SSS - ISD - Instructions for Use

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Table of Contents

Sound Scouts Solution - Instructions for Use

Manufacturer Information
Sound Scouts HQ Pty Ltd 107, 4 Clarke St Crows Nest NSW 2065 Australia Email: contact@soundscouts.com Website: soundscouts.com

1. Product Description

The Sound Scouts Solution is a Class IIa medical device under the Therapeutics Good Administration Regulations (rule 4.5.1.e)

Intended Medical Indication

The Sound Scouts Solution is a Software application intended to assist with the evaluation of a person's hearing capability. It may be used by healthcare professionals in a healthcare facility, in the context of an institutional screening program (eg school or aged care setting) or by the person in the home. The app includes two modes for testing hearing; The Triple Factor Hearing Screener (TFHS), which consists of a test of speech-in-quiet, speech-in-noise, and tone-in-noise, and the Automatic Audiometer (available only on iOS / iPadOS devices). Clinical studies, including Dillon et al. (2018), have validated the device's sensitivity of 85% and specificity of 98% for detecting hearing loss, achieving 100% sensitivity for hearing losses greater than 30 dB HL in the poorer ear.

Characterisation of User Profile

It may be administered by:
- healthcare professionals in a healthcare facility (GPs, otologists, speech pathologists, other clinicians)
- supervised by responsible adults such as educators or assistants in an organisation or facility (e.g. school or aged care setting), or
- by the person in the home, or
- by a person in the home supervised by a caregiver (e.g. parent, caregivers, support staff)

Training is available prior to product use for those testing in an institutional (eg school or aged care setting) or clinical setting but is not required for product use.

Characterisation of Patient Population

The intended treatment group is from four (4) years of age. It is also usable by adults.
Sound Scouts can be used in the context of an institutional screening program or individually by a patient or a caregiver, either voluntarily or following the recommendation of a healthcare professional.

Warnings and Exclusions

Regardless of the test result from Sound Scouts, if there are ongoing concerns about the Client/Player's hearing, they should consult their healthcare professional.

- Sound Scouts is not suitable for people with severe cognitive issues.
- All testing must be carried out in a quiet space.
- Only suitable for ages 4yrs+
- The use of audio splitters or other in-line devices will affect the results
- A touchscreen device with an internet connection must be used

Triple Factor Hearing Screener:
Using poor quality headphones may affect test accuracy. Only use headphones or earbuds that provide clear, balanced sound in both ears from established manufacturers - do not use unbranded models, gaming headsets, open air / bone conduction devices, children's headphones, or any headphones with uneven sound between ears or poor audio quality, as this may lead to unreliable results. Lower cost headphones (< AU $25) are less likely to be suitable.

- The same headphones must be used by the Supervising adult and the Client/Player. Do not use children’s or gaming headphones.
- You can use the Trial Run under the New Session tab to experience the test activities before purchase.
- When testing children the correct age - year and birth month - must be entered to receive the most reliable result.

Automatic Audiometer:

- Only available on iOS / iPadOS devices
- Must only use listed headphones
- This test is one method to screen hearing and the person should see a healthcare professional for further assessment if a 'Refer' result is received. If the result is not in line with other indicators, we recommend re-testing and/ or seeking further advice from a healthcare professional.

Clients/Players with behavioural, cognitive, or learning challenges or vision impairments may require additional support to complete the Sound Scouts test effectively. Supervisors should allocate extra time, provide one-on-one supervision, and minimise environmental distractions to ensure accurate results.

Clients/Players who speak English as an Additional Language (EALD)

- For those who speak English as an additional language, when testing with the TFHS it is recommended to review words and phrases prior to testing using the resources available on our School Resources (https://www.soundscouts.com/au/schools/school-resources/) page. We encourage verbal repetition of each word to ensure comprehension. The ability to identify 5 words used in the speech in quiet activity is necessary to complete the TFHS. The Automatic Audiometer, which is language independent, can be used as an alternative.

This test is just one way to assess hearing and it is possible that other tests would give different results. A course of action may be recommended depending on the test being used and the results.

2. Software Information

The Sound Scouts Solution is delivered through the **Sound Scouts App** (SSAPP), with optional management and data functionality for schools, organisations and clinicians available on the **SSIMPL** (Sound Scouts Integrated Management Platform).

