GSI AMTAS PRO™

USER MANUAL

Did you hear the TONE?

YES

NO

2%

Title: GSI AMTAS Pro™ User Manual

Manufacturer
Grason-Stadler, Inc.
10395 West 70th Street
Eden Prairie, MN 55344
USA

This product incorporates software developed by others and redistributed according to license agreements. Copyright notices and licenses for these external libraries are provided in a supplementary document that is included with the other software applications distributed with this product.

Compliance
The CE 0086 mark identifies compliance with the Medical Device Directive 93/42/EEC. Grason-Stadler is an ISO 13485 certified corporation.

EC	REP
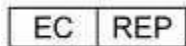
European Authority Representative
Grason-Stadler
c/o Interacoustics A/S
Audiometer Alle 1
5500 Middelfart
Denmark

$C\epsilon$
0086

> **Caution:** US Federal law restricts this device to sale by or on the order of a physician or licensed hearing care professional.

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Preface

This user manual provides information about the GSI AMTAS Pro™ software program. This manual is intended for technically qualified personnel.

Please note: This operating manual is not intended as a training manual for audiometry. The reader should consult standard audiology texts for the theory and application of the auditory tests provided by this software when connected to an instrument.

Manual Conventions

In this manual the following label identifies conditions or practices that may present danger to the patient and/or user or damage to the equipment.

Important Safety Instructions

The software program configuration and audiometer must be used only by practitioners qualified to perform audiometric tests. It is intended for transient use as a screening and diagnostic tool; however no surgical or medical procedure should be undertaken solely on the basis of results obtained from the program.

Consult the audiometer manual for the important safety information regarding the audiometer. Ensure that all transducers are properly connected to the audiometer. Do not connect the transducers to the audiometer while attached to the patient.
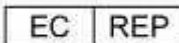
Consult the PC manual for the PC for the important safety information for the PC.

Precautions

READ THIS OPERATING MANUAL BEFORE ATTEMPTING TO USE THE SOFTWARE
This software configuration and audiometer should only be used by a hearing health care professional such as an audiologist, otolaryngologist, researcher or a technician under the direct supervision by the aforementioned specialist. Users should use their professional skills when interpreting the results and this should be done in conjunction with other testing as deemed appropriate given their professional skills. Appropriate placement of the transducers on the patient is required for accurate test results. Patient discomfort could lead to confusing results from the patient. Incorrect use could lead to wrong results.

Regulatory Symbols

Symbol	IEC Pub.	Description
$C\epsilon$	980 & 60601-1	Conforms to European Medical Device Directive 93/42/EEC.
SN	980 & 60601-1	Symbol for "SERIAL NUMBER."
REF	980	GSI Part Number.
(crossed-out wheeled bin)	980 & 60601-1	Return to Authorized Representative, Special disposal required.
(ETL Listed mark)	980 & 60601-1	Medical Equipment Classified by Intertek Testing Services NA Inc. with respect to electric shock, fire, and mechanical hazards only, in accordance with UL 60601-1. Classified under the Medical Device Directive (93/42/EEC) as a Class IIa device.
EC REP	980 & 60601-1	Symbol for "European Representative."
(manufacturer symbol)	980 & 60601-1	Symbol for "Manufacturer."
(date of manufacture symbol)	980 & 60601-1	Symbol for "Date of Manufacture."
⚠	980 & 60601-1	Attention, consult accompanying documents.
(patient applied part symbol)	60601-1	B Patient Applied Part according to IEC 60601-1.
(consult instructions symbol)	980 & 60601-1	Consult Operating Instructions.
(follow instructions symbol)	ISO 7010-M002	Follow Instructions for Use.

Introduction

GSI AMTAS Pro™ is a software program that provides an automated method for obtaining a diagnostic hearing test including air and bone conduction thresholds with masking applied to the non-test ear. GSI AMTAS Pro also provides automated tests of speech reception. Both Speech Recognition Threshold (SRT) and Word Recognition Scores (WRS) may be obtained.

AMTAS was developed through a partnership between Audiology Incorporated and three research institutions, the University of Minnesota, the University of Utah, and the James H. Quillen Veterans Administration Medical Center. The development was funded by the National Institutes of Health Small Business Technology Transfer (STTR) Program.

AMTAS Pro is based on a psychophysical procedure that uses the patient's responses to determine signal levels needed to find auditory thresholds. Once the transducers are placed on the patient, the test is self-administered. The test is self-paced so that patients proceed at the rate that is comfortable for them. Feedback is provided to the patient that helps them distinguish between test tones and other auditory sensations. GSI AMTAS Pro was designed to provide the same test results that would be obtained by an expert audiologist with a psychophysical procedure that has advantages over the commonly used clinical ("Hughson-Westlake") method.

Quality indicators provide information about the validity of results. Air conduction audiograms are classified based on configuration, severity, and symmetry. The program generates a report and interfaces with GSI Suite and the data may be transferred to other software programs.

The software performs these tests by controlling a GSI audiometer connected to the PC running the software.

Indication for Use of GSI AMTAS Pro

GSI audiometers are intended to be used for the identification and etiology of hearing loss in patients of any age. It is intended to be used by an audiologist, ENT, hearing healthcare professional, or trained technician in a hospital, clinic, healthcare facility or other suitable quiet environment.

Intended Use of GSI AMTAS Pro

GSI AMTAS PRO is intended to be used to obtain diagnostic audiometric data through a GSI audiometer. It is intended to be used for routine clinical testing in any environment in which pure-tone audiometry and speech recognition testing is performed. Anyone who can follow the instructions used for manual audiometry may be tested by GSI AMTAS Pro. Patients unable to cooperate because of young age or other conditions that cannot undergo pure tone audiometry and may need to have the auditory system tested by other methods.

Installation and Setup

Precautions

The following precautions will aid in the secure collection and storage of patient data:

- **Disable the "suspend USB" power option to ensure proper communication between instrument and PC.**
- To avoid unwanted data transfer from PC to the network, ensure that an appropriate virus & spyware scanner is installed, updated, and effective. Please contact a local administrator for help and guidance.
- All users should have a unique login to the PC.

NOTE: To ensure proper sound presentation all speaker enhancements in Windows should be **disabled**. The Sound Playback - Speaker Properties dialog, Enhancements tab has the option to disable all enhancements.

Prerequisites

GSI AMTAS PRO PC Minimum Requirements

- CPU: 2.0 GHz, Intel i5 (dual or quad core) or better
- RAM: 4 GB
- Hard Disk: 128 GB or larger
- USB Ports: 1
- Display: 19" or larger
- Resolution: 1280 x 800 minimum
- Touch screen or mouse/trackball
- CD-ROM Drive or USB for software installation
- Network LAN Card (if connecting to database via a network)

GSI AMTAS PRO Supported Operating Systems

- Microsoft Windows® 10 Pro
- Microsoft Windows® 7 Professional

GSI AMTAS PRO Software Requirements

The following will be installed automatically with the GSI Suite installation, if they are not already present on the PC.

- Microsoft .NET Framework version 4.6.2
- Driver for the GSI audiometer

### GSI AMTAS PRO Audiometer Requirements

- GSI AMTAS Pro License
- Bone conduction Oscillator: B71, B81
- Headphones: HDA200, DD450

Installing on Windows® 7 and 10

Initiating GSI AMTAS Pro

Insert the GSI AMTAS Pro CD into the CD-ROM drive. If the program is delivered on a USB drive, insert the drive into a USB port on the PC. If auto-run is disabled, browse the CD or USB drive and double click on the *Setup_GSI_AMTAS_Pro.exe* file.

NOTE: In order to install this application, the user must either be an Administrator or know the Administrator password.
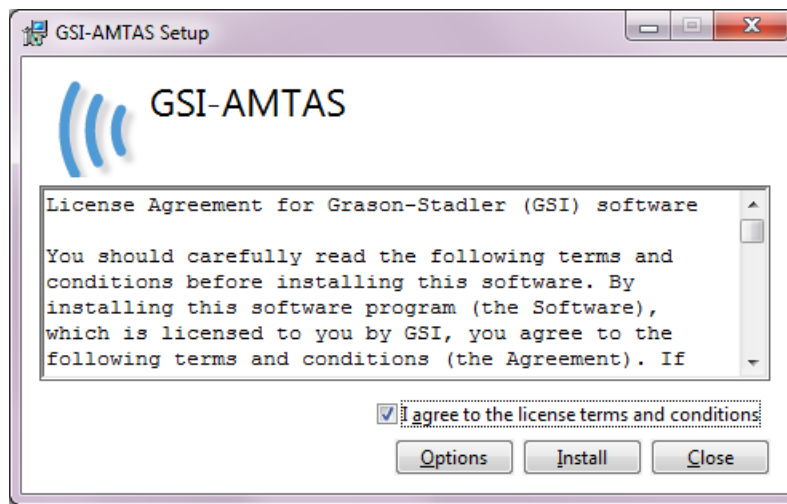
1. Read the license agreement carefully. Select the "I Agree" check box to accept the agreement and press "Install" to continue or select "Close" to avoid acceptance of the license agreement and exit Setup.
2. Windows may present a User Account Control dialog that asks if you want to allow the program to make changes to the computer. Answer "Yes" to continue the installation.
3. In order to use the GSI-AMTAS Pro, it is necessary to have .NET and Adobe Reader installed on the computer. Before the GSI AMTAS Pro application is installed, the setup will evaluate the computer for these programs. If they are not currently installed, GSI AMTAS Pro will display a dialog box indicating that it is necessary to install these programs. Press "Install" to install the prerequisite software. This may take several minutes. Follow the on-screen instructions to complete the installation of these programs.
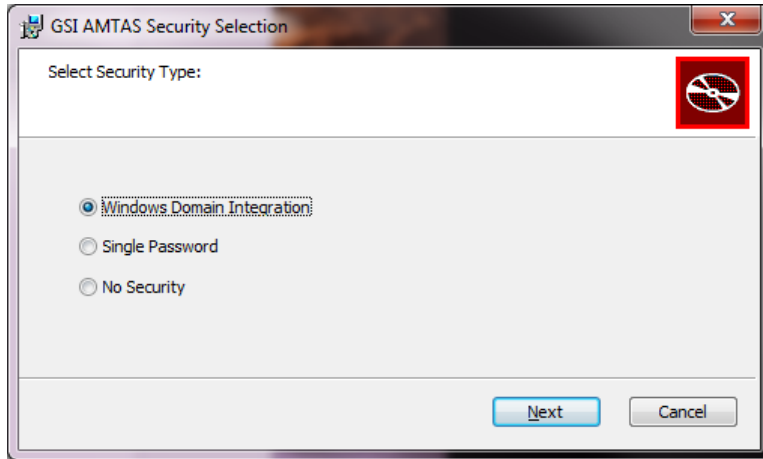
4. The type of security that is used with the program is setup during the installation. A security selection dialog is presented with three (3) security options. Select the appropriate security type for your facility.

- **Windows – Domain Integration Security**
  When the program requires authentication, it will verify the user identity and password based on Windows authentication. The software will automatically add this installation user to the AMTAS administrator group. Additional AMTAS administrators may be added by running the GSI AMTAS Pro Config app as an administrator with this user account.

- **Single Password Security**
  There is one administrator account which will have the user identity of "admin" and initial password of "admin". You will be able to set the password using the GSI AMTAS Pro Config App. This account will have no connection to the Window authentication. When the program requires authentication, it will verify the identity and password based on this one admin account.

- **No Security**
  The program will not restrict access based on the user (i.e., it will never prompt for identification or password).
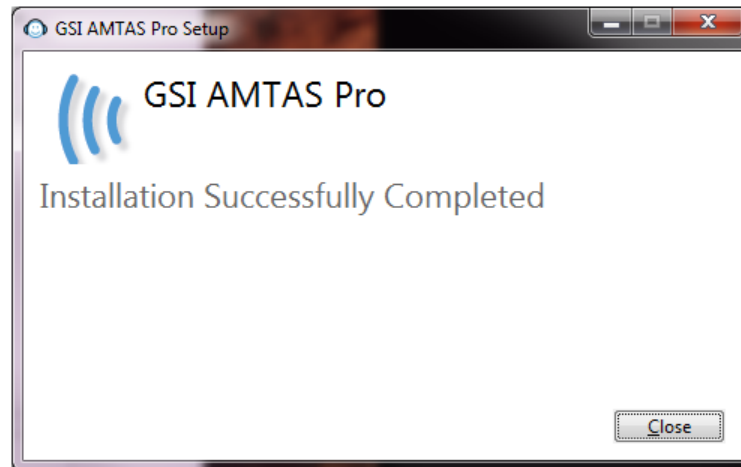
5. A message will be displayed to indicate that the software has been successfully installed. Select "Close".

