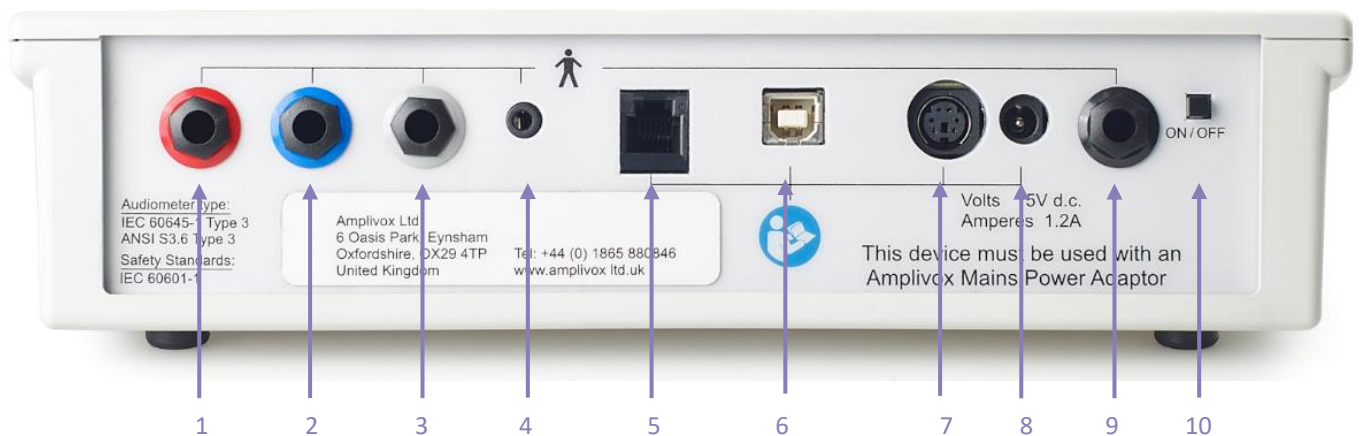
Please refer to the Model 240 instruction for use to learn about the functionalities and usage of the product.



Please note: When using the Model 240 for Speech in Noise tests, the set-up is slightly different to the regular Model 240. Please refer to the chapters below on how to set-up your Model 240 when Speech in Noise tests are required.

2.2. CONNECTIONS FOR SIN MEASUREMENTS (MODEL 240)

All connections required for Speech in Noise tests made to the rear panel of the audiometer as shown below.



1	Right (Red)	6.3 mm jack	Air Conduction Headset (Right Ear)
2	Left (Blue)	6.3 mm jack	Air Conduction Headset (Left Ear)
3	(not enabled)		
4	Stereo Audio Cable	3.5 mm jack	Connect to SiN Module
5	(not enabled)		
6	USB	USB connector	Computer (via USB port)
7	(not enabled)	6 pin mini DIN	
8	Power	2.5 mm DC jack	Mains AC/DC Adapter
9	Response (Black)	6.3 mm jack	Patient Response Switch
10	On/Off switch		Push and hold to switch on or off



Please note: Only connect the accessories supplied with the instrument or supplied by Amplivox or an Amplivox distributor. These parts have been tested for use with the Amplivox 240 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.

2.3. SiN MODULE SETUP

To set up the SiN Module, please connect the Power Cable (B) and the Stereo Audio Cable (A)



2.4. HARDWARE INSTALLATION

Connect the relevant transducers, the patient response switch and the speech unit with the device, before connecting the power adapter.

The instrument is designed for continuous operation and is powered by a mains adapter. Connect the output lead from the adapter into the **POWER** input socket on the back of the 240.

3. AMPLISUITE INSTALLATION

3.1. PRE-INSTALLATION NOTES

3.1.1. PC AND SYSTEM REQUIREMENTS

The PC-requirements are as follows:

- Processor: 1 GHz or faster, one or multi-core
- RAM: 1 GB or more
- Available hard disk space: minimum 200 MB
- Resolution: minimum 1378 x 768
- Graphics device: DirectX 9 with WDDM 1.0 or higher driver
- Available 2.0 or 3.0 USB Port

3.1.2. OPERATION SYSTEM COMPATIBILITY

ampliSuite is supported on the following Microsoft Operating Systems:

- Windows 7
- Windows 8 / 8.1
- Windows 10

3.2. INSTALLATION

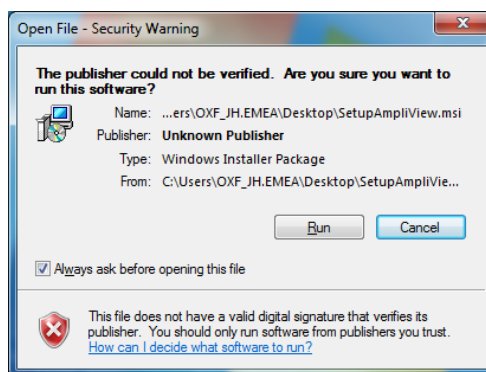
3.2.1. GENERAL

Installation is a straightforward process, but the steps must be carried out in the correct order. To ensure you are familiar with the instructions please read this entire user manual before commencing installation.