Software Component	Applicable Version Number
SSAPP	15.0.0 and newer
SSIMPL	6.3 and newer

Hardware and Software Requirements

Sound Scouts App

Triple Factor Hearing Screener:

Operating System	Version
iOS / iPadOS	15.0 or newer
Android	6 "Lollipop" or newer
Windows	version 11

Automatic Audiometer:

Operating System	Version
iOS / iPadOS	15.0 or newer

The device must have:

- A touchscreen
- Network connectivity
- Headphone audio output (either through 3.5mm jack, Bluetooth, or device-appropriate audio adaptor)

SSIMPL Web Portal

Browser	Version
Google Chrome	130 or newer
Firefox	140 or newer

3. Sound Scouts App Instructions for Use

Installation

The app is downloaded through the device's official app distribution system (App Store for iOS / iPadOS, Google Play Store for Android, Microsoft Store for Windows PCs)

Test Preparation

All testing must be carried out in a quiet space

1. **Triple Factor Hearing Screener (TFHS):**
   - The same decent quality adult headphones or earbuds must be used by both the Supervising adult and the person being tested.
   - Do not use telephony, gaming or children's headphones, or in-line devices such as: audio splitters or headphone amplifiers
   - Before testing set the device volume to maximum. Adjust if too loud.
   - The Supervising adult should concentrate and respond to the sounds to the best of their listening ability while doing the set-up activity
   - Undertake the Trial Run activities to ensure understanding, particularly important for clients/players with behavioural, cognitive, or learning challenges
2. **Automatic Audiometer:**
   - Available on iOS / iPadOS only
   - Must only use listed headphones (https://www.soundscouts.com/au/docs/SS_Automatic_Audiometer_Guide.pdf)

Credits must be purchased to complete a test and receive a result.

Testing

- Ensure the room you are testing in is quiet and free from distractions.
- Clients/Players, particularly children, should be well rested, fed and have been to the bathroom. Nose blowing prior to testing is recommended.
- The Supervising adult should tell the person being tested to listen carefully and only tap or interact when they hear the sounds.
- Excessive tapping can void the test. It is important for the Supervising adult to watch and be aware of on-screen alerts.

Results

- An internet connection is required to process and return the results on completion of the test. Results will be shown on the device and a Report can be emailed if an address is provided (TFHS only).
- The results are provided with interpretations
- If you have any concerns about the person tested, we encourage further assessment with a suitable healthcare provider.

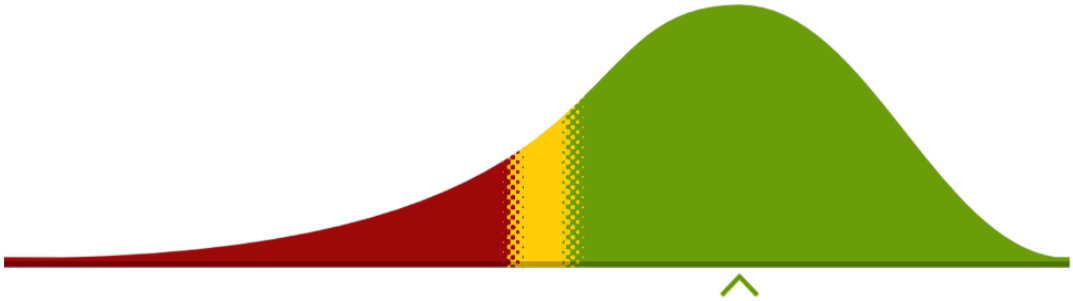
Checklist

- Turn off device notifications to avoid interruptions
- Check headphones are correctly connected to the device
- Supervisor and Client/Player must use the same headphones
- Do not change the volume after completing the supervisor activity

- Supervise children to ensure they are listening and responding to the sounds

4. Interpreting Triple Factor Hearing Screener (TFHS) Results

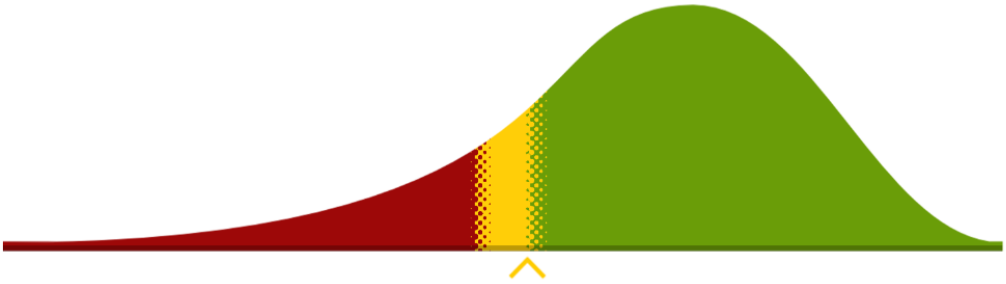
Examples included below are for a child. The Report will vary depending on the age of the person being tested.



