((gsi
Grason-Stadler

AUTOMATED
AUDIOMETRY
SOFTWARE

Did you hear the TONE?

YES

NO

2%

((gsi
Grason-Stadler
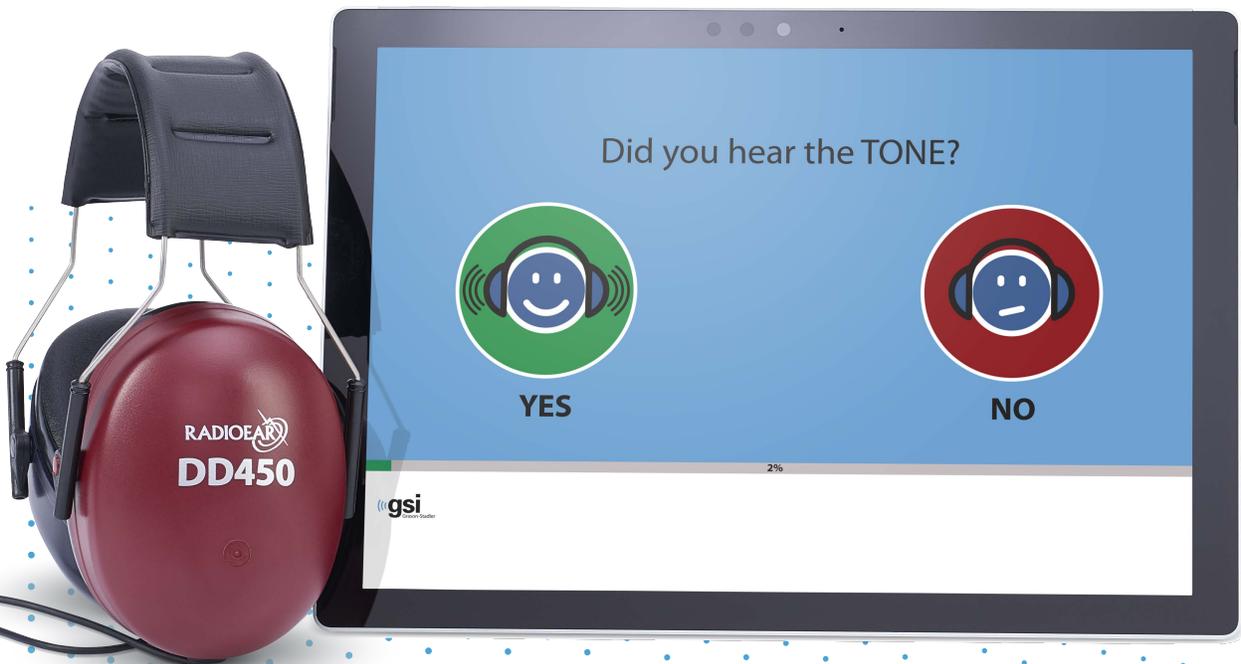
RADIOEAR
DD450

AMTAS FLEX
USER MANUAL

Title: GSI AMTAS Flex™ User Manual

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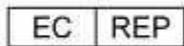10395 West 70th Street
Eden Prairie, MN 55344
USA

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

EC | REP

European Authorized Representative

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

$C\!\epsilon$

0123

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

TABLE OF CONTENTS

PREFACE

This user manual provides information about the GSI AMTAS Flex™ 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 Flex 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 should only be used 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 PC manual for the PC for the important safety information for the PC. Ensure that all transducers are properly connected. Do not connect the transducers to the PC while attached to the patient.

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 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.

WARNINGS AND CAUTIONS

This product and its components will perform reliably only when operated and maintained in accordance with the instructions contained in this manual, accompanying labels, and/or inserts. A defective product should not be used. Make sure all connections to external accessories are snug and secured properly. Parts which may be broken or missing or are visibly worn, distorted, or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from GSI.

The GSI AMTAS Flex can be operated from the battery powered computer or tablet. If the device is to be operated while connected to a power outlet, a medical grade power supply or isolation transformer should be used. To avoid the risk of electric shock, this equipment must only be connected to a power outlet with protective earth.

This product should not be used in the presence of fluid that can contact any of the electronic components or wiring. Should the user suspect fluids have contacted the system

components or accessories, the unit should not be used until deemed safe by a GSI certified service technician.

Do NOT use in the presence of flammable gaseous mixtures. Users should consider the possibility of explosions or fire when using this device near flammable anesthetic gases. Do NOT use in a highly oxygen-enriched environment, such as a hyperbaric chamber, oxygen tent, etc.

The GSI AMTAS Flex is designed for compliance to IEC and ES 60601-1 when used in the patient vicinity. Periodically, have a service technician perform electrical safety checks on the unit to maintain continued compliance to IEC and ES 60601-1.

The icon to the left indicates that the GSI AMTAS Flex complies with applied part, Type B requirements of IEC 60601-1.

Latex is not used anywhere in the manufacturing process. The base material for the earphone cushions is made from natural and synthetic rubber.

No modifications of the equipment are allowed by anyone other than a qualified GSI representative.   Equipment is not user repairable. Repairs must be performed by a qualified service representative only. GSI will make available any instructions and diagrams to repair devices that it deems appropriate to be repaired in the field.

Electrostatic discharge (ESD) precautions need to be observed when handling ports on the computer and/or speakers on the computer or inside the headphones. Computer ports include: DC power, USB ports, Ethernet ports, SD card slots, and stereo jack, display ports, etc. Follow ESD precaution guidelines such as: being properly grounded, avoiding activities like rubbing, keep equipment away from ESD generating materials (some plastics, Styrofoam, cellophane tape, nylon, wool, etc.).

REGULATORY SYMBOLS

Symbol	Description
CE	Conforms to the Medical Device Regulation (EU) 2017/745.
MD	Indicates that the device is a Medical Device
SN	Symbol for "SERIAL NUMBER."
REF	GSI Part Number.
(crossed-out wheeled bin)	Return to Authorized Representative, Special disposal required.
(ETL listed mark)	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.
EC | REP	Symbol for "European Authorized Representative."
(factory symbol)	Symbol for "Manufacturer."
(date of manufacture symbol)	Symbol for "Date of Manufacture."
(patient figure symbol)	B Patient Applied Part according to IEC 60601-1.
(power symbol)	On/Off
(consult instructions symbol) 7d www.grason-stadler.com	Consult the operating instructions/directions for use. A copy of the operating manual is available on this website: www.grason-stadler.com
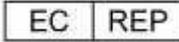
Symbol	Description
	A printed copy of the operating instructions can be ordered from Grason-Stadler for shipment within 7 days; or you can contact your local representative.
	Consult the operating instructions/directions for use. A copy of the operating manual is available on this website: www.grason-stadler.com 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.

INTRODUCTION

GSI AMTAS™ is a software program that provides an automated method for obtaining a diagnostic hearing test. 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 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. AMTAS 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 the data may be transferred to other software programs. The software performs these tests by controlling a sound card connected to the PC running the software. The GSI AMTAS Flex system includes the headset and sound card along with the software.

INDICATION FOR USE OF GSI AMTAS FLEX

GSI AMTAS Flex audiometers are intended to be used for the identification of hearing loss. The device may be used with patients of any age provided that the patient can follow the instructions for pure tone audiometry testing.

INTENDED USE OF GSI AMTAS FLEX

The GSI AMTAS Flex is intended to be used to obtain diagnostic or screening hearing evaluations. It is intended to be used for routine clinical testing in any quiet environment in which pure-tone audiometry can be performed. Anyone who can follow the instructions used for manual audiometry may use and be tested by the GSI AMTAS Flex. The resulting audiograms are intended to be used by an audiologist, ENT, hearing healthcare professional or trained technician. The audiogram may be used for assisting in the diagnosis of possible otologic disorders and for programming and fitting devices such as hearing aids.

CONTRAINDICATIONS

Patients unable to cooperate because of young age or other conditions that prevent the patient from following the instructions for pure tone audiometry testing may need to have the auditory system tested by other methods.

ELIMINATION OF AMBIENT NOISE

The GSI AMTAS Flex may be installed in any quiet environment. Excessive noise in the test environment, such as that produced by conversation, office equipment, or printers, reduces test validity because it tends to mask the test signals or distract the patient. This is especially true at the lower frequencies where earphone cushions provide less effective attenuation. A room that attenuates sound may be required if ambient noise at the patient's ears reaches levels enough to cause apparent hearing loss at the lower frequencies.

The following table shows the maximum background levels (octave band) that can be present inside the room while a valid hearing test is being conducted. These values are derived by adding the difference in ambient noise attenuation for circumaural and supra-aural earphones used in the ANSI S3.1 standard.

Test Tone Freq. (Hz)	250	500	1000	2000	4000	8000
Test Room level Max dB SPL, Ears covered (RadioEar DD 65V2)	35	41	47	61	59	60
Test Room level Max dB SPL, Ears covered (RadioEar DD 450)	36	38	43	49	61	58

Notes: Maximum permissible octave band level.

NOTE: A room providing sound isolation from ambient noise is highly recommended so that hearing threshold values may be obtained. If a separate examination (sound) room is used, it is considered sufficiently quiet for the purposes of these tests if a group of otologically "normal" listeners with their ears occluded is unable to detect any ambient noise during the test period. See ANSI S3.1 (R2008) Criteria for Permissible Ambient Noise during Audiometric Testing for maximum allowable outside octave band noise levels with three prefabricated sound room types.

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 Flex 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: 10" or larger recommended
- Resolution: 1280 x 800 minimum
- Touch screen or mouse/trackball
- USB for software installation
- Wireless Network LAN (if connecting to database via a network) or Bluetooth

GSI AMTAS Software Requirements
- Microsoft Windows® 10 Pro
- Microsoft .NET Framework version 4.7.2

UNPACKING THE SYSTEM

Notify the carrier immediately if any damage is noted. This will ensure that a proper claim is made. Save all packing material so the claim adjuster can inspect it as well. Notify your dealer or GSI when the adjuster has completed the inspection

SAVE ALL THE ORIGINAL PACKING MATERIAL AND THE SHIPPING CONTAINER SO THE INSTRUMENT CAN BE PROPERLY PACKED IF IT NEEDS TO BE RETURNED FOR SERVICE OR CALIBRATION.

- It is recommended that you unpack your GSI AMTAS Flex carefully making sure that all components are removed from the packing materials.
- Verify that all components are included as shown on the packing slip included with your shipment. If any component is missing, contact your distributor immediately.
- Check that all accessories have been received in good condition. If any component appears to be damaged in shipment, contact your distributor immediately to report it. Do not attempt to use any component or device that appears to be damaged.

Standard Components
- Carrying Case
- GSI AMTAS Flex Headset
- GSI AMTAS Noise Monitoring Microphone
- USB Y cable
- GSI AMTAS Flex Software and Manuals USB Flash Drive
- GSI AMTAS Flex Calibration File USB Flash Drive
- Calibration Certificate

Optional Components
- GSI AMTAS Flex Tablet PC

Applied Parts
The following items are considered applied parts according to IEC60601-1.

- Headset

Connections
The USB Y cable connects to the tablet/PC at one end. The headset assembly plugs into a USB port on the Y cable. The noise monitoring microphone plugs into a USB port on the Y cable (optional).

INSTALLING ON WINDOWS® 10 PRO

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

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1. Insert the GSI AMTAS Flex USB drive into a USB port on the PC. If auto-run is disabled, browse the USB drive and double click on the *GsiAMTASFlexSetup.exe* file.
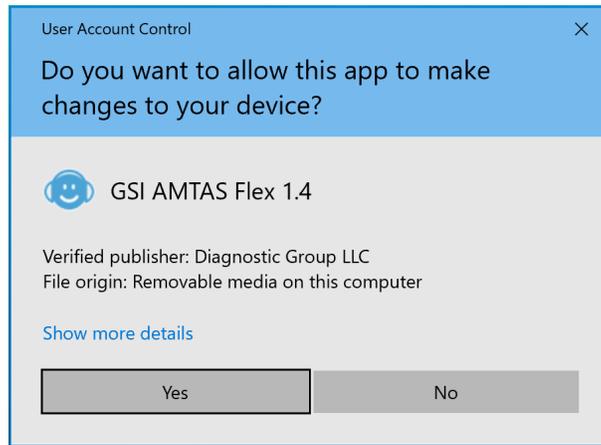
2. When the installation begins, Windows User Account Control may ask for permission to install the software. Answer "Yes" to the dialog to proceed with the installation. The GSI AMTAS Setup Wizard dialog screen will be presented.