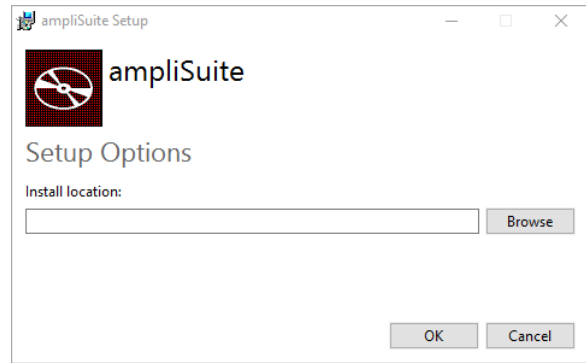
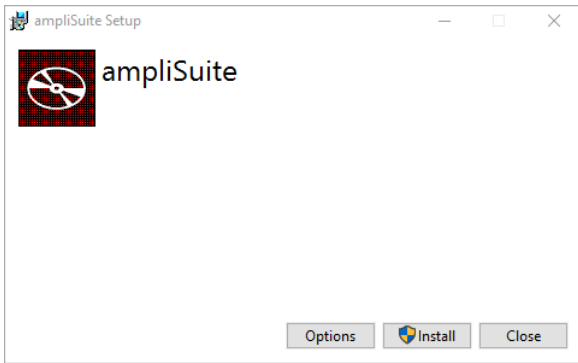
3.2.2. AMPLISUITE SIN SOFTWARE INSTALLATION PACKAGE

Run ampliSuiteInstaller.exe

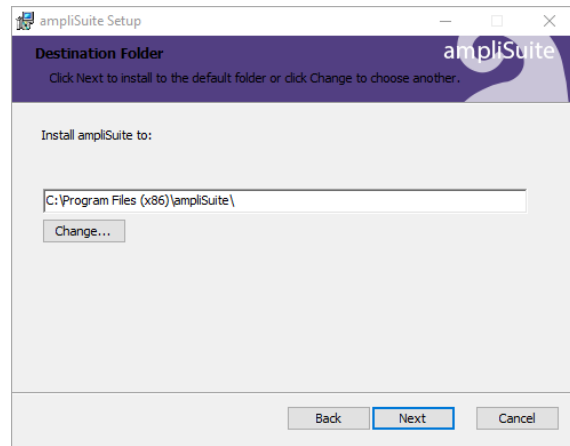
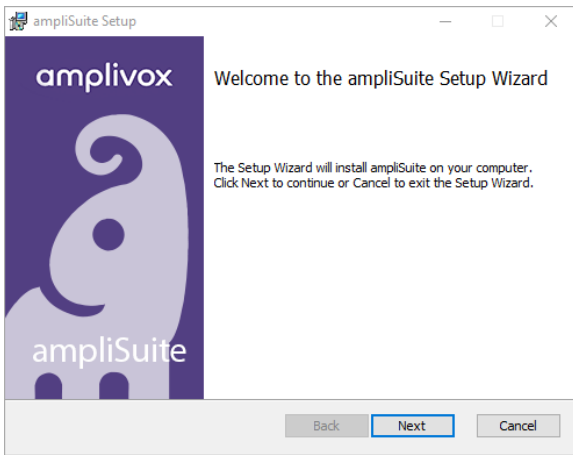
Select Run to any security warnings that are displayed:



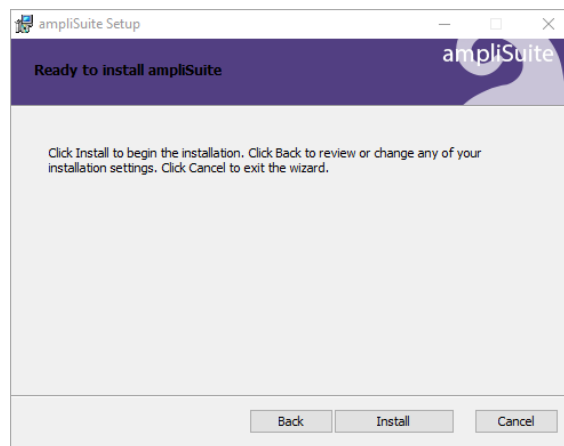
If desired, change the installation location by Options. Select Install on the welcome screen to proceed with the installation:



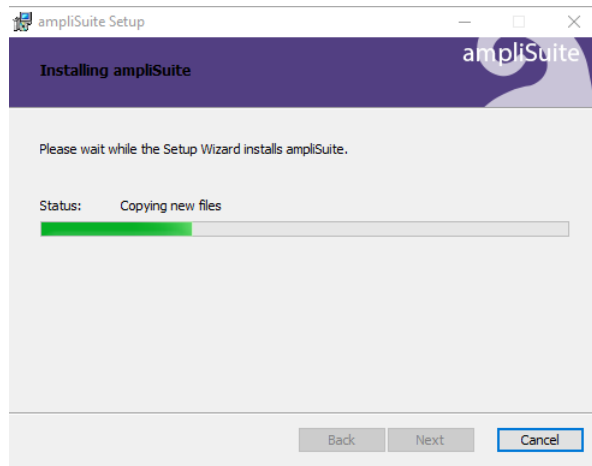
Select Next to proceed with the installation:



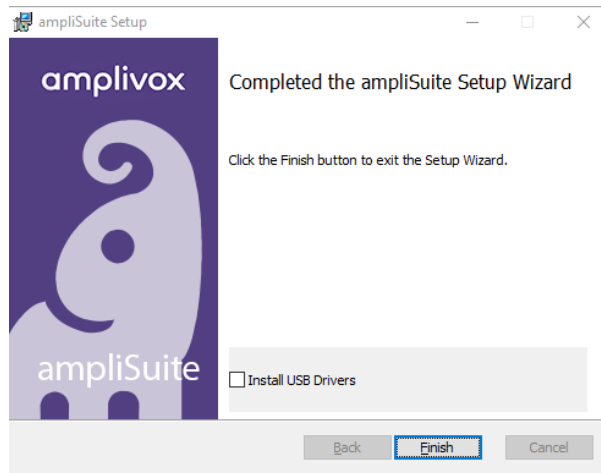
Select Install to proceed with the installation:



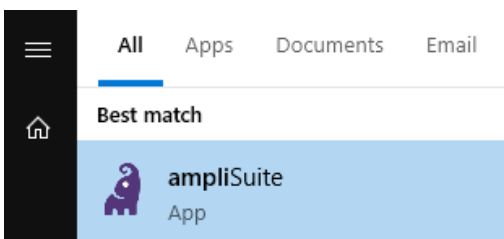
ampliSuite installation will then commence:



ampliSuite installation will continue until complete. Tick the box to install the USB drivers if you don't currently have the latest Amplivox USB drivers installed. Select Finish.



