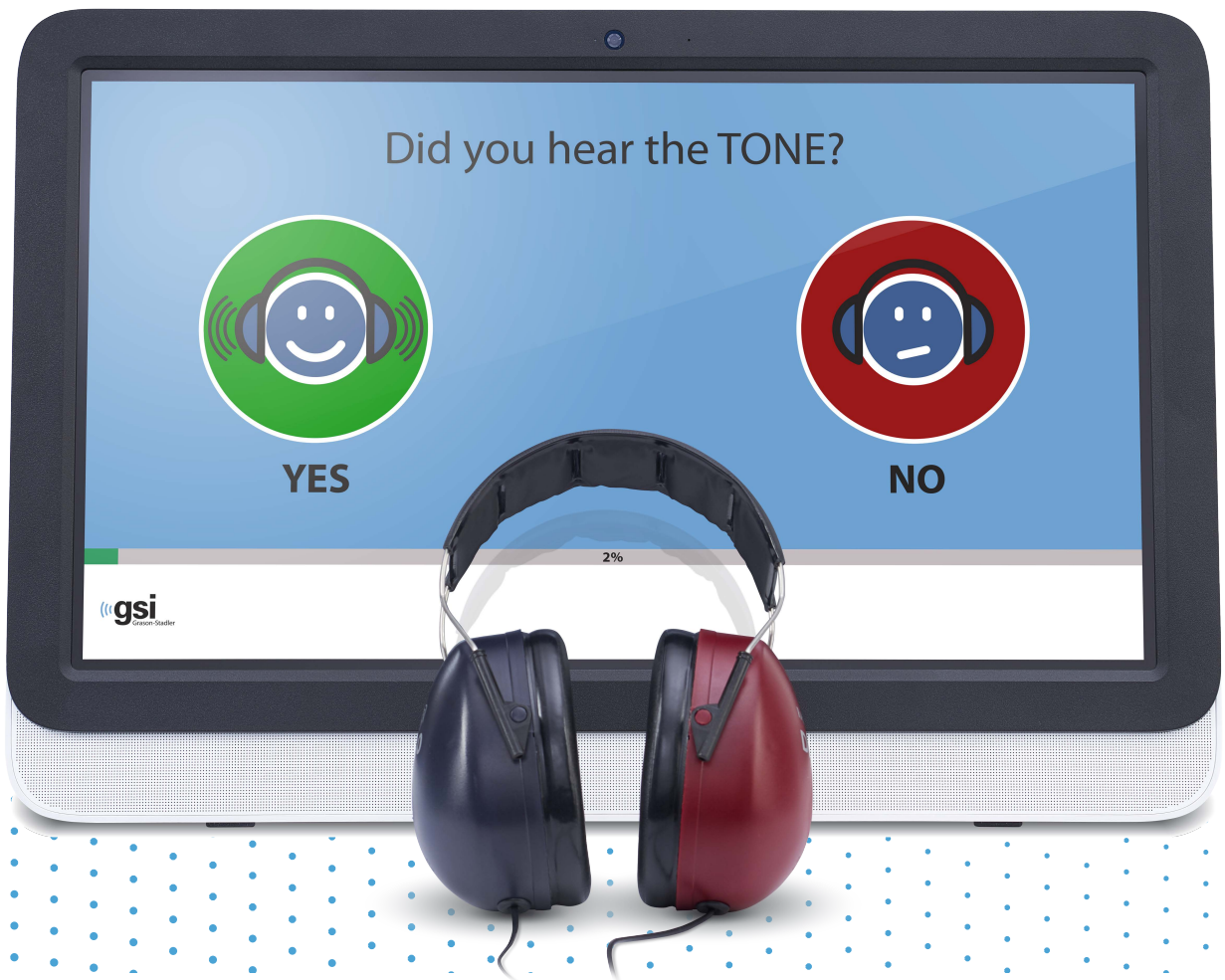




AUTOMATED AUDIOMETRY SOFTWARE



AMTAS PRO

USER MANUAL

Title: GSI AMTAS Pro™ User Manual

Manufacturer

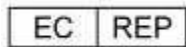
Grason-Stadler
10395 West 70th Street
Eden Prairie, MN 55344
USA

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Compliance

The CE 0123 mark identifies compliance with the Medical Device Regulation (EU) 2017/745. Grason-Stadler is an ISO 13485 certified corporation.



European Authorized Representative

Grason-Stadler
c/o DGS Diagnostics A/S
Audiometer Alle 1
5500 Middelfart
Denmark



0123

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.

This operating manual contains information pertinent to the use of the AMTAS Pro system including safety information.



READ THIS ENTIRE MANUAL BEFORE ATTEMPTING TO USE THIS SYSTEM!

MANUAL CONVENTIONS

Throughout this manual, the following meaning of warnings, cautions and notices are used.

WARNING



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

CAUTION



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

NOTE: Notes help you identify areas of possible confusion and avoid potential problems during system operation.

WARNINGS AND CAUTIONS

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 based on 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.







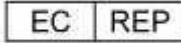





Consult the PC manual for the PC for the important safety information for the PC.


In case of death or serious incident in relation to the use of the device, the incident must immediately be reported to Grason-Stadler and the local national competent authority

PRECAUTIONS

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 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	Description
	Conforms to the Medical Device Regulation (EU) 2017/745.
	Indicates that the device is a Medical Device
	Symbol for "SERIAL NUMBER."
	GSI Part Number.
	Return to Authorized Representative, Special disposal required.
	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 Regulation (EU) 2017/745 as a Class IIa device.
	Symbol for "European Authorized Representative."
	Symbol for "Manufacturer."
	Symbol for "Date of Manufacture."
	B Patient Applied Part according to IEC 60601-1.
	On/Off
	Consult the operating instructions/directions for use. A copy of the operating manual is available on this website: www.grason-stadler.com

Symbol	Description
	<p>A printed copy of the operating instructions can be ordered from Grason-Stadler for shipment within 7 days; or you can contact your local representative.</p>
 <p>7d www.grason-stadler.com</p>	<p>Consult the operating instructions/directions for use.</p> <p>A copy of the operating manual is available on this website: www.grason-stadler.com</p> <p>A printed copy of the operating instructions can be ordered from Grason-Stadler for shipment within 7 days; or you can contact your local representative.</p>

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. Audiograms are classified based on configuration, severity, and symmetry. The program generates a report, and the data may be transferred to GSI Suite to other software programs. The software performs these tests by controlling a GSI audiometer connected to the PC.

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 protect your data, ensure that an appropriate virus & spyware scanner is installed, updated, and effective. Please contact a local IT 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.

In order to ensure proper operation, you should not connect other audio devices (i.e. Bluetooth headphones) to the PC running the AMTAS software.

PREREQUISITES

Before installing the software confirm that the computer meets the minimum requirements.

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 minimum
- Display: 19” or larger recommended
- Resolution: 1280 x 800 minimum
- Touch screen or mouse/trackball
- USB for software installation
- Network LAN Card (if connecting to database via a network)

GSI AMTAS PRO Software Requirements

- Microsoft Windows® 10 Pro (64 bit)
- Microsoft .NET Framework version 4.7.2

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

- Driver for the GSI audiometer

GSI AMTAS PRO Audiometer Requirements

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

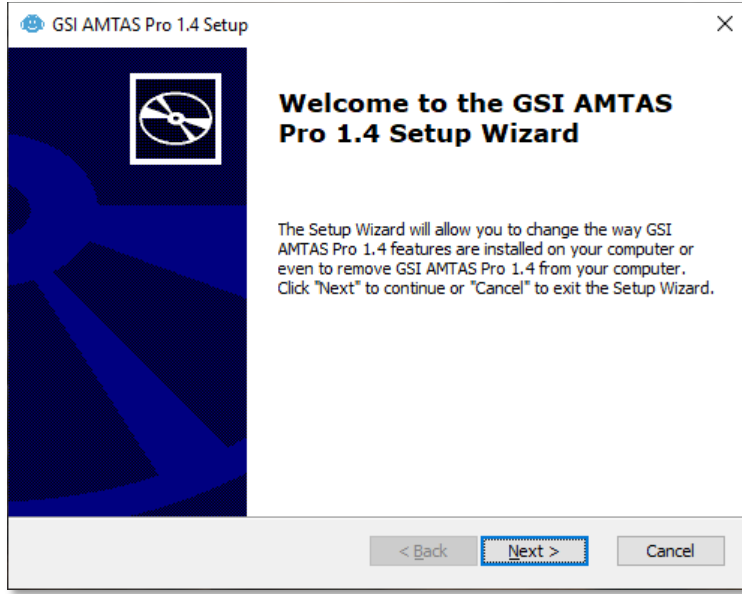
INSTALLING ON WINDOWS® 10 PRO

NOTE: To install this application, the user must either be an Administrator or know the Administrator password.

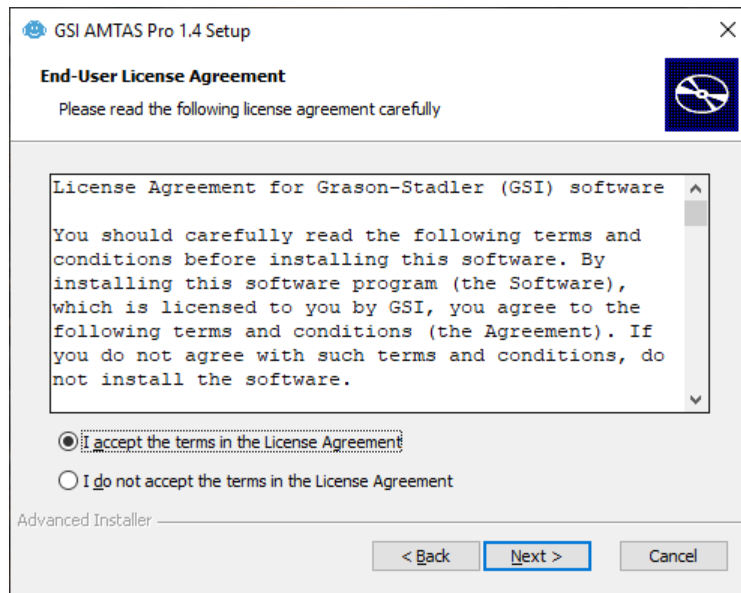
1. Insert the GSI AMTAS Pro USB drive into a USB port on the PC. If auto-run is disabled, browse the USB drive and double click on the *GsiIAMTASProSetup.exe* file.



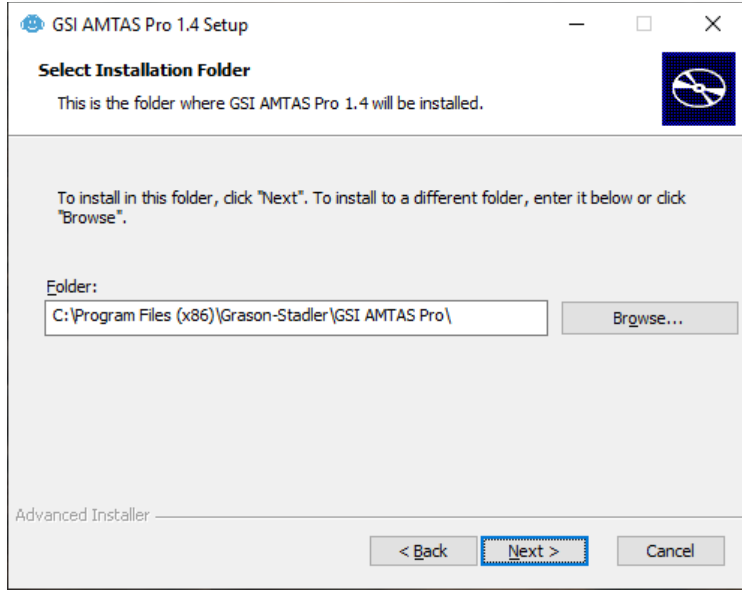
2. When the installation begins, Windows User Account Control may ask for permission to install the software. Answer "Yes" to the dialog to proceed with the installation. The GSI AMTAS Setup Wizard dialog screen will be presented.



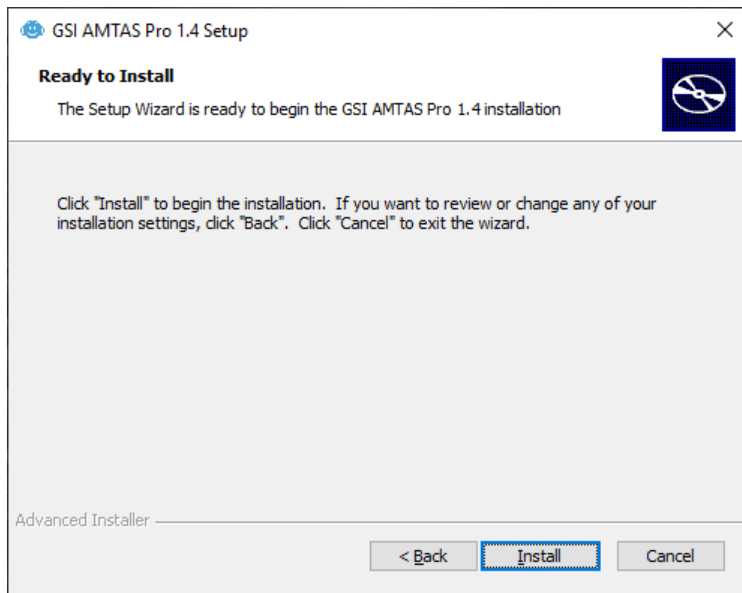
3. Press "Next"



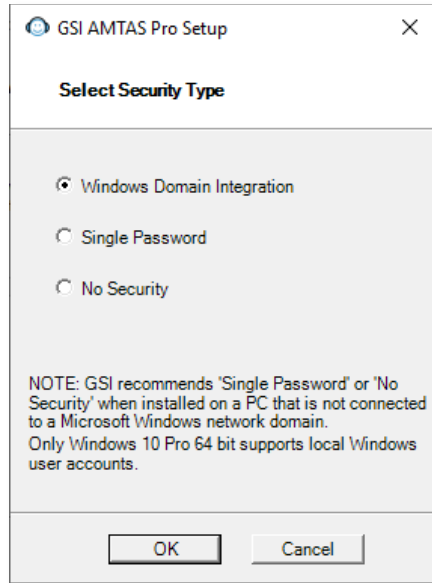
4. Read the license agreement. Select the "I accept ..." button to accept the agreement and press "Next" to continue. If you do not wish to install the software, select "Cancel" to exit the Setup. The Setup Wizard then presents the Select Installation Folder dialog.