3. Press "Next"
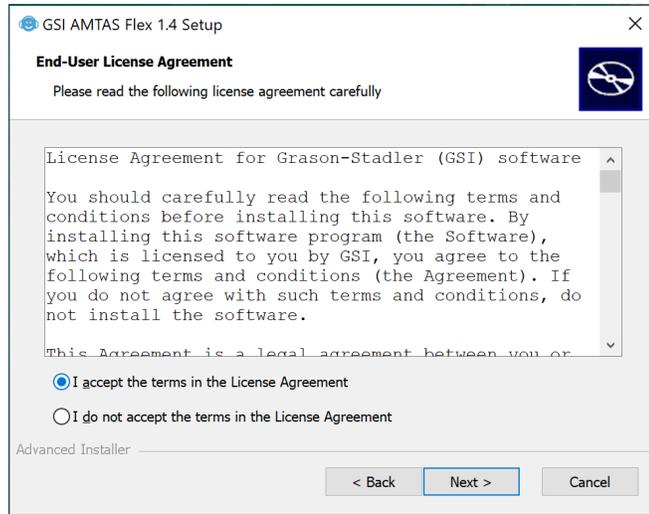
4. Read the license agreement. Select the "I accept …" button to accept the agreement and press "Next" to continue.   If you do not wish to install the software, select "Cancel" to exit the Setup. The Setup Wizard then presents the Select Installation Folder dialog.
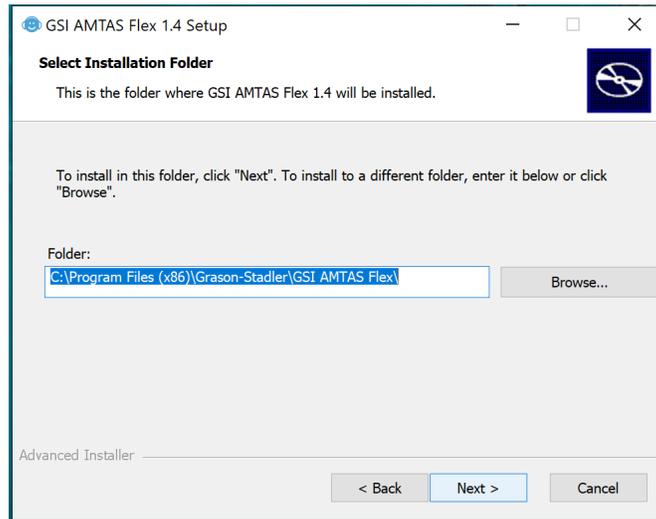
5. To use the default folder (recommended) press the "Next" button. If you wish to install the program in a different directory, use the Browse button to locate the Folder for installation and then select "Next". The Ready for Install dialog is presented to allow you to review or change your installation settings.
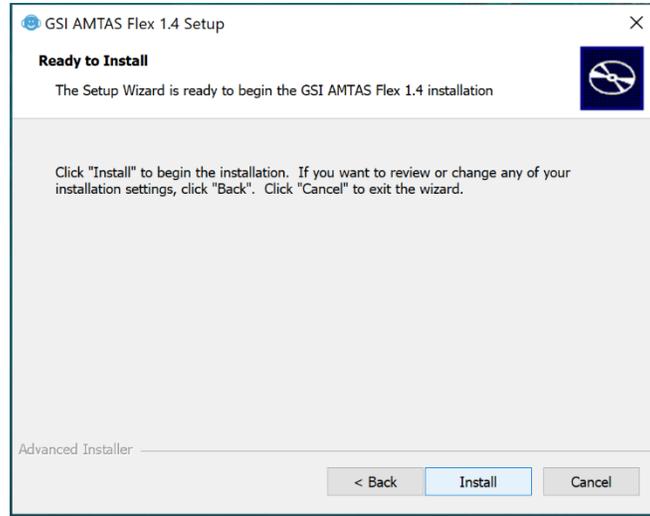
6. Press "Install" to proceed with the installation. The Select Security Type dialog is presented.

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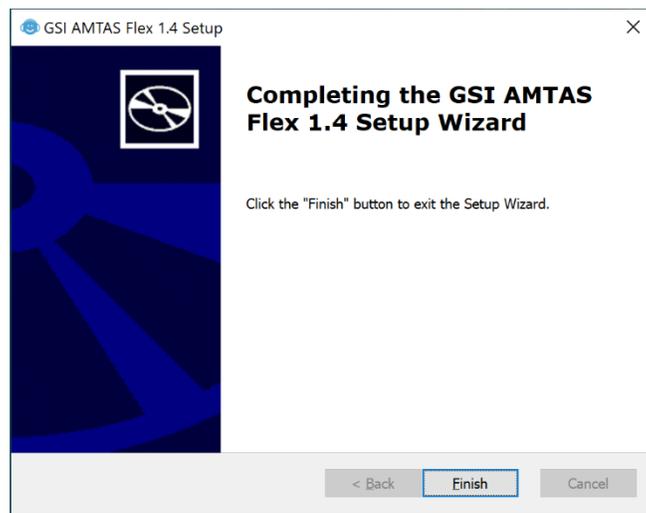
8. A message will be displayed to indicate that the software has been successfully installed. Select "Finish".

NOTE: Installing GSI AMTAS Flex will also install the GSI Wireless Service software package. The GSI Wireless Service is used to transfer GSI AMTAS Flex results to other PCs running GSI Suite via Bluetooth connection.

UNINSTALLING GSI AMTAS FLEX

1. Open Windows Settings
2. Select Apps
3. Select GSI AMTAS Flex in Apps & features
4. Select Uninstall
5. Follow the onscreen instructions

GSI AMTAS LICENSE

GSI AMTAS requires a license on the PC. The licensing is specific to the PC running the GSI AMTAS Flex software. A license to run GSI AMTAS Flex is obtained from your authorized GSI distributor.

OPERATION

Preliminary Checks

Check that all cords from the transducers fit securely in their connectors. Inspect all cords for fraying and damage. If there is any damage to any cord, do not use the GSI AMTAS Flex.

Handle earphones with care. Do not drop them nor allow them to be banged together. Severe mechanical shock can alter their operating characteristics or change the output levels, which may require that the transducers be replaced.

It is recommended that all parts that come into direct contact with the patient (e.g., earphone cushions) are subjected to standard disinfecting procedures between patients. This includes physically cleaning and using a recognized disinfectant. Individual manufacturer's instructions should be followed for use of any disinfecting agent to provide an appropriate level of sterilization.

1. Turn on the instrument and allow it to come to operating temperature (approximately 5 minutes).
2. Check that the transducers and other system components are operating properly.
3. Seat the patient comfortably in the test area.
4. Place the selected transducers on the patient.

PATIENT PREPARATION

Although the GSI AMTAS 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 program running.

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 FLEX PROGRAM

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

The GSI AMTAS Flex 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 Flex program.

NOTE: The GSI AMTAS Flex 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 FLEX

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

WELCOME SCREEN

Once the GSI AMTAS Flex 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.
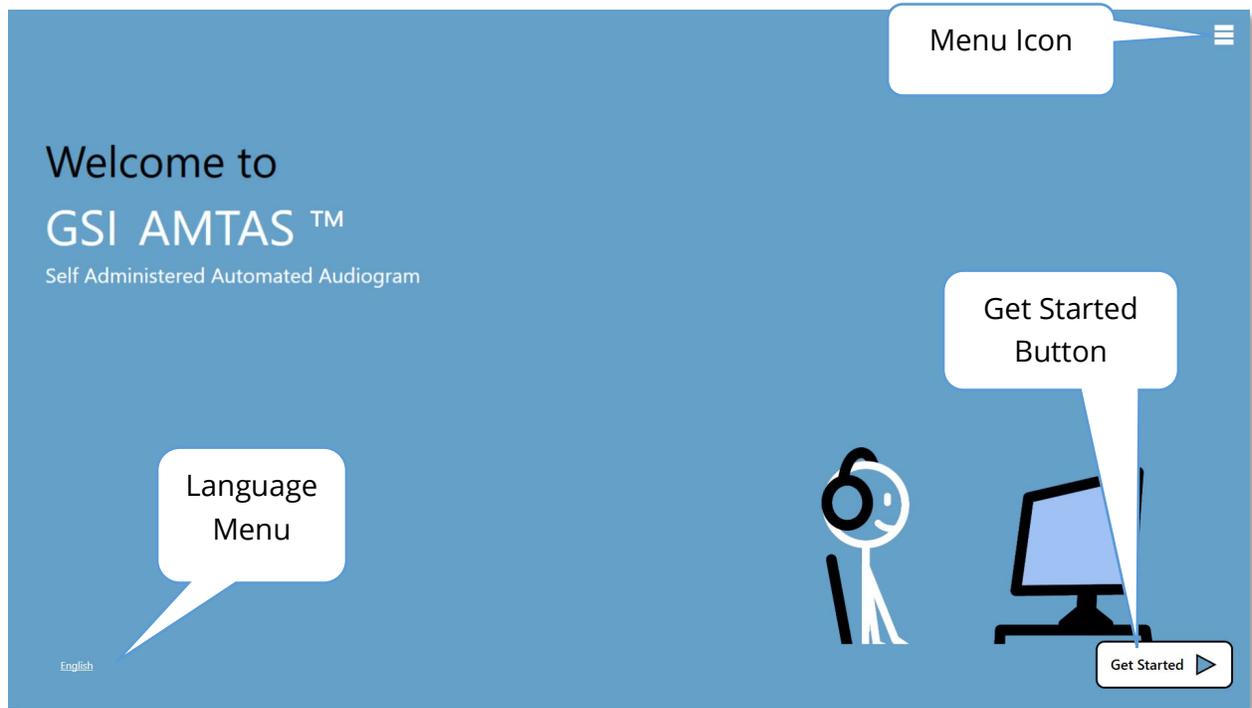
Menu
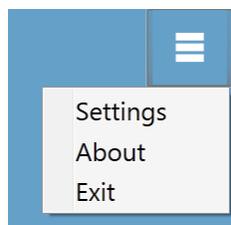
When the menu icon is selected on the opening screen, a list of 3 menu items is presented. When the Settings or Exit menu item is selected, a prompt for a password will appear if security has been enabled. The password should be the Windows password of the user who is currently logged into the PC or 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 Flex Config App program.

Get Started Arrow

The Get Started arrow is pressed to proceed with the GSI AMTAS Flex 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 Flex 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.

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 Flex Config App section of this manual for details). The configuration Test Options also determines the types of exams that will be performed: screening or air conduction diagnostic. A Quit button in the lower left of the screen exits the screen and returns to the Welcome screen.