To start ampliSuite, select ampliSuite from the start menu or the ampliSuite icon on the desktop.



The ampliSuite Software can also be started by double-clicking on the ampliSuite.exe file. A desktop shortcut to this may be created if desired.

4. AMPLISUITE SIN SOFTWARE

4.1. GENERAL PRECAUTIONS

When operating the instrument, please observe the following general precautions:



CAUTION

1. Use this device only as described in this manual.
2. Be sure to use only stimulation intensities acceptable to the patient.
3. Clean the headphones, insert phones and patient response switch regularly using a recognised disinfectant.
4. The presence of tinnitus, hyperacusis or other sensitivity to loud sounds may contraindicate testing when high intensity stimuli are used.



Please note:

Careful handling of the instrument whenever in contact with a patient should be given high priority. Calm and stable positioning while testing is preferred for optimal accuracy.

1. Never clean the transducer housing with water or insert non-specified instruments into the transducer.
2. Do not drop and avoid other undue impact to this device. If the instrument is dropped or in any other way damaged, return it to the manufacturer for repair and/or calibration. Do not use the instrument if any damage is suspected.

4.2. SETTINGS PASSWORD

The default password for the settings is: amplivoxculham.

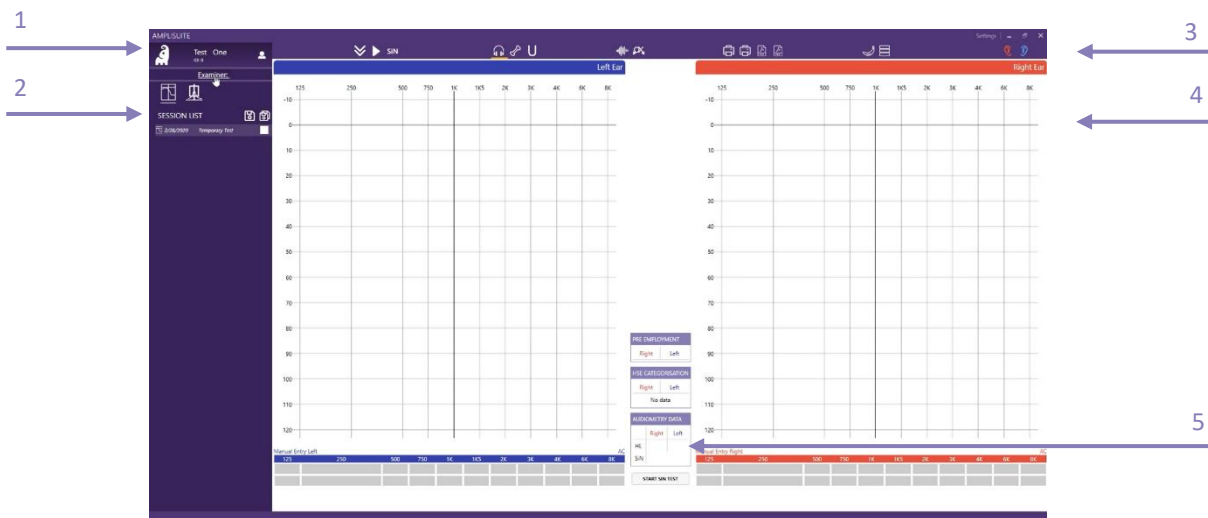
4.3. ABOUT AMPLISUITE

4.3.1. GENERAL



Open ampliSuite by double-clicking on the shortcut icon on the desktop.

The Suite will start in the tone audiometry module, as shown below. The audiometry module consists of patient information (1), the currently uploaded session details (2), the control bar (3), audiograms for the left and right ear in table (4) and diagram format and the PTA calculation, HSE categorisation and SiN test outcome (5).



4.3.2. SELECTION OF AC, BC AND UCL

In the toolbar, select the corresponding icon of the graph that shall be plotted. The following selection is possible:



Air Conduction (AC): Select this icon to plot the air conduction.



Bone Conduction (BC): Select this icon to plot the bone conduction.



U-Threshold (UCL/ULL): Select this icon to plot the uncomfortable loudness threshold.

In addition to the selection of AC, BC and UCL, masking can be activated. It is also possible to mark.



Masking: Select this icon in addition to AC or BC to mark a masked threshold.



Not heard/no response (NR): Select this icon in addition to AC or BC to mark a not heard point.