5. To use the default folder (recommended) press the “Next” button. If you wish to install the program in a different directory, use the Browse button to locate the Folder for installation and then select “Next”. The Ready for Install dialog is presented to allow you to review or change your installation settings.



6. Press “Install” to proceed with the installation. The Select Security Type dialog is presented.



7. The type of security that is used with the program is setup during the installation. The security selection dialog has three (3) security options. Select the appropriate security type for your facility.

- **Windows – Domain Integration Security**

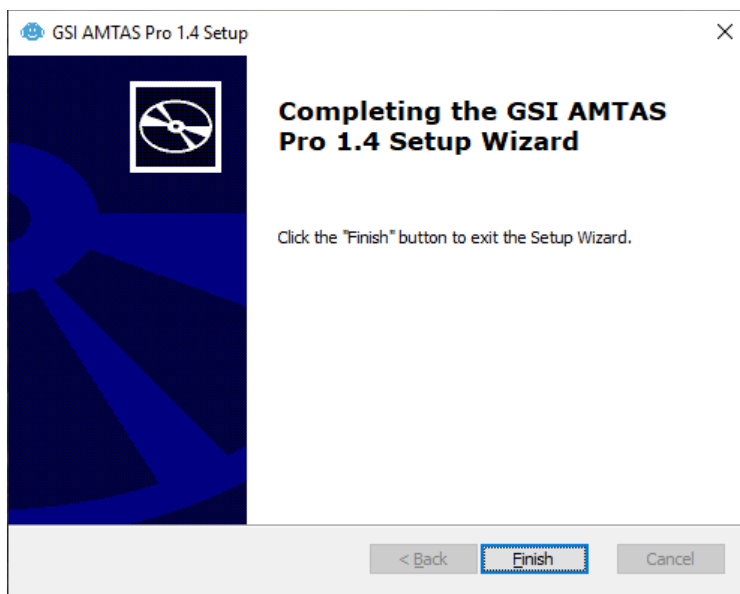
When the program requires authentication, it will verify the user identity and password based on Windows authentication. The software will automatically add this installation user to the AMTAS administrator group. Additional AMTAS administrators may be added by running the GSI AMTAS Pro Config app as 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).



8. A message will be displayed to indicate that the software has been successfully installed. Select "Finish".

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 Windows Settings
2. Select Apps
3. Select GSI AMTAS Pro in Apps & features
4. Select 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 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 one end of the audio out cable to the external in port (EXT A+B) on the audiometer using the supplied audio cable. a) If you are using the noise monitoring microphone, connect the other end of the audio cable to the jack on the noise monitoring microphone USB. b) If you are not using the noise monitoring mic, connect the other end of the audio cable to the PC Audio Out.
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 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). 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.

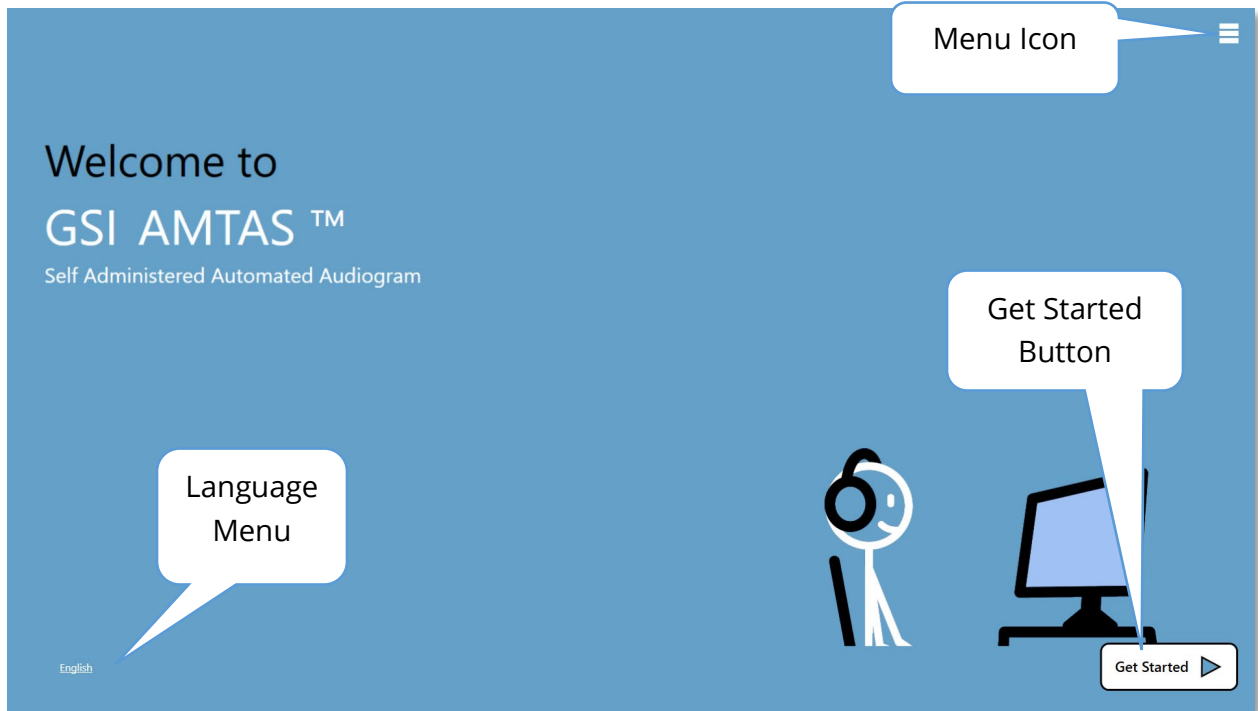
LAUNCHING AND RUNNING GSI AMTAS PRO



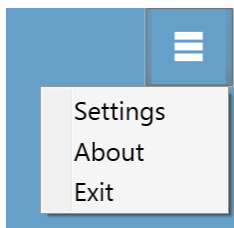
After installation of the program, a shortcut icon appears on the desktop. Double-click the desktop icon to open GSI AMTAS Pro. It is also possible to open this application from Start > All Programs > Grason-Statler > GSI AMTAS Pro.

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.

Language Menu



The current language is indicated in the lower left corner of the screen. Clicking on the language presents a list of available languages for the AMTAS program. Select the language from the list and the AMTAS will change the text

of the program to the chosen language. This change is only for the current test session and does not save the choice for future test sessions. To change the default language, use the AMTAS Pro Config App program.

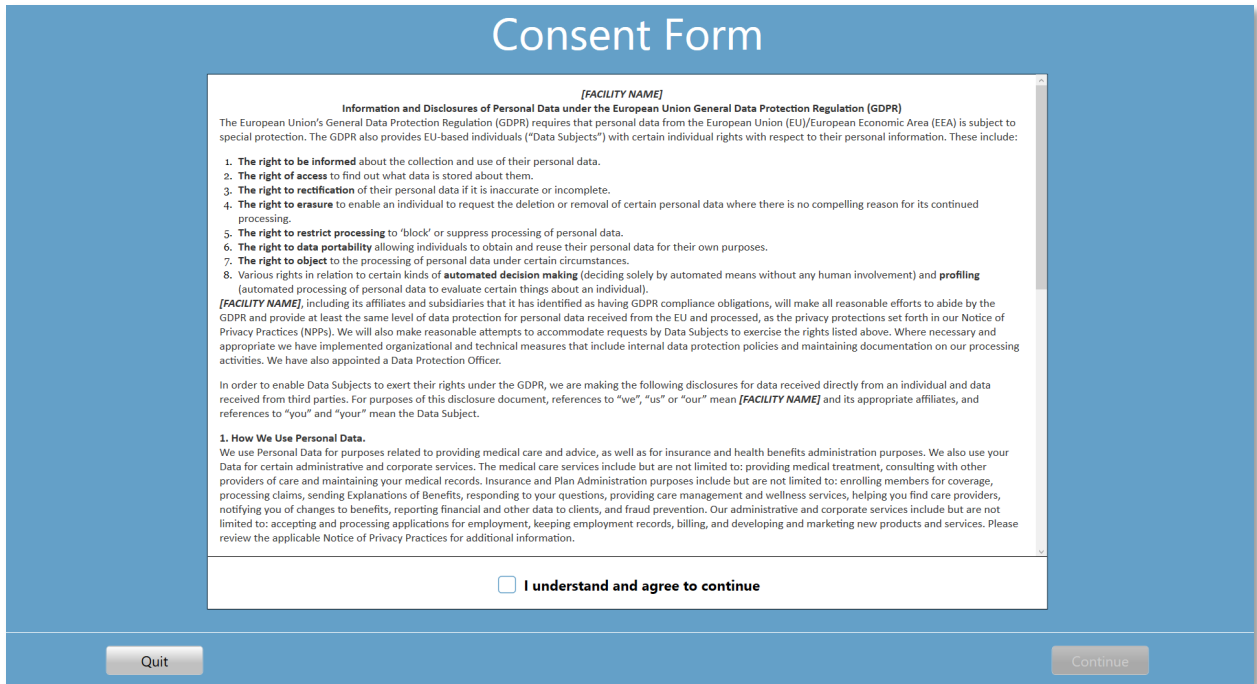
Get Started Arrow



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 consent form or registration screen depending on the workflow setup.

PATIENT CONSENT FORM SCREEN

The Patient Consent Form is the first screen presented if the option has been selected as part of the workflow setup in the AMTAS Pro Config App. There is an acceptance check box in the lower middle of the form that must be checked for the Continue button to become available and the test to proceed. The Consent Form is saved as a report file with the test record. A Quit button in the lower left of the screen exits the screen and returns to the Welcome screen.



Consent Form

[FACILITY NAME]

Information and Disclosures of Personal Data under the European Union General Data Protection Regulation (GDPR)

The European Union's General Data Protection Regulation (GDPR) requires that personal data from the European Union (EU)/European Economic Area (EEA) is subject to special protection. The GDPR also provides EU-based individuals ("Data Subjects") with certain individual rights with respect to their personal information. These include:

1. **The right to be informed** about the collection and use of their personal data.
2. **The right of access** to find out what data is stored about them.
3. **The right to rectification** of their personal data if it is inaccurate or incomplete.
4. **The right to erasure** to enable an individual to request the deletion or removal of certain personal data where there is no compelling reason for its continued processing.
5. **The right to restrict processing** to 'block' or suppress processing of personal data.
6. **The right to data portability** allowing individuals to obtain and reuse their personal data for their own purposes.
7. **The right to object** to the processing of personal data under certain circumstances.
8. Various rights in relation to certain kinds of **automated decision making** (deciding solely by automated means without any human involvement) and **profiling** (automated processing of personal data to evaluate certain things about an individual).

[FACILITY NAME], including its affiliates and subsidiaries that it has identified as having GDPR compliance obligations, will make all reasonable efforts to abide by the GDPR and provide at least the same level of data protection for personal data received from the EU and processed, as the privacy protections set forth in our Notice of Privacy Practices (NPPs). We will also make reasonable attempts to accommodate requests by Data Subjects to exercise the rights listed above. Where necessary and appropriate we have implemented organizational and technical measures that include internal data protection policies and maintaining documentation on our processing activities. We have also appointed a Data Protection Officer.

In order to enable Data Subjects to exert their rights under the GDPR, we are making the following disclosures for data received directly from an individual and data received from third parties. For purposes of this disclosure document, references to "we", "us" or "our" mean [FACILITY NAME] and its appropriate affiliates, and references to "you" and "your" mean the Data Subject.

1. How We Use Personal Data.
We use Personal Data for purposes related to providing medical care and advice, as well as for insurance and health benefits administration purposes. We also use your Data for certain administrative and corporate services. The medical care services include but are not limited to: providing medical treatment, consulting with other providers of care and maintaining your medical records. Insurance and Plan Administration purposes include but are not limited to: enrolling members for coverage, processing claims, sending Explanations of Benefits, responding to your questions, providing care management and wellness services, helping you find care providers, notifying you of changes to benefits, reporting financial and other data to clients, and fraud prevention. Our administrative and corporate services include but are not limited to: accepting and processing applications for employment, keeping employment records, billing, and developing and marketing new products and services. Please review the applicable Notice of Privacy Practices for additional information.

I understand and agree to continue

Quit Continue

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.