NOTE: The GSI AMTAS Flex 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 Flex uses this screen for screening and air diagnostic threshold testing. There is a progress bar at the bottom of the screen to indicate the percentage of the test that has been completed. Masking is presented to the non-test ear but may be disabled for the air conduction test in the configuration app.
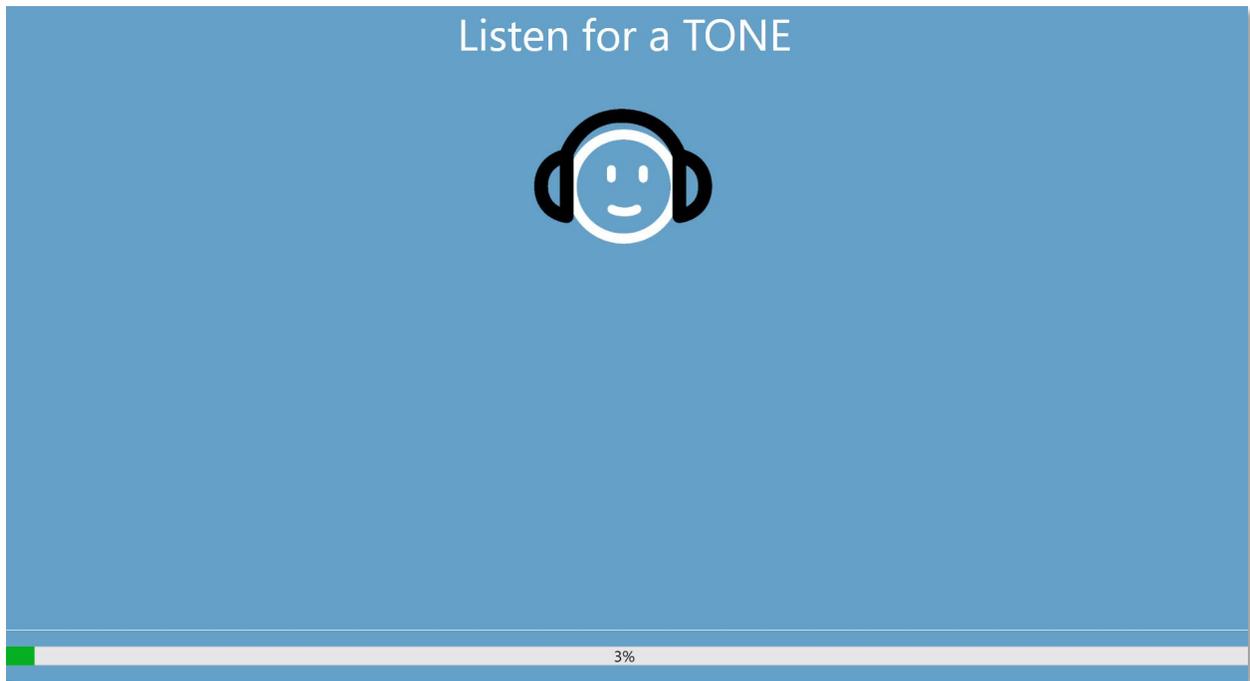
Once the tone has been presented, a new the screen is displayed to allow the patient to respond.

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.
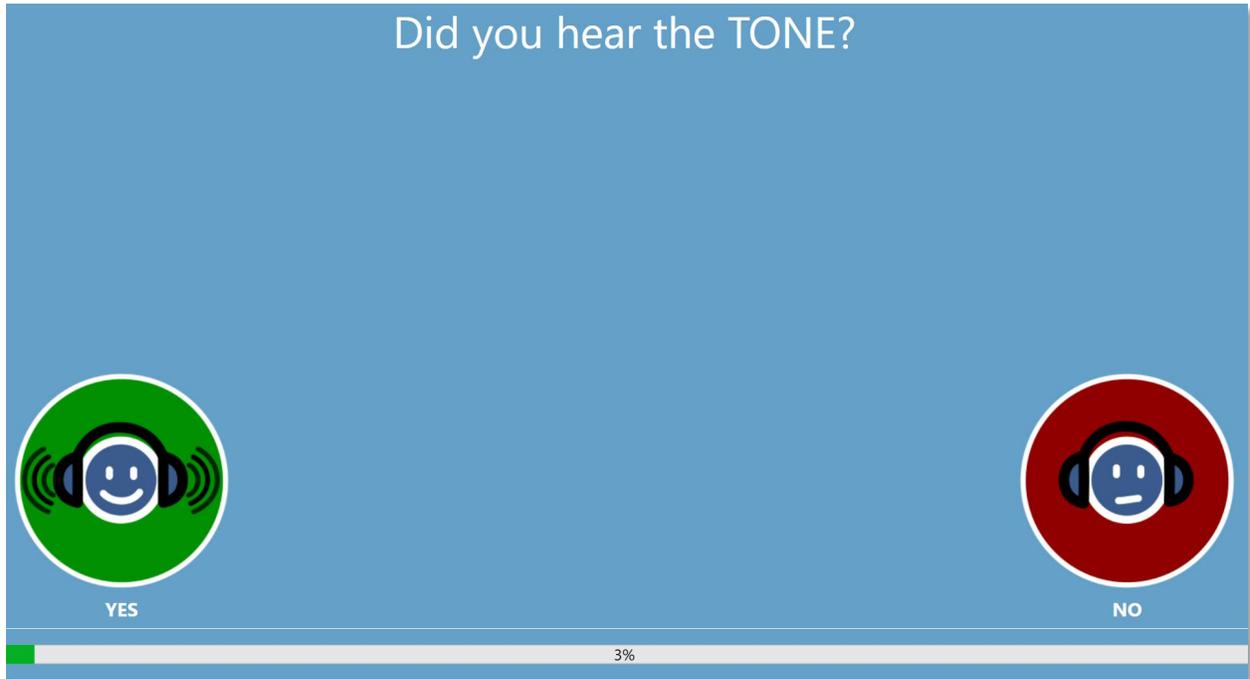
The "Listen for a TONE" and "Did you hear the TONE" screens repeat to test the different levels and frequencies as needed to determine the patient's threshold.

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, the Welcome Screen or notify the administrator 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.
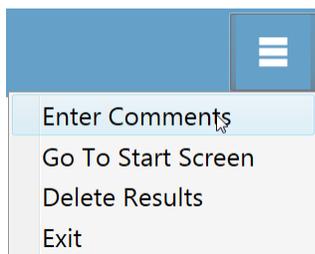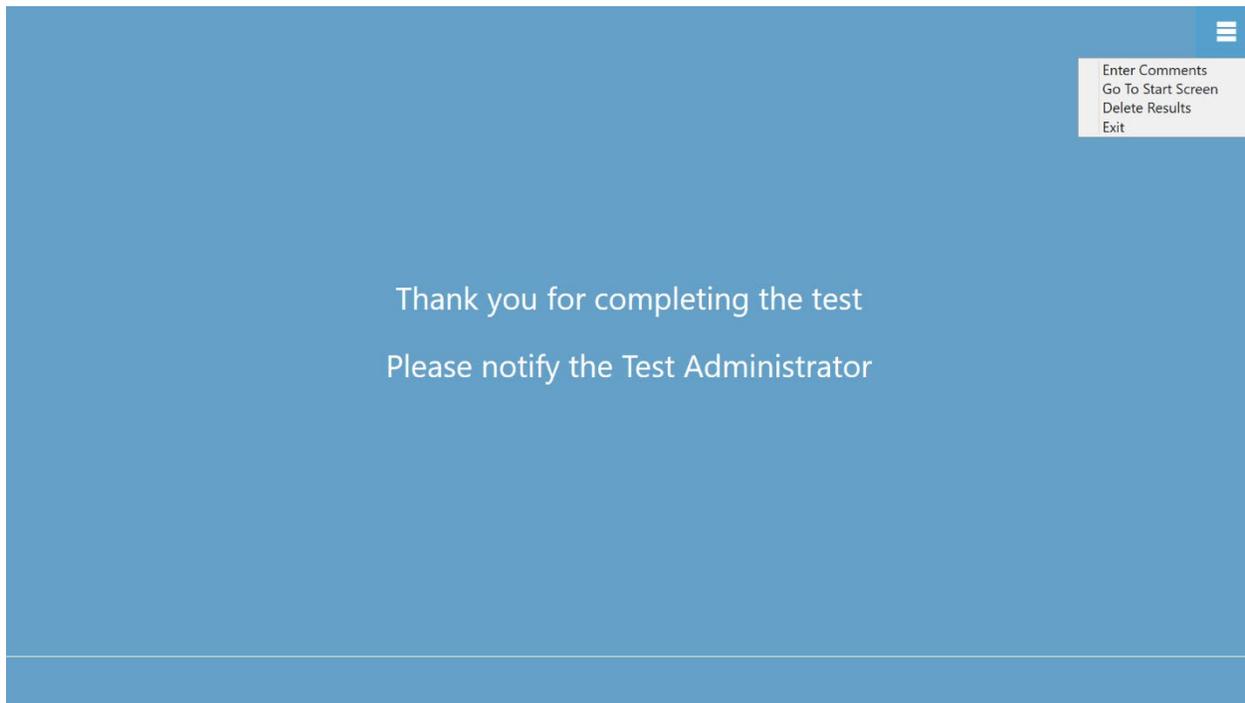
Test Complete Menu

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 FLEX 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 Flex Config App program has similar options. Both the Settings menu option and the GSI AMTAS Flex 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).
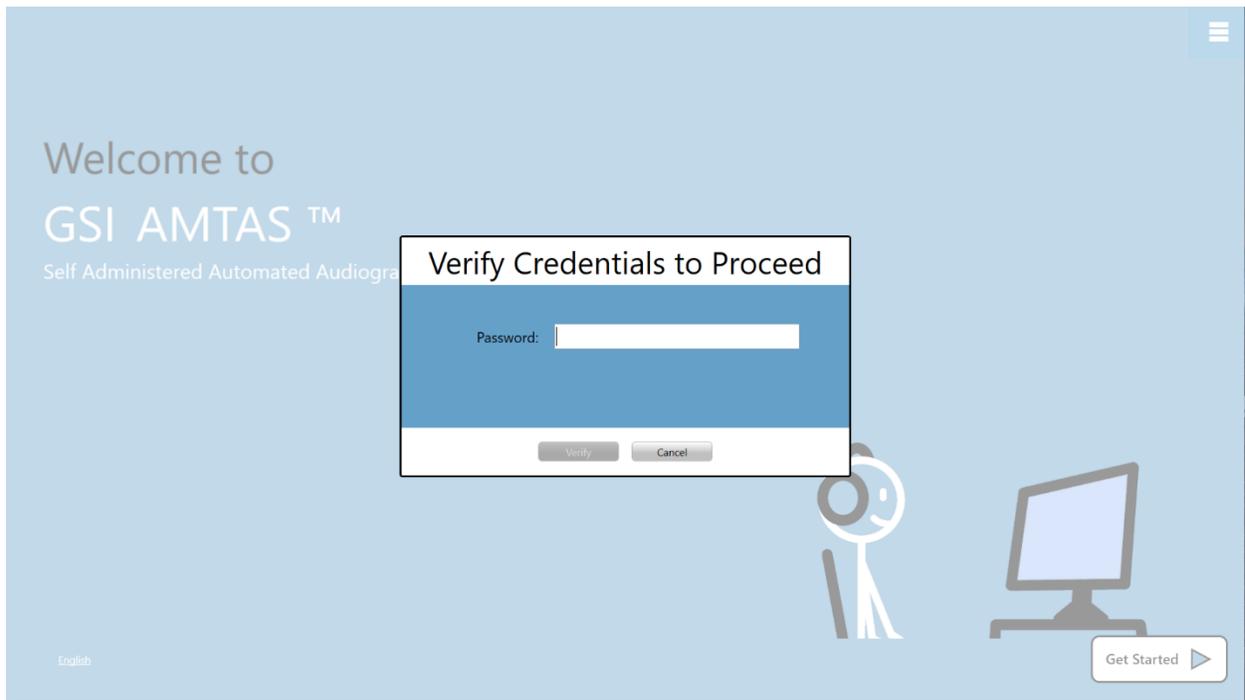
GSI AMTAS Flex has an option to use Windows authentication for the user IDs and passwords or a simple security that has a single admin user with a password. When GSI AMTAS prompts for a password, it is the person's Windows password that should be entered if using the Windows security or the single admin 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 Flex program.

