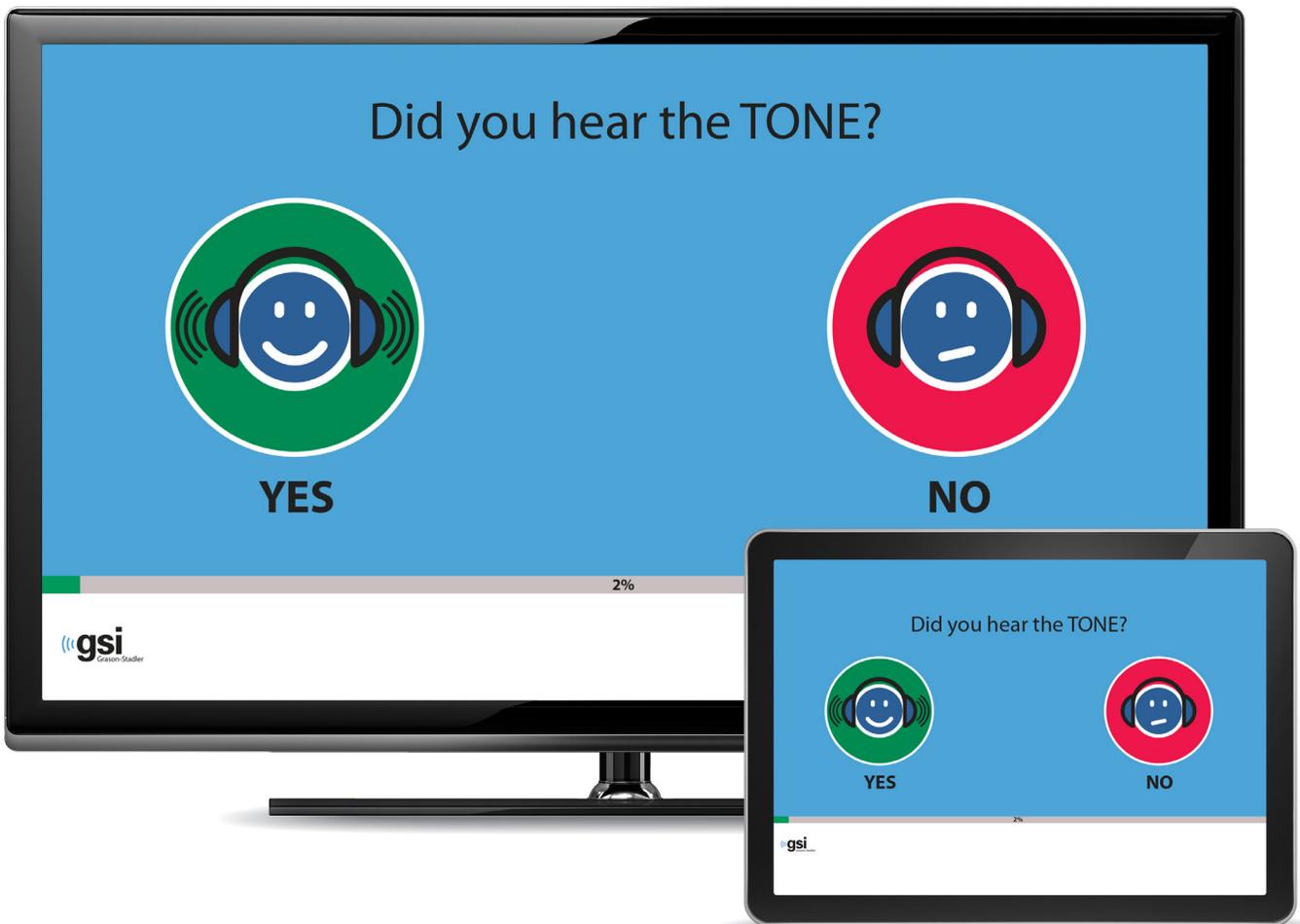




## USER MANUAL



Part Number D-0118200 Rev. A

**Title:** GSI AMTAS™ Flex User Manual

**Manufacturer**

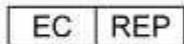
Grason-Stadler, Inc.  
10395 West 70<sup>th</sup> Street  
Eden Prairie, MN 55344  
USA

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**Compliance**

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



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



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

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## Preface

This user manual provides information about the GSI AMTAS software program and GSI AMTAS Flex system. 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.

## Manual Conventions



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

## Important Safety Instructions



The software program configuration (GSI AMTAS Flex Config App) should be used only by practitioners qualified to perform audiometric tests. This system is intended for transient use as a screening and diagnostic tool; however no surgical or medical procedure should be undertaken solely on the basis of results obtained from the program.

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

## Precautions

### **READ THIS OPERATING MANUAL BEFORE ATTEMPTING TO USE THE SOFTWARE**

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

## Warning 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 supply mains, 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 supply mains with protective earth.