The screenshot displays the 'Patient Information' screen with the following fields and values:

Field	Value
First Name	
Last Name	
Patient ID	
Gender	Male
Birth Date	7/5/2020
Phone Number	
Email	

* = Required Field

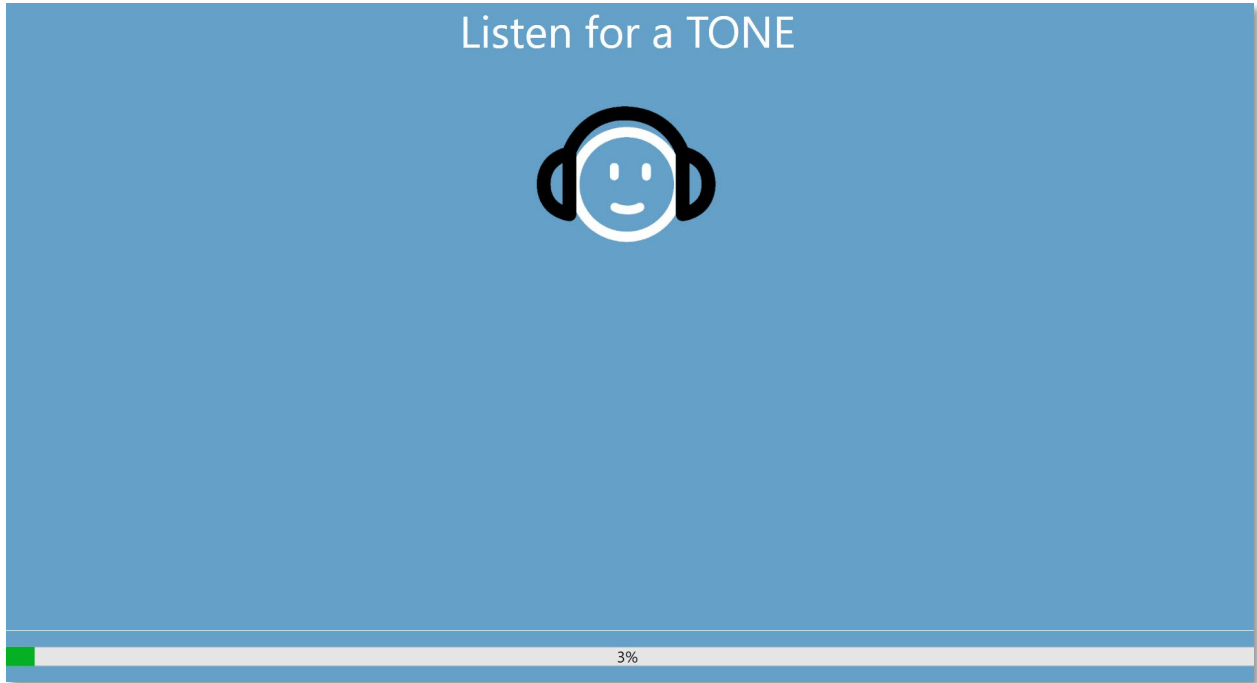
Buttons: Quit (bottom left), Continue (bottom right)

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. A Quit button in the lower left of the screen exits the screen and returns to the Welcome screen.

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 for the 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 for bone conduction and an option that may be disabled for the air conduction test.



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

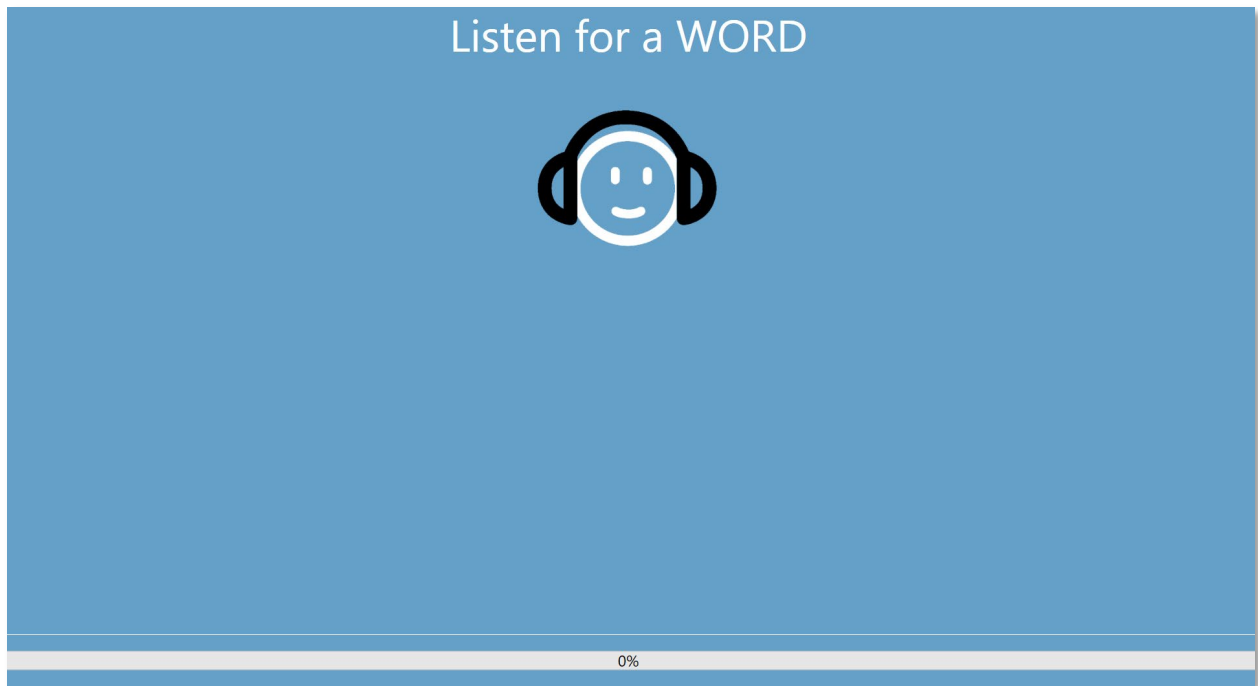
The response screen prompts the user with the question about hearing the tone and presents two icons. The patient indicates that they heard the tone by choosing the icon on the left and to indicate that they did not hear the tone by choosing the icon on the right.



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

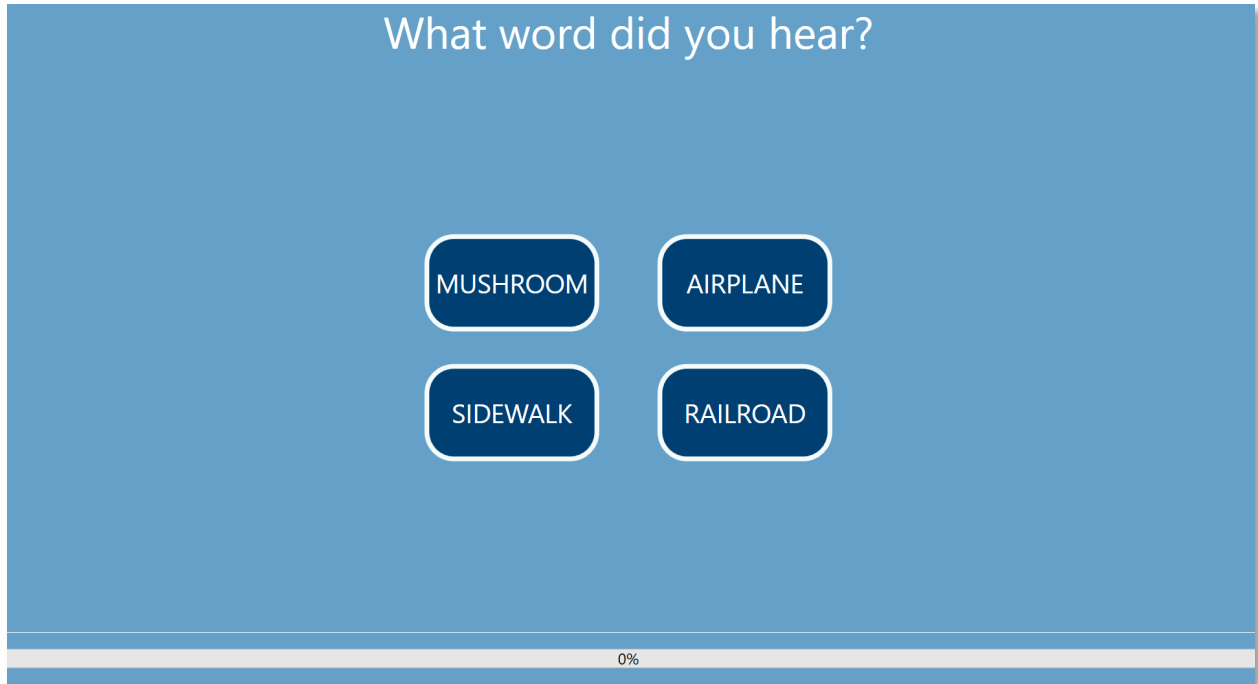
The “Listen for a WORD” screen is presented to alert the patient that they should pay attention and listen to see if they hear a word. GSI AMTAS Pro uses this screen for speech recognition threshold and word recognition scoring. There is a progress bar at the bottom of the screen to indicate the percentage 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

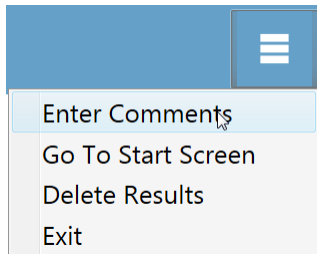
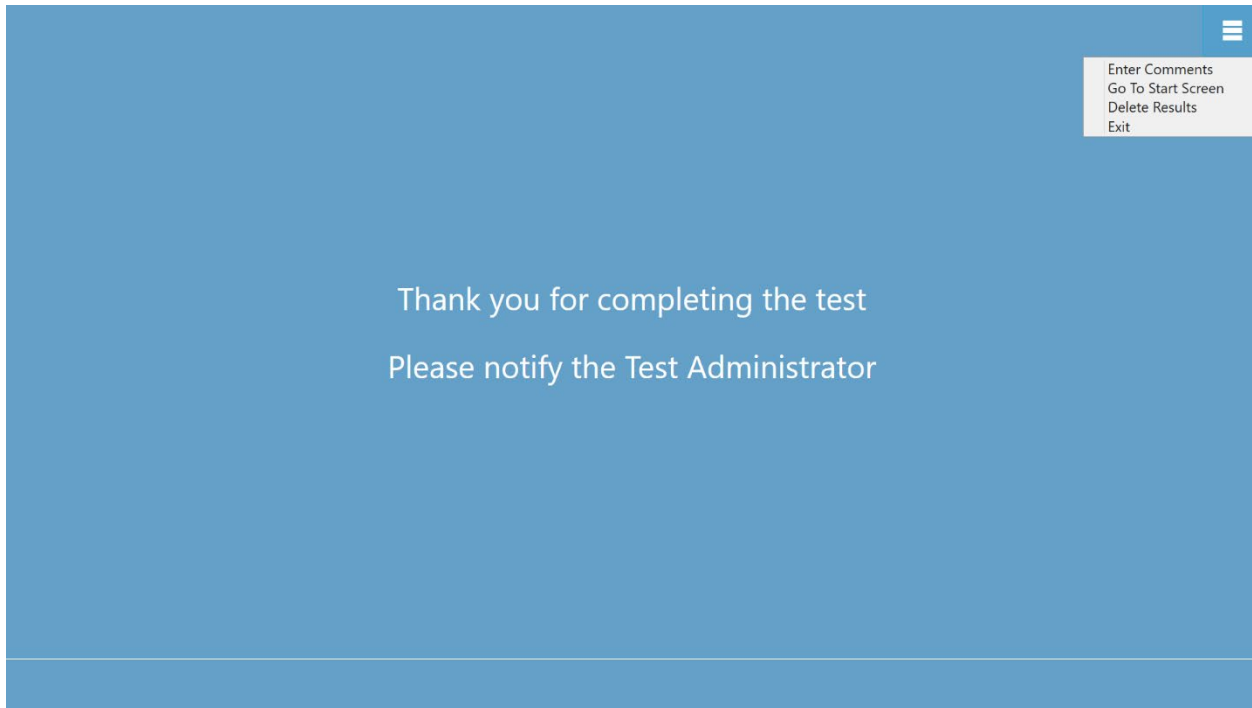
The response to a word screen prompts the user with the question about hearing the word and presents a list of four words from which to choose. The patient indicates that they heard the word by choosing the matching word.



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 Workflow configuration, there may be a menu at the top right of the screen.

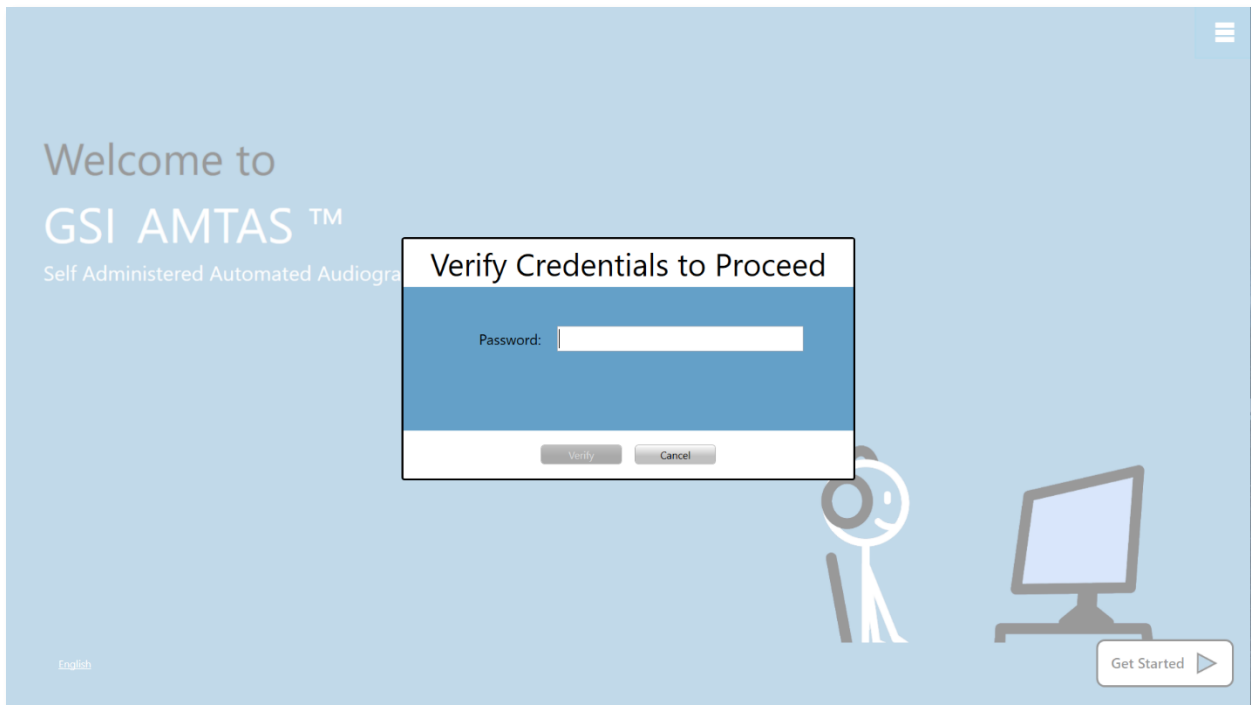


Test Complete Menu

When the Workflow, After Test configuration does not “Return to Welcome screen” a menu is available at the end of the test. If any item in the sub menu is selected, a prompt for a password will appear if security has been enabled. 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. The ‘Go To Start Screen’ returns the program to the Welcome Screen, ready to start the next test. The ‘Delete Results’ option presents a confirmation dialog. Upon confirmation of the delete action, the test that was just completed is removed. The Exit option closes the program and returns the user to the PC desktop.