NOTE: There is a difference in the persistence of the changes made to the options depending on how the GSI AMTAS Flex Config App is launched. When changes are made from the Settings menu in the GSI AMTAS Flex program, the changes are only applicable for the current test session. When changes are made from the GSI AMTAS Flex 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.
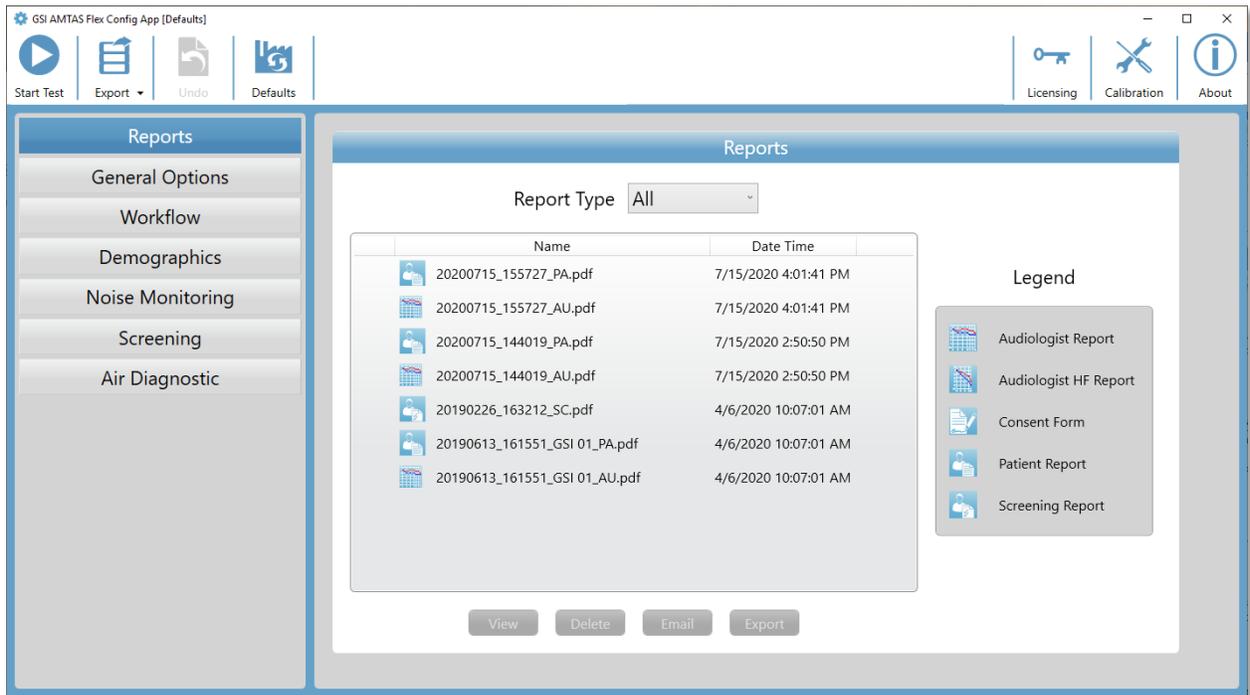
The Config App screen contains two main areas and a menu bar at the top. The left panel has the configuration categories, and the middle panel displays the options for the category.

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.

Export
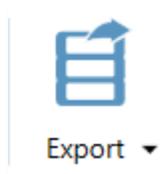
The Export button saves the AMTAS Flex data to a file location that you specify. This location could be a USB drive or network location. The data includes all the data that has not been previously exported. Typically, this option is used to transfer data to GSI Suite. The data is moved and then marked for deletion from the AMTAS Flex repository. Before the data is transferred, a confirmation dialog is presented. There is a sub-menu option via the Export icon down arrow. The sub-menu has the option to Restore the most recent previously exported data. When the Export button transfers data, the data is marked for deletion but is not deleted until the next export – this data that has been marked for deletion can be restored up until the next export.

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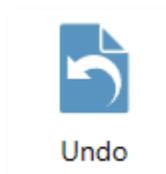
The Undo button returns the settings to the original values (when the screen was loaded). After a confirmation, any changes that were made are discarded and the previous configuration reloaded. This only applies to the current category option. For example, if you make a change to the General Options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

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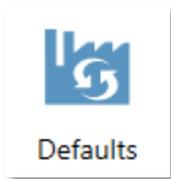
The Defaults button returns the settings to the original values (factory settings when the program was installed). Any changes that were made are discarded and the previous factory settings loaded.

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 numbers of the headphones and noise monitoring microphone and the calibration dates are shown. A button at the bottom of the dialog provides the option to import the headphone and microphone calibration files.

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
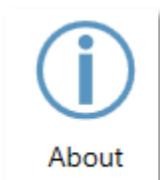
The About button displays information regarding the software version and patent and copyright information. The About dialog has an Export Logs and Email Logs buttons that will output the logs from the program to the selected location. The logs may be useful for troubleshooting should problems occur with 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.
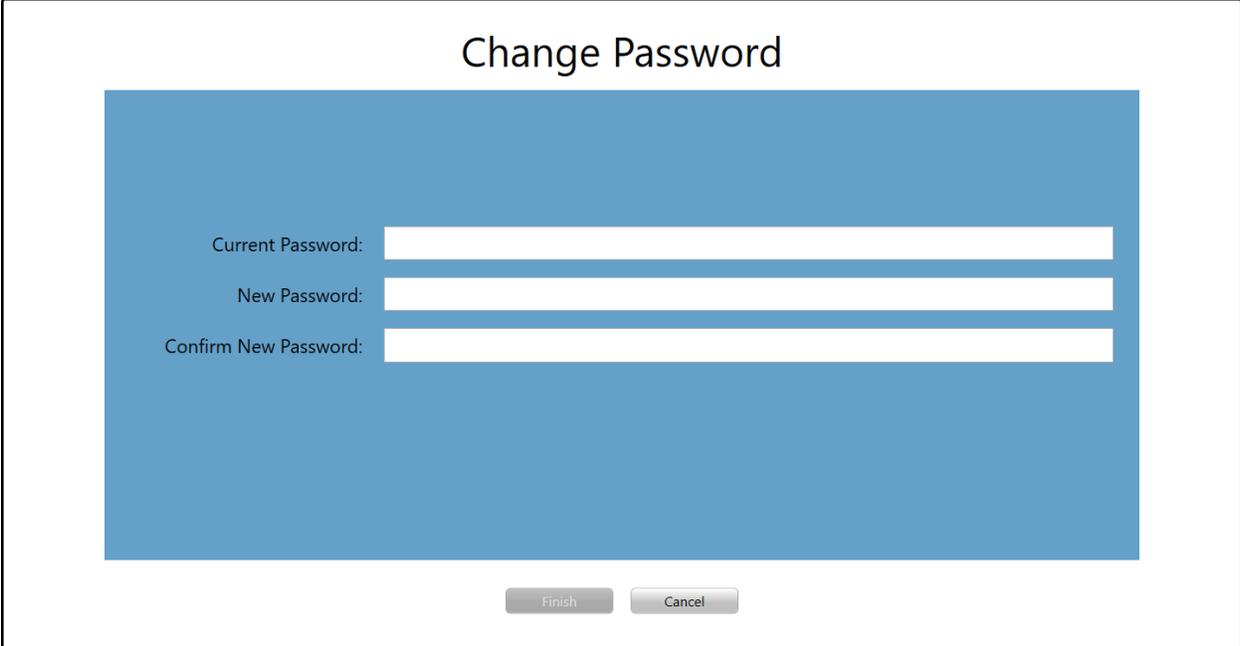
To change the password, you must enter the old password, then enter the new password and a confirmation of the new password. Press the finish button to save the new password.

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.
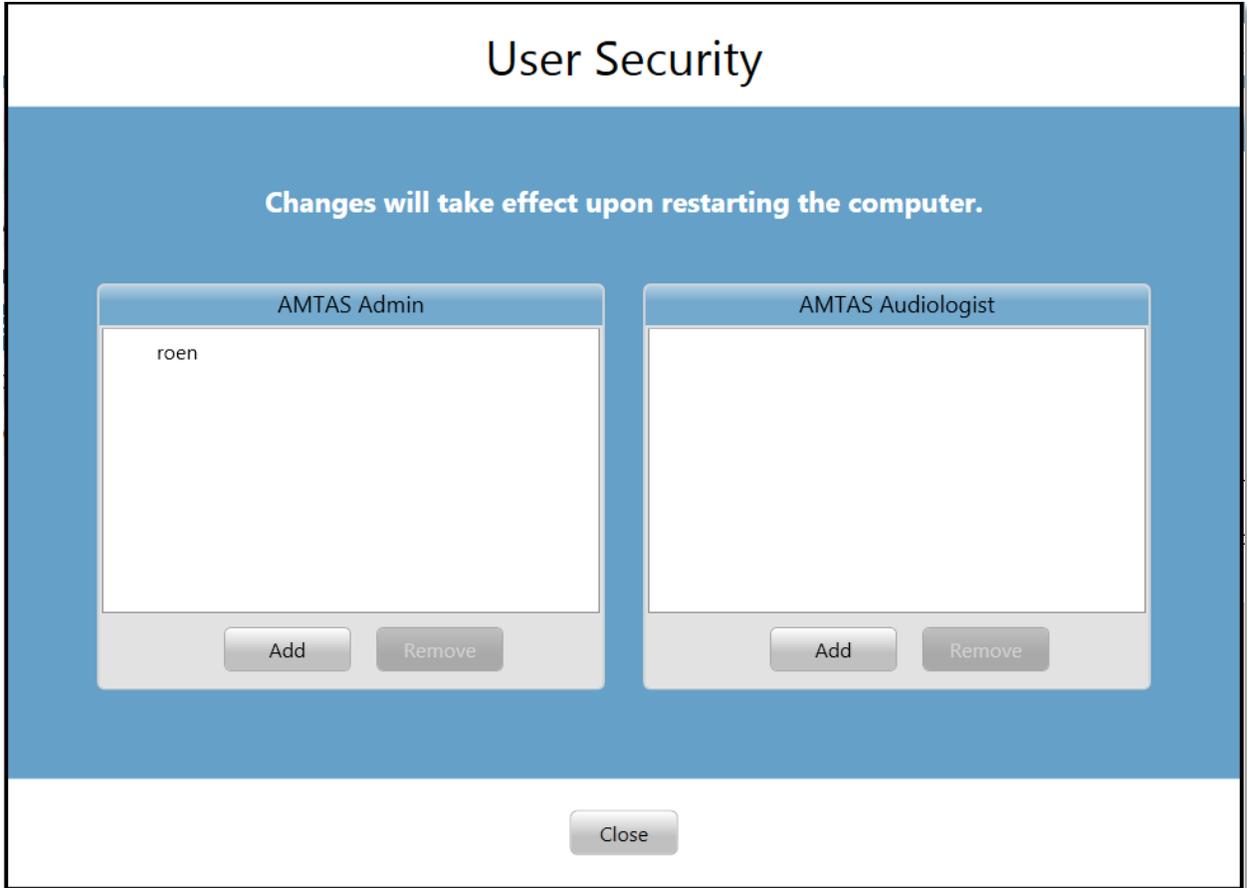
For each user type section there are buttons to add and remove users. To add a new admin or user press the add button and the add dialog is presented.
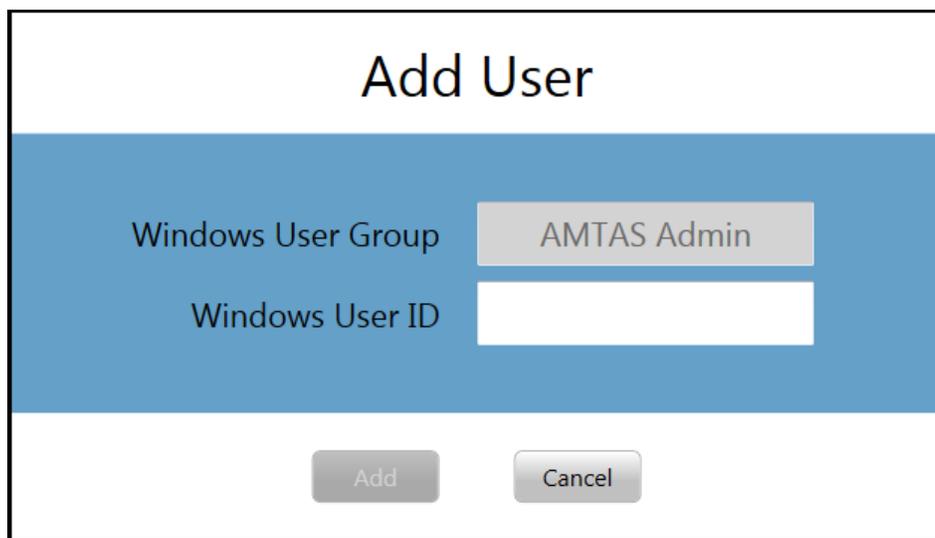
Enter the Windows User ID (this is the username that is used to log into the PC) and press the Add button. To remove a name, highlight the name in the list and select the Remove button. A confirmation dialog is presented to confirm the removal.