Example Player B has received a score of: 100
The average score is: 100

For Pass Results:

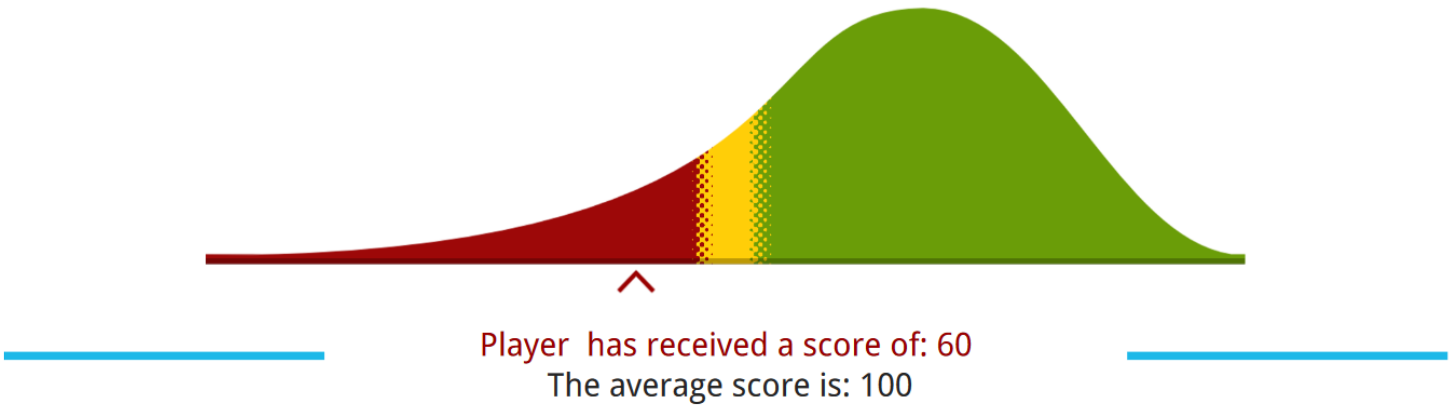
If the child receives a Pass, the Report will state that the child has passed the Sound Scouts hearing check. This means that the child's results are within the normal range for children of the same age. If you have ongoing concerns about the child's hearing we strongly recommend seeing your GP or a hearing professional.



Child Q has received a score of: 76
The average score is: 100

For Borderline Results:

If the child receives a Borderline result, hearing may be on the edge of normal. When a Borderline result is received it is recommended that the child is retested after 24 hours. If the child receives a similar result further investigation may be necessary.



For Results Outside Normal Range:
If the child receives a result outside the normal range we recommend retesting after 24 hours. If the child receives a second result outside the normal range then further diagnostic assessment is recommended. See below for the next steps for a child whose results are outside the normal range.

Next Steps Following a Result that is 'Outside Normal Range'

Clients/Players who have results outside the normal range may be flagged as having an issue in one of the following areas:

Outer and Middle Ear (Conductive Hearing Loss)
If the Client/Player receives a fail result with an indication of a conductive, or outer/middle ear, hearing loss, the Sound Scouts report will recommend visiting your doctor for further assessment. A conductive issue may be caused by things such as a build up of wax or fluid, and in most cases, with the appropriate treatment, hearing will return to normal.

Inner ear (Sensorineural Hearing Loss)
If the Client/Player receives a fail result with an indication of a sensorineural, or inner ear, hearing loss, the report recommends follow up with Hearing Australia (AUS only) or an audiologist for a diagnostic assessment. Please note, Hearing Australia provides free services to children with sensorineural hearing loss (conditions apply). We recommend speaking to the Hearing Australia representatives about the costs when booking an appointment. (AUS only).

Difficulty Hearing in Noise
If the Client/Player receives a fail result with an indication of difficulty hearing in noise, the possible causes need to be considered. Difficulty hearing in noise can be caused by poor attention, language disorders, English as an additional language
language (ESL or EAL/D) and Auditory Processing Disorders (APDs), which are related to the brain’s ability to process sounds.

People who experience difficulty hearing in noise can typically hear in quiet environments but struggle in noisy environments like the classroom or playground. By determining the most likely possible cause, the Client/Player's care team can determine who best to see for further assessment.

For clients from non-English speaking families or those with developmental delays, consider the additional cognitive load and language processing challenges as these may impact results. Retesting is recommended to confirm findings.

4.1 Clinical Evidence

Sound Scouts has been validated through several clinical studies. Dillon et al. (2018) demonstrated a sensitivity of 85% and specificity of 98% for detecting hearing loss in children, with 100% sensitivity for hearing losses greater than 30 dB HL in the poorer ear. The app has shown effectiveness in various populations, including Aboriginal and Torres Strait Islander children (Mealings et al., 2020) and in school screening programs (Bowers et al., 2023). A cost-effectiveness study by Gumbie et al. (2022) found that screening children with Sound Scouts is likely to be cost-effective.