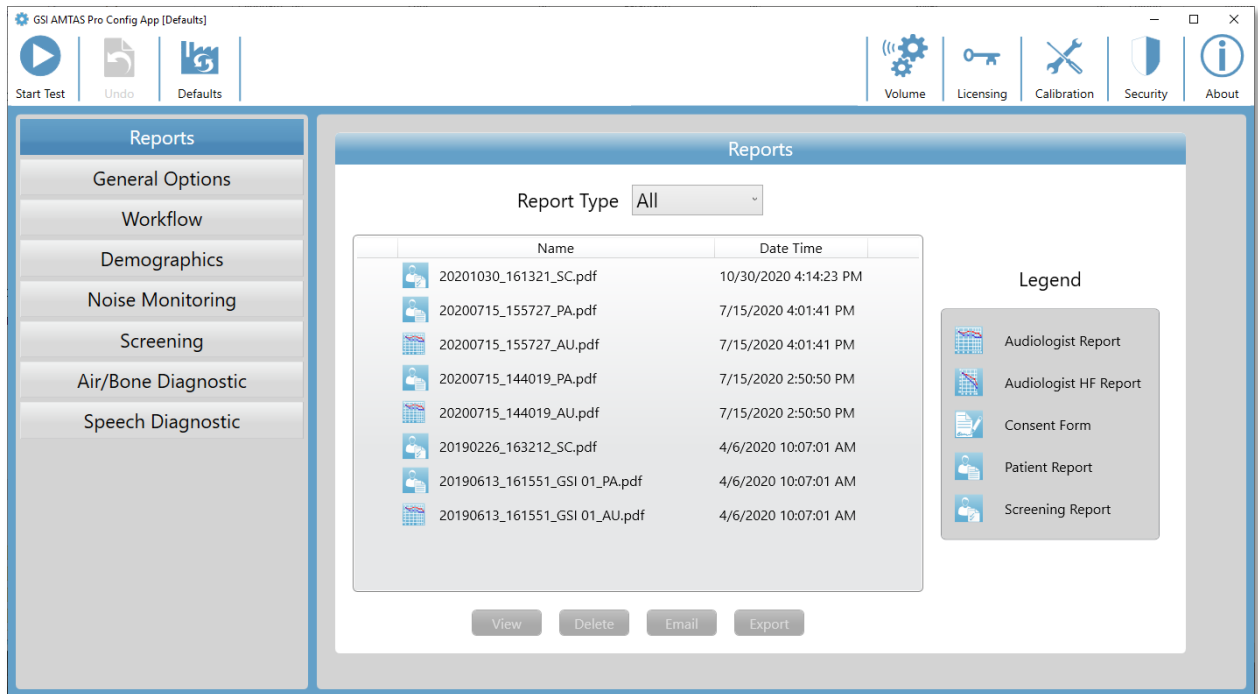
GSI AMTAS PRO CONFIG APP SETTINGS

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. 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 username and password have been authenticated, the main Config App screen is presented and displays the parameters used for the GSI AMTAS Pro program.

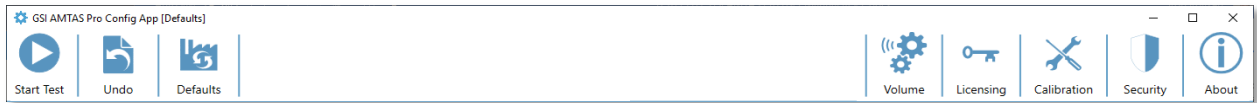
NOTE: There is a difference in the persistence of the changes made to the options that depends on how the GSI AMTAS Pro Config App is launched. When changes are made from the Settings menu in the GSI AMTAS Pro program, the changes are only applicable for the current test session. When changes are made 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 title bar of the Config App program indicates the mode as Session Settings or Defaults.



The 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 start the test, undo changes or load the defaults. The menu bar also contains options to adjust the output levels for the instructions that are presented to the patient, display and import license and calibration files, set up the administrative users of the system and display information about the program.

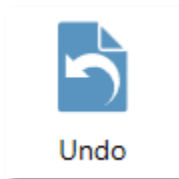


Start Test



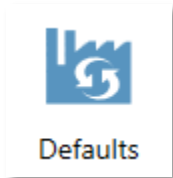
The Start Test button begins the AMTAS test. The settings of the Config App are saved. The Config App is closed the Welcome screen is presented ready for testing to begin.

Undo



The Undo button returns the settings to the original values (when the screen was loaded). After a confirmation, any changes that were made are discarded and the previous configuration reloaded. This only applies to the current category option. For example, if you make a change to the General Options then go to Workflow, the changes made in General Options are saved and the undo button would only undo changes made in Workflow.

Defaults



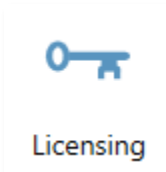
The Defaults button returns the settings to the original values (factory settings when the program was installed). Any changes that were made are discarded and the previous factory settings loaded.

Volume



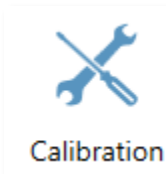
The Volume icon on the menu bar presents a screen to adjust the output level of the patient instructions that may be played to the patient prior to the test. This volume is only for the output level of the instructions and does not impact the presentation of the tones and speech signals presented by 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.

Licensing



The Licensing button displays a License dialog that shows the license information for the system. This information includes the Hardware ID which is used to obtain a license for the system. The buttons at the bottom of the dialog provide options to email, export and import the information needed to obtain and install a license.

Calibration



The Calibration button displays the Calibration Information dialog. The serial number of the noise monitoring microphone and the calibration dates are shown. A button at the bottom of the dialog provides the option to import the microphone calibration file.

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.

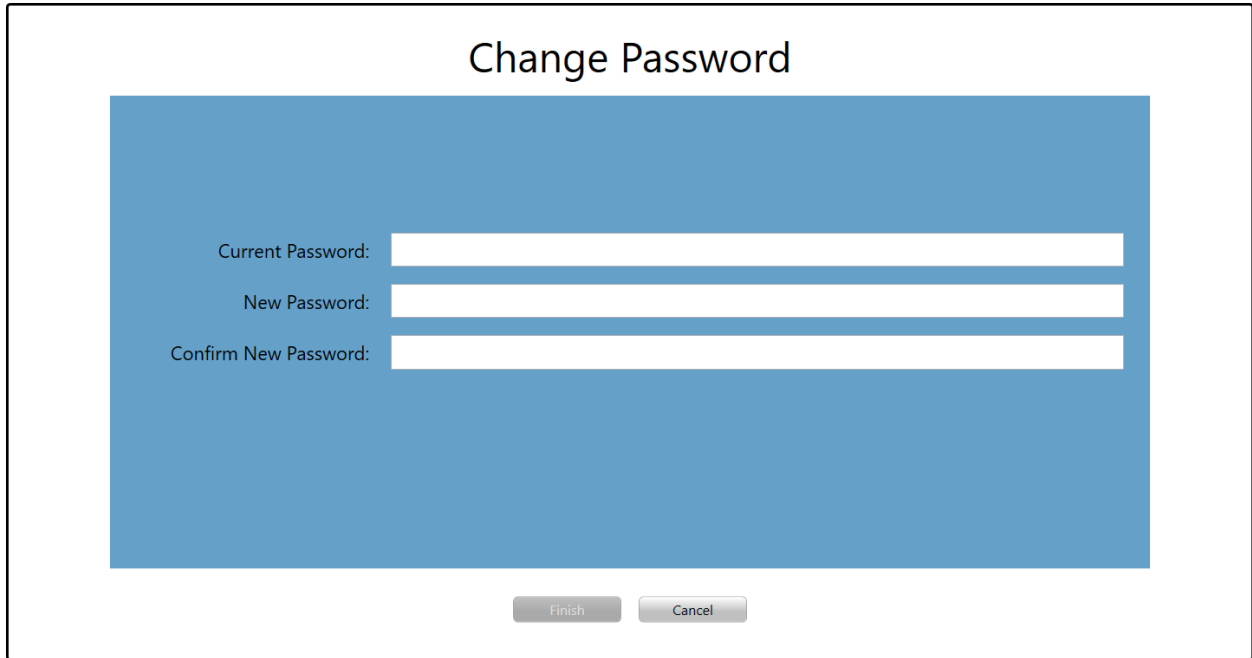
About



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 troubleshooting should problems occur with the program.

AMTAS SECURITY

The type of security that AMTAS uses is determined at the time of the installation of the software. The security options are No Security, Single Password and Windows Domain Integration. The security type cannot be changed after installation. The Security option on the toolbar in the Config App provides the options for the type of security installed. The Single Password security has a single user and a password **admin** for the user that should be changed using the security button.



Change Password

Current Password:

New Password:

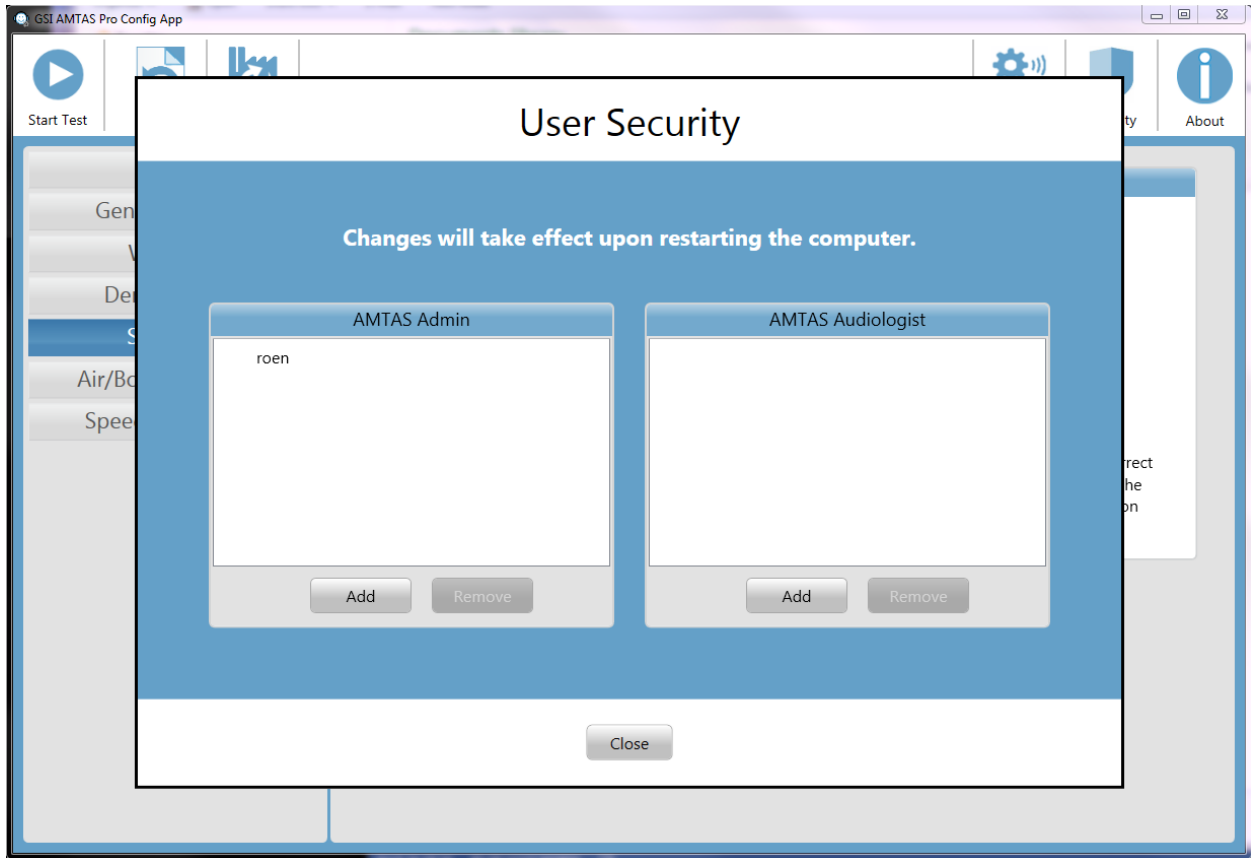
Confirm New Password:

Finish Cancel

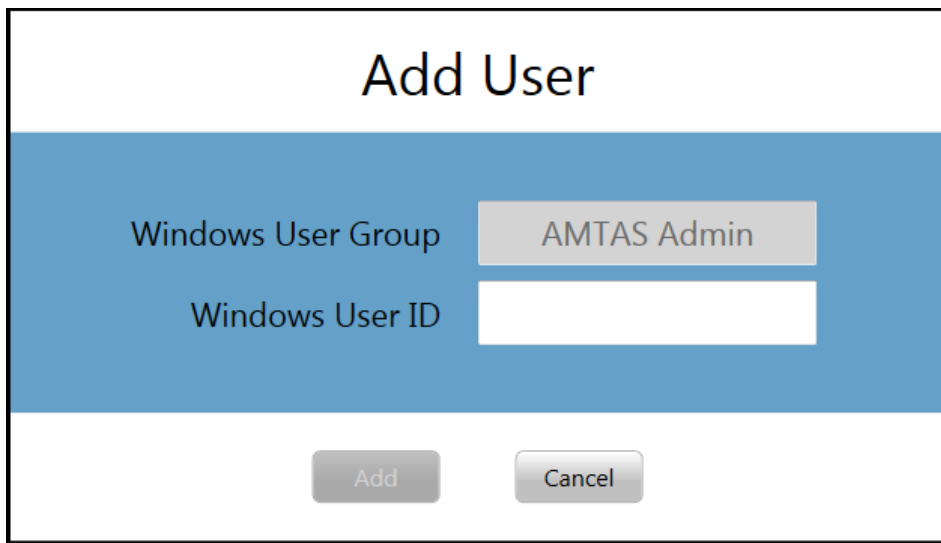
To change the password, you must enter the old password, then enter the new password and a confirmation of the new password. Press the finish button to save the new password.