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
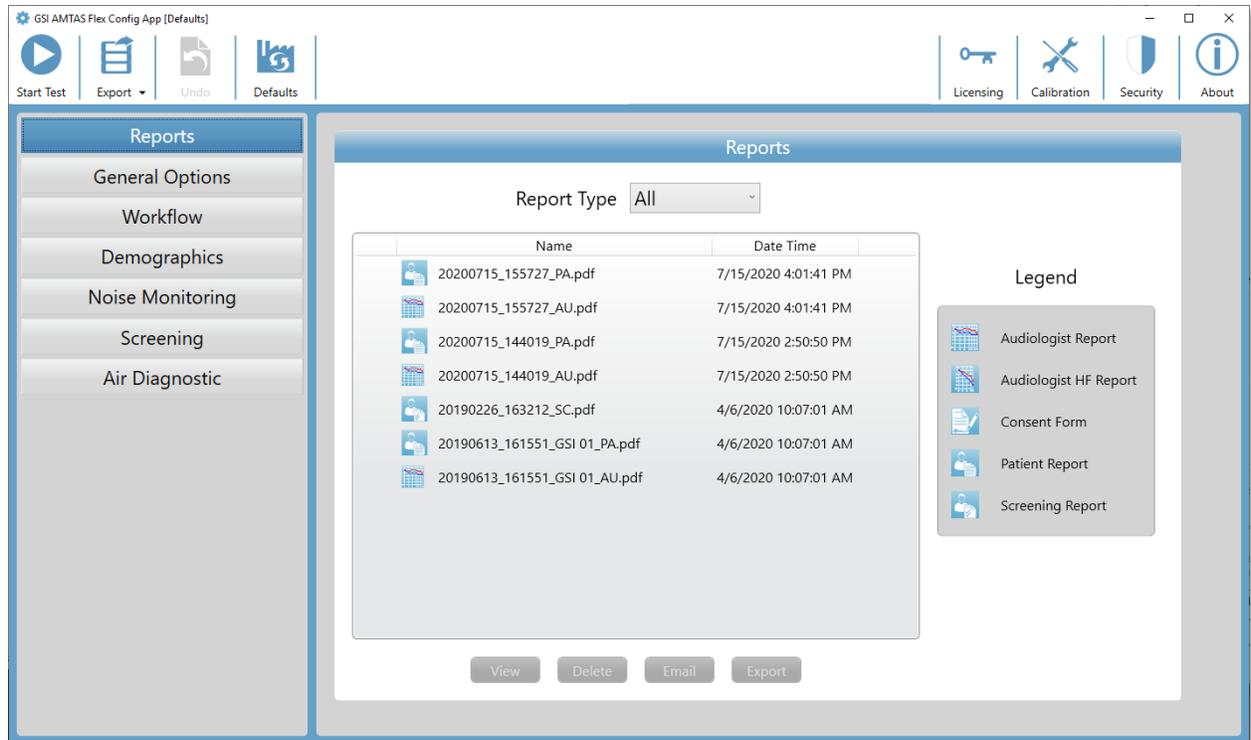
The Reports configuration section is used to display, delete, email, or export the test reports. The report type icon, name and date are listed with a legend to the right of the reports listing. There are two types of audiologist reports available in the program: the standard audiogram and high frequency 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
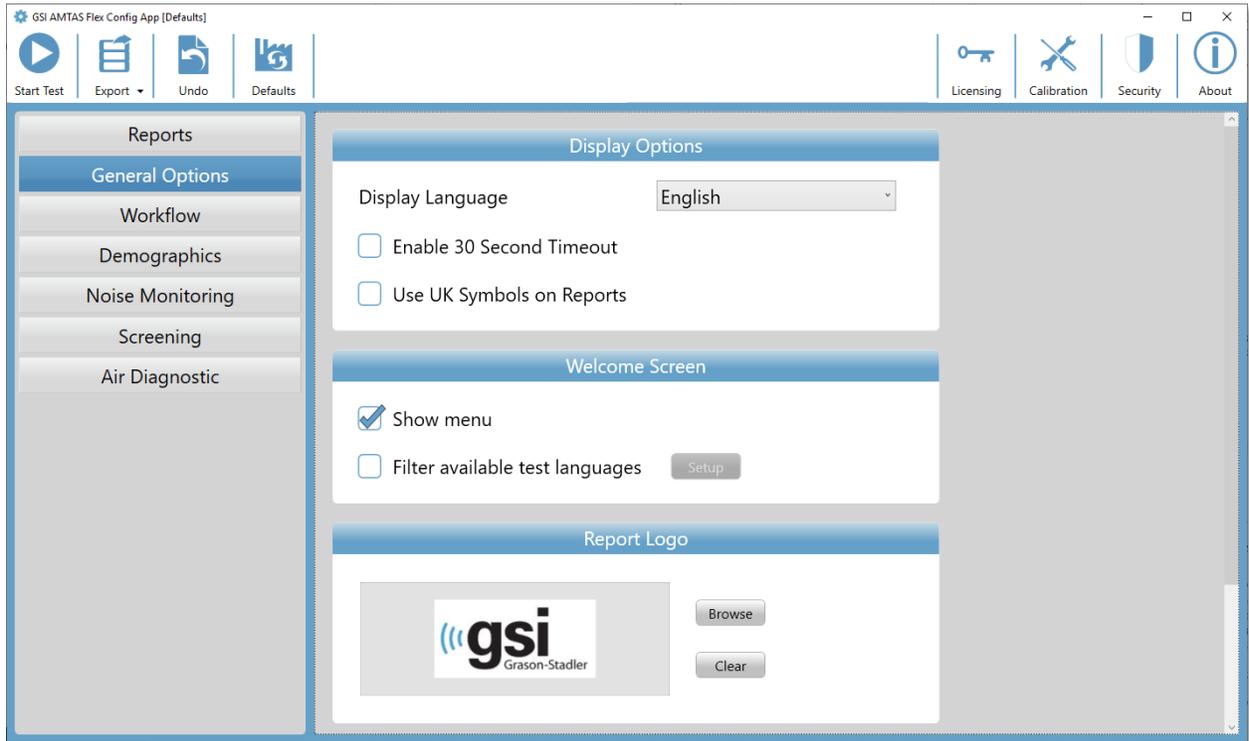
Display Options

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
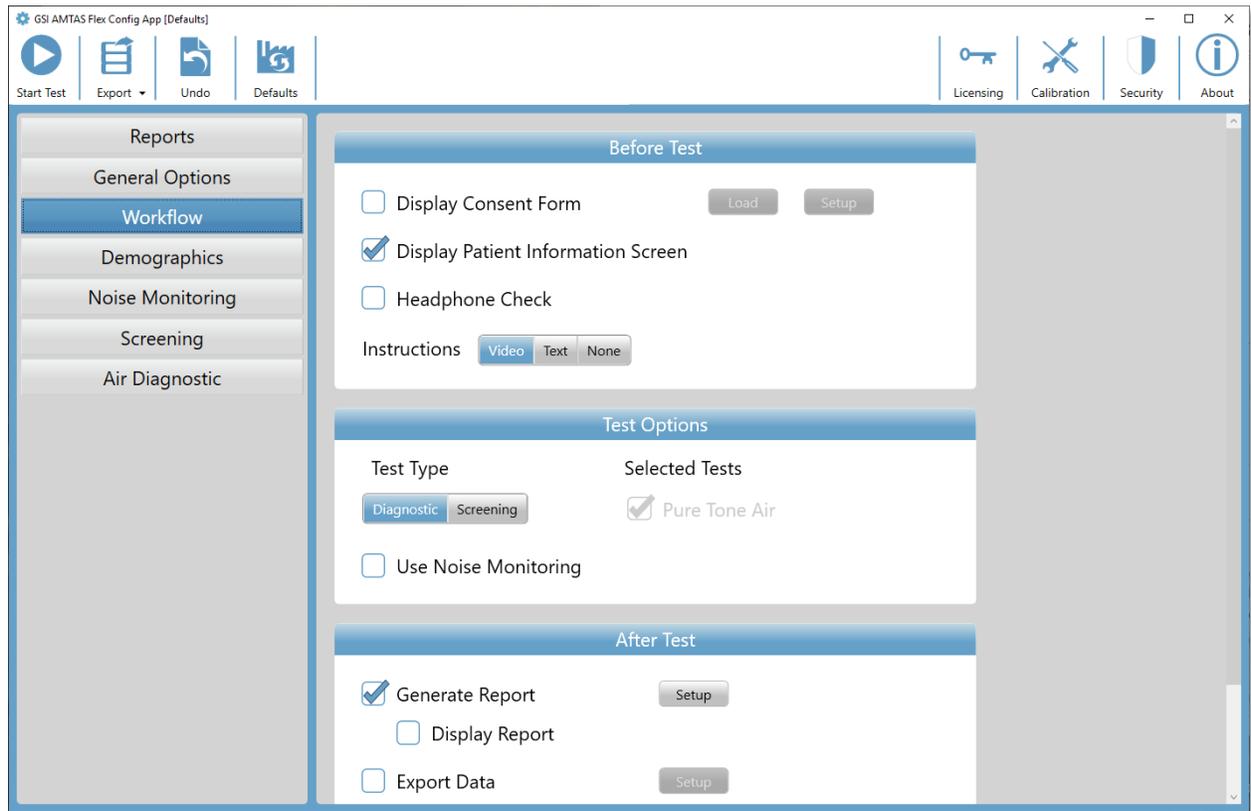
Before Test