4.2 Test Accuracy

Hearing Loss Range (4FAHL - Four Frequency Average Hearing Level)	Sensitivity	Specificity	False Negative Rate (FNR)	False Positive Rate (FPR)	95% Confidence Interval (CI)	Reference
Normal hearing range: less than 20 dB 4FAHL in both ears	N/A	95%	N/A	5%	Specificity: 93.8% to 96.2%	Bowers, P. Graydon, K. & Rance, G. (2023)
Priority target hearing loss range: greater than 30 dB 4FAHL in the poorer ear	100%	N/A	0%	N/A	Sensitivity: 92% to 100%	Dillon, H., Mee, C., Moreno, J.C., & Seymour, J. (2018).
Widened hearing loss range: greater than 20 dB 4FAHL in the poorer ear	85%	N/A	15%	N/A	Sensitivity: 75% to 93%	Dillon, H., Mee, C., Moreno, J.C., & Seymour, J. (2018).

Sensitivity and specificity of the **Triple Factor Hearing Screener (TFHS)** with inconclusive results treated in different ways (Dillon, H. 2018), considering the widened hearing loss range (greater than 20 dB 4FAHL in the poorer ear):

	Inconclusive results treated as pass	Inconclusive results treated as fail	Inconclusive results excluded
Sensitivity	76%	86%	85%
Specificity	98%	93%	98%

4.3 Identified Residual Risks and Issues

The following residual risks for the device have been considered borderline in terms of acceptability, however mitigation measures can be undertaken as detailed below.

Description	Mitigation Measures
Headphone Quality: Inaccurate test results due to subpar headphone performance, which can impact frequency output during tone tests. This may lead to unreliable results. (TFHS)	• Use decent quality adult headphones • Do not use telephony, gaming or children's headphones, or in-line devices such as: audio splitters or headphone amplifiers
Unhygienic Shared Use: Potential spread of infections due to the shared use of headphones and devices	• Refer to supplemental guidance on hygienic use (https://www.soundscouts.com/au/schools/school-resources/)
USB-C Adaptors: When using some headphone adaptors for USB-C phones, half a second of the audio may be cut off. This can be more common in low-cost adaptors.	• Use the Trial Run to ensure that the adaptor is working properly • Use a different adaptor or use a Bluetooth headset

5. Triple Factor Hearing Screener Detailed Guides

Detailed Guides can be accessed at the following URLs:

Parents at Home

- https://www.soundscouts.com/au/school-resources-pack/AU-Guide-To-Testing-Your-Child's-Hearing-At-Home.pdf

Clinicians

- https://www.soundscouts.com/au/school-resources-pack/Screening%20Guide%20For%20Health%20Professionals.pdf

Schools

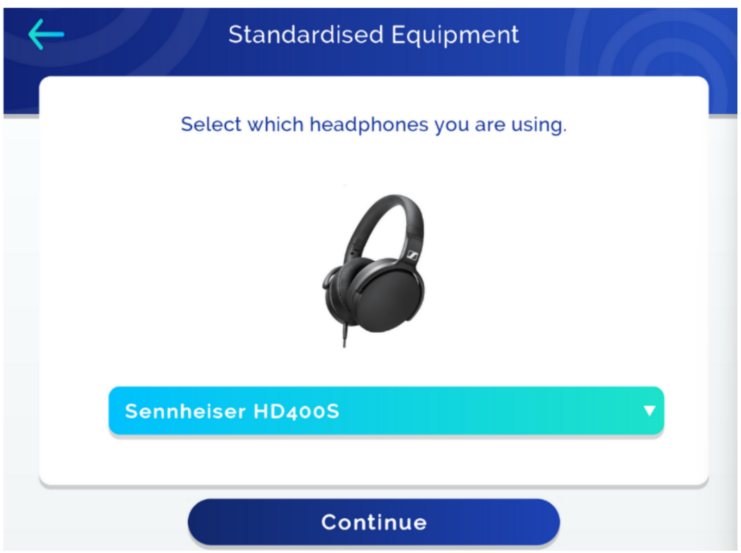
- https://www.soundscouts.com/au/school-resources-pack/Sound-Scouts-Screening-Guide.pdf
- https://www.soundscouts.com/au/schools/school-resources/