The Windows security is based upon the security and authentication in Windows. 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.

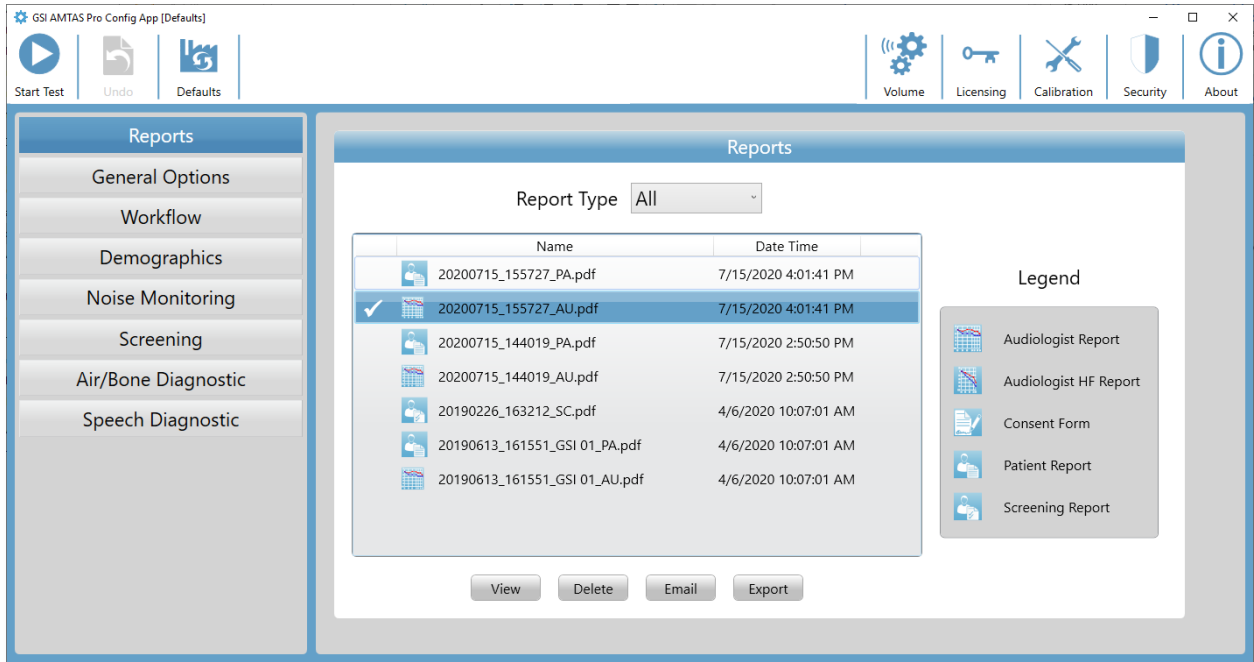


Enter the Windows User ID (this is the username that is used to log into the PC) and press the Add button. To remove a name, highlight the name in the list and select the Remove button. A confirmation dialog is presented to confirm the removal.

NOTE: GSI AMTAS uses Windows authentication for the user IDs and passwords. The usernames 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.

CONFIGURATION OPTIONS

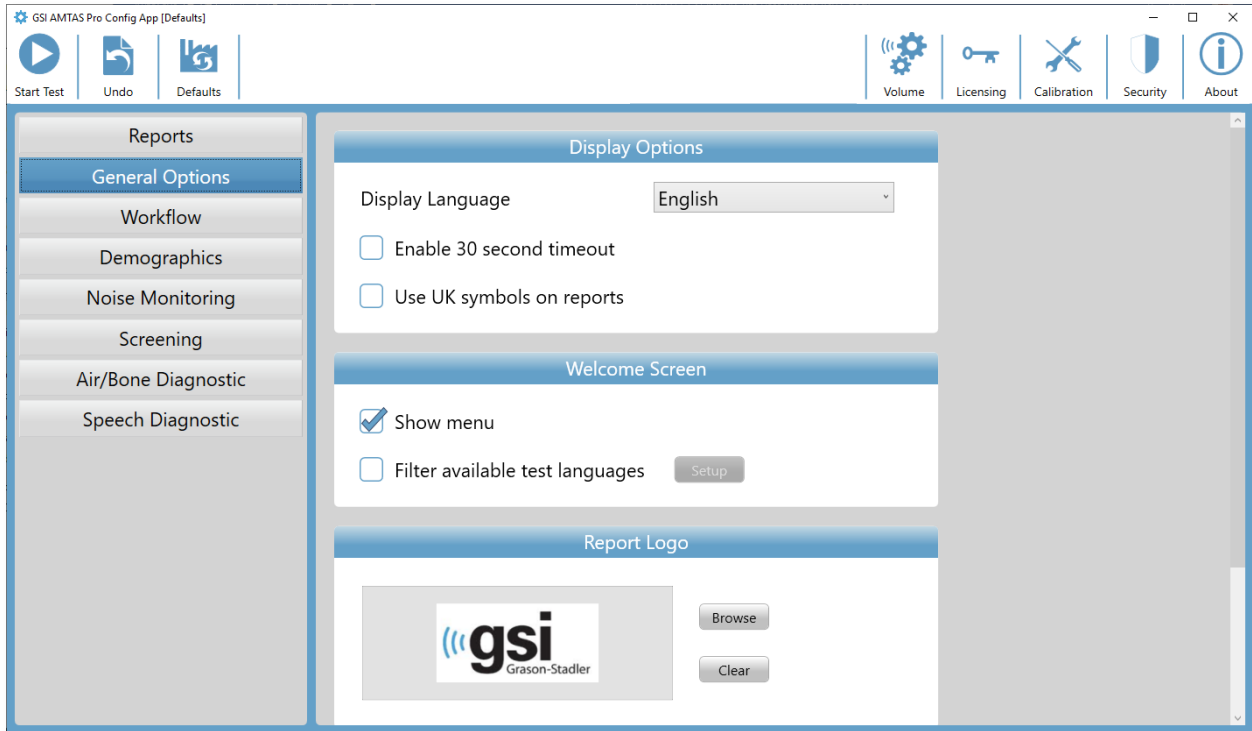
REPORTS



The Reports configuration section is used to display, delete, email, or export the test reports. The report type icon, name and date are listed with a legend to the right of the reports listing. There are two types of audiologist reports available in the program: the standard audiogram and high frequency audiogram report. There is also a patient consent form, patient report and screening report. The reports are described in detail in the GSI AMTAS Reports section of this manual. The Report Type drop-down selection at the top of the listing allows you to filter the list of reports. Clicking on a report selects the report. Multiple reports may be selected. To view a report, press the View button at the bottom of the section. 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 report and the export files are pdf formatted files. The Delete button removes the selected reports.

GENERAL OPTIONS



Display Options

The *Display Language* provides a drop-down list of supported languages for the program. If a new language is selected a restart of the program is required to display the new language.

When the *Enable 30 second timeout* checkbox is checked, the program returns to the opening screen if the program sits idle for 30 seconds.

If the *Use UK symbols on reports* checkbox is selected, the audiogram on the report will display the British Society of Audiology audiometric symbols.

Welcome Screen

The *Show Menu* option is used to display the menu icon in the top right of the opening screen.

The *Filter available test languages* checkbox, when selected, provides a button to select the program languages that are available as choices to the user on the opening screen.

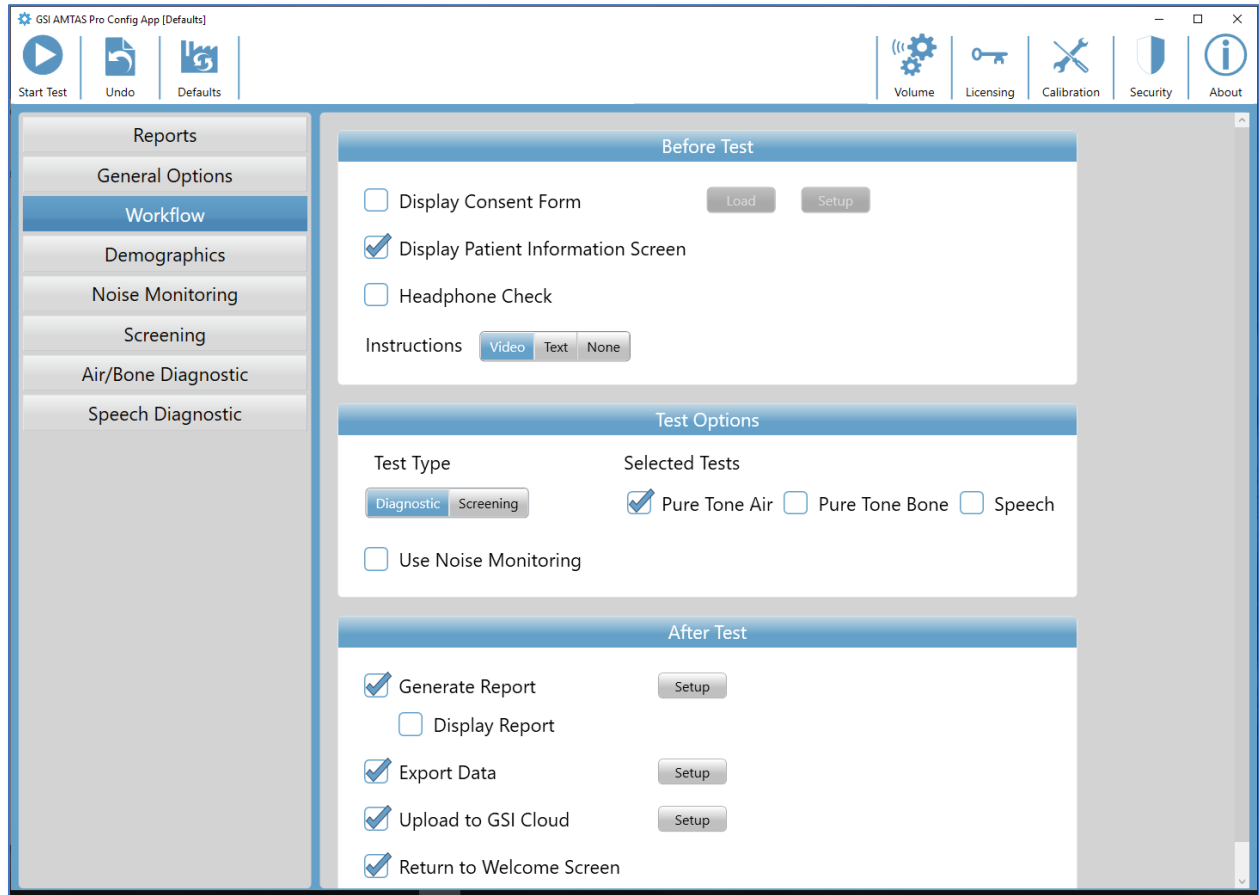
Report Logo

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 the *Turn on extended logging* option which 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.

The *Display Consent Form* checkbox enables a form to be displayed and agreed to by the patient before the test begins. When the checkbox is selected, the *Load* button provides a dialog to select the consent form file. The consent form file should be in a PDF format and a sample form is provided. The *Setup* button is used to define the location and naming for the saved consent forms. The consent forms are saved as PDF files with the patient's name and test date appended to the form.

The *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 Test Type *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 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. The Use Noise Monitoring checkbox determines if the background noise levels are monitored during the test. An optional microphone is required for the noise monitoring and the noise monitoring configuration is set in the Noise monitoring panel.

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.

Report File Name Setup

File Location

File Name Fields

Available		Selected
Patient First Name		Session Date
Patient Last Name	<input type="button" value=">"/>	Session Time
Patient ID		
Birth Date	<input type="button" value="<"/>	
Gender		
Phone Number		

Delimiter

File Type

Example

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 File Type determines the format of the file that is saved.

The *Export Data* checkbox provides an option to send the data to a location defined by the Setup button. The Setup button presents the Data File Export dialog which 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 Example shows the format of the file name as defined. The data is exported in an XML format.