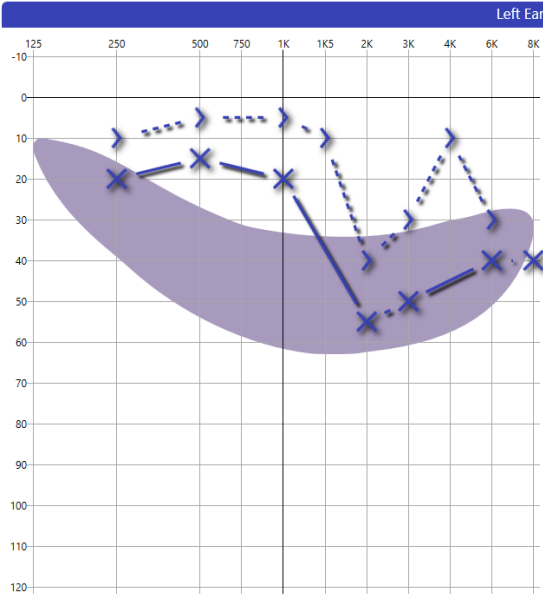
Please note: The data shown in the table below the graph, plotted or deleted is always equivalent to the selection (AC, BC, UCL) made in the toolbar. If the air conduction is selected, no bone data can be deleted and vice versa.

4.3.3. COUNSELING OVERLAYS

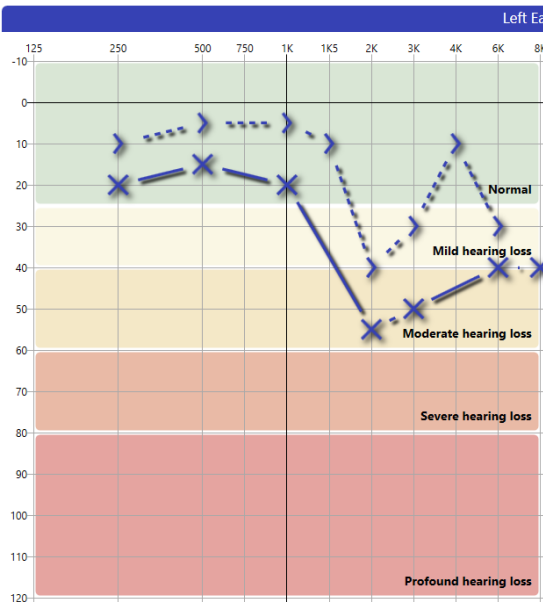
It might be desired to use additional explanation tools to help the patient better understand his or her hearing threshold.



Speech Banana: Will show the speech area as it is selected in the settings.



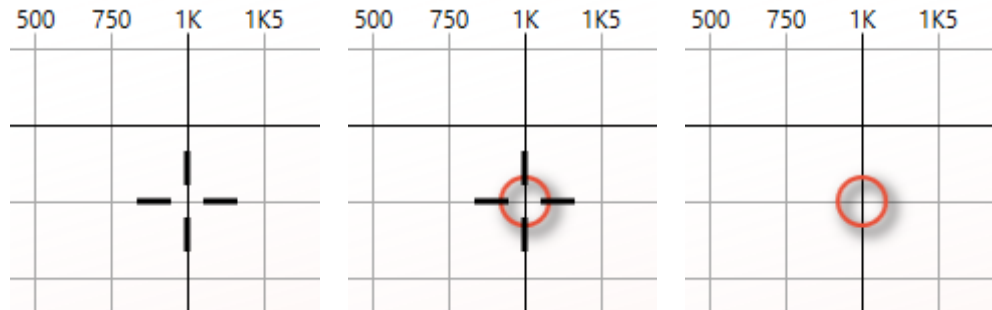
Hearing Levels: Will show the degrees of hearing loss based on the World Health Organization's (WHO) recommendation.



4.3.4. MANUAL ENTRY OF DATA

There are different options to enter test data. Data can be plotted directly into the graph using the mouse or the keyboard, or the **Manual Entry Table** below the audiogram.

Select the desired ear side and test method (AC, BC, UCL, (un)masked and NR) to start plotting data.



- | | | | |
|------------------|---|---|--|
| Mouse: | Use the mouse to move the cursor to the desired frequency and level. | Double-click left and store the test point. | Right-click at any level of the frequency to delete the test point again. |
| Keyboard: | Use the arrow keys to move the cursor to the desired frequency and level. | Hit the Enter-key or S-key on the keyboard to store the test point. | Hit the Delete key on the keyboard at any level of the frequency to delete the test point again. |




As soon as the point has been entered, the table below the graph will show the equivalent value.

Manual Entry Table: Click in the table below the graph to enter the corresponding level of the selected frequency. The top row represents the Air or Bone conduction values, whereas the second row represents the masking values, if any exist. To move to the next cell, press the Tab key.

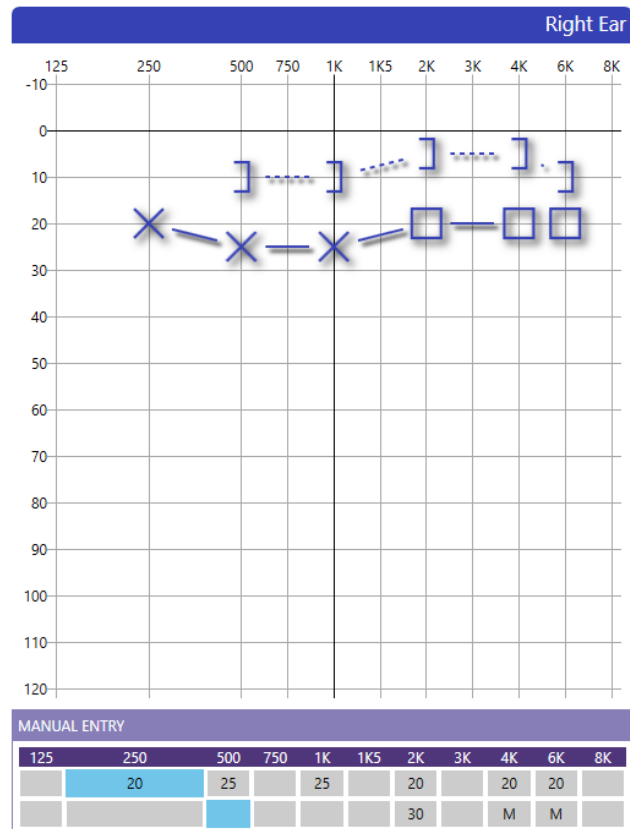
MANUAL ENTRY										AC
125	250	500	750	1K	1K5	2K	3K	4K	6K	8K
	20	15		20		55	50		40	40

4.3.5. MASKING

Masking values can be added in two different ways.