NOTE: Installing GSI AMTAS Pro will also install the GSI Instrument Service software package and any drivers needed for the audiometer. The installation may require a restart of the computer to continue.

Uninstalling GSI AMTAS Pro

1. Open the Windows Control Panel
2. Select Programs and features
3. Select GSI-AMTAS Pro
4. Select Remove or Uninstall
5. Follow the onscreen instructions

Connecting GSI Instruments

To configure GSI AMTAS Pro to a specific GSI audiometer you need to make the connection between the instrument and the PC running the GSI AMTAS Pro software.

GSI AMTAS Pro License

GSI AMTAS Pro requires a license on the audiometer in order for the program to connect to the audiometer. The licensing is specific to the audiometer and not the PC running the GSI AMTAS Pro software. Existing license information for an audiometer is found in the Configuration screen of the audiometer. A license to run GSI AMTAS Pro is obtained from your authorized GSI distributor.

Connecting the GSI Audiometer to the GSI AMTAS PRO PC

1. Use a standard A/B USB Cable.
2. Plug the hexagon connector (B plug) into the USB port on the GSI audiometer.
3. Plug the USB connector (A plug) into a USB port on the computer.
4. Connect the audio out port on the PC to the external in port (EXT A+B) on the audiometer using the supplied audio cable.
5. Power on both the audiometer and the PC.
6. Launch GSI AMTAS Pro.
7. GSI AMTAS Pro will automatically detect the audiometer.

AudioStar Pro rear panel – USB and External Input ports
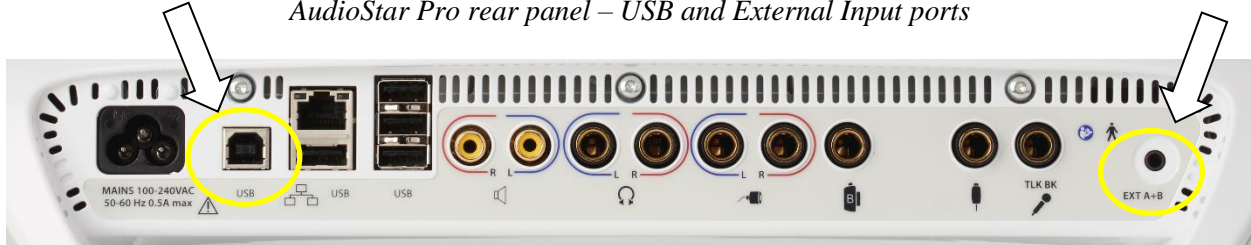
Pello rear panel – USB and External Input ports

Patient Preparation

Although the GSI AMTAS Pro is a self-administered test, it is recommended that the transducers be placed on the patient by trained health care personnel. It is also appropriate to provide general instructions to the patient about the test and how to interact with the computer. The patient should be seated comfortably in front of the PC with the GSI AMTAS Pro program running.

Bone Oscillator Placement

The bone oscillator should be placed prior to the placement of the headphones. The AMBAND headband should be used to couple the bone conduction vibrator to the head in the forehead position. A Velcro dot (provided with the headband) can be attached to the back of the bone vibrator to stabilize it under the headband. Follow the AMBAND instructions and use the appropriate attachment point based on the age and head size.

Headphone Placement

- Take the headphones and pull both sides out while placing the headband on the very top middle part of the patient's head.
- Make sure that the ears are in the center part of the headphone cups.
- Ensure the headband remains in the middle of the very top of the head
- The ears should be in the center and completely surrounded by the ear cups.
- If you need to change the height of the ear cups, take the headphones completely off and adjust by using your thumb and fingers on the yoke and block. Push the yoke and block closer together to reduce the overall ear cup height. Conversely, if you need to increase the height of your headphone ear cups, pull the yoke and blocks apart.
- Once adjusted, place the headphones back on the patient's head.

GSI AMTAS Pro Program

GSI AMTAS Pro and the GSI AMTAS Pro Config App are installed as part of the software installation. GSI AMTAS Pro is the program that the patient interacts with to obtain the audiometric data. The GSI AMTAS Pro Config App is used by the administrator to set the users of the GSI AMTAS Pro program and the parameters used for the test. The GSI AMTAS Pro Config App also manages the data obtained from the GSI AMTAS Pro program.

The GSI AMTAS Pro program operates in full screen, kiosk mode (no other program can be run and the desktop is not available). In order to exit the program and return the computer to the desktop, a password may be required depending on the security type selected during installation. A password may also be required to enter the configuration from the GSI AMTAS Pro program.

NOTE: The GSI AMTAS Pro program runs in kiosk mode preventing most keystrokes from being recognized and preventing the user from leaving the program. However, the Ctrl+Alt+Del key combination is a special sequence that is not trapped by the program. Pressing Ctrl+Alt+Del invokes Windows Security with an interface that allows the user to lock the system, switch user, log off, change password or invoke the Windows Task Manager. The IT administrator should adjust the Window user's security to deny or allow the options accessible with this key combination.

Launching and running GSI AMTAS Pro

After installation of the program, a shortcut icon appears on the desktop. Double-click the desktop icon to open GSI AMTAS Pro. It is also possible to open this application from Start > All Programs > Grason-Stadler > GSI AMTAS Pro.
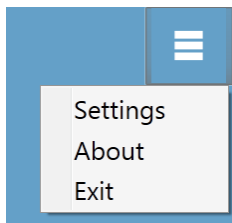
User Interface – Screen Layout and Controls

Welcome Screen

Once the GSI AMTAS Pro is started, the program presents the Welcome screen in full screen, kiosk mode. The Welcome screen contains a menu icon in the top right corner and a Get Started arrow in the bottom right corner.

Menu

When the menu icon is selected on the opening screen, a list of 3 menu items is presented. When the Settings or Exit menu item is selected, a prompt for a password will appear if security has been enabled. The password should be the Windows password of the user who is currently logged into the PC or the GSI AMTAS admin password depending on the type of security selected at the installation of the software. Once the password has been authenticated, the Settings menu option displays the parameters used for the GSI AMTAS program. Once the password has been authenticated for the Exit menu option, the user is returned to the PC desktop. The About selection will display the version, copyright, patent and trademark information of the GSI AMTAS program.

Get Started Arrow

The Get Started arrow is pressed to proceed with the GSI AMTAS Pro testing. The program takes the user to the next screen - the patient registration screen.

Patient Information Screen

The patient information screen provides fields for patient information. Required fields are indicated by an '*'. The required fields may be set in the configuration program or via the settings menu option. The First Name, Last Name and ID fields have a maximum character limit of 50.

Once the required fields have been entered, the Continue button will become selectable to indicate the test is ready to begin. Pressing the Continue button will move to the next screen. The next screen that is displayed depends on the configuration settings. Options include a headphone check and/or the instructional video or text (see the Setup and GSI AMTAS Pro Config App section of this manual for details). The configuration Test Options also determines the exams that will be performed. Available tests include any combination of air thresholds, bone thresholds, speech recognition threshold and word recognition.

NOTE: The GSI AMTAS Pro Config App provides an option to skip the patient information screen.

Listen for a Tone Screen

The "Listen for a TONE" screen is presented to alert the patient that they should pay attention and listen to see if they hear a tone. GSI AMTAS Pro uses this screen for air and bone diagnostic threshold testing as well as screening. There is a progress bar at the bottom of the screen to indicate the percentage of the test that has been completed. Masking is always presented to the non-test ear.

Once the tone has been presented, a new the screen is displayed to allow the patient to respond.

NOTE: Because of the psychophysical procedure that is employed by the program, there may be times in which no stimulus is presented. In addition, if the patient does not respond in a timely fashion, a warning message will be presented. The fourth non-response will result in the application ending the test and proceeding to the Finish screen

Response to a Tone Screen

The response screen prompts the user with the question about hearing the tone and presents two icons. The patient indicates that they heard the tone by choosing the icon on the left and to indicate that they did not hear the tone by choosing the icon on the right.
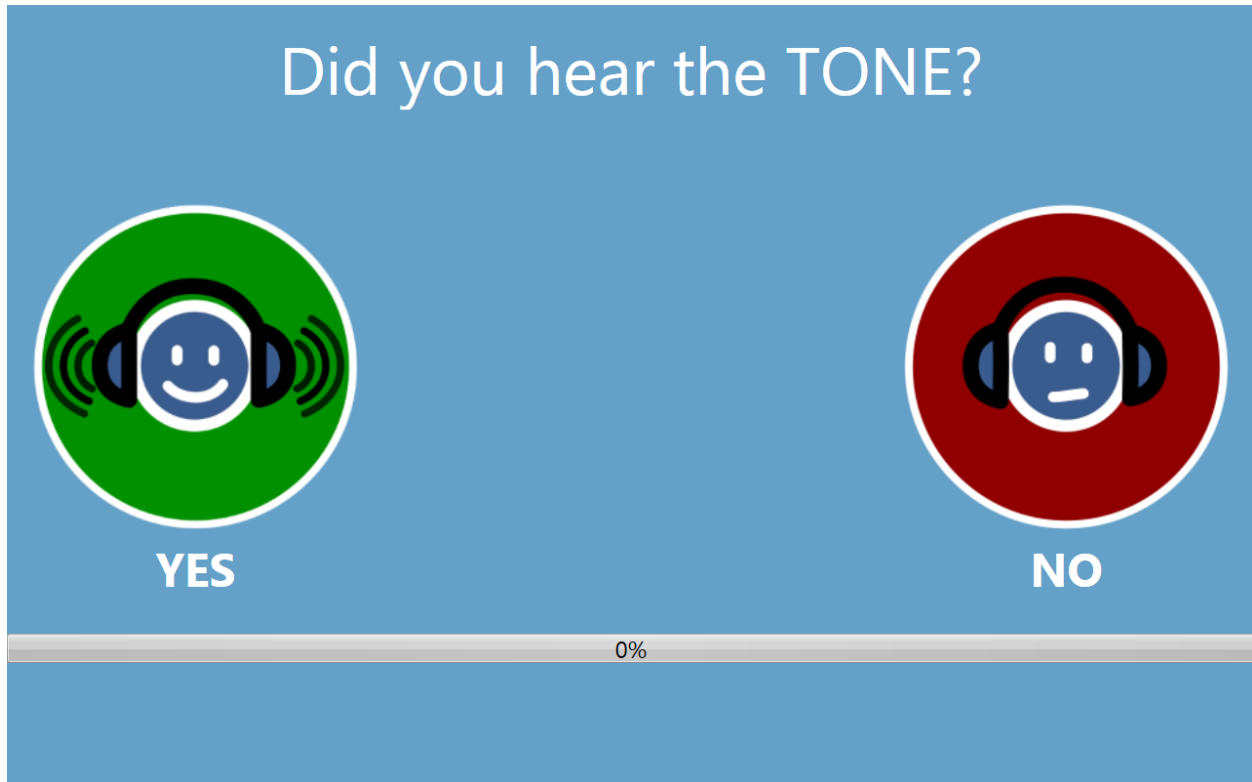
The "Listen for a TONE" and "Did you hear the TONE" screens repeat to test the different levels and frequencies as needed to determine the patient's threshold. The air conduction threshold test is followed by the bone conduction threshold test (if both tests have been selected in the settings). The screens are the same for the two tests and there is no indication to the patient that the air threshold test has completed and the bone threshold test has started.

Listen for a Word Screen

The "Listen for a WORD" screen is presented to alert the patient that they should pay attention and listen to see if they hear a word. GSI AMTAS Pro uses this screen for speech recognition threshold and word recognition scoring. There is a progress bar at the bottom of the screen to indicate the percentage of the test that has been completed. Masking is always presented to the non-test ear.


Once the word has been presented, a new the screen is displayed to allow the patient to respond.