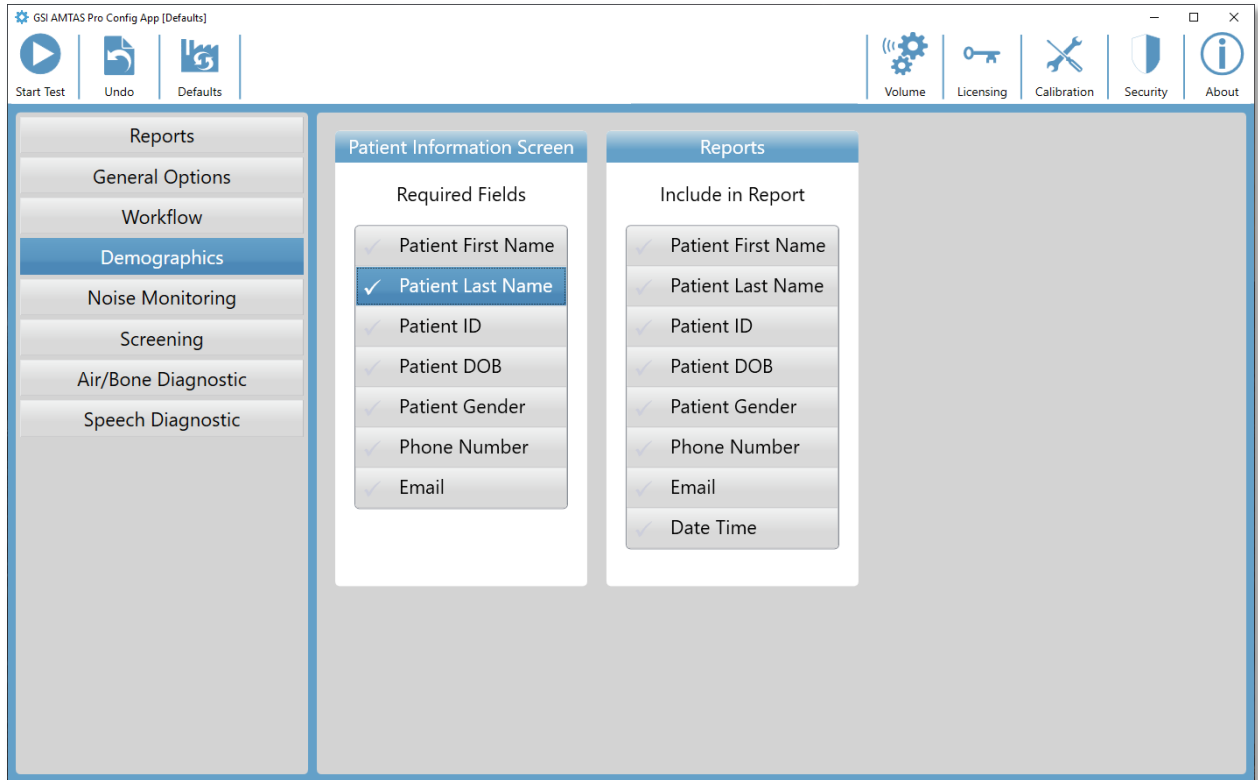
The *Upload to GSI Cloud* checkbox is an option to store the data to the GSI Cloud. This option requires a license for the device and a subscription to the GSI Cloud. The data is

uploaded when there is an internet connection with the PC. If no internet connection is available, the data is saved and uploaded the next time an internet connection becomes available.

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 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.

NOTE: In the General section of the configuration, you may choose to not show the menu on the Welcome screen. If you have Return to the Welcome Screen selected and no menu option on the Welcome screen to exit the AMTAS program press Shift + Alt + M. This will cause the menu button to be displayed on the Welcome screen where you may choose Exit from the menu.

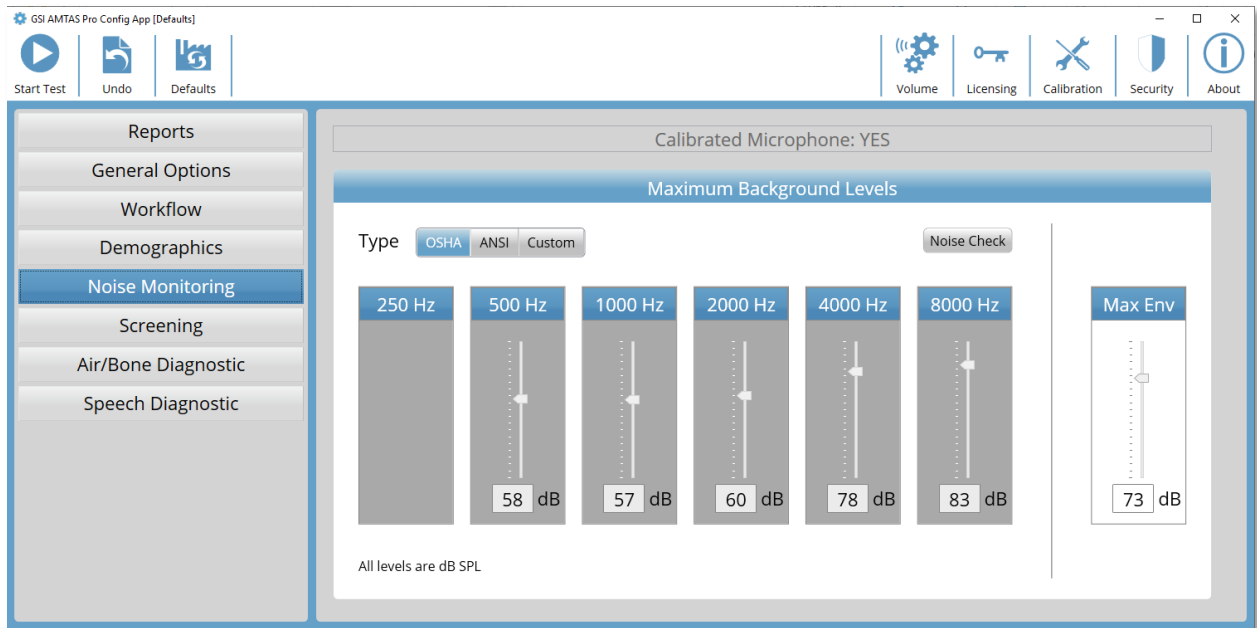
DEMOGRAPHICS



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.

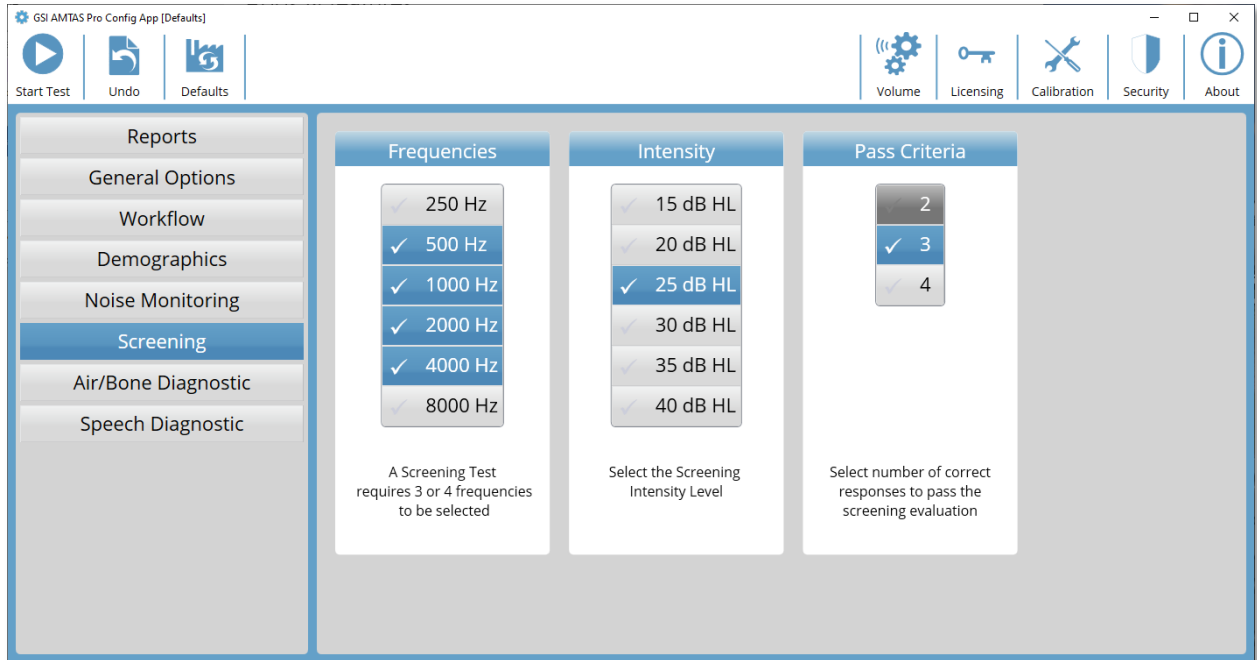
NOISE MONITORING

The Noise monitoring section is used when Noise Monitoring has been selected as part of the Workflow, Test Options configuration. The Noise Monitoring section is used to define the maximum background noise levels that are permitted during the threshold test. The program uses these values to indicate that the noise levels were excessive as part of the test report. The report will display the average level for each of the octave band frequencies. The report will also indicate if the background noise may have impacted the threshold.



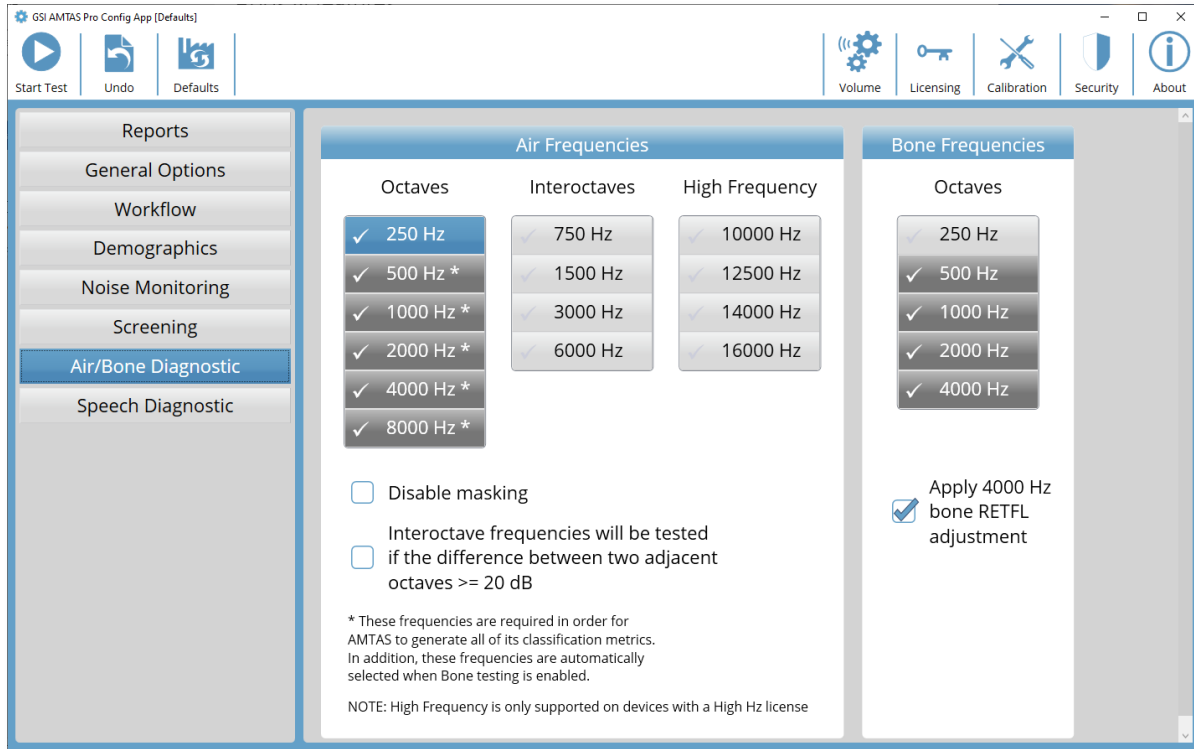
The Noise Monitoring section has information on the calibration of the microphone and headphones at the top of the section. The Noise Monitoring Type has options defined with 3 buttons. When the OSHA or ANSI buttons are selected the values for each octave band frequency are automatically filled with the adjusted values from their respective publication. The Custom option enables the level to be selected for each octave band by using the slider bar or by directly entering the value in the text box at the bottom of the control. The Max Env selector determines the overall noise – this is not separated into the octave band frequency components. The number of times that the noise exceeded the Max Env is indicated in the report. The Noise Check button displays the Ambient Noise dialog which shows the real time octave levels being recorded from the microphone. This noise check may be used to confirm that the environment is appropriate for testing. The noise monitoring is only active during the threshold testing of the standard frequencies.

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 to perform the test. The Intensity section determines the output level for the test. The Pass Criteria section determines the number of presented frequencies where a response is required to pass the screening test.