Either, the masking button  in the toolbar is selected together with the AC  or BC  function, or the **Manual Entry** table is used to manually add the masking values.

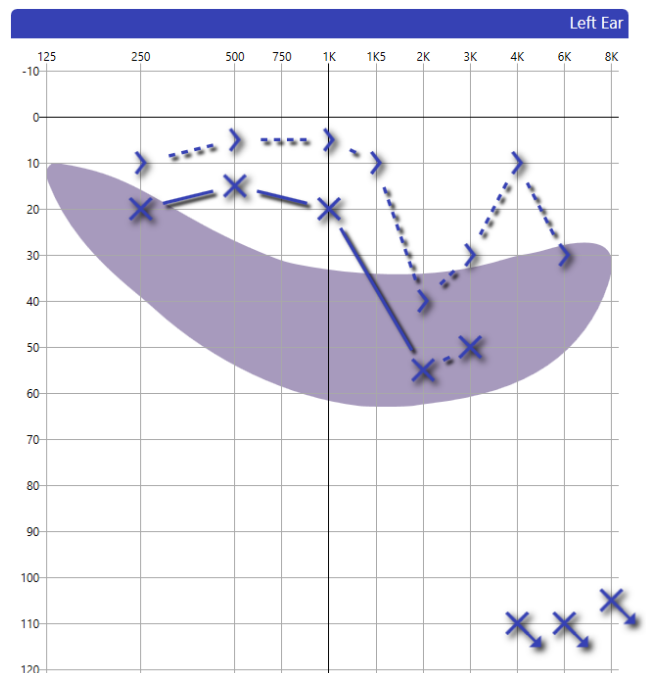
When masking is used, but the actual masking value is unknown, the table will show an **M** to indicate masking was active. If the masking value is known, a number will show in the second row of the table.



4.3.6. NO RESPONSE

In the case where the patient did not respond to the test signal, the symbol of **no response** (NR) can be added to the audiogram.

Select the NR button  in the toolbar together with the AC  or BC  function to mark the level as not heard.

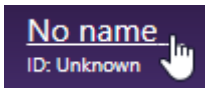


4.3.7. DELETE A TEST POINT

In case a test point was placed incorrectly and should be removed, it is possible to delete a test point. Select the threshold that should be removed (air or bone) and move the mouse over the corresponding level, ideally the test point, to be deleted.

To delete the point, select the **delete** button on the **keyboard** or click the right button on the **mouse**.

4.4. ADD PATIENTS TEST DETAILS



To enter basic patient information, click on the patient name on the top of left side corner of the session bar. If no patient name has been assigned yet, the patient is called **No name**.

The patient details form will then be displayed. Enter the patient details and select **OK**. The details will then be displayed on the main patients details screen. The information provided will be included in the patient printout.

Details

Title	<input type="text"/>	Gender	<input type="text" value="Unknown"/>
First name	<input type="text"/>	Patient No:	<input type="text"/>
Middle names	<input type="text"/>	NHS number	<input type="text"/>
Last name	<input type="text"/>		
Date of Birth	<input type="text" value="1/1/0001"/>		

When the patient information is recorded, we recommend to continue running a screening audiometry test using the Audiometer.

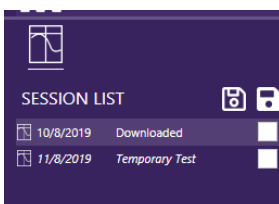
Hearing test results can only be categorised to HSE standards when a subjects Gender and Date of Birth have been entered.

4.5. STARTING OTOSURE SOFTWARE

From ampliSuite, the Otosure software can be started to run a screening audiometry test. Please refer to the instruction of use of the Otosure on how to conduct a test using the equipment.

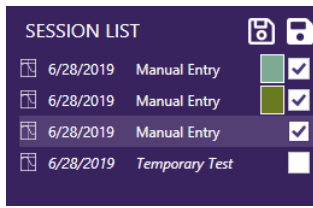


Run otosure.exe to perform test (be notice that connected device is required). Please refer to the Otosure instruction for use about how to use the Otosure software.



As soon as a test is downloaded and selected, the result will be shown, and further details can be found in the session panel.