Response to a Word Screen

The response to a word screen prompts the user with the question about hearing the word and presents a list of four words from which to choose. The patient indicates that they heard the word by choosing the matching word.
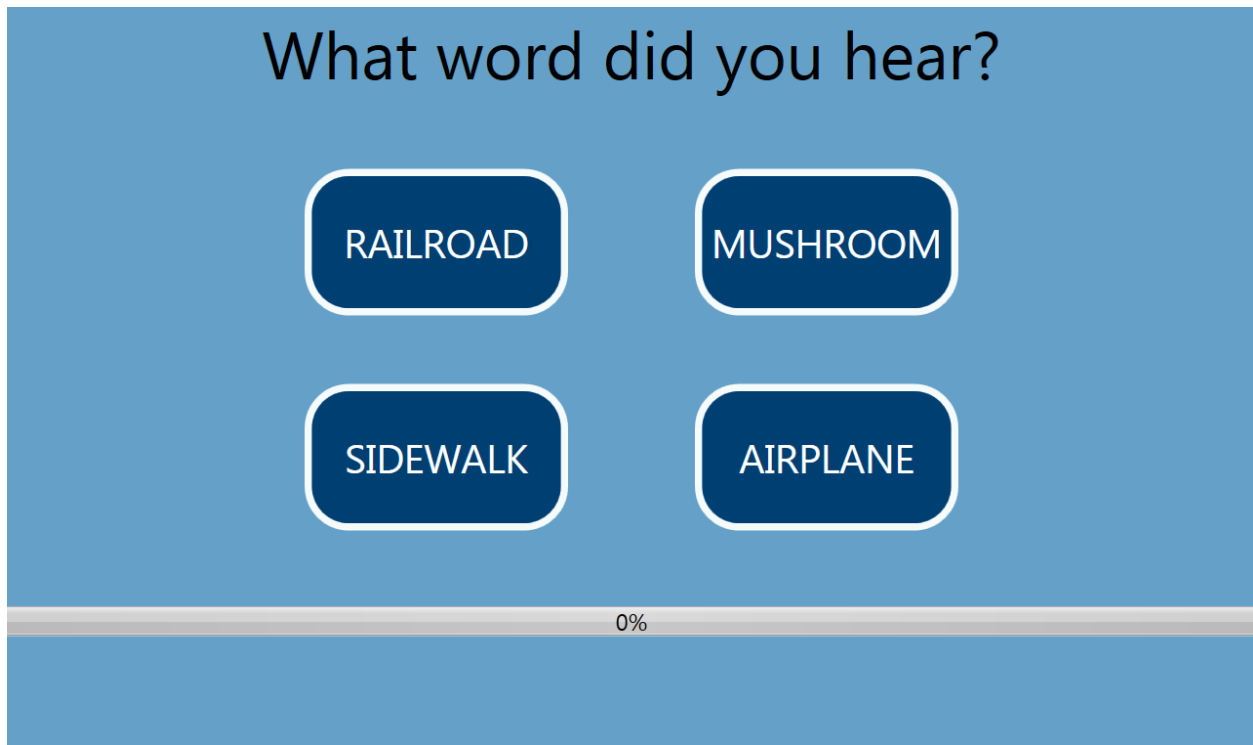
The "Listen for a Word" and "What word did you hear?" screens repeat to test the different levels as need to determine the patient's threshold. The speech recognition threshold test is followed by the word recognition test (if both tests have been selected in the settings). The screens are the same for the two tests and there is no indication to the patient that the speech recognition threshold test has completed and the word recognition test has started.

Test Completed Screen

When the tests have been completed, the screen that is displayed depends on the settings in the configuration. The program may display a report of the completed test or notify the user and wait at the "Test Completed" screen. Depending on the settings in the test configuration, there may be a menu at the top right of the screen. If any item in the sub menu is selected, a prompt for a password will appear if security has been enabled.
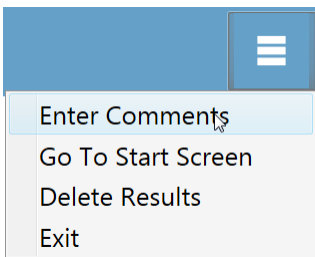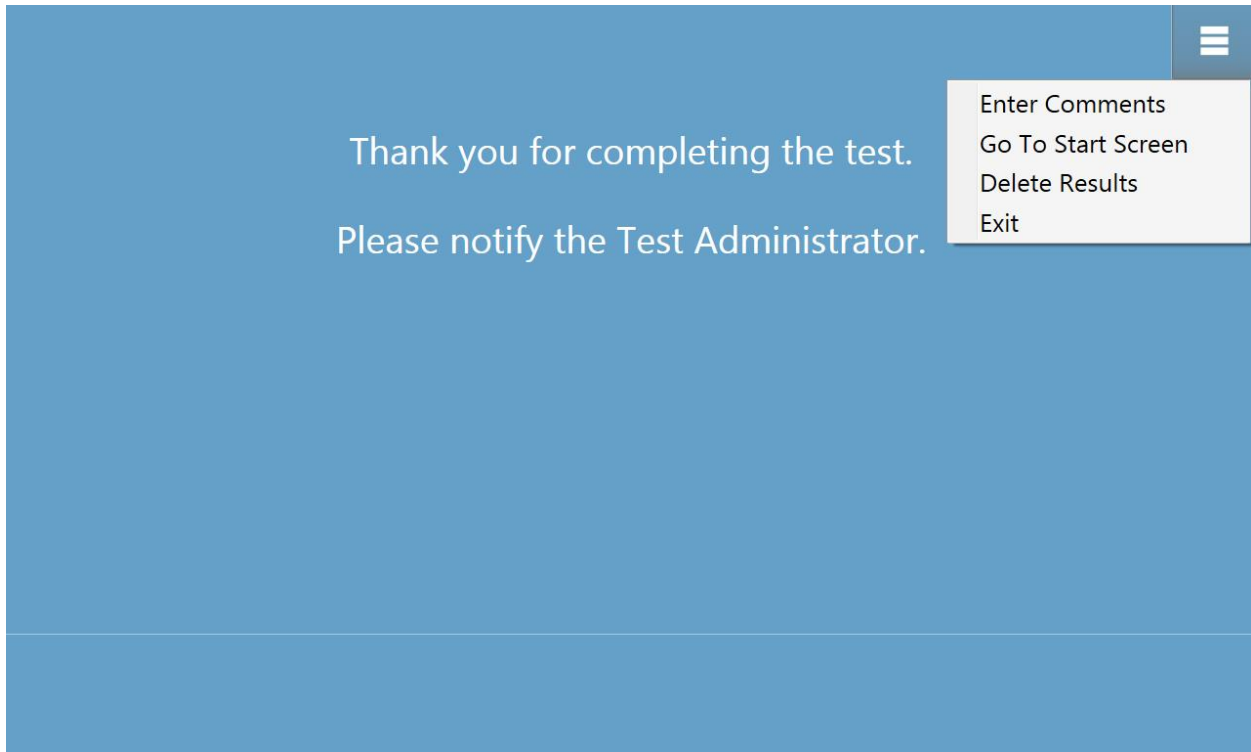
Enter Comments
The 'Enter Comments' sub menu item provides an option for the entry of free text. A dialog is presented for the user to enter the comments. This text is stored with the test results and printed as part of the report.

Go To Start Screen
The 'Go To Start Screen' returns the program to the Welcome Screen ready to start the next test.

Delete Results
The 'Delete Results' option presents a confirmation dialog. Upon confirmation of the delete action, the test that was just completed is removed.

Exit
The exit option closes the program and returns the user to the PC desktop.

Settings and GSI AMTAS Pro Config App

The Settings option from the menu on the Welcome Screen allows a user to set the parameters for running the GSI AMTAS test. The GSI AMTAS Pro Config App program has similar options. Both the Settings menu option and the GSI AMTAS Pro Config App program require a password and confirm that user has the proper security privileges, if security has been enabled. In order to configure users, the program must be in the Windows security mode and "Run as administrator" must be selected (right clicking on the desktop shortcut offers this option).
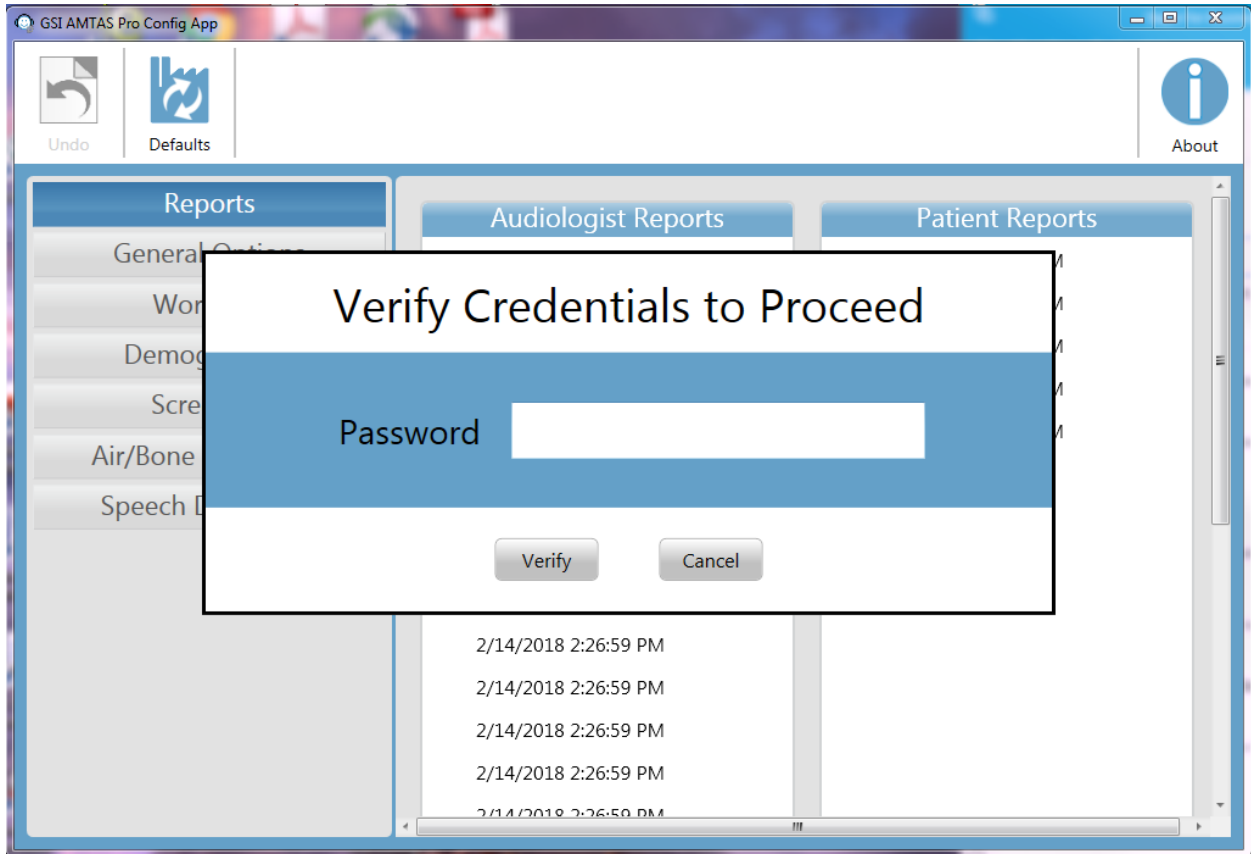
GSI AMTAS Pro has an option to use Windows authentication for the user IDs and passwords or a simple security that has a single admin user with a password. When GSI AMTAS prompts for a password, it is the person's Windows password that should be entered if using the Windows security or the single admin password for the single password security (shown above). Once the user name and password have been authenticated, the main Config App screen is presented and displays the parameters used for the GSI AMTAS Pro program.