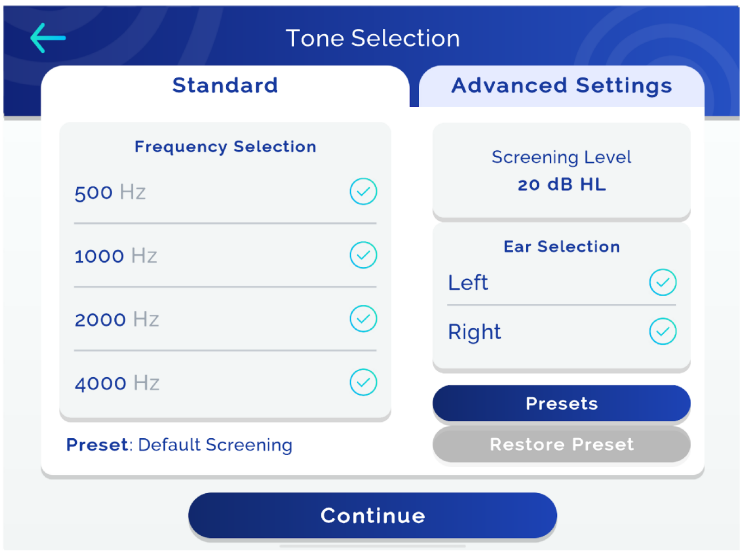
More / Other

- https://www.soundscouts.com/au/support/

6. Automatic Audiometer Information

The Automatic Audiometer delivers a traditional style pure tone hearing test. Set to screen at 20dB HL, four frequencies are measured: 500Hz, 1000Hz, 2000Hz, 4000Hz. The Automatic Audiometer can only be used with an iOS / iPadOS device and a list of recommended headphones. The test takes approx. 4.5 minutes when set to screening (may vary with age).





Standardised Equipment - Headphone selection

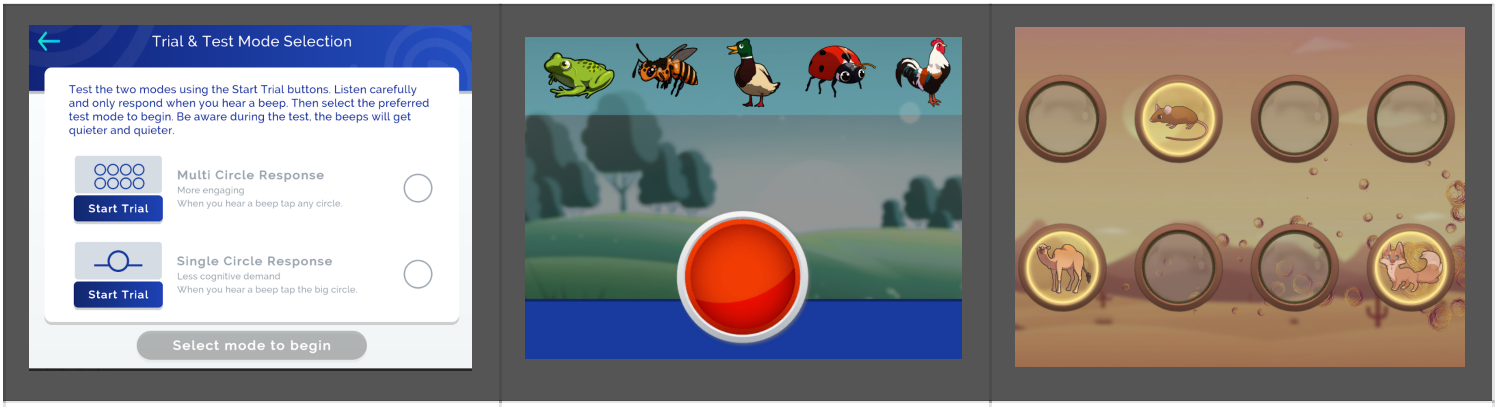
- Choose from the list of compatible headphones (https://www.soundscouts.com/au/docs/SS_Automatic_Audiometer_Guide.pdf)
- Confirm headphone selection
- Set the device volume to maximum

Tone Selection:

- **Standard tab:** Screening level: the frequency selection is defaulted to 500, 1000, 2000, and 4000hz in L & R ears. Frequency and ear can be selected. Screening level is set to 20dB HL. This can be customised by selecting or creating a Preset.
- **Advanced tab:** Frequency selection: 250, 500, 1000, 2000, 3000, 4000, 6000, 8000hz in L & R ears. Range -10 to 100 dB HL.

Test Mode Selection

- Multi-Circle Response: More engaging, when you hear the beeps tap any circle
- Single-Circle Response: Less cognitive demand, when you hear the beeps tap the big circle
- You may trial each mode with the Client/Player before the actual test



Test Administration

- Instruct the Client/Player to listen carefully and respond only when they hear the beeps