4.6. BASELINE COMPARISON



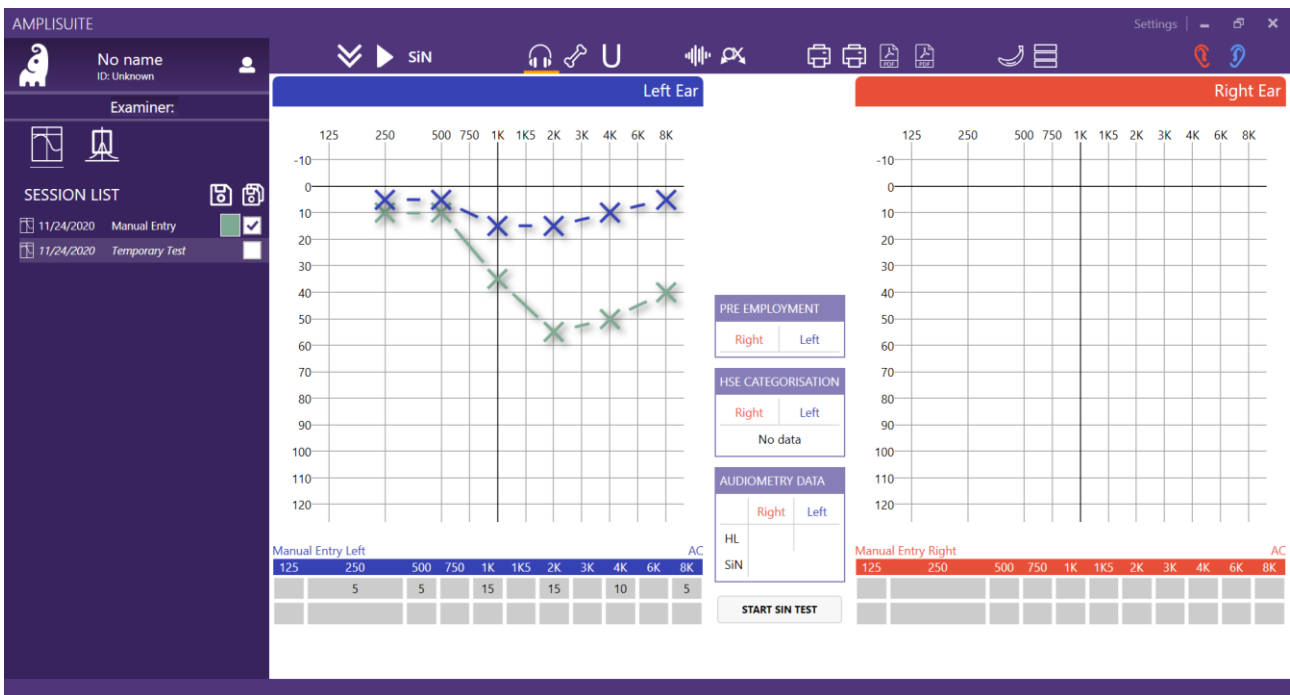
Measurements obtained for the same patients can be overlapped and displayed at the same time for review purposes.

To show several curves at once, select the check box next of the test you want to display. The selected thresholds will be shown in different color to allow a differentiation of the different measurements. The color will be displayed next to the selected test.

To override previous test dates before saving, click the Data and override with desired date. For HSE (Category 4) comparison, ensure the relevant dates are within the given timeframe.



Please note: You can show up to 10 tests at once. If you select more than 10, the first selected test will be deselected.



4.7. USING THE SIN TOOL SOFTWARE

4.7.1. WHEN A SIN TEST IS RECOMMENDED



After the completion of the screening audiometry test via Otosure, ampliSuite will indicate if a speech in noise test is recommended or not, by illuminating the SiN button.



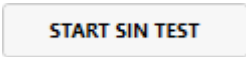
The film icon to the right of the SiN button contains a 1.5 minute subject explanation of the test.

4.7.2. STARTING THE SIN TEST



Run SiNTool.exe to perform speech in noises test (be notice that connected device is required).

or

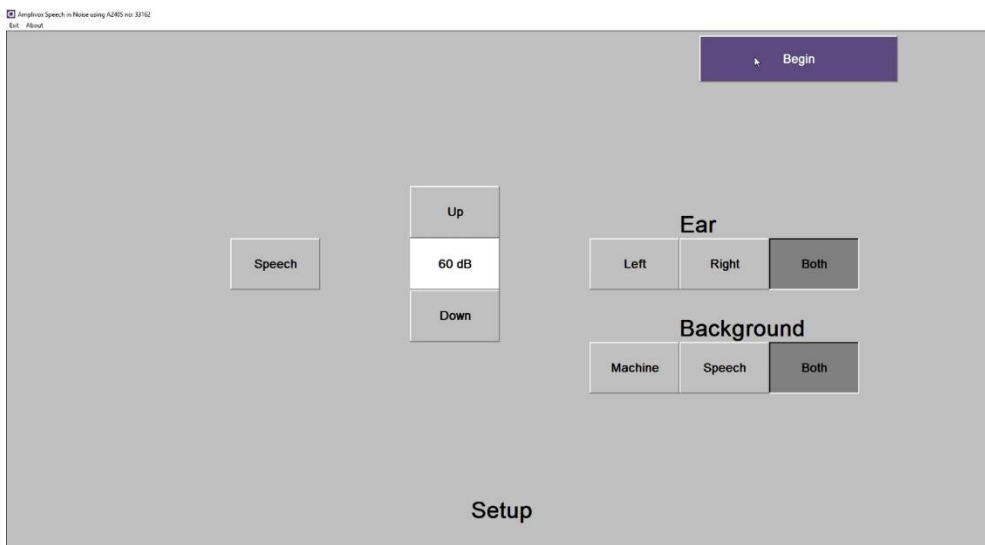


As soon as a test is downloaded and selected, the result will be shown, and further details can be found in the session panel.

The SiN module will then be started.