> **NOTE:** There is a difference in the persistence of the changes made to the options that depends on how the **GSI AMTAS Pro** Config App is launched. When changes are made from the Settings menu in the **GSI AMTAS Pro** program, the changes are only applicable for the current test session. When changes are made from the **GSI AMTAS Pro** Config App launched from the Windows Start menu (or desktop icon) the changes are saved as the defaults setting for all future test sessions.
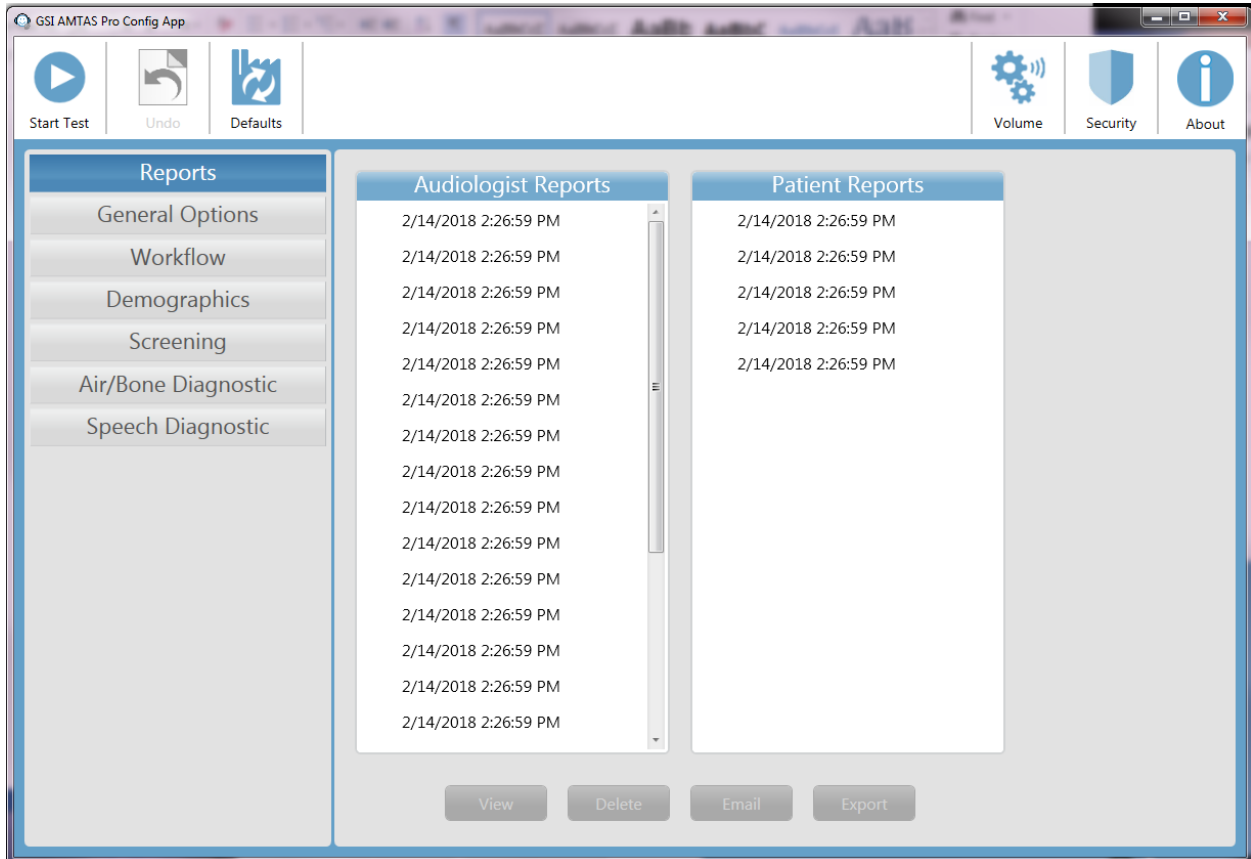
The main Config App screen contains two main areas and a menu bar at the top. The left panel has the configuration categories and the middle panel displays the options for the category.

Menu Bar

The Menu Bar at the top of the screen provides options to save or cancel the changes that have been made in the Test Options and General Options sections. The menu bar contains an option to calibrate the output levels for the instructions that are presented to the patient, set up administrative users of the system and to view the reports.
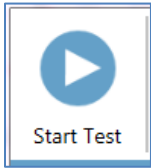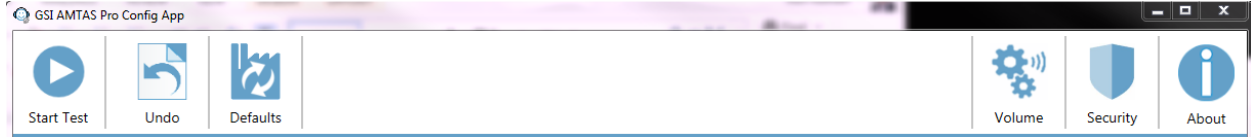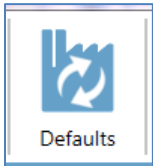

Start Test

The Start Test button begins the AMTAS test. The settings of the Config App are saved. The Config App is closed the Welcome screen is presented ready for testing to begin.
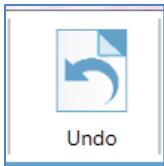
Undo

The Undo button returns the settings to the original values (when the screen was loaded). Any changes that were made are discarded and the previous configuration reloaded.

Defaults

The Defaults button returns the settings to the original values (factory settings when the program was installed). Any changes that were made are discarded and the previous factory settings loaded.
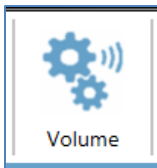
Volume

The Volume icon on the menu bar presents a screen to adjust the output level of the patient instructions that may be played to the patient prior to the test. This volume is only for the output level of the instructions and does not impact the presentation of the tones and speech signals presented by the audiometer. The audiometer calibration has a separate program and should only be performed by an authorized GSI distributor. Follow the instructions presented in the dialog to adjust the level of the patient instructions.

Security

The Security button on the menu bar allows you to configure the users of the GSI AMTAS program. This button will only appear if security has been enabled at the time of installation. There are two types of security options available in GSI AMTAS; Windows and Single Password.

The Single Password security has a single user "admin" and a password for the user that may be changed using the security button.
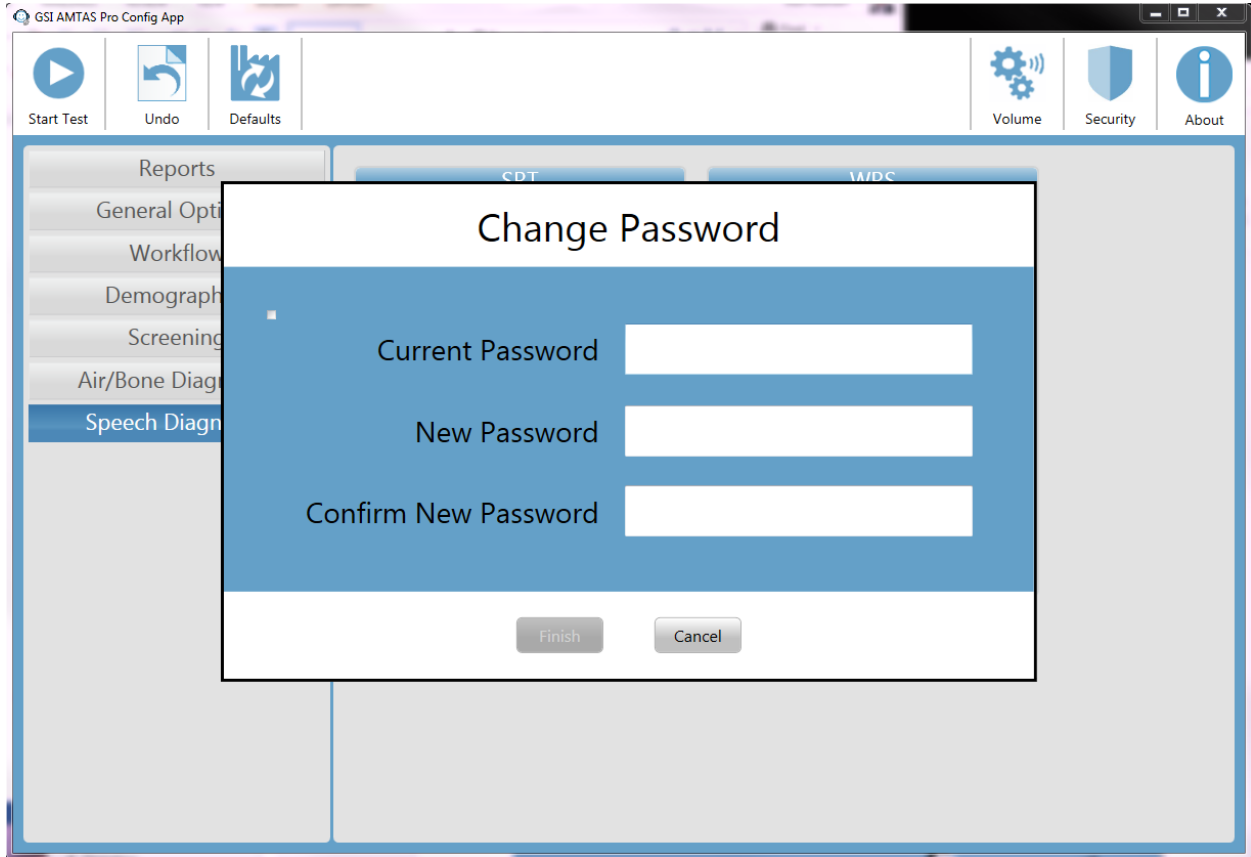
To change the password you must enter the old password, then enter the new password and a confirmation of the new password. Press the finish button to save the new password. A confirmation dialog will be displayed to indicate that the password has been changed.

The Windows security is based upon the security and authentication in Windows. In order to configure Windows users, the program must be "Run as administrator" (right clicking on the desktop shortcut offers this option). For the Windows security, there are two user types in the program; Admin and Audiologist. The Admin user type has all the security privileges and is permitted to add and delete users. The Audiologist type is permitted to configure the GSI AMTAS settings for the current test but is not allowed to add or change users. Any user that can log into the PC has privileges to run the GSI AMTAS program.

The AMTAS Windows Security screen contains two sections; Admin and Audiologist user that correspond to the types of users defined in GSI AMTAS.
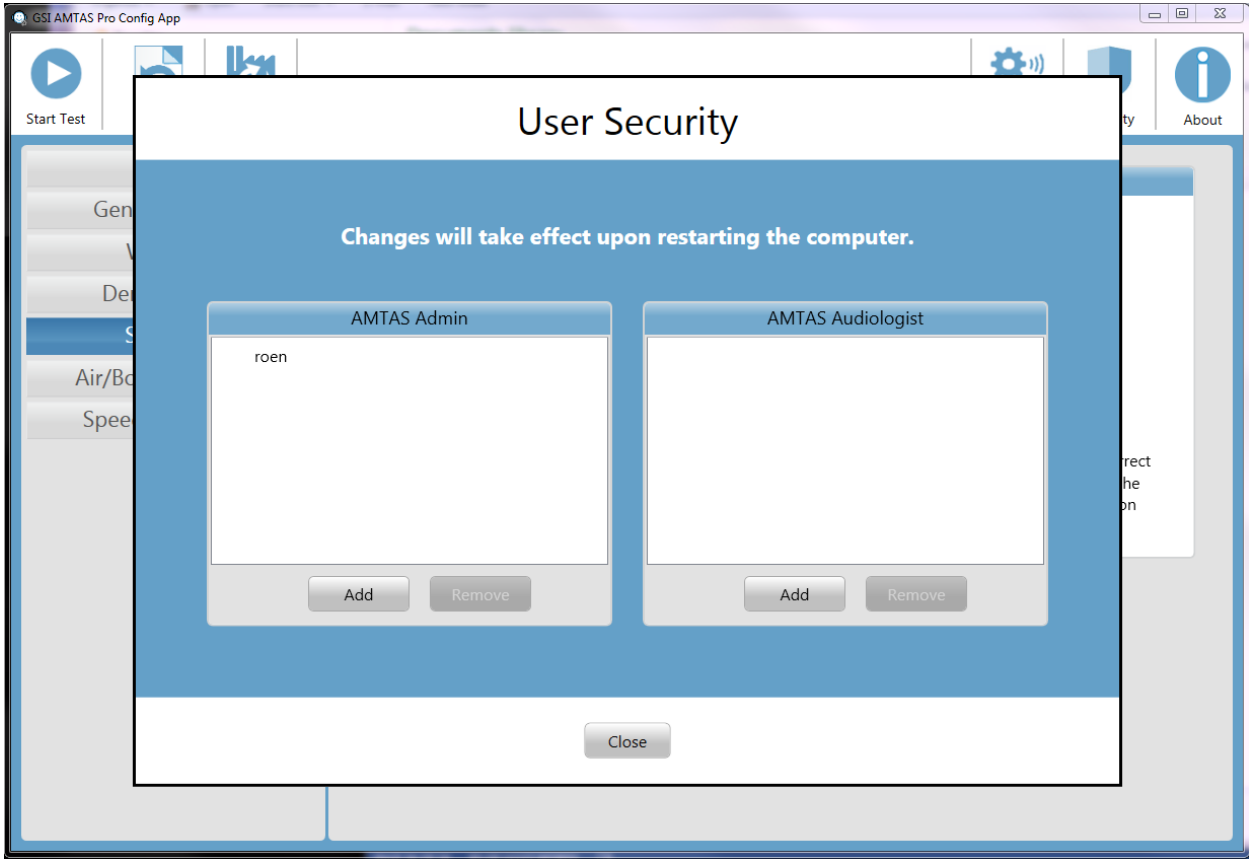
For each user type section there are buttons to add and remove users. To add a new admin or user press the add button and the add dialog is presented.
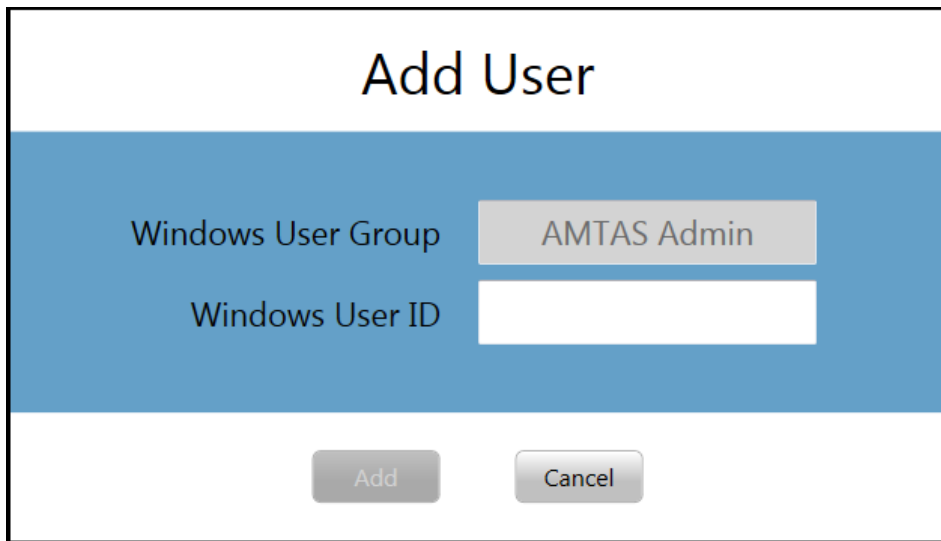
Enter the Windows User ID (this is the user name that is used to log into the PC) and press the Add button. To remove a name, highlight the name in the list and select the Remove button. A confirmation dialog is presented to confirm the removal.