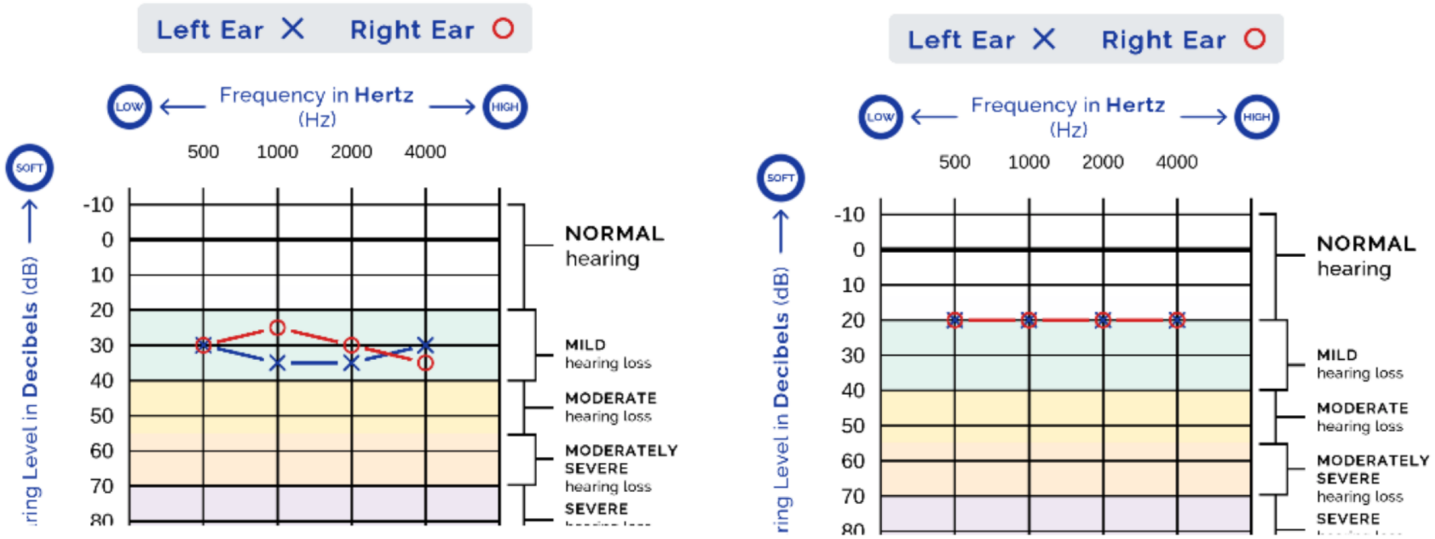
- Monitor the test progress
- Be aware that the beeps volume will decrease throughout the test

Audiometer Results

When the test is completed, an audiogram is generated. The audiogram will indicate if the results are outside normal range.

Along the top of the graph the numbers refer to frequencies, or different pitches of sounds. Frequency is expressed in terms of the number of cycles per second, or Hertz. The higher the number, the higher the pitch of the sound. Normal, young, healthy human ears can hear frequencies as low as 20Hz and as high as 20,000Hz, but we typically only screen hearing in the range of 500 to 4000Hz, as most sounds of speech occur in this frequency range.

Loudness or intensity of sounds is measured in units called decibels (noted on the vertical axis). Zero decibels (0dB) does not mean ‘no sound’ – it is just extremely soft. Conversational voice level is around 65 decibels, and 120 decibels (120dB) is very, very loud.



Thresholds for the right ear (i.e. the softest sounds the ear can hear at each frequency) are marked as an ‘O’ in red, and the left ear is an ‘X’ in blue on the audiogram.

For results from the Automatic Audiometer, a ‘Pass' result indicates that hearing thresholds for the tested frequencies are within the specified threshold level. No further action is required unless there are ongoing concerns about the Client/Player’s hearing. A 'Refer' result indicates that the Client/Player may have hearing thresholds above the selected threshold in one frequency or more. In this case, it is recommended to see a healthcare professional for further assessment. The report will also indicate if the responses were unreliable for any specific frequency in either ear and that retesting those specified frequencies in the specified ear is recommended.

NB: When screening at 20 dB, the quietest sound that can be heard will be at 20 dB, therefore a flat line is shown, This means that the person could hear the lowest sounds presented to them. 20dB is considered to be the cut off for normal hearing.

7. Automatic Audiometer Detailed Guide

A Detailed Guide can be accessed at the following URLs:
https://www.soundscouts.com/au/docs/SS_Automatic_Audiometer_Guide.pdf

It includes important information on which headphones are compatible with it.

8. Safety and Maintenance

When a new version of the Sound Scouts Solution is available, the app can be updated through the mobile device's app distribution system (App Store for iOS / iPadOS, Google Play Store for Android, Microsoft Store for Windows PCs). Older versions of the app may become unsupported over time, the lifespan and time frames are dependent on the criticality of the changes in new versions. Users can check their app version in the 'About' section of the app.