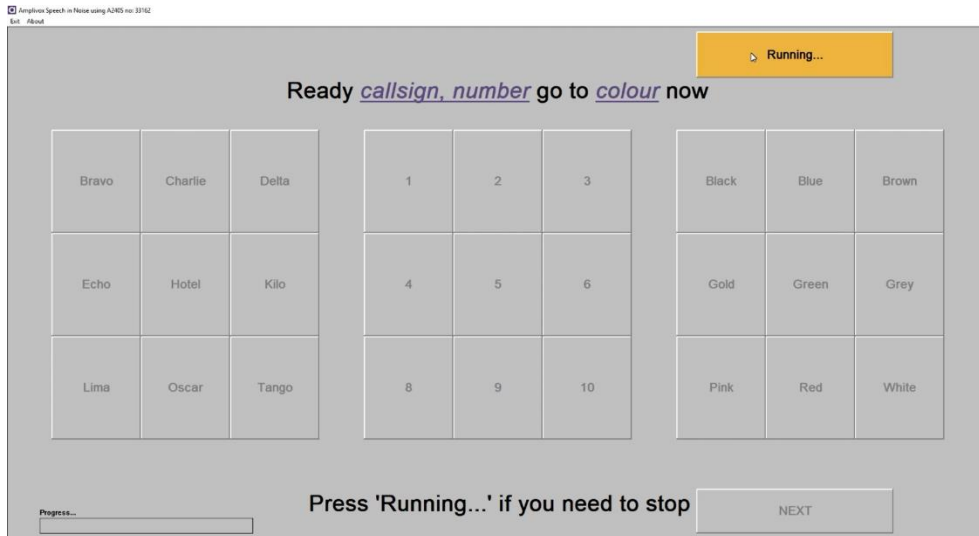
Please note: The Speech in Noise test consists of two parts and takes about 30 minutes in total to complete. Retesting can be considered, the test has been shown to have little learning effect.



Start with select the starting level. For hearing levels above 40 dB, we recommend a starting level of 60dB or 70dB as well as which part of the test and which ears to test. Please note that the default test routine is to test both ears on both parts.

To start the test press begin and then pressing Start will fully start the test. Please note to only press once – the system takes a few seconds to start, otherwise will close if pressed again.

The test will complete and indicate on a results screen as a summary of completion for each ear. To stop the test, press “Running...”



When the test has been completed, follow the on-screen prompts.

When returning to ampliSuite, the summary results will be presented.



The full results will be displayed in the medical record, which can be created by printing or PDF filing of the test results.



Please note: Remember to process results (Print / Save) before further testing. Results will not be saved.

4.7.3. UNDERSTANDING THE TEST RESULTS

4.7.3.1. AUDIOMETRY DATA REFER TABLE

The test results will be categorized with the following information displayed.

	Main Display	Patient Printout	Medical Record
Both tests / ears completed	PASS / REFER	PASS / REFER	PASS / REFER + Actual test scores
Not tested	“-“	“-“	“-“
Partial completion or testing	n/a	Incomplete	“-“ in the ear which has not been tested, or “NO SNR” if a level cannot be defined. Other test will display test result
Unable to find a threshold	n/a	Incomplete	No threshold has been established; NO SNR will be displayed.

AUDIOMETRY DATA		
	Right	Left
HL	PASS	REFER
SNR 1	REFER	REFER
SNR 2	REFER	REFER



or



HL indicators show PASS or REFER depending on sum of 2 ranges of high and low frequencies. If HL is higher than acceptable values the indicator REFER is shown and start buttons for SiN test are marked green. After Sin result are downloaded indicators for SNR 1 and SNR 2 are presented as well.

4.7.3.2. MANUAL RESULTS CALCULATIONS

Where it has not been possible to complete the full test routine in one run through, the test can be completed separately where appropriate. To establish a combined SNR score for each ear, a result must be present with a Machine (M) and Speech (S) background. These scores should be added together and interpreted according to the Pass / Refer criteria. Where only one part result per ear can be established, the result should be classified as a fail.

4.7.3.3. PASS LEVELS AND FURTHER STEPS

The Pass / Refer levels have been determined according to the table set out below.

Combined SNR Scores (Machine (M) and Speech (S) background per ear	Example calculation	
Lower than -22dB SNR	Pass	M: -22.5 + S: -0.5 = -23 dB SNR (PASS)
Greater than -22dB SNR	Refer (Fail)	M: - 21 + S: 0.5 = -20.5 dB SNR (REFER)

4.7.3.4. HSE CATEGORISATION TABLE

HSE CATEGORISATION	
Right	Left
CAT 3	CAT 3
Cat 4 - No data	
UNILATERAL HEARING LOSS	

This table shows HSE category for each ear. First row presents right / left ear label, next shows category from 1 to 3, next is for 4th category. It can contain Cat4 – No data, Cat4 or be empty depending on audiogram and historical data. In last row the table present information about UNILATERAL HEARING LOSS if it occurs.

4.7.3.5. PTA CALCULATION

AUDIOMETRY DATA		
	Right	Left
PTA	55	33.3

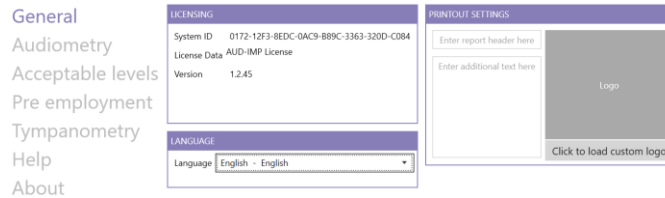
An automatic PTA calculation takes place when adding air conduction values and will be visible for each ear side in the **Audiometry Data** table, shown below the audiograms.

The PTA is calculated out of the average of the hearing threshold for specific test frequencies. These specific frequencies can be customized in the audiometry settings.

4.8. SETTINGS

4.8.1. GENERAL

Selecting the settings button **Settings** at the top of ampliSuite will open a pop-up with all available settings for the audiometry modules.