NOTE: GSI AMTAS uses Windows authentication for the user IDs and passwords. The user names entered in the GSI AMTAS setup should be the same as those used for the computer login. When a new user is added, the program will authenticate the user and indicate a successful authentication by placing the name in the list. When GSI AMTAS prompts for a password, it is the person's Windows password that should be entered. A user password is required.
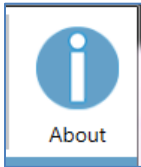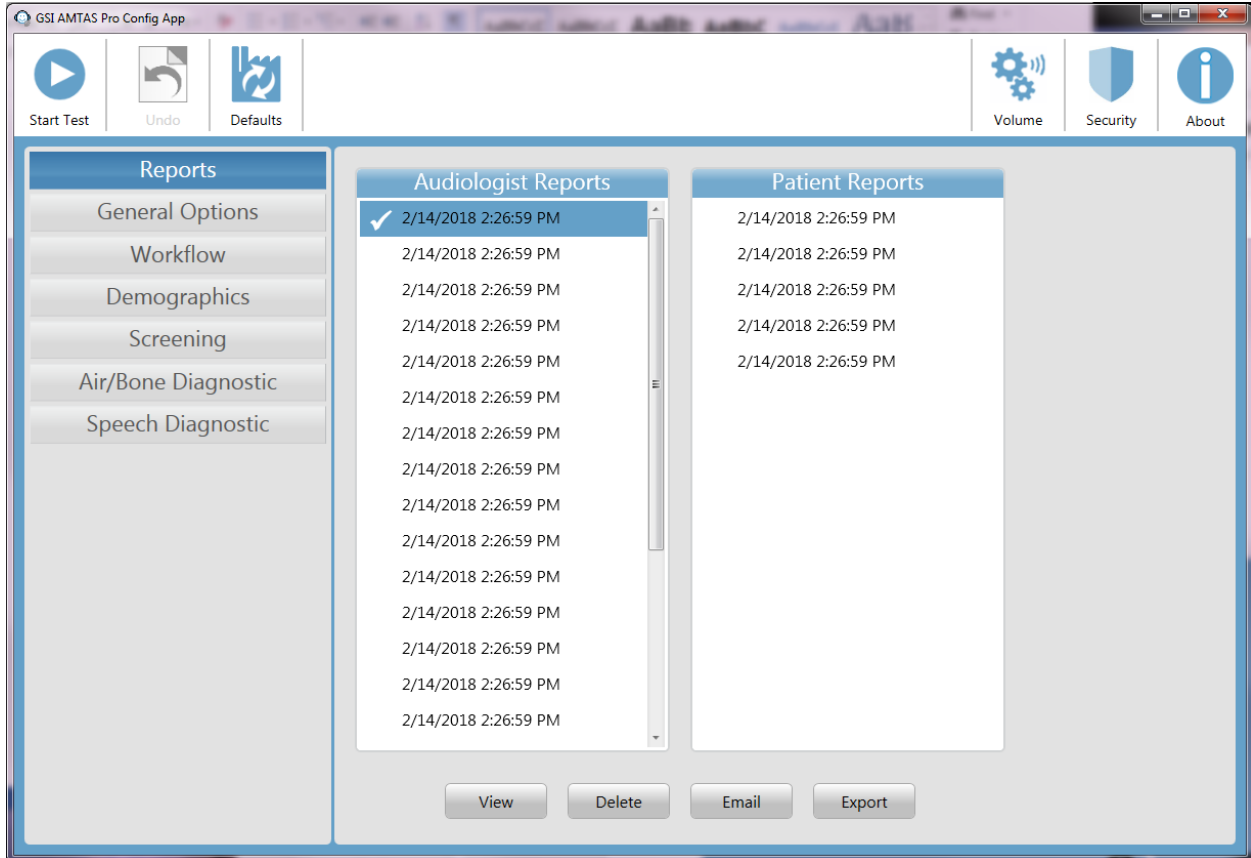

About

The About button displays information regarding the software version and patent and copyright information. The About dialog has an Export Logs and Email Logs buttons that will output the logs from the program to the selected location. The logs may be useful for trouble shooting should problems occur with the program.

Configuration Options

Reports

The Reports configuration item is used to display, email or export the test reports. There are two types of reports available in the program; audiologist reports and patient reports. The reports are described in detail in the GSI AMTAS Reports section of this manual. When the report configuration item is selected the list of reports is displayed. The reports display has two sections, one for the audiologist reports and the other for the patient reports. Clicking on a report in either section selects the report. Multiple reports may be selected. To view a report, press the View button at the bottom of the section. If more than one report has been selected only the first report that has a check mark will be viewed. You may also view a report by double clicking on the item in the list.

The bottom of the screen has buttons that are used to send the report to an email address or to export the report to another location. Sending a report by email requires that an email client is installed on the PC. When the Email button is selected, the default email client displays its send dialog where you enter the email address, subject line and any message. When the Export button is pressed, the program displays a dialog to allow the selection of a location to send the report file. The reports and the exports file are pdf formatted files.

General Options
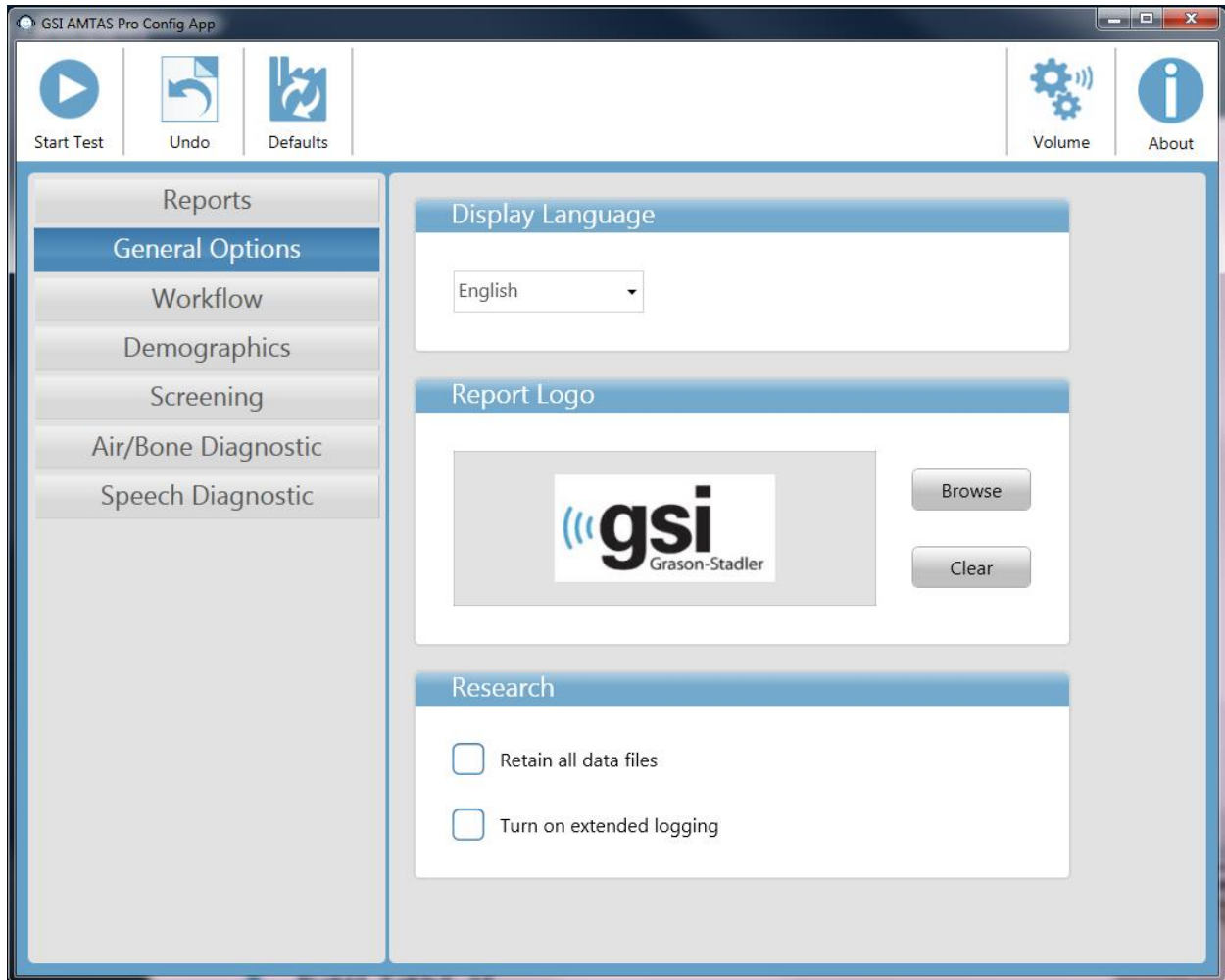
Display Language

The Display Language section provides a drop down list of supported languages for the Config App program. If a new language is selected a restart of the program is required in order to display the new language.

Report Logo

The Report Logo section allows the specification of a graphic that is placed in the top left corner of the report header. The Browse button is used to select the graphic file. The Clear button removes the graphic.

Research

The Research section contains a checkbox option to keep all of the generated data files. These files are normally stored to the audiometer and then deleted from the PC. Selecting the option keeps the files on the PC in the program data directory. Contact GSI for more details if you need the files for your research. The "Turn on extended logging" option is used for troubleshooting and should only be checked when requested by GSI support.