This product should not be used in the presence of fluid that can come into contact with 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 in close proximity to 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 in order to maintain continued compliance to IEC and ES 60601-1.



The icon to the left indicates that the GSI AMTAS Flex is in compliance 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.).

## Recycling / Disposal

Many local laws and regulations require special procedures to recycle or dispose of electrical equipment and related waste including batteries, printed circuit boards, electronic components, wiring and other elements of electronic devices. Follow all local laws and regulations for the proper disposal of batteries and any other parts of this system.

Below is the contact address for proper return or disposal of electronic wastes relating to Grason-Stadler products in Europe and other localities.

The contact information for the WEEE in Europe:



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

Within the European Union, it is illegal to dispose of electric and electronic items in unsorted municipal waste. Electric and electronic waste may contain hazardous substances and therefore has to be collected separately. Such products will be marked with the crossed-out wheeled bin symbol, shown above. The cooperation of the user is important in order to ensure a high level of reuse and recycling of electric and electronic waste. Failing to recycle such waste products in an appropriate way may endanger the environment and consequently the health of human beings.

## Regulatory Symbols

Symbol	IEC Pub.	Description
	980 & 60601-1	Conforms to European Medical Device Directive 93/94/EEC.
	980 & 60601-1	Symbol for "SERIAL NUMBER."
	980	GSI Part Number.
	980 & 60601-1	Return to Authorized Representative, Special disposal required.
	980 & 60601-1	Medical Equipment Classified by Intertek Testing Services NA Inc. with respect to electric shock, fire, and mechanical hazards only, in accordance with UL 60601-1. Classified under the Medical Device Directive (93/42/EEC) as a Class IIb device.
	980 & 60601-1	Symbol for "European Representative."
	980 & 60601-1	Symbol for "Manufacturer."
	980 & 60601-1	Symbol for "Date of Manufacture."
	980 & 60601-1	Attention, consult accompanying documents.
	60601-1	B Patient Applied Part according to IEC 60601-1.
	980 & 60601-1	Consult Operating Instructions.
	ISO 7010-M002	Follow Instructions for Use.

## 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.

GSI 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. GSI AMTAS was designed to provide the same test results as would be obtained by an expert audiologist. The psychophysical procedure that is employed 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 for assisting in the diagnosis of possible otologic disorders. The audiogram may also be used 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.

## Installation and Setup

### Precautions

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

- To avoid unwanted data transfer from PC to the network, ensure that an appropriate virus & spyware scanner is installed, updated, and effective. Please contact a local administrator for help and guidance.
- All users should have a unique login to the PC.

### Prerequisites

#### GSI AMTAS Flex PC Minimum Requirements

- CPU: 2.0 GHz, Intel dual or quad core processor or better
- RAM: 4 GB
- Storage: 64 GB or larger
- USB Ports: 1 minimum
- Display: 10" or larger
- Resolution: 1280 x 800 minimum
- Touch screen or mouse/trackball
- Wireless Bluetooth

#### GSI AMTAS Flex Supported Operating Systems

- Microsoft Windows® 10 Pro

#### GSI AMTAS Software Requirements

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

- Microsoft .NET Framework version 4.5.2

### Unpacking the system

Notify the carrier immediately if any damage is noted. This will insure 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 to report the shortage.
- 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**

- GSI AMTAS Flex Headset
- 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 headset assembly plugs into a USB port on the Tablet/PC.

## 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 sufficient to cause apparent hearing loss at the lower frequencies.

The following table shows the maximum background levels that can be present inside the room while a valid hearing test is being conducted. These values apply for hearing threshold measurements to 10 dB HL.

Test Tone Freq. (Hz)	250	500	1000	2000	4000	8000
<b>Test Room level Max dB SPL, Ears covered (Sennheiser HD 280 Pro)</b>	30	37	41	54	53	42

**Notes:** Maximum permissible 1/3 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 (R2003) Criteria for Permissible Ambient Noise during Audiometric Testing for maximum allowable outside octave band noise levels with three prefabricated sound room types.

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## Installing on Windows® 10