Users can report malfunctions, clinical incidents, lost passwords or a potential security breach by contacting Sound Scouts on 1300 424 122 (AUS only) or contact@soundscouts.com

Special Precautions and Troubleshooting

- Ensure a stable internet connection for processing results
- If connection is lost during a test:
  1. Do not close the app. The test may be completed offline
  2. To obtain results, re-establish a connection at the end of the test, or
  3. Return to Past Sessions from the main menu and tap on a session to receive its results when a connection is reestablished
- For optimal performance:
  1. Close other apps running in the background
  2. Ensure device has sufficient battery life or is plugged in
  3. Turn off notifications
  4. Use in a quiet environment free from distractions
- If experiencing technical issues:
  1. Restart the app
  2. Update to the latest version if available
  3. Get in touch with support (contact@soundscouts.com) if problems persist

Issues and Solutions:

Audio not playing through headphones

- Check headphone connection (wired or Bluetooth)
- Ensure device volume is set to maximum
- Try a different pair of headphones

Test results not processing or other connection issues

- Check internet connection
- Wait a few minutes and try again
- If at a school, organisation or clinic, contact IT for firewall or whitelisting support
- If you are using SSIMPL account, make sure you are logged in on the app.
- Get in touch with support (contact@soundscouts.com) if problems persist. Attaching a screenshot of the error message if possible and advise device, device model and operating system.

Player excessively tapping or not responding

- Repeat the instructions ensuring the Client/Player understands the task
- Practice the trial run activities before testing again
- For young Clients/Players, ensure they are well rested, fed and have been to the bathroom

- Consider retesting at another time

SSIMPL sync issues

- Check internet connection
- Log out and log back into the app

App crashes or freezes

- Close and restart the app. If a session was already completed, it may be found under "Past Sessions" in the main menu
- Ensure your device's operating system is up to date
- Get in touch with support (contact@soundscouts.com) if problems persist

9. Sound Scouts Integrated Management Platform (SSIMPL)

SSIMPL is an integrated management platform that allows organisations to:

- Create and manage user accounts
- Upload Client/Player information
- Access and manage test sessions
- Download and/or email reports

The use of SSIMPL provides enhanced Client/Player record & results security.

An organisation account can be created on SSIMPL via web browser and a user can then login on the app with a password protected User ID. Client/Player records and results will be synced to their SSIMPL account. Logging out of the app removes access to the organisation and list of Clients/Players. Results (stored in Past Sessions) can be deleted from the device.

Key SSIMPL Concepts		
Organisations		Only one Organisation should be created per school/clinic. Each Organisation can have multiple Users (eg school staff) and these Users can be assigned different roles with different permission levels.
Account (User)		Your personal SSIMPL account is called a User account. Every individual using SSIMPL should create an individual User account and then be attached to an Organisation. Multiple users can belong to an Organisation under a variety of roles and permissions.
Clients/Players		Clients/Players are the individuals being tested with the Sound Scouts Hearing Check app. Each Client/Player has access to 4 tests per credit purchased. Both the Triple Factor Hearing Screener (available on Apple, Android and Microsoft touchscreen devices) or the Automatic Audiometer (restrictions apply) can be used.
Session		Every time a Player completes a test on the app, their results are saved as a Session on the platform and are accessed via the My Players section

To access SSIMPL:

1. Create an account at ssimpl.soundscouts.com.au (for Australia) or ssimpl.soundscouts.com (for the rest of the world)
2. Follow the on-screen prompt to create an organisation
3. You can now log in to the Sound Scouts App using your SSIMPL credentials
4. From the app, you can sync Client/Player records and results with your SSIMPL account

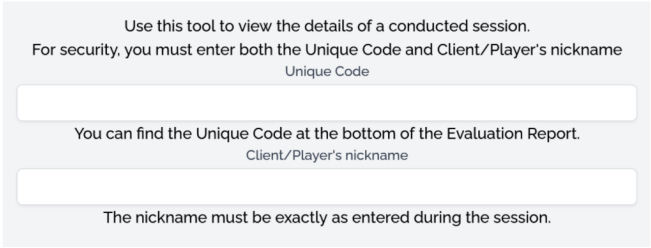
To view Player Results:

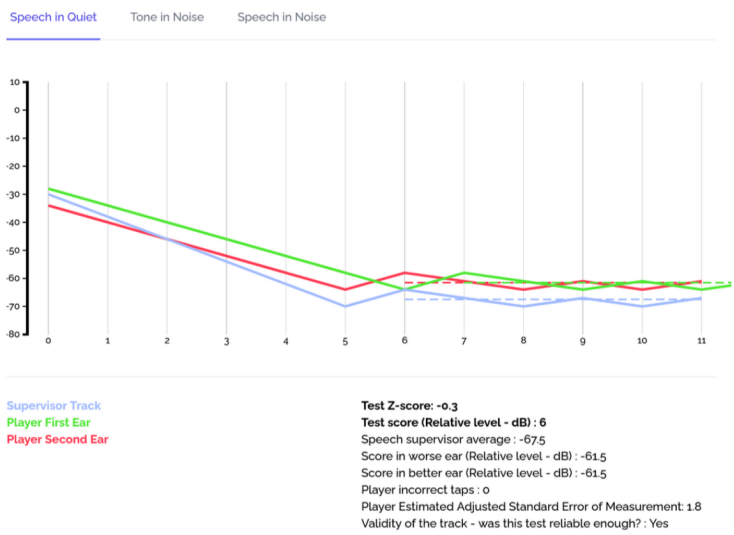
1. Click on My Clients/Players in the left hand menu to see all Clients/Players who have been uploaded into SSIMPL
2. At a glance, you can see - how many Sound Scouts Sessions (e.g. tests) the Client/Player has completed, if they have been tested and their last session result.
3. Click on Search/Filters and Exports to Filter your view, search for specific Clients/Players and Export records to a CSV file.
4. Click on a Client/Player's name to see their record and results (known as Sessions).

10. Clinical Portal

In SSIMPL, Clinicians can register to access the response tracks to review the details of the person's interactions and confirm they have responded in a reliable manner. This Portal is only available for the **Triple Factor Hearing Screener** results.

Clinicians must click on the Clinical Registration menu and complete the Request Form. A member of the Sound Scouts team will review the request and provide access to the Clinical Portal.





The search portal works by entering a Client/Player's Sound Scouts session ID and name used during the test. The ID can be found on the Report.

Clinical Results

Triple Factor Hearing Screener tests:

1. **1.** Test score for Speech in quiet is the amount by which the Client/Player's threshold (from monaural listening) exceeds the supervisor's threshold (for binaural listening). Lower numbers indicate better hearing.
2. **2.** Test score for Speech in Noise is the signal-to-noise ratio at which the Client/Player could understand 60% of the speech items. Lower numbers indicate better hearing.

3. **3.** Test score for Tone in Noise is the signal-to-noise ratio at which the Client/Player could detect the tone (with a frequency varying around 1500 Hz) 60% of the time. Lower numbers indicate better hearing.
4. **4.** Validity of the track takes into account random tapping, and the variability of the track, as reflected in the estimated standard error of measurement.

Z-scores

The results of each test are expressed as a z-score. Z-scores show the Client/Player's results relative to other Clients/Players of the same age, and taking into account the spread of scores that children and adults with no hearing problems have on this test. The z-score is calculated as the difference between the individual Client/Player's score and the mean score for players of that age, divided by the standard deviation of the spread of results that Clients/Players of that age have.

A score of zero means average for age. A score of -1.0 is a low score, but well within the normal range. A score of -2.0 is a very low score, and scores more negative than this are regarded as being below the normal range. (A score of -1.5 is often also regarded as being the lower end of the normal range).

Z-scores can readily be converted into percentiles (by assuming a normal distribution of scores), showing the proportion of Clients/Players with no problems who would get a score poorer than the one found, as shown in the table below.

z-score	Percentile
+1.0	84%
0	50%
-1.0	16%
-1.5	7%
-2.0	2%
-2.5	0.6%
-3.0	0.1%
-4.0	0.003%

Simply put, the z score shows how many standard deviations the Client/Player above or below average for age. Positive z-scores represent better than average performance, and negative z-scores worse than average.

11. References:

1. Dillon, H., Mee, C., Moreno, J.C. & Seymour, J. (2018). Hearing tests are just child's play: the sound scouts game for children entering school. Int J Audiol, 57(7):529-537.
2. Mealings, K., Harkus, S., Hwang, J., Fragoso, J., Chung, K., & Dillon, H. (2020). Hearing loss and speech understanding in noise in Aboriginal and Torres Strait Islander children from locations varying in remoteness

and socio-educational advantage. Int J Pediatr Otorhinolaryngol, 129:109741.
3. Bowers, P., Graydon, K. & Rance, G. (2023). Evaluation of a game-based hearing screening program for identifying hearing loss in primary school-aged children. Int J Audiol, 62(6):512-520.
4. Gumbie, M., Parkinson, B., Dillon, H., Bowman, R., Song, R., & Cutler, H. (2022). Cost-Effectiveness of Screening Preschool Children for Hearing Loss in Australia. Ear Hear, 43(3):1067-1078."

Review & Approval

Activity	Date	Name (Role)
Created (v17)	2026-02-05 01:56:05	Lisa Teager
Review approved	2026-02-05 02:59:09	Cuauhtemoc Moreno (CIO)

Approved Review by Cuauhtemoc Moreno as CIO:

No comment provided.