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, the Pure Tone Air is automatically selected. 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 what 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 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
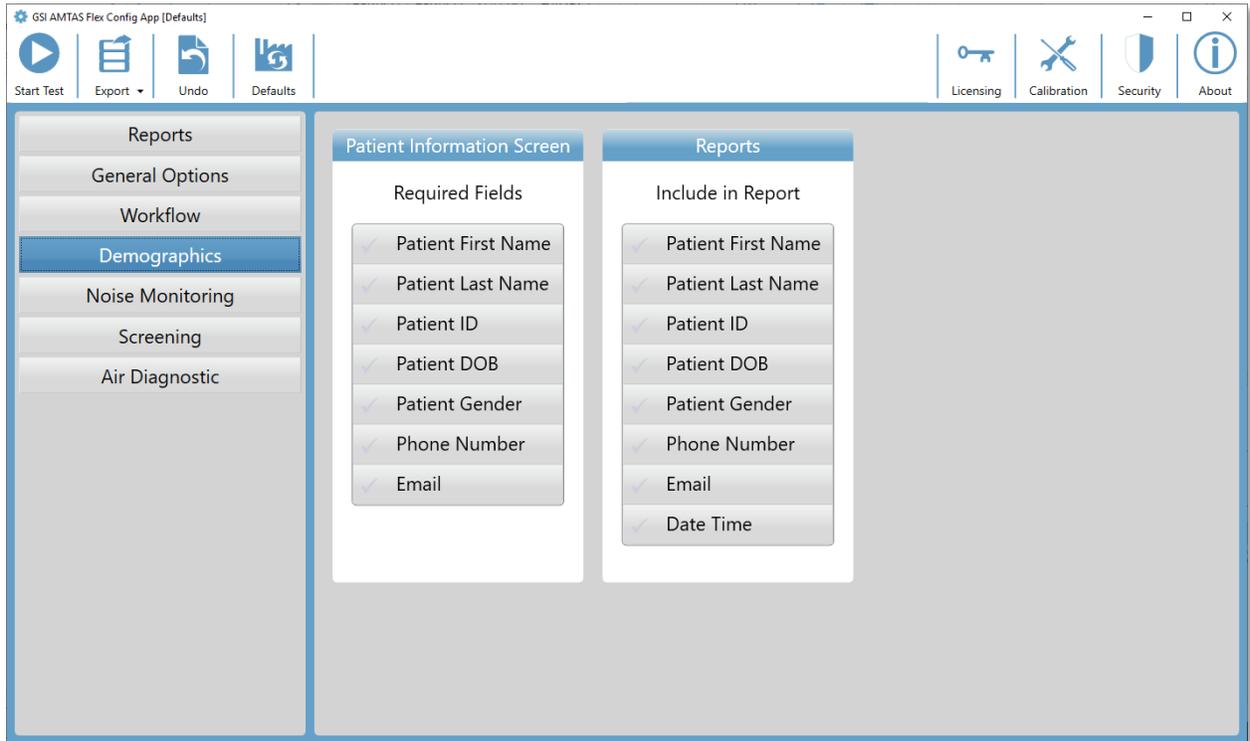
The Demographics section determines the required fields for the patient information entry. This section also determines the fields that are included in the report. The individual fields are selected/unselected by clicking the field name button. Fields that are selected are indicated by a checkmark next 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 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.
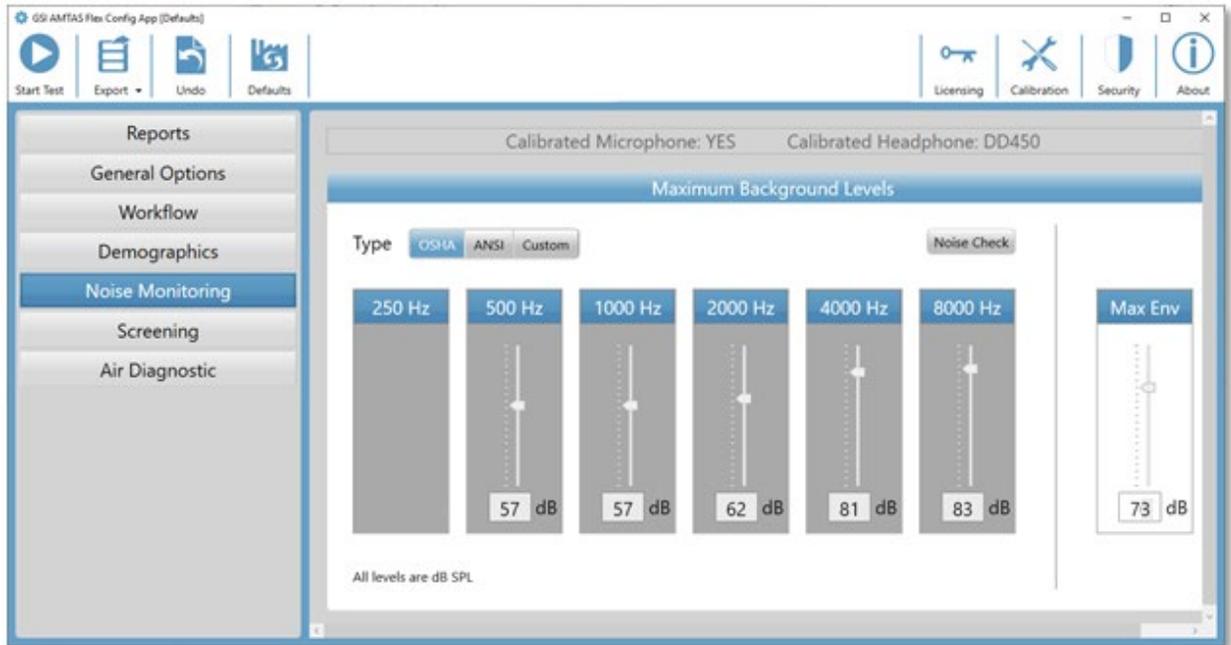
The Noise Monitoring section has information on the calibration of the microphone and headphones at the top of the section. The Noise Monitoring Type has options defined with 3 buttons. When the OSHA or ANSI buttons are selected the values for each octave band frequency are automatically filled with the values based on 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
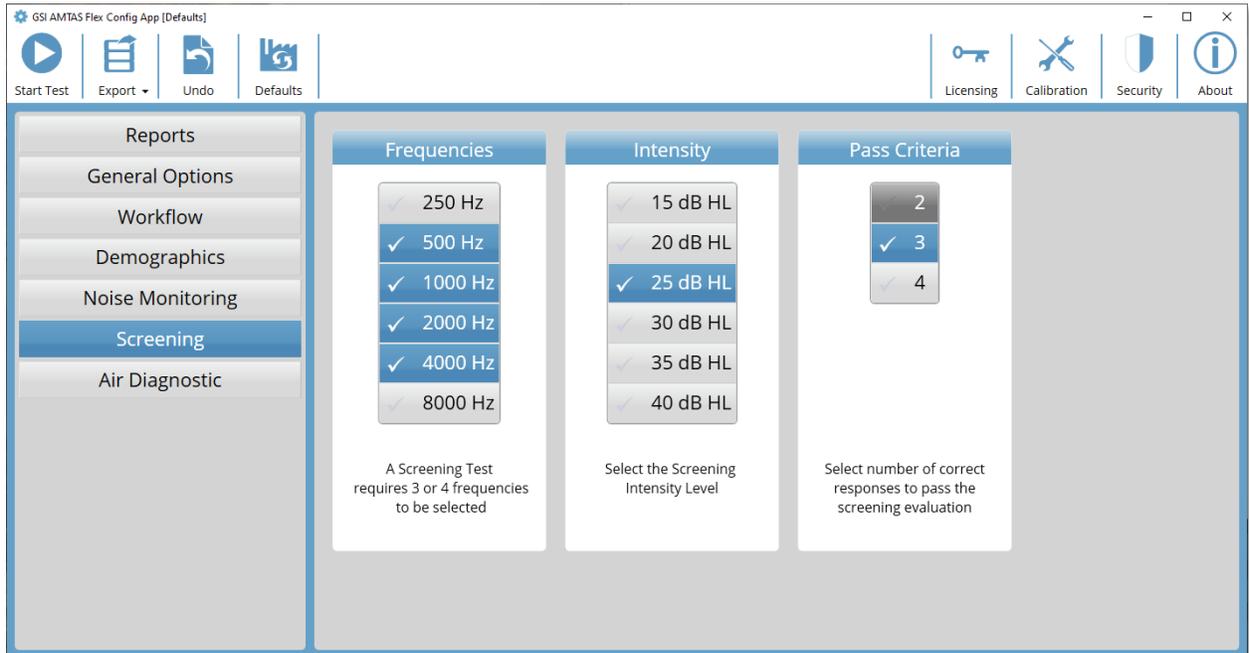
The Screening section determines the parameters that are used for the air conduction screening testing. There are three sections in the screening settings that control the parameters used for the screening test. The Frequencies section controls the pure tone frequencies (up to 4 may be selected) that are presented in the test. Three 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 DIAGNOSTIC
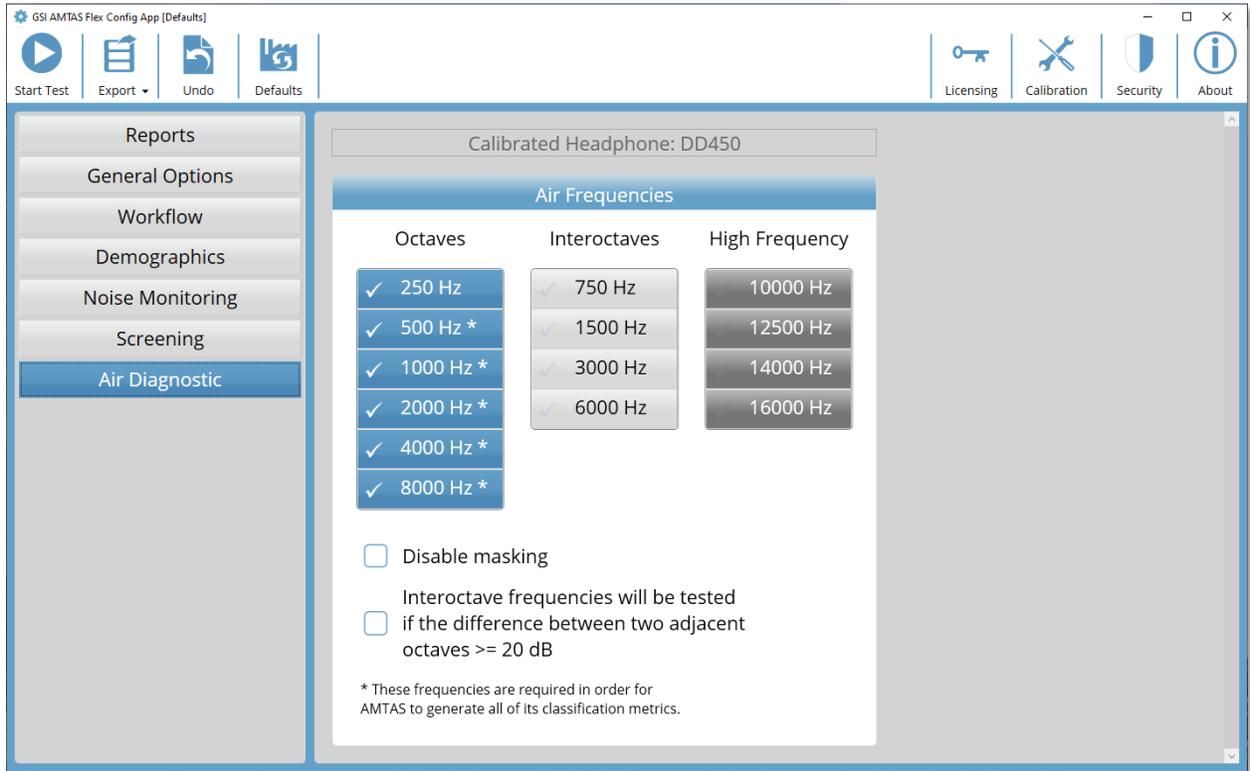
The Air Frequencies section shows the octave frequencies that will be tested. Some of the octave frequencies, with asterisks, are required to be tested to obtain all the quality metrics. The interoctave frequencies may be configured by selecting the desired frequency – a check mark will be displayed to indicate that the frequency has been selected for testing. Masking is presented to the non-test ear (recommended) 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.

GSI AMTAS Flex Noise Monitoring

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

Setup

The AMTAS Flex 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 Flex Config App.