Workflow
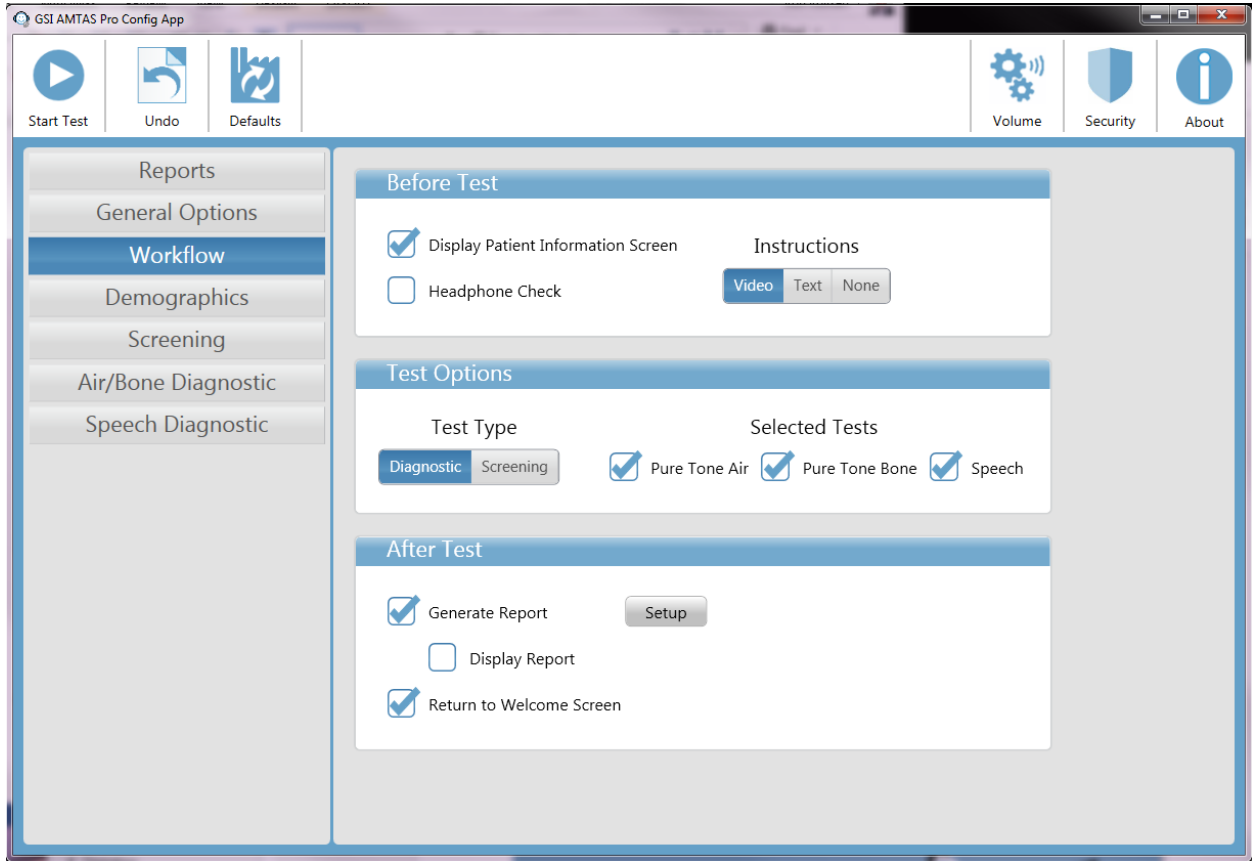
Before Test

The Before Test section has options for what screens are displayed before the test begins. Display Patient Information Screen, when checked, displays a screen for entering the patient demographics. The fields required and displayed in the program and on the report are configured in the Demographics section. The Headphone Check checkbox determines if an instruction for headphone placement is displayed and provides a test to determine if the headphones are placed on the correct ears. Test Instructions are also an option and may be presented as a video or as a text displayed on the screen. The Instructions buttons determine the format and if any test instructions are presented.

Test Options

The Test Options section determines the testing performed by AMTAS. The Diagnostic/Screening button controls the type of pure tone testing that will be performed. The Diagnostic option is used to identify hearing threshold levels of the patient. The Screening option presents the pure tones at a fixed level (upper limits of normal hearing) and records the results as pass/fail for the frequencies that are tested. When the Diagnostic button is selected, checkboxes for the selected tests determine the combination of air, bone and speech testing that is performed. The configurations for the diagnostic tests are determined in the specific test configuration items; Screening, Air/Bone Diagnostic and Speech Diagnostic.

After Test

The After Test section determines the displays to the user after the test has completed. The Generate Report checkbox determines if the reports from the test are generated. The Display Report checkbox, if selected, displays the Patient report at the completion of the test where it can be immediately printed. The Setup button will display a dialog where you can specify the configuration of the report name.
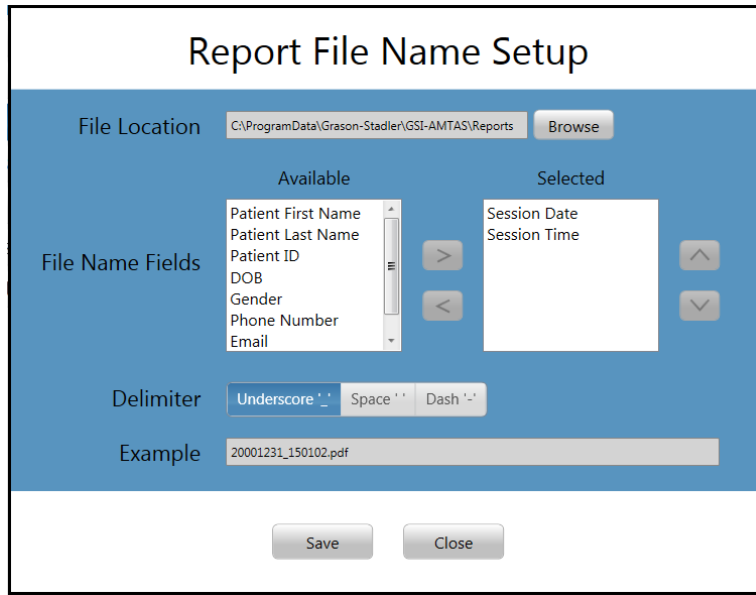
The Report File Name Setup dialog has a Browse button to allow the selection of the location for the report files. The File Name Fields provide the field list that may be used to name the file. Select a Field from the available fields and use the right/left arrow buttons to include/remove as part of the file name. The Selected column indicates the fields selected for the name and the order may be changed using the up/down arrow buttons. The Delimiter is the character that is placed between the fields in the filename.

The Return to Welcome Screen checkbox determines, if upon completion of the test, the program returns to the Welcome screen or remains at the Finished test screen. If this option is checked, the program proceeds to the test Welcome screen – ready for the next patient. If this option is unchecked, the program waits at the Finished Test screen. When this option is unchecked, there is a menu icon in the upper right corner with the submenu containing the options to add comments, go to the start screen, delete results or exit the program. When an option is selected from the menu, the program prompts for a password in order to proceed with the menu choice if security is enabled. If comments are entered, these comments are stored as part of the test results report.

Demographics
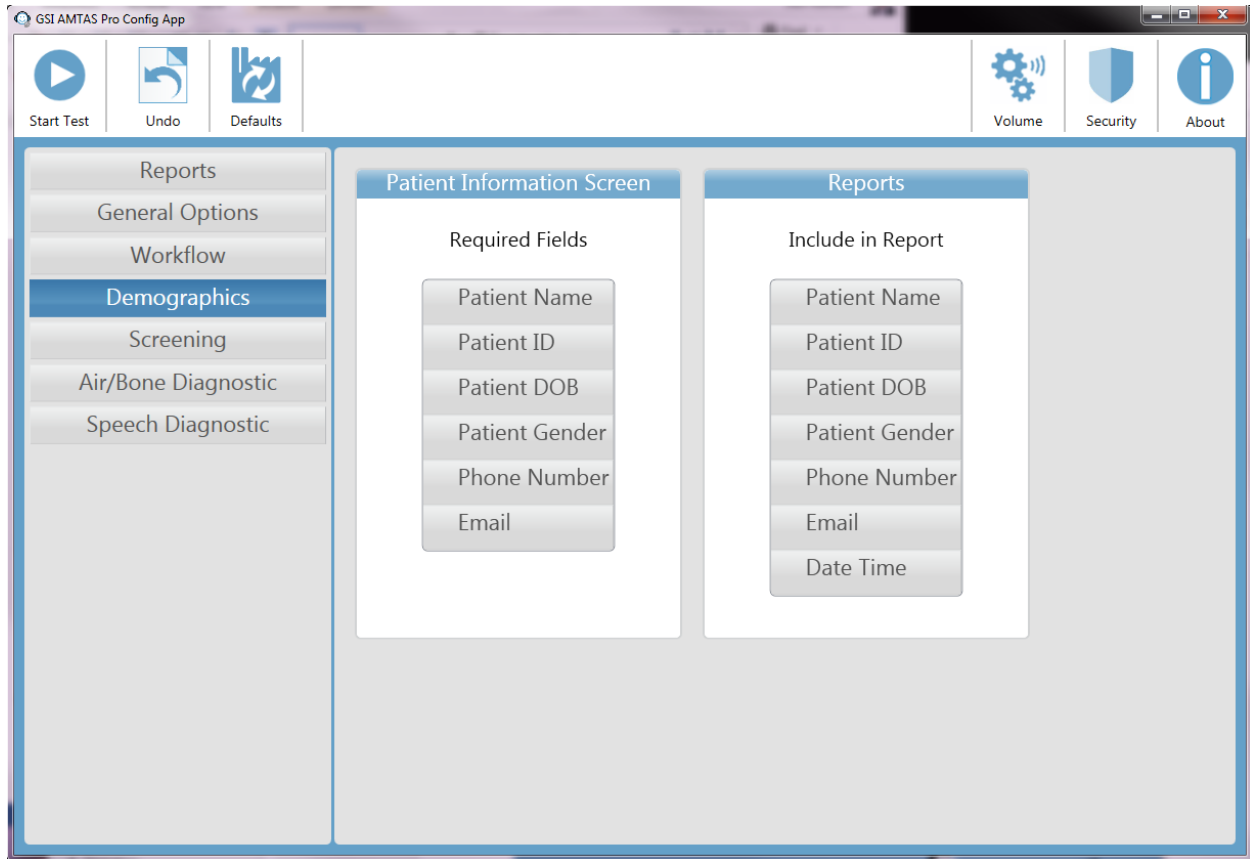
The Demographics section determines the required fields for the patient information entry. This section also determines the fields that are included in the report. The individual fields are selected/unselected by clicking the field name button. Fields that are selected are indicated by a checkmark next to the field name.

Screening
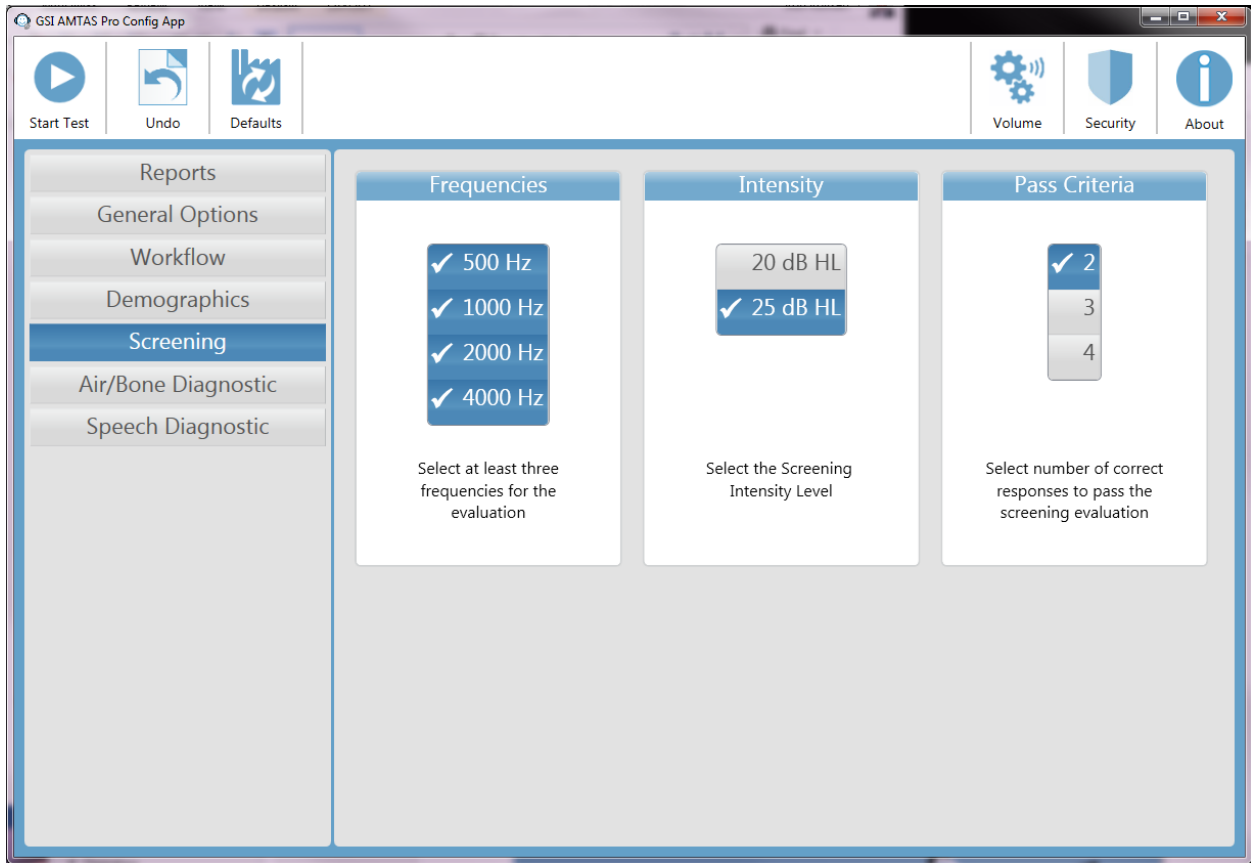
The Screening section determines the parameters that are used for the air conduction screening testing. There are three sections in the screening settings that control the parameters used for the screening test. The Frequencies section controls the pure tone frequencies (500, 1000, 2000 and 4000 Hz) that are presented in the test. Three of the four frequencies are required in order to perform the test. The Intensity section determines if the output level for the test is at 20 or 25 dB HL. The Pass Criteria section determines the number of presented frequencies where a response is required in order to pass the screening test.