4.8.2. AUDIOMETRY SETTINGS

4.8.2.1. POSITION OF EAR SIDE SPECIFIC AUDIOGRAM

Depending on your preferences, you might like to have the audiogram of the right ear displayed on your right hand side and the one of the left ear on your left hand side. In this case, select **Left ear on left side**.

Others prefer to see the audiogram arrangement according to the patients view. In this case, select **Left ear on right side**.

If you want to see the thresholds for both ears on one audiogram, please select Both ears on the **same graph**.

4.8.2.2. AUDIOGRAM ICON SET

The audiogram icons used in the audiometry module might be dependent on your location. The ampliSuite audiometry module offers you 5 different icon sets, based on your location: ASHA (US), Australia, BSA (UK) or Hong Kong.

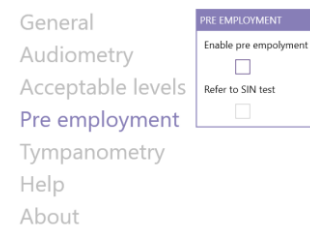
4.8.3. ACCEPTABLE LEVELS

Other settings view linked with audiometry module is acceptable levels. Here you can define the acceptable hearing level for 0.5, 1 and 2 kHz and 3, 4 and 6 kHz as well as the SNR 1 and 2 acceptable levels.



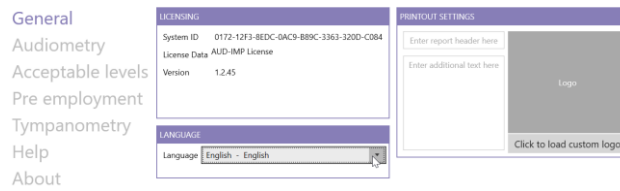
4.9. PRE EMPLOYMENT

Select PRE EMPLOYMENT to find the pre employment settings on the right-hand side. Check both boxes (enable pre employment and refer to SiN test), so that ampliSuite will inform you when a speech in noise test is required.



4.9.1. CHANGING THE LANGUAGE

Select **SETTINGS** in the upper right corner of ampliSuite. A popup will open with all available ampliSuite settings. Select **GENERAL** to find the language settings on the left-hand side.



The following languages are available to use in the ampliSuite: Chinese (中文), English, Estonian (eesti), French (français), German (Deutsch), Hebrew (עברית), Hungarian (magyar), Italian (italiano), Japanese (日本語), Korean (한국어), Polish (polski), Portugese (português), Russian (русский), Serbian (srpski), Spanish (español), Turkish (Türkçe) or Vietnamese (Tiếng Việt).

Select the language you would like ampliSuite to be in and confirm the change by clicking **OK**. ampliSuite will require a restart for the changes to take place.

4.9.2. HELP

Under **HELP** the ampliSuite manual and SiN instructional video are stored. The manual can also be opened from every screen by pressing the F1 key.

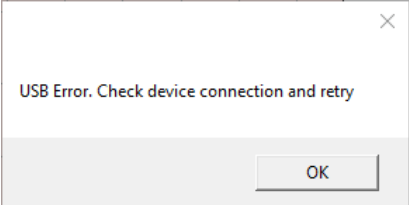


4.9.3. ABOUT

In the **About** section you can find useful information about Amplivox. You can contact us directly via email or access our website.

4.9.4. TROUBLESHOOTING



Please note: Refer to the installation & operating instructions provided with your instrument(s) for details of the data transfer operation and errors that could possibly occur. If a fault cannot be fixed, the operator is cautioned against repeatedly restarting the instrument.

PROBLEM	CAUSE	SOLUTION(S)
Instrument doesn't connect. 	<ul style="list-style-type: none"> • Device is not switched on • USB connection unstable 	<ul style="list-style-type: none"> • Switch on /Restart device • Check USB connection in both instrument and PC • Ensure cable is in good working order
No data is transferred to PC.	<ul style="list-style-type: none"> • Specified location to store data is different than expected • Specified location to store data does not exist • LoadIt.exe is stored in a different location 	<ul style="list-style-type: none"> • Review the store location in the settings • Store LoadIt.exe in same folder as ampliSuite.exe
Not all tests completed	<ul style="list-style-type: none"> • A subject may have difficulty getting used to the test or unable to get a result in one ear. 	<ul style="list-style-type: none"> • In this instance, the subject can be retested where they have been unable to complete a test. Results can be combined and will require manual addition.
Error 20 type b 	<ul style="list-style-type: none"> • USB connection to Otosure unstable 	<ul style="list-style-type: none"> • Switch on /Restart device • Check USB connection in both instrument and PC • Ensure cable is in good working order
	<ul style="list-style-type: none"> • Model 240 is not switched on • USB connection to Model 240 unstable 	<ul style="list-style-type: none"> • Switch on /Restart device • Check USB connection in both instrument and PC • Ensure cable is in good working order

<p>Subject cannot hear a command in an ear, or gain a threshold.</p>	<ul style="list-style-type: none"> • If a test result is shown as Incomplete or No SNR, the system has not been able to establish a repeatable threshold for that test or ear. 	<ul style="list-style-type: none"> • In this case, it would be advisable to retest the subject with a higher starting level (70dB), and potentially one part of a test at a time. If a subject still cannot hear and respond correctly, their hearing ability cannot be assessed with this test.
<p>Starting level set at 70dB, subject cannot understand a command.</p>	<ul style="list-style-type: none"> • Subject's hearing may be too poor to be able to identify a SRT with this test. • Subject is unwilling to participate in the test. 	<ul style="list-style-type: none"> • If a subject cannot hear and respond correctly to establish a SRT threshold, their hearing ability cannot be assessed with this test.



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