AIR/BONE DIAGNOSTIC

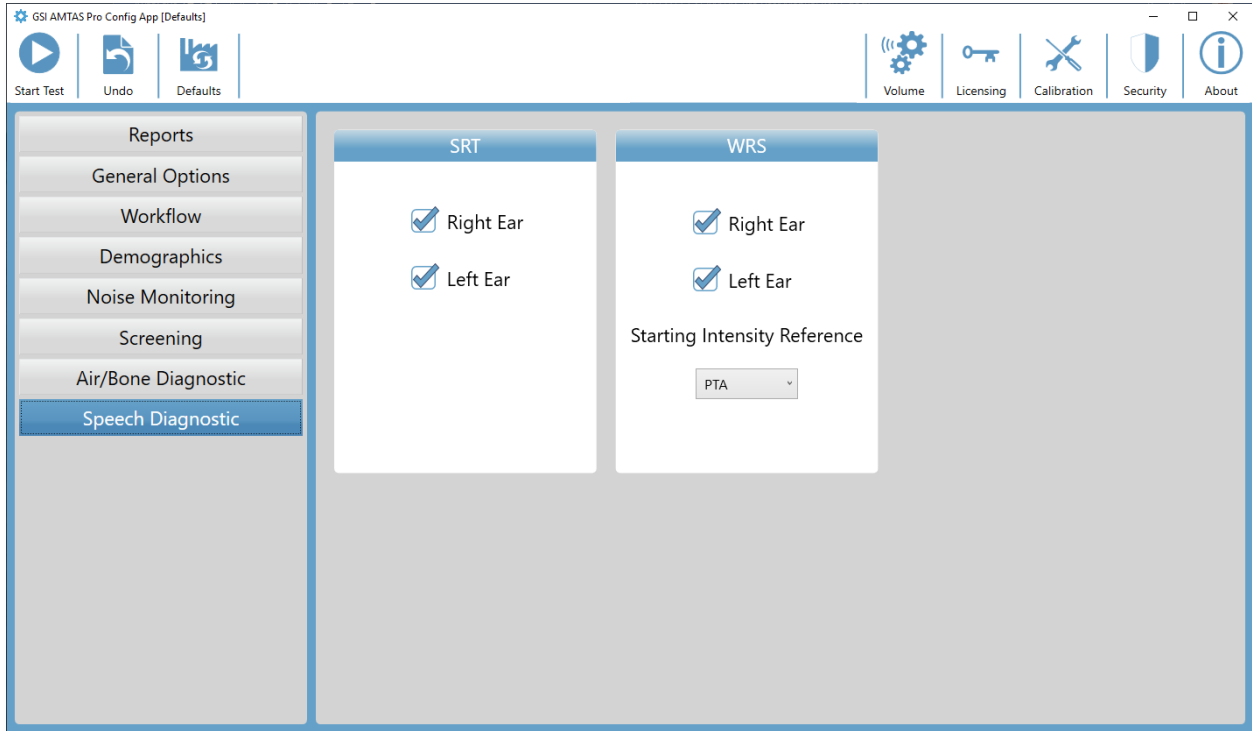


There are two sections in the air/bone settings that display the parameters used for the diagnostic pure tone threshold tests. The Air Frequencies section shows the octave frequencies that will be tested. Some of the octave frequencies, with asterisks, are required to be tested to obtain all the quality metrics. 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. 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. The four checked frequencies are required to obtain the quality metrics; 250 Hz is optional and may be selected. 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 greater than 10 dB HL and not ‘No Response’.

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 text box where the intensity in dB HL may be entered.

GSI AMTAS PRO NOISE MONITORING

The AMTAS noise monitoring option provides recording and analysis of the ambient noise of the test environment.

SETUP

The AMTAS Pro noise monitoring kit contains the following components:

- Microphone with attached cable
- Microphone stand
- USB disk

Before you can monitor the noise during the AMTAS test, the calibration for the microphone must be imported to the AMTAS PC using the AMTAS Pro Config App.

1. Attach the USB disk included with the microphone to the AMTAS Pro PC
2. Launch the AMTAS Pro Config App
3. Select the Calibration tool bar icon
4. Select Import from the Calibration Information dialog
5. Navigate to the USB drive and select the calibration file and select Open
6. Program imports and displays the calibration information in the Calibration Information dialog
7. Remove the USB and store in a safe location

To monitor the background noise during the AMTAS test, connect the microphone to a USB port on the AMTAS PC and turn on the noise monitoring option in the AMTAS Pro Config App (Workflow, Test Options, Use Noise Monitoring). Use the microphone stand as needed and place the microphone in a location that does not interfere with the patient but would record the background noise that would be experienced by the patient.

CONFIG APP SETTINGS

The Noise Monitoring panel in the Config App provides options for specifying the maximum permissible noise levels. There are three Type options, OSHA, ANSI and Custom. The Occupational Safety and Health (OSHA) and the American National Standards Institute (ANSI) have standards that provide guidance for controlling ambient noise during hearing testing. These standards specify the Maximum Permissible Ambient Noise Levels (MPANL) in the test space using supra-aural headphones. Circumaural earphones (e.g., RadioEar DD450) attenuate the ambient noise level that reaches the ear more than supra-aural headphones, reducing the masking effect of the ambient noise. The corrected MPANLs used by AMTAS are the sum of the OSHA or ANSI MPANL and the additional attenuation provided by the circumaural earphones. The Corrected MPANLs (octave band) for the

circumaural earphones used by AMTAS are shown in the tables below and are the default values when selecting the OSHA or ANSI option type.

Frequency Hz	OSHA Supra-aural dB SPL	OSHA AMTAS DD450 dB SPL	OSHA AMTAS DD65 dB SPL
250			
500	40	58	61
1000	40	57	60
2000	47	60	71
4000	57	78	75
8000	62	83	85

Frequency Hz	ANSI Supra-aural dB SPL	ANSI AMTAS DD450 dB SPL	ANSI AMTAS DD65 dB SPL
250	25	37	37
500	21	39	42
1000	26	43	46
2000	34	47	58
4000	37	58	55
8000	37	58	60

NOTE: OSHA standard 1910.95, Appendix D and ANSI S3.1-1999. The standards only provide information on supra-aural headphones. AMTAS uses circumaural headphones. The corrected MPANLs used by the AMTAS program are not given in the standard and so their use is a variance from the recommendations in the standard. The standard does not discuss or recommend modifying MPANLs to account for the ambient noise attenuation provided by circumaural earphones.

The Custom option type allow the user to enter their own values for each of the octave bands. The Config App also provides a Max Env setting. This is the overall sound level (not octave band) and is used for counting the number of times during the test where the level is exceeded.

NOISE ANALYSIS AND REPORTING

The noise monitoring begins a few seconds before the presentation of the first tone and ends at the completion of the standard tone test. The microphone records the background noise in the test environment, the program samples (44.1 kHz) the incoming data and an analysis is performed each second during the test for peak noise levels and approximately each 1.1 seconds for the octave band analysis. When the test is complete, the program displays the results of the ambient noise analysis as part of the audiologist report.

Average Noise Levels

The Average Noise Levels display the average dB SPL recorded for each octave band during the AMTAS test. The levels for the OSHA/ANSI/Custom MPANL are displayed above the average level for reference.

OSHA/ANSI/Custom Limits

The Limits table displays the number of times (count) that the ambient level exceeded the levels for the OSHA/ANSI/Custom MPANL for each octave band during the AMTAS test. The levels are displayed above the count and the percentage of time that the levels exceeded the OSHA/ANSI/Custom MPANL are shown below the count.

Maximum Noise Level

The Maximum Noise Level displays the number of times (count) and percentage of time that the overall peak level exceeded the user specified Max Env level during the AMTAS test.

Threshold Alerts

The Threshold Alerts are displayed as additional symbols on the audiogram when the background level may have had an impact on the audiometric threshold. This alert considers the octave background levels and the AMTAS threshold.

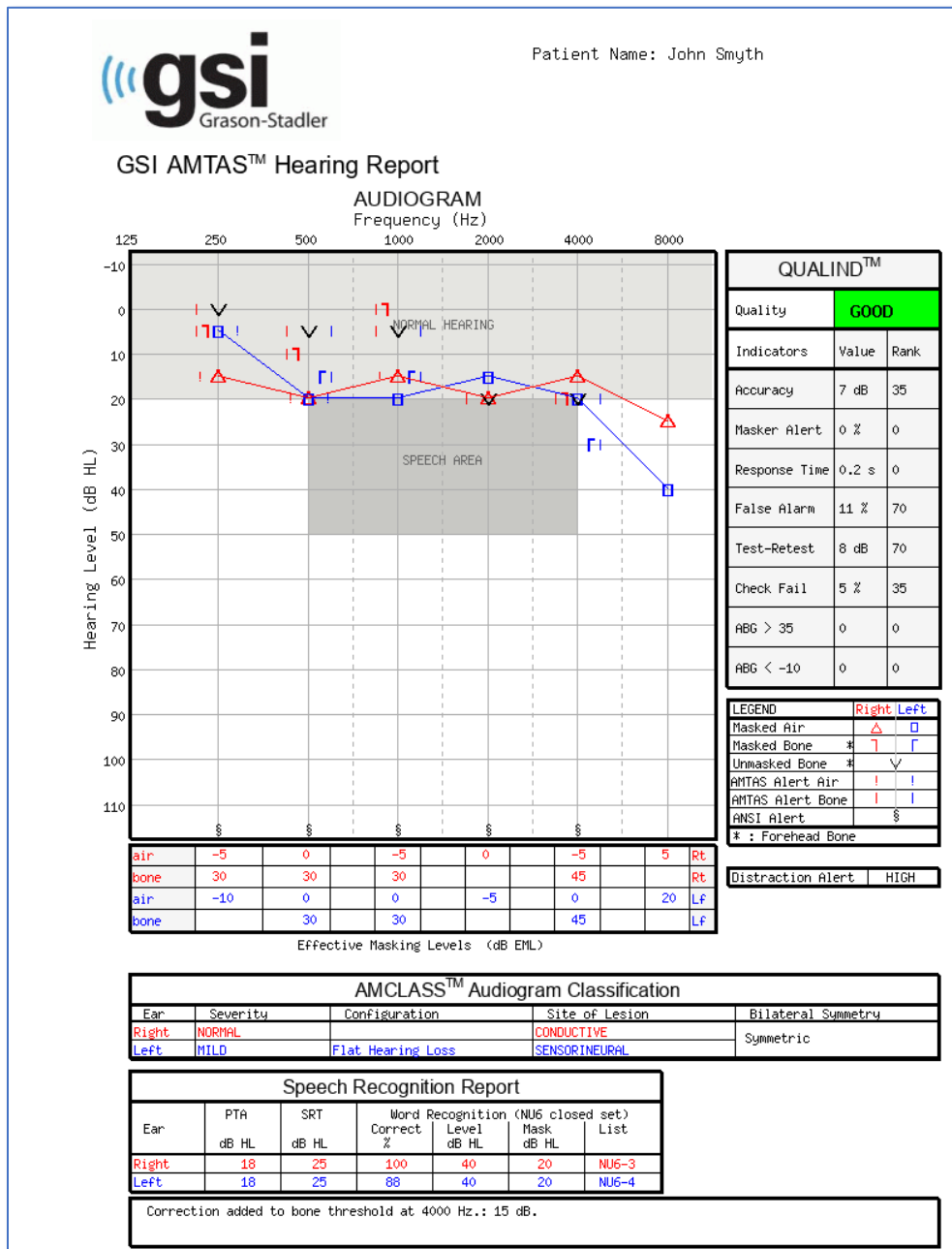
Distraction Alert

The Distraction Alert uses an AMTAS rule for notifying the tester of a possible contaminating influence of background noise that is separate from the MPANL. A Distraction Alert is reported as High when 50% or greater of the peak levels exceed an AMTAS defined (72.5) dB SPL.

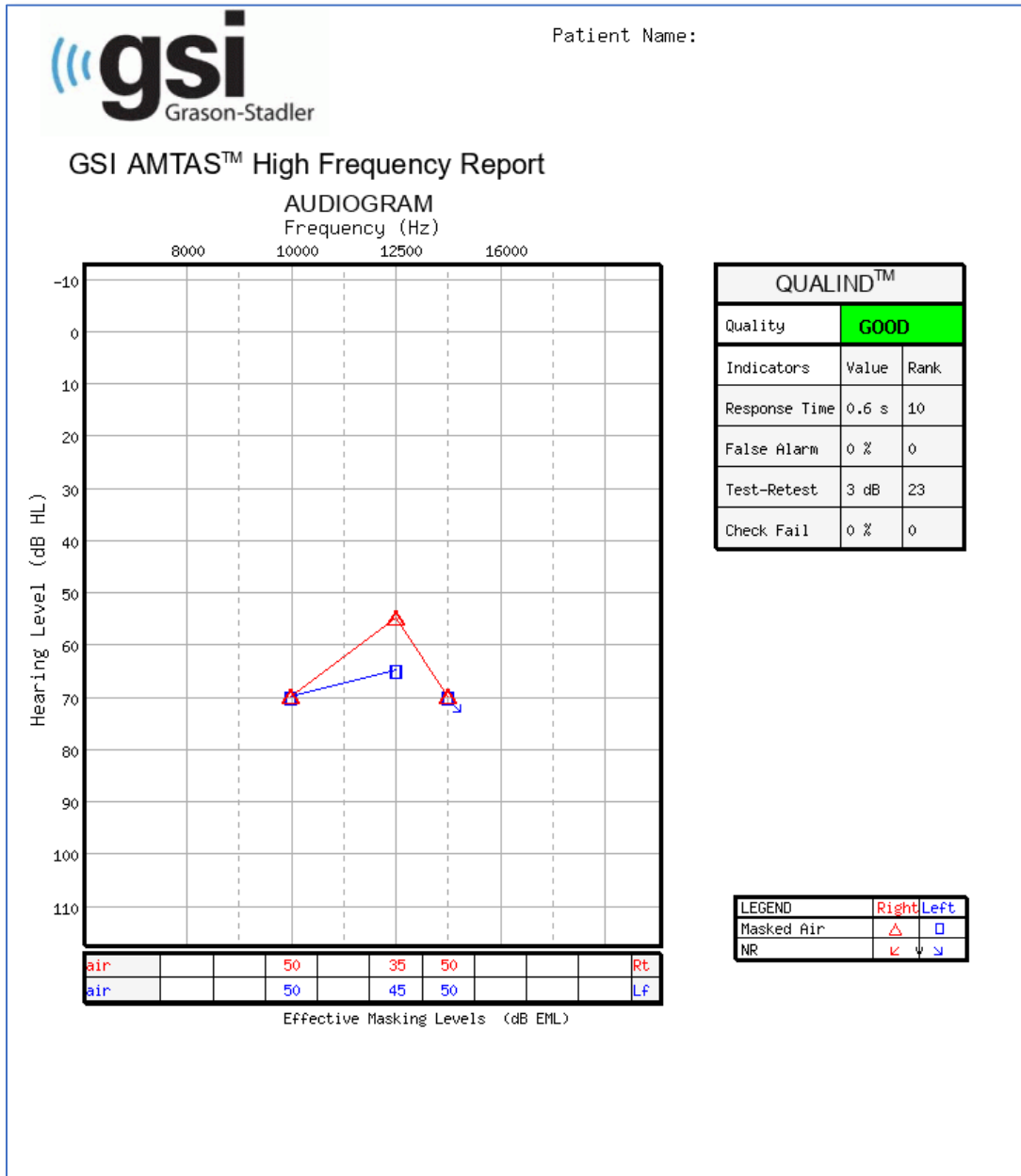
GSI AMTAS PRO REPORTS

The GSI AMTAS Pro program creates reports when set in the configuration. 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. The Screening report provides basic information from a screening test.