Air/Bone Diagnostic
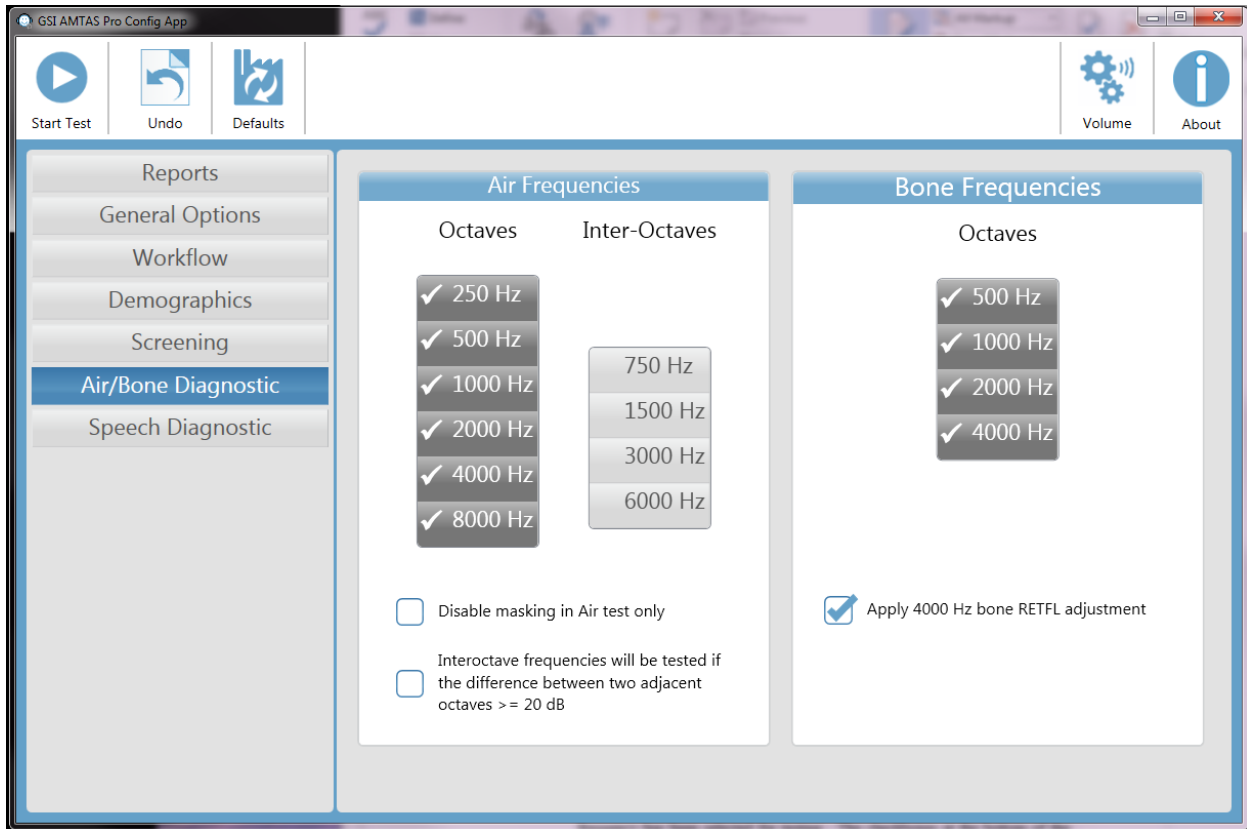
There are two sections in the air/bone settings that display the parameters used for the diagnostic pure tone threshold tests. The Air Frequencies section shows the octave frequencies that will be tested. The octave frequencies are always tested and not configurable. The inter-octave frequencies may be configured by selecting the desired frequency – a check mark will be displayed to indicate that the frequency has been selected for testing. The checkboxes at the bottom of the section allows the user to disable the masking for the air conduction testing and to select when the inter-octaves are tested. Masking is presented to the non-test ear unless the Disable masking button is checked. When the Inter-octave frequencies box is checked, the selected inter-octave frequencies are only tested when the difference between the adjacent octaves are 20 dB or greater. If the box is not checked the selected inter-octave frequencies will always be tested.

The Bone Diagnostic section displays the frequencies that will be tested if the test configuration includes bone conduction testing. All four frequencies are tested and not configurable. The "Apply 4000 Hz bone RETFL adjustment" adds a 15 dB adjustment to the 4 kHz bone threshold when checked. This adjustment is provided to eliminate the air-bone gap at 4 kHz that has been reported in the literature.

NOTE: GSI AMTAS Pro will only test bone conduction thresholds when the threshold for the air conduction is 10 dB HL or greater.

Speech Diagnostic
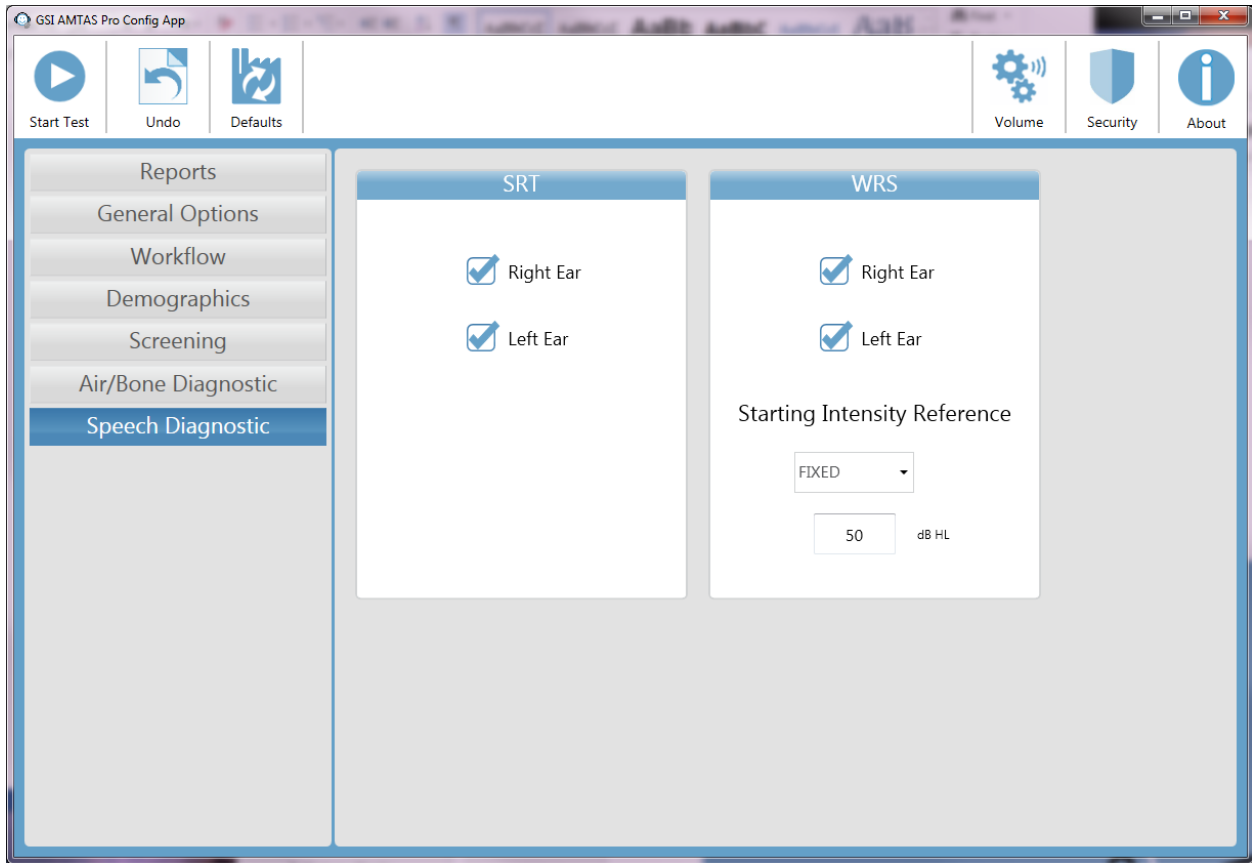
There are two sections in the Speech Diagnostic settings that display the parameters used for the speech tests. The SRT section has check boxes to select the ears that will be tested for the speech recognition threshold. The WRS section also has check boxes to select the ears that will be tested for word recognition. The starting intensity may also be configured for the word recognition testing. The options for the starting intensity are the SRT (speech recognition threshold), PTA (pure tone average) and Fixed. The Fixed selection displays an additional box where the intensity in dB HL may be entered.

GSI AMTAS Pro Reports

The GSI AMTAS Pro program creates two reports. The Audiologist report is designed to communicate with professionals who are knowledgeable about hearing testing and audiogram interpretation. The Patient report is designed to provide the patient with their test results in a less technical format.

Audiometric Report
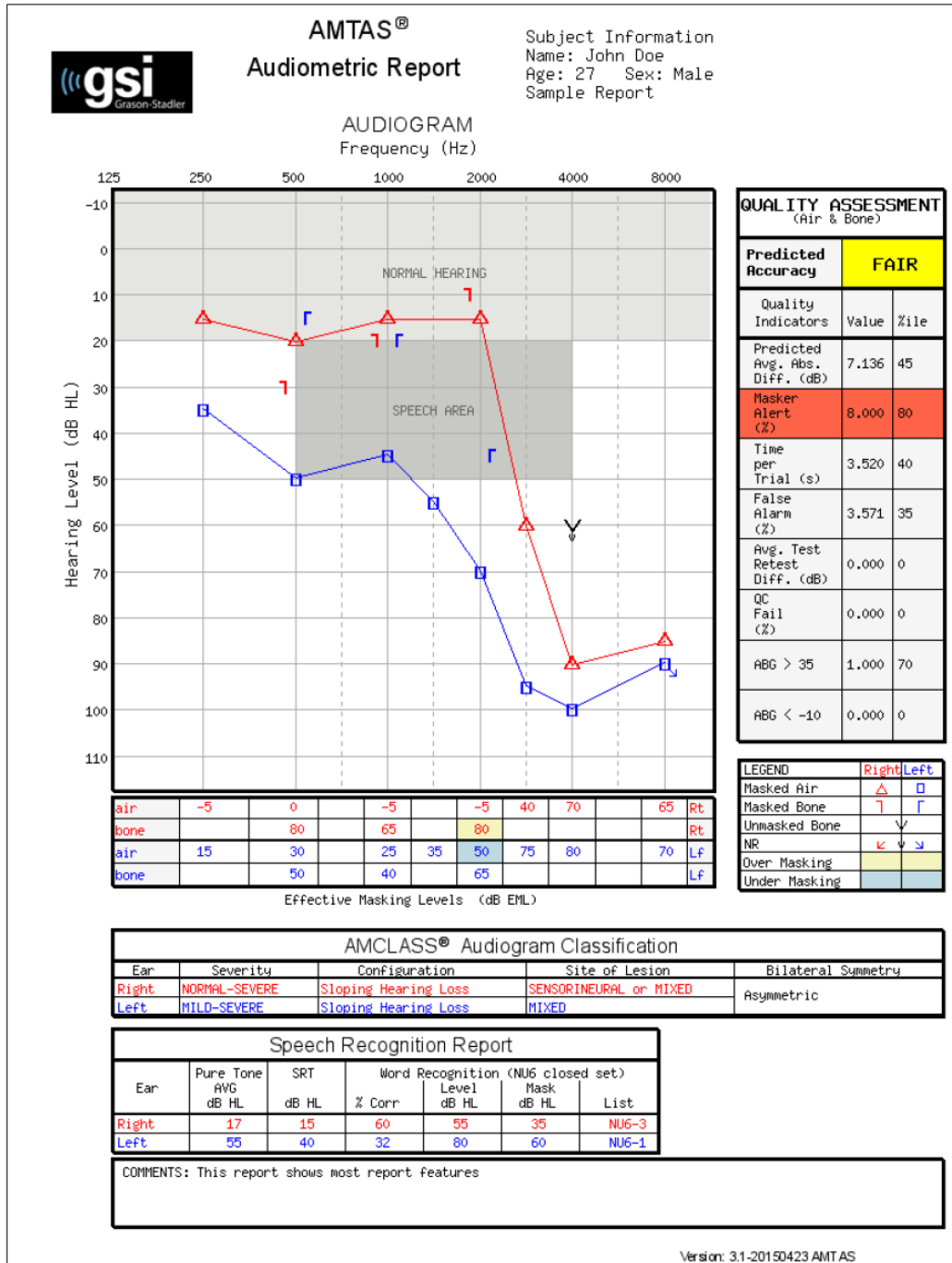
The report is automatically generated at the completion of the test and is accessed from the GSI AMTAS Pro Config App. The report contains the following sections:

- Patient Information
- Audiogram
- Audiogram Symbol Legend
- Masking Level Table
- Quality Assessment Table
- Audiogram Classification Table
- Speech Recognition Table
- Comments

Patient Information

The patient information that is included on the report may be specified in the configuration options.