1. Attach the USB disk included with the microphone to the AMTAS Flex PC
2. Launch the AMTAS Flex 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 the AMTAS Flex headphone USB Y cable and turn on the noise monitoring option in the AMTAS Flex 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 allows 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 background 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 threshold 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 FLEX REPORTS

The GSI AMTAS Flex 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
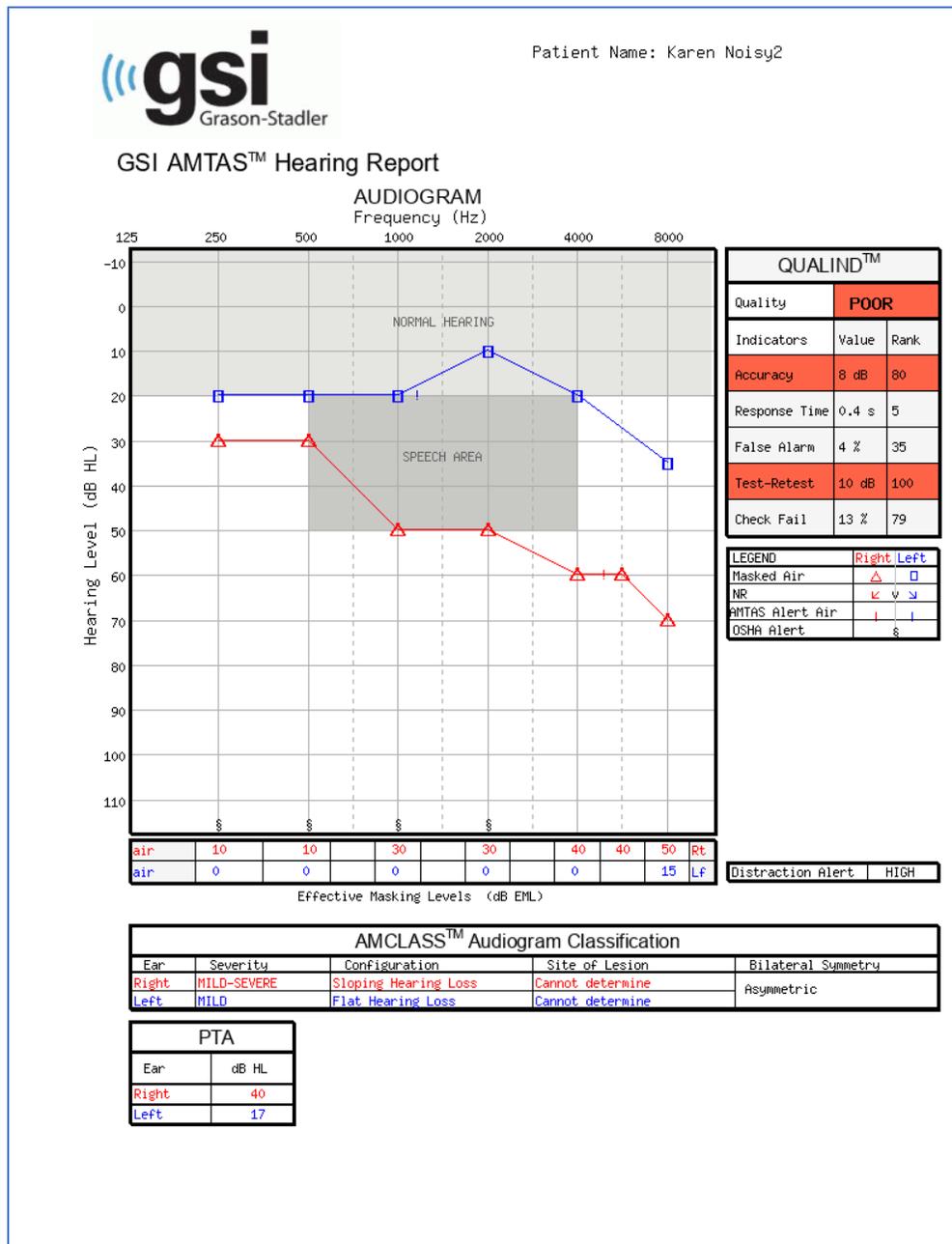
If high frequency testing was performed an additional High Frequency Report page is generated. This page contains the threshold data for the 10-16 kHz frequency range.
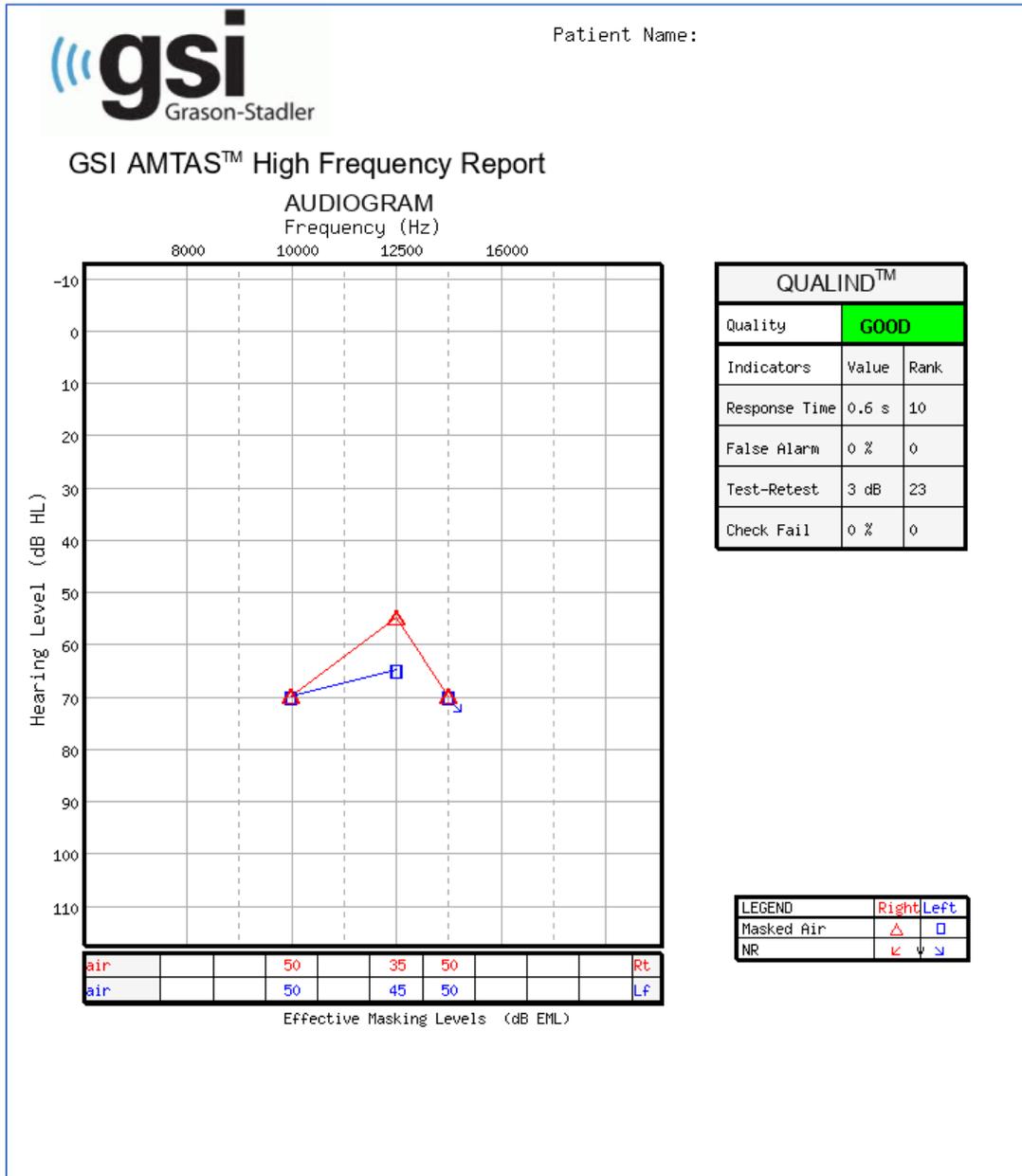
The report is automatically generated at the completion of the test and is accessed from the GSI AMTAS Flex Config App. The report contains the following sections:

- Patient Information
- Audiogram
- Audiogram Symbol Legend
- Masking Level Table
- Quality Assessment Table

- Audiogram Classification Table
- Pure Tone Average
- Comments

If noise monitoring was enabled, any threshold alerts are added to the audiogram and the audiogram legend extended to indicate the alert symbols. 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 the air conduction 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.

Quality Assessment Table (Qualind)

AMTAS incorporates 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.

Response Time

The Response Time is the time per trial 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.

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

For the GSI AMTAS Flex this will be labeled as "Incomplete Bone Conduction" since bone conduction is required to determine the site of lesion.

Bilateral Symmetry

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

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.

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 Flex 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.

The

AMTAS Audiometric Report

Patient Name: flex three

Environmental Noise Report

Any noise level that may have had an impact on the threshold is indicated on the audiogram with an 'I' 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	64	70	66	58	56	51

* 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	374	374	374	364	125	50
Alert Percent	100%	100%	100%	97%	33%	13%

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
70	417	100%	06:23	418

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.

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's name and date and time of the consent appended as the last page of the form.

Additional page added to the form.

UPLOADING GSI AMTAS FLEX RESULTS TO GSI SUITE

GSI-Suite versions 2.5 and above is required to transfer data collected using GSI AMTAS Flex. Data from the GSI AMTAS Flex system may be uploaded to GSI Suite by two different methods: File export/import or Wireless transfer.

File Export/Import

To transfer data from the GSI AMTAS Flex system you may use the file export option from the GSI Flex Config App. The Export option is found on the menu bar.

This Export option provides a dialog that allows you to specify the location for the exported files. It will export all files that have not been previously exported. The location for the exported file should be a location that you can import from with GSI Suite. A confirmation dialog will be presented to confirm that you wish to export the files. The exported files will then be marked for deletion. After the files have been successfully exported a confirmation dialog is presented.

NOTE: In the Config App Workflow category there is an option for Export Data in the After Test section. This option is for export of an individual test result and is in an XML format intended for third party applications. This option does not export a Suite compatible file.

GSI Suite needs to be configured to receive data from the AMTAS Flex device. In the Configure option from the main menu, select the Devices tab and under the Connected Devices section make sure that GSI AMTAS Flex has been checked. In the GSI Suite program the Batch Transfer option on the menu bar has the option to import when the Audiometry tab has been selected. This Batch import option provides a dialog to select the location and choose the files. Once the files have been imported, Suite presents the Assign Test dialog to associate the files with patients that are in Suite. See the GSI Suite documentation for more details on the Assign Test dialog.

NOTE: If GSI Suite is installed on the same computer as the AMTAS Flex program, the Batch Transfer button on the GSI Suite menu will have a sub menu item Local. Use the Local option to transfer the data from AMTAS Flex when both programs are on the same computer. The Local option will present the Assign Test dialog using the AMTAS Flex data from the local computer.
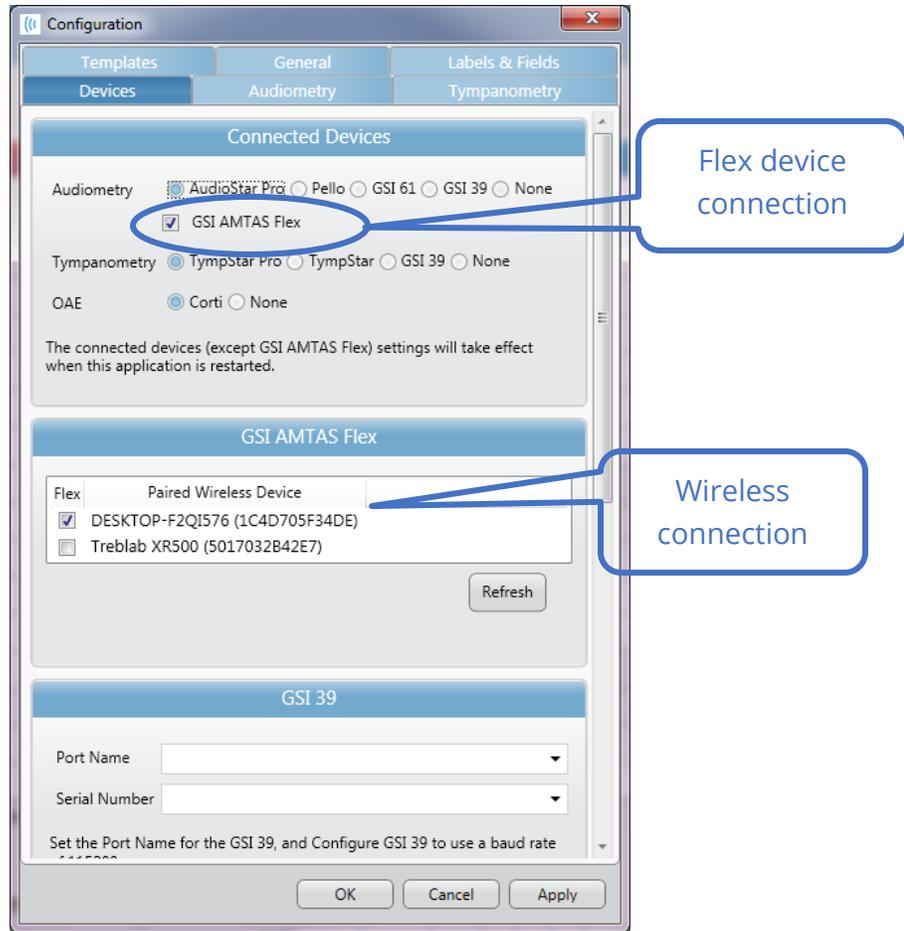
Wireless (Bluetooth) Transfer

To transfer data from the GSI AMTAS Flex system via a wireless (Bluetooth®) connection, the two devices (AMTAS Flex and PC with GSI Suite) need to be paired in Windows. The details may be found in your Windows documentation but generally involves turning on Bluetooth on both devices and adding the AMTAS Flex device to the PC. Once the devices have been paired in Windows the GSI Suite program needs to be configured.