AUDIOMETRIC REPORT



If high frequency testing was performed an additional High Frequency Report page is generated. This page contains the threshold data for the 10-16 kHz frequency range.



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

If Noise Monitoring was enabled, any threshold alerts are added to the audiogram and a second page is added to the audiologist report with the results of the noise monitoring. Noise monitoring includes the following additional information:

- Threshold Alerts
- Average noise level for each octave band
- Number of times the octave band level exceeded maximum
- Distraction Alert
- Number of times the overall level exceeded Max Env

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. If noise monitoring was enabled during the test, any threshold noise alerts are indicated on the audiogram with an additional symbol next to the threshold. If any octave band average level exceeded the maximum ambient permissible noise levels (MPANL) for OSHA/ANSI/Custom, then a symbol is placed at the octave on the bottom of 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.

Quality

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

Accuracy

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

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.

Response Time

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

False Alarm

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).

Test-Retest

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

Check Fail

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

ABG >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.

ABG <-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.

Noise Monitoring

When noise monitoring is enabled, information may be added to the audiogram to indicate any threshold measurement where the noise may have had an impact on the threshold. A symbol (as indicated in the legend) is placed next to the audiogram symbol to indicate this possibility. If the ambient noise level exceeds the sum of MPANL and the threshold level minus 5 dB, then an alert is reported. These alerts are frequency and ear specific.

When any peak in an octave band of the ambient background level exceeds the OSHA/ANSI limit for a specific frequency, a symbol is placed on the audiogram on the bottom axis of the audiogram.

There may also be a Distraction Alert indicated under the audiogram legend. The distraction alert is reported when the ambient noise measures 50% or greater of the peak levels exceed 72.5 dB SPL over the course of the test.

In addition to the noise monitoring information presented on the audiogram page, a second page is added to the audiometric report with the ambient noise details.

AMTAS Audiometric Report



Patient Name: John Smyth

Environmental Noise Report

Any noise level that may have had an impact on the threshold is indicated on the audiogram with an '!' next to the audiometric symbol

Average Noise Levels

Average noise levels for each octave band during testing

	250 Hz	500 Hz	1000 Hz	2000 Hz	4000 Hz	8000 Hz
ANSI Limit (dB SPL)*	37	39	43	47	58	58
Measured	57	60	59	55	49	43

* Maximum Permissible Ambient Noise Levels (MPANL) used by AMTAS are adjusted for the additional attenuation provided by the circumaural earphones

ANSI Limits

Number of times the octave band noise exceeded the maximum limits during the test

	250 Hz	500 Hz	1000 Hz	2000 Hz	4000 Hz	8000 Hz
Limit (dB SPL)	37	39	43	47	58	58
Alerts Count	548	546	541	500	12	0
Alert Percent	100%	100%	99%	91%	2%	0%

Maximum Noise Level during testing

Number of times the noise level exceeded the overall maximum

Maximum Limit (dB SPL)	Exceeded Max Count	Exceeded Max Percent	Total Test Time (min:sec)	Total Test Count
73	599	98%	10:11	611


Distraction Alert

Overall likelihood that distractions affected patient responses

HIGH

PATIENT REPORT

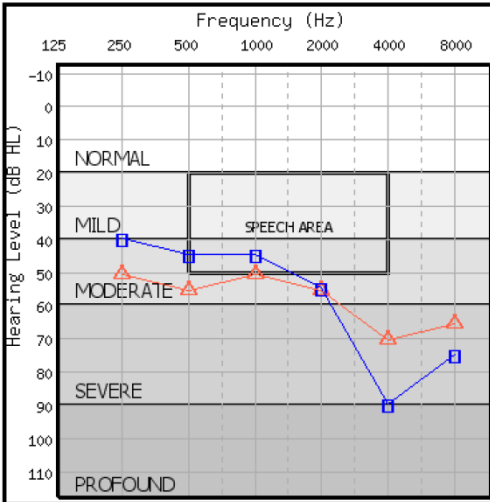
The patient report is designed to communicate with the patient. This report provides an overview of their test results along with educational material about hearing testing and audiogram interpretation.



GSI-AMTAS™ Your Hearing

Patient Name: Ken Grove

AUDIOGRAM



Predicted Accuracy	GOOD					
	LEGEND					
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="font-size: x-small;">Masked Air</td> <td style="font-size: x-small; text-align: center;">△</td> <td style="font-size: x-small; text-align: center;">□</td> </tr> <tr> <td style="font-size: x-small;">NR</td> <td style="font-size: x-small; text-align: center;">↙</td> <td style="font-size: x-small; text-align: center;">↘</td> </tr> </table>	Masked Air	△	□	NR	↙
Masked Air	△	□				
NR	↙	↘				

The audiogram is a graph that shows what sounds you are able to hear and what sounds you can't hear. Each mark on the audiogram is the softest sound you can hear - your threshold - for a particular frequency or pitch. Normal - hearing people hear sounds that are 20 decibels (dB) or less at all the frequencies.

Hearing loss can be described by the degree of loss - how loud sounds have to be for you to hear them - and the pattern of the thresholds shown on the audiogram. The degree of loss can be mild, moderate, severe, or profound.

The speech area on the audiogram represents the sounds that make up everyday conversational speech. The location of your thresholds - above, in, or below the speech area - tells us how much of normal speech you can hear and how much you can't hear.

Hearing loss is a symptom of a problem somewhere in the ear. It can be in the outer ear, the middle ear, or the inner ear. Some of these conditions can be treated with medication or surgery. Many people with hearing loss are helped by hearing aids. It is important to find out the cause of the hearing loss so that the appropriate treatment can be provided.

Your Hearing Report:

Your audiogram shows that the hearing in your **RIGHT** ear is A **MODERATE, FLAT HEARING LOSS**.

A flat hearing loss is one where the thresholds are about the same for all frequencies. When there is a moderate, flat hearing loss the thresholds are in or below the speech area so many of the sounds of speech can't be heard. This causes difficulty understanding speech in almost all situations. A hearing aid for this ear will probably be very helpful for you.

Your audiogram shows that the hearing in your **LEFT** ear is A **MILD TO SEVERE, SLOPING HEARING LOSS**.

A sloping hearing loss is one where the thresholds for the low frequencies (the left side of the audiogram) are better (higher) than the thresholds for high frequencies (on the right side of the audiogram). Your hearing for low frequencies is in the speech area so you probably don't hear some of the low pitches in speech (like vowel sounds). Your hearing at high frequencies drops below the speech area so you don't hear most of the high pitches in speech (like s, p, t, th). You probably have difficulty understanding speech in quiet conditions and more difficulty when there is background noise, a soft speaker, or a reverberant room. A hearing aid for this ear may be very helpful for you.

CONSENT FORM

The Consent form is user defined in the Config App, Workflow. If the Consent form is part of the workflow the form is stored as a PDF file with the patient name and date and time of the consent appended as the last page of the form.

[FACILITY NAME]

Information and Disclosures of Personal Data under the European Union General Data Protection Regulation (GDPR)

The European Union's General Data Protection Regulation (GDPR) requires that personal data from the European Union (EU)/European Economic Area (EEA) is subject to special protection. The GDPR also provides EU-based individuals ("Data Subjects") with certain individual rights with respect to their personal information. These include:

1. **The right to be informed** about the collection and use of their personal data.
2. **The right of access** to find out what data is stored about them.
3. **The right to rectification** of their personal data if it is inaccurate or incomplete.
4. **The right to erasure** to enable an individual to request the deletion or removal of certain personal data where there is no compelling reason for its continued processing.
5. **The right to restrict processing** to 'block' or suppress processing of personal data.
6. **The right to data portability** allowing individuals to obtain and reuse their personal data for their own purposes.
7. **The right to object** to the processing of personal data under certain circumstances.
8. Various rights in relation to certain kinds of **automated decision making** (deciding solely by automated means without any human involvement) and **profiling** (automated processing of personal data to evaluate certain things about an individual).

[FACILITY NAME], including its affiliates and subsidiaries that it has identified as having GDPR compliance obligations, will make all reasonable efforts to abide by the GDPR and provide at least the same level of data protection for personal data received from the EU and processed, as the privacy protections set forth in our Notice of Privacy Practices (NPPs). We will also make reasonable attempts to accommodate requests by Data Subjects to exercise the rights listed above. Where necessary and appropriate we have implemented organizational and technical measures that include internal data protection policies and maintaining documentation on our processing activities. We have also appointed a Data Protection Officer.

In order to enable Data Subjects to exert their rights under the GDPR, we are making the following disclosures for data received directly from an individual and data

Additional page added to the form with the patient's name, ID, and a timestamp.

Patient Name: Jane Doe
Patient ID: 123456
Session Date Time: 2/8/2021 1:20:51 PM

UPLOADING GSI AMTAS PRO RESULTS TO GSI SUITE

GSI-Suite versions 2.4 and above is required 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

Unable to connect to device.

Indicates that the program does not find the audiometer. The audiometer is connected via USB cable to the PC running the AMTAS program. Check that the USB cable is connected between the audiometer and the PC and that the audiometer is turned on.

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 usernames 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 usernames 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.

Test Incomplete Please notify the Test Administrator

This message is displayed if the test is stopped voluntarily via the Quit option, or there are too many trials without a response or a timeout of the program. The error message is presented to indicate that the test was not completed. You should determine the cause of the incomplete test and reinstruct the patient if necessary.

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. The configuration application has an option to disable the masking for the air conduction testing.

For bone conduction testing, narrow band masking noise is presented to the non-test ear at the same level as the stimulus level. Bone is not tested when the air threshold is ≤ 10 dB. When the air threshold is >10 dB unmasked bone is tested first. Then masked bone is tested for each ear/frequency combination where there is an air-bone gap (air threshold - unmasked bone threshold) ≥ 10 dB.

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

GENERAL OPTIONS

Display Options

- Display Language: English
- Enable 30 Second Timeout: Off
- Use UK Symbols on Reports: Off

Welcome Screen

- Show Menu: On
- Filter available test languages: Off

Report Logo

- GSI Logo

Research

- Turn on extended logging: On

WORKFLOW

Before Test

- Display Consent Form: Off
- Display Patient Information Screen: On
- Headphone Check: Off
- Instructions: Video

Test Options

- Test Type: Diagnostic
- Selected Tests: Pure Tone Air, Bone and Speech
- Use Noise Monitoring: Off

After Test

- Generate Report: On
 - Display Report: Off
- Export Data: Off
- Upload to GSI Cloud: Off
- Return to Welcome Screen: On

DEMOGRAPHICS

Patient Information Screen

Required Fields

- Patient First Name: Off
- Patient Last Name: Off
- Patient ID: Off
- Patient DOB: Off
- Patient Gender: Off
- Phone Number: Off
- Email: Off

Reports

Include in Reports

- Patient First Name: Off
- Patient Last Name: Off
- Patient ID: Off
- Patient DOB: Off
- Patient Gender: Off
- Phone Number: Off
- Email: Off
- Date Time: Off

NOISE MONITORING

Maximum Background Levels

- Type: Custom
- 250 Hz: 51
- 500 Hz: 57
- 1000 Hz: 57
- 2000 Hz: 62
- 4000 Hz: 81
- 8000 Hz: 83
- Max Env: 70

SCREENING

Frequencies

- 250 Hz: Off
- 500 Hz: On
- 1000 Hz: On
- 2000 Hz: On
- 4000 Hz: On
- 8000 Hz: Off

Intensity

- 15 dB HL: Off
- 20 dB HL: Off
- 25 dB HL: On
- 30 dB HL: Off
- 35 dB HL: Off
- 40 dB HL: Off

Pass Criteria

- 2: Off
- 3: On
- 4: Off

AIR/BONE DIAGNOSTIC

Air Frequencies

Octaves

- 250 Hz: On
- 500 Hz: On
- 1000 Hz: On
- 2000 Hz: On
- 4000 Hz: On
- 8000 Hz: On
- Max Env: On

Inter-Octaves

- 750 Hz: Off
- 1500 Hz: Off
- 3000 Hz: Off
- 6000 Hz: Off

High Frequency

- 10000 Hz: Off
- 12500 Hz: Off
- 14000 Hz: Off
- 16000 Hz: Off

- Disable masking in Air test only: Off
- Inter octave frequencies will be tested if the difference between two adjacent octaves ≥ 20 dB: Off

Bone Frequencies

- 250 Hz: Off
- 500 Hz: On
- 1000 Hz: On
- 2000 Hz: On
- 4000 Hz: On

- Apply 4000 Hz bone RETFL adjustment: On

Bone octave frequencies: 500, 1000, 2000, 4000 Hz (not configurable)

SPEECH DIAGNOSTIC

SRT

- Right Ear: On
- Left Ear: On

WRS

- Right Ear: On
- Left Ear: On
- Starting Intensity Reference: PTA

AMTAS PUBLICATIONS AND PATENTS

AMTAS PUBLICATIONS

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