Audiogram

The audiogram displays both the air and bone thresholds for both ears. It has shaded areas to indicate the normal hearing range as well as the speech areas. A legend indicates the symbols used in the audiogram.

Masking Level Table

The masking level table displays the masking level used for each test frequency. The level may be highlighted to indicate the possibility of over or under masking. Under masking is indicated with grey shading and is a masker level at threshold that is less than the air conduction threshold of the non-test ear plus 10 dB. Over masking is indicated with yellow shading and is a masker level at threshold that is greater than the bone conduction threshold of the test ear plus air conduction interaural attenuation.

Quality Assessment Table

AMTAS incorporates eight quality indicators into the test procedure and uses them to predict test accuracy.

Predicted Accuracy
A summary that is based on the predicted average absolute difference for assessing the accuracy of a diagnostic audiogram as Good, Fair or Poor. The category is based on a validated statistical process that is based on agreement with expert manual testers.

Predicted Average Absolute Difference
The predicted average absolute difference between automated and manually tested thresholds. The value is derived from a predictive equation from a multiple regression analysis of a set of quantitative quality indicators on a measure of test accuracy.

Masker Alert Rate
The proportion of thresholds for which the masking noise presented to the non-test ear may have been either too low or too high divided by the number of measured thresholds.

Time per Trial
The elapsed time from the onset of the stimulus to the subject's response averaged across all observation intervals.

False Alarm Rate
The number of false alarms (trials in which the subject reported the presence of a stimulus when no stimulus was presented) divided by the total number of catch trials (trials in which there was no stimulus).

Average Test-Retest Difference
The average difference between 1-kHz test and retest threshold measures obtained for the right and left ears.

Quality Check Fail Rate
The total number of occurrences of quality check fails (failure to respond to stimuli presented above threshold) divided by the number of measured thresholds.

Air-Bone Gap >35 dB
Number of air-bone gaps (difference between thresholds obtained for air and bone-conducted stimuli for each frequency/ear combination) that exceed 35 dB.

Air Bone Gap <-10 dB
Number of air-bone gaps (difference between thresholds obtained for air and bone-conducted stimuli for each frequency/ear combination) that are less than -10 dB.

Audiogram Classification Table
The air- and bone-conduction thresholds are analyzed and the audiogram is given three descriptive categories based on configuration, severity, and site of lesion. In addition, the audiogram is analyzed for interaural asymmetry.

Configuration
Describes the shape of the hearing loss with one of the following descriptors:
- Normal Hearing
- Flat Hearing Loss
- Sloping Hearing Loss
- Rising Hearing Loss
- Trough-shaped Hearing Loss
- Peaked Hearing Loss
- Other

Severity
Describes the degree of hearing loss with one or a combination of the following descriptors:
- Normal
- Mild

- Moderate
- Severe
- Profound

Site of Lesion
Describes the type of hearing loss with one or a combination of the following descriptors:
- Conductive
- Sensorineural
- Mixed

Bilateral Symmetry
Describes the interaural difference, for the hearing thresholds, as symmetric or asymmetric.

Speech Recognition Table
Results from the speech testing are displayed in the Speech Recognition table and include the following measurements.

Pure Tone AVG dB HL
The pure tone average is the average air conduction threshold at 500, 1000, and 2000 Hz for a given ear. When there is a difference of >= 20 dB between any two frequencies the pure tone average is the average of the better two thresholds.

SRT dB HL
Speech Recognition Threshold

Word Recognition % Corr
Percentage of correct responses for a word list

Word Recognition Level dB HL
Presentation level of the words

Word Recognition Mask dB HL
Contralateral masker level

List
Word list used (List NU6 1-4)

Comments
The examiner may enter comments into the report from the Comments option from the menu when the test has finished. The ability to enter comments must be enabled in the GSI AMTAS Pro Config App.
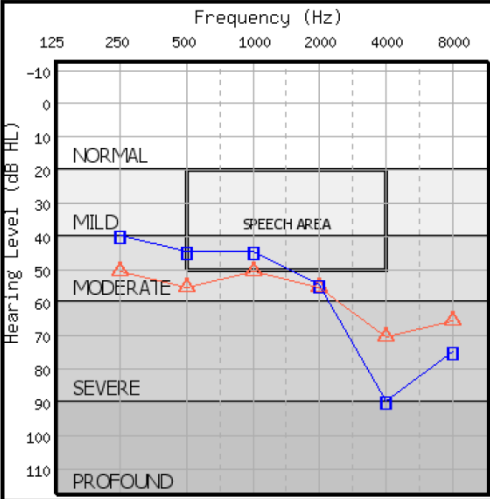
Patient Report

The patient report is designed to communicate with the patient. This report provides an overview of their test results along with educational material about hearing testing and audiogram interpretation.

Uploading GSI AMTAS Pro Results to GSI Suite

GSI-Suite versions 2.4 and above is required in order to transfer data collected using GSI AMTAS Pro.

1. If the application is not already running, double-click the GSI Suite icon on the desktop or select from the Windows Start menu to launch the program.
2. Select or enter the patient demographics.
    a. If the patient has been seen before and has data in GSI Suite:
        i. Press the Lookup icon.
        ii. Scroll through the patient list (left column) or enter search criteria in the top field to sort the patient list.
        iii. Select the desired patient and then press the new session icon.
    b. For a new patient:
        i. Press the New Patient button.
        ii. Enter the patient information (name, date of birth, ID) if not already entered from GSI AMTAS Pro.
3. Select the Patient button on the front panel of the GSI audiometer. Then select Transfer Session from the menu bar. From the list of sessions navigate to the session that you wish to transfer and press Select. All data from that session will be transferred to the appropriate audiogram within GSI Suite.
4. Press the Save icon on the GSI Suite toolbar to store the audiometric data to the session.

Error Messages

Your response was not detected. You may have taken too long or did not tap on a button.

When a tone or word is presented, the program waits for a response for 10 seconds. If there is no response within 10 seconds it is considered a non-response and the error message is displayed. The patient should be reinstructed.

You did not respond within the time limit.
Press the button below to conclude the test.

When a tone or word is presented, the program waits for a response for 10 seconds. If there is no response within 10 seconds it is considered a non-response. If there are 3 non-response timeouts during the test, the test is stopped with the error message. The patient should be reinstructed and the test would need to be restarted.

Domain not found. Try using a local account to complete login.
Contact network administrator for Domain assistance.

GSI AMTAS Pro may use Windows authentication for the user IDs and passwords. The user names entered in the GSI AMTAS Pro setup should be the same as those used for the computer login. If the user account was setup while connected to a domain, the domain needs to be available in order to login to the program. The error message may be displayed if the network cable has been removed or wireless access turned off. If the computer for GSI AMTAS Pro is no longer going to be connected to the domain then a local user account should be setup by the IT administrator so that the GSI AMTAS Pro program can be accessed.

The username or password was incorrect.

GSI AMTAS Pro may use Windows authentication for the user IDs and passwords. The user names entered in the GSI AMTAS Pro setup should be the same as those used for the computer login. Check the state of the Caps Lock as passwords are case sensitive.

GSI AMTAS Pro Testing Protocol

Psychophysical Method

GSI AMTAS Pro was designed to provide the same test results that would be obtained by an expert audiologist with a psychophysical procedure that has advantages over the commonly used clinical ("Hughson-Westlake") method. The psychophysical procedure is a single-interval, Yes-No, forced choice procedure with feedback. This means that there is a defined period in which the stimulus may occur (the observation) interval, after which the patient votes Yes or No. A predetermined proportion of trials are "catch trials", observation intervals in which no stimulus is presented. A Yes response to a catch trial is a "false alarm". When a false alarm occurs, the patient is informed and instructed to be sure to respond Yes only when there is a tone (feedback).

Masking

In routine clinical testing it is common to begin the test without masking, discover that masking is needed, and retest with masking. GSI AMTAS Pro avoids this inefficiency by always masking. A proprietary method is used to select the masker level based on the information that is available at the time. When the test is completed, an analysis is performed of masker levels and thresholds of both ears to determine if over masking or under masking may have occurred. When this occurs, the thresholds are identified with "masker alerts". When masker alerts occur, those thresholds should be retested manually.

For pure tone air conduction testing, narrow band masking noise is presented to the non-test ear at –20 dB relative to the stimulus level in all cases. For bone conduction testing, narrow band masking noise is presented to the non-test ear at the same level as the stimulus level. For Speech testing, speech noise masking is presented to the non-test ear at –20 dB relative to the word level.

Speech

Speech Recognition Threshold (SRT) testing is obtained using a closed set of spondaic words. The Word Recognition Score (WRS) is obtained using a closed set of NU-6 words. The reference level at which the WRS testing is performed is specified in the GSI AMTAS Pro Config App. The reference can be based on the SRT, Pure Tone Average (PTA) or a user specified fixed level. For the SRT and PTA reference, the WRS test is presented at 22 dB above the reference. If the score is less than 88% then a second test is presented at 28 dB above the reference. No second test is given for a user specified fixed level.

Speech WRS testing will not occur if:
- SRT value > 68 dB
- PTA value > 68 dB
- Fixed value > 80 dB

Pure Tone Average Calculation

The Pure Tone Average (PTA) is calculated as the average of the threshold for 500 Hz, 1000 Hz and 2000 Hz. The PTA is not calculated if more than one of the frequencies is a No Response (NR). If a single frequency is a No Response, then the PTA is calculated from the average of the 2 frequencies with a response. If there is a difference of 20 dB or greater between any 2 of the 3 frequencies then the PTA is calculated as the average of the best 2 frequencies.

Non Responses

If the patient does respond within 10 seconds, a warning message will be presented to the patient and a timeout occurs. If three timeouts occur at any time during the pure tone testing (i.e., it does not have to be consecutive), the application will end the test and proceed to the Finish screen.

A timeout during speech test is treated as an incorrect response. For the spondee test that would result in raising the level which will eventually hit the max and abort if there are no correct responses.

Config App Default Settings

Test Options
- Diagnostic
- Selected Tests: Air/Bone, Speech
- Use Video Instructions: Yes
- Display Patient Information Screen: Yes
- Upon Test completion, go to Start Screen: Yes

General Options
- Patient Name: Not required, Not included in Report
- Patient ID: Not required, Not included in Report
- Patient DOB: Not required, Not included in Report
- Patient Gender: Not required, Not included in Report
- Generate PDF Report: Yes, Path: C:\ProgramData\Grason-Stadler\GSI AMTAS Pro\Reports
- Select Report Image: Not defined

Air/Bone Settings
Air Diagnostic
- Octave frequencies: All tested (not configurable)
- Inter-Octaves: Not tested
- Inter-Octave testing if > = 20 dB between octaves: No

Bone Diagnostic
- Octave frequencies: All tested (not configurable)

Speech Settings
SRT
- Ear: Right and Left

WRS
- Ear: Right and Left
- Starting Intensity Reference: PTA

Screening Settings
- Frequencies: 500, 1000, 2000, 4000 Hz
- Intensity: 25 dB HL
- Pass Criteria: 2

AMTAS Publications and Patents

AMTAS PUBLICATIONS

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4. Margolis, R.H., Saly, G.S. Toward a standard description of hearing loss. Int. J. Audiology 46, 746-758, 2007.
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AMTAS PATENTS

1. Margolis, R.H. Adaptive Method and Apparatus for Testing Auditory Sensitivity. U.S. Patent # 6,496,585, December 17, 2002.
2. Margolis, R.H. Method for Assessing the Accuracy of Test Results. U.S. Patent # 7,704,216, April 27, 2010.
3. Margolis, R.H. and Saly G.S. Audiogram Classification System. U.S. Patent # 8,075,494, December 13, 2011.
4. Margolis, R.H., Saly, G.S., Birck, J. D. Calibration of Audiometric Bone Conduction Vibrators, U.S. Patent # 8,577,050, November 5, 2013.