In the Configure option from the main menu, select the Devices tab and under the Connected Devices section make sure that GSI AMTAS Flex has been checked. In the GSI AMTAS Flex section make sure that the Flex device is listed, and that the device is checked. To import GSI Flex data wirelessly, select the Audiometry tab.

In the GSI Suite program the Batch Transfer option on the menu bar has an arrow with a dropdown sub menu – select the wireless option. The GSI Suite program will connect to the configured wireless device. Suite presents the Assign Test dialog to associate the files with patients that are in Suite. See the GSI Suite documentation for more details on the Assign Test dialog.

ROUTINE MAINTENANCE

TABLET/PC

Follow the instructions included with the computer for information on the computer cleaning and maintenance.

BIOLOGICAL CALIBRATION CHECK

The design of the GSI AMTAS Flex should provide trouble-free service for a long time. It is recommended to routinely record and file the audiogram of one person for the purpose of biologic calibration. This person (or group of persons) should have a known stable audiometric curve that does not exceed 25 dB HL at any frequency. This procedure should start when the GSI AMTAS Flex is first installed and then be continued thereafter. Remember that individual thresholds can shift by as much as 5 dB from day to day; however, variations that exceed this range may point to difficulties which require attention.

HEADSET CABLE CHECK

With extended use, all transducer cords tend to fray internally at the connectors. To evaluate the cord status, perform the biological calibration check and bend the cord next to the plug at both ends of each earphone. Listen for an intermittent signal, abrupt changes in the signal level, or a scratchy sound that coincides with the flexing of the cord. The presence of any of these conditions signifies that the cord should be replaced. Inspect all cords for fraying and damage. If there is any damage to any cord, do not use the GSI AMTAS Flex.

CLEANING THE SYSTEM

Turn OFF the system and disconnect power before cleaning the instrument. Follow the Tablet/PC cleaning instructions included with the system for cleaning the Tablet/PC. For other parts of the system, use a soft cloth lightly dampened with cleaning solution to clean all exposed surfaces. Take care to not allow liquid to contact the metal parts inside the transducers (e.g., earphones / headphone). Do not permit solutions or disinfecting agents to seep into the electronic portions of the system. Remove any dust from the exterior of the system with a soft brush or cloth. Use a brush to dislodge any dirt on or around the connectors and panel edges. Remove stubborn dirt with a soft cloth slightly dampened

with mild detergent and water. Wipe surfaces dry afterward. Do not use instrument or transducers until they are completely dry.

CLEANING AND DISINFECTING AGENTS

According to the recommendations from the CDC, audiometric equipment is non-critical medical equipment and typically requires cleansing followed by low to intermediate level disinfecting, depending on the nature of the contamination. Cleaning should be done with a mild soapy detergent (such as dishwashing liquid) and a damp cloth, or an Endozime Sponge followed by an application of EPA-registered hospital disinfectant. Do not use any abrasive cleaners.

Use of a non-alcohol-based disinfectant is recommended for the headphones. Non-alcohol-based products contain the active ingredient referred to as quaternary ammonia compound or hydrogen peroxide-based cleaner such as Oxivir Disinfectant Wipes to clean the ear cushions and headset. The quaternary ammonia compound and hydrogen peroxide are specifically designed to disinfect rubber, plastic, silicone, and acrylic products which are commonly used in hearing evaluation instruments.

ERROR MESSAGES

Unable to connect to device.

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

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 Flex may use Windows authentication for the user IDs and passwords. The usernames entered in the GSI AMTAS Flex 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 Flex 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 Flex program can be accessed.

The username or password was incorrect.

GSI AMTAS Flex may use Windows authentication for the user IDs and passwords. The usernames entered in the GSI AMTAS Flex 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 Flex Testing Protocol

Psychophysical Method

GSI AMTAS Flex 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 Flex 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.

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
- 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 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
- Interoctave frequencies will be tested if the difference between two adjacent octaves >= 20 dB: Off

SPECIFICATIONS

Refer to the Tablet/PC specifications in the Tablet/PC documentation for Physical, Environmental and Power specifications for the Tablet/PC.

AIR CONDUCTION PURE TONE

Frequency Range: 250 Hz to 8000 Hz (DD65V2)

Frequency Range: 250 Hz to 16000 Hz (DD450)

Level Range: 0 dB to 90 dB HL

Masking: Narrow band 250 Hz to 16000 Hz

The masking narrow band noise is geometrically centered at the selected test frequency and contains a 3 dB down bandwidth of a 1/3 octave at a minimum and ½ octave at a maximum.

Masking Level Range: 10 to 60 dB HL

Transducers: RadioEar DD65V2 or RadioEar DD450

CALIBRATION

The GSI AMTAS Flex is supplied from the factory calibrated for the specific transducers that were purchased with it. The calibration file is included on the supplied USB disk and is only valid with the specific headphones and sound card supplied. The calibration data supplied from the factory cannot be applied to other transducers.

It is recommended that calibration of the instrument and transducers be performed annually by authorized GSI Representatives using appropriate calibration instrumentation. If periodic checks are also desired, the biological calibration check described in a previous section may be used.

EARPHONES - PURE TONE RETSPL, AMBIENT ATTENUATION

Transducer	DD65 V2		DD450	
Impedance	10 Ω	Ambient	40 Ω	Ambient
Coupler	318-1	Noise	318-1	Noise
	RETSPL (dB)	Attenuation	RETSPL (dB)	Attenuation
125 Hz	30.5	8.3	30.5	15
250 Hz	17	15.5	18	16
500 Hz	8	26.1	11	23
750 Hz	5.5		6	
1000 Hz	4.5	32.4	5.5	29
1500 Hz	2.5		5.5	
2000 Hz	2.5	43.6	4.5	32
3000 Hz	2		2.5	
4000 Hz	9.5	43.8	9.5	46
6000 Hz	21		17	
8000 Hz	21	45.6	17.5	44
10000 Hz			22	
12500 Hz			27.5	
14000 Hz			35	
16000 Hz			56	

Artificial ear uses IEC60318-1 coupler with type 1 adaptor.

AMTAS PUBLICATIONS AND PATENTS

AMTAS PUBLICATIONS

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2. Margolis, R.H. Automated Audiometry: Progress or Pariah. Audiology Today 17:21, 2005.
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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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8. Margolis, R.H., Morgan D.E. Automated Pure-Tone Audiometry – An Analysis of Capacity, Need, and Benefit. Amer. J. of Audiology, 17, 109-113, 2008.
9. Margolis, R.H., Glasberg, B.R., Creeke, S., Moore, B.C.J. AMTAS – Automated Method for Testing Auditory Sensitivity: Validation Studies. Int. J. Audiology,49, 185-194, 2010.
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11. Margolis, R.H., Moore, B.C.J. Automated method for testing auditory sensitivity: III. Sensorineural hearing loss and air-bone gaps. *Int J Audiology,* 50, 440-447, 2011.
12. Margolis, R.H., Eikelboom, R.H., Johnson, C., Ginter, S.M., Swanepoel, D.W., Moore, B.C.J. False Air-Bone Gaps at 4 kHz in Listeners with Normal Hearing and Sensorineural Hearing Loss. *Int. J. Audiology* 52:526-532, 2013.

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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.

EMC COMPATIBILITY

Portable and Mobile RF communications equipment can affect the GSI AMTAS Flex. Install and operate the device according to the EMC information presented in the Tablet/PC documentation and presented in this section.

The GSI AMTAS Flex has been tested for EMC emissions and immunity as a standalone instrument. Do not use the device adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, the user should verify normal operation in the configuration.

The use of accessories, transducers, and cables other than those specified, except for servicing parts sold by GSI as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the device. Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard.

This instrument is suitable in hospital environments except for near active HF surgical equipment and RF shielded rooms of systems for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high.

Use of this instrument adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this instrument and the other equipment should be observed to verify that they are operating normally.

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. The list of accessories, transducers and cables can be found in this appendix.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this instrument, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

NOTICES

ESSENTIAL PERFORMANCE for this instrument is defined by the manufacturer as: This instrument does not have an ESSENTIAL PERFORMANCE. Absence or loss of ESSENTIAL PERFORMANCE cannot lead to any unacceptable immediate risk.

Final diagnosis shall always be based on clinical knowledge. There are no deviations from the collateral standard and allowances uses.

This instrument complies with IEC60601-1-2:2014, emission class B group 1. There are no deviations from the collateral standard and allowances uses. All necessary instruction for maintaining compliance regarding EMC can be found in the general maintenance section in this instruction. No further steps required.

ELECTRICAL SAFETY, EMC AND ASSOCIATED STANDARDS

ES 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety

IEC/EN 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety

CAN/CSA-C22.2 No. 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety Electrical Equipment for Laboratory Use

IEC/EN 60601-1-1: Collateral Standard, Safety Requirements for Medical Electrical Systems

IEC/EN 60601-1-2: Medical Electrical Equipment, Part 1 - Electromagnetic Compatibility - Requirements and Tests

Essential Requirements of the current Medical Device Regulation (EU) 2017/745

RoHS (Restriction of the use of certain Hazardous Substance)

WEEE (Waste Electrical & Electronic Equipment) Legislation

Guidance and Manufacturer's Declaration Electromagnetic Emissions		
The GSI AMTAS Flex is intended for use in the electromagnetic environment specified below. The customer or the user of the GSI AMTAS Flex should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - Guidance**
RF Emissions CISPR 11	Group 1	The GSI AMTAS Flex uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B Limits	The GSI AMTAS Flex is suitable for use in all commercial, industrial, business, hospital, and residential environments.
Harmonic Emissions IEC 61000-3-2	Class A Category	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Complies	

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the GSI AMTAS Flex			
The GSI AMTAS Flex is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the GSI AMTAS Flex can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the GSI AMTAS Flex as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output Power of Transmitter **W**	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.23\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitters, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **Note 1**: At 80 MHz and 800 MHz, the higher frequency range applies. **Note 2**: These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Guidance and Manufacturer's Declaration Electromagnetic Immunity			
The GSI AMTAS Flex is intended for use in the electromagnetic environment specified below. The customer or the user of the GSI AMTAS Flex should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance**	**Electromagnetic Environment-Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be greater than 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial, hospital, or residential environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial, hospital, or residential environment.
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles 5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles 5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial, hospital, or residential environment. If the user of the GSI AMTAS Flex requires continued operation during power mains interruptions, it is recommended that the GSI AMTAS Flex be powered from an uninterrupted power supply.
Power Frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the AC mains voltage prior to application of the test level.			

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Guidance and Manufacturer's Declaration
Electromagnetic Immunity

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The GSI AMTAS Flex is intended for use in the electromagnetic environment specified below. The customer or the user of the AMTAS Flex should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance**	**Electromagnetic Environment-Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the GSI AMTAS Flex, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 1.17\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field Strengthens from fixed RF transmitters, as determined by an electromagnetic site survey (a*), should be less than the compliance level in each frequency range (b*).Interference may occur in the vicinity of equipment marked:
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. **Note 2**: These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

(a*) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field

strength in the location in which the AMTAS Flex is used exceeds the applicable RF compliance level above, the AMTAS Flex should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the AMTAS Flex.

(b*) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

To ensure compliance with the EMC requirements as specified in IEC 60601-1-2, it is essential to use only the following accessories:

ITEM	MANUFACTURER	MODEL
HD65V2 Audiometric Headset	RadioEar	DD65V2
DD450 Audiometric headset	RadioEar	DD450

Conformance to the EMC requirements as specified in IEC 60601-1-2 is ensured if the cable types and cable lengths are as specified below:

Description	Length	Screened/Unscreened
Mains Cable	2.5 m	Unscreened
DD65V2 Headset	2.5 m	Screened
DD450 Headset	2.5 m	Screened