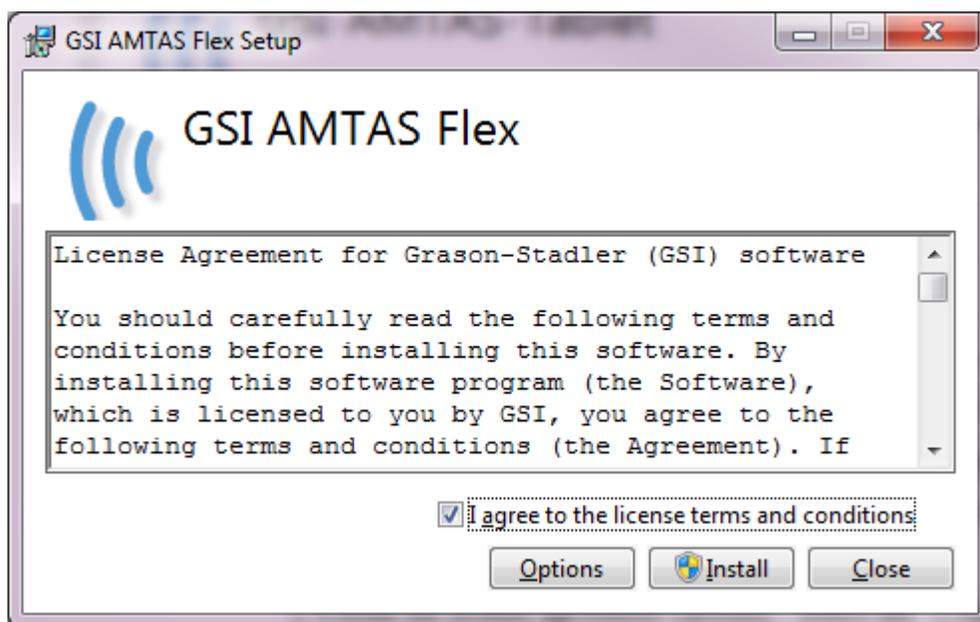
### Initiating GSI AMTAS Flex

Insert the Software USB drive into a USB port on the PC. Browse the USB drive and double click on the *Setup\_GSI\_AMTAS\_Flex.exe* file.

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**NOTE:** In order to install this application, the user must either be an Administrator or know the Administrator password.

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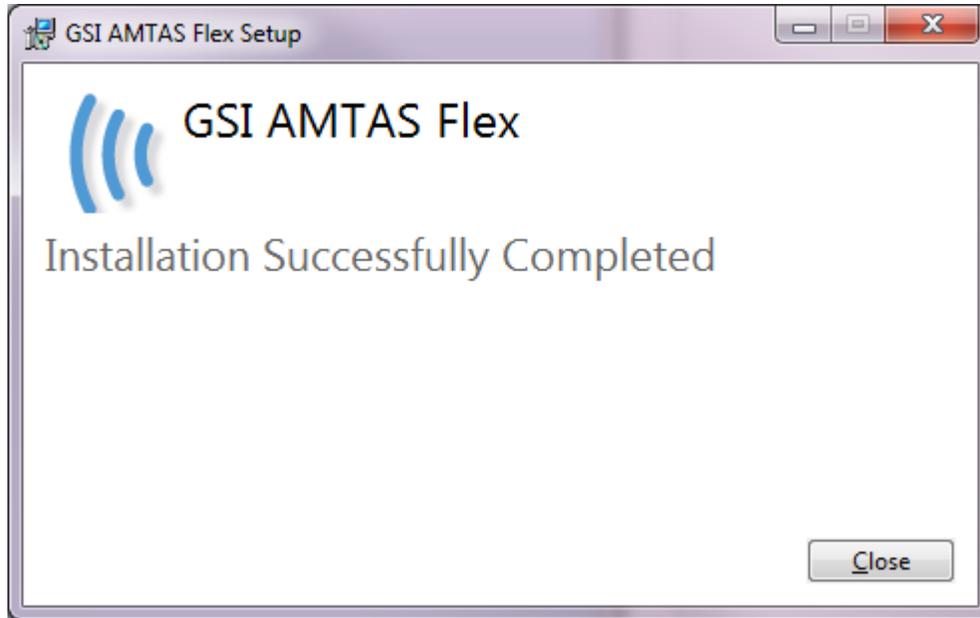


1. Read the license agreement carefully. Select the “I Agree” check box to accept the agreement and press “Install” to continue or select “Close” to avoid acceptance of the license agreement and exit Setup.
2. Windows may present a User Account Control dialog that asks if you want to allow the program to make changes to the computer. Answer “Yes” to continue the installation.
3. In order to use the GSI AMTAS, it is necessary to have .NET and Adobe Reader installed on the computer. Before the GSI AMTAS application is installed, the setup will evaluate the computer for these programs. If they are not currently installed, GSI AMTAS will display a dialog box indicating that it is necessary to install these programs. Press “Install” to install the prerequisite software. This may take several minutes. Follow the on-screen instructions to complete the installation of these programs.



4. The type of security that is used with the program is setup during the installation. A security selection dialog is presented with three (3) security options. Select the appropriate security type for your facility.
  - Windows – Domain Integration Security  
When the program requires authentication, it will verify the user identity and password based on Windows authentication.
  - 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).

5. A message will be displayed to indicate that the software has been successfully installed. Press the Close button to finish. It is recommended to reboot the machine after installation.



## Uninstalling GSI AMTAS

1. Open the Windows Control Panel
2. Select Programs and features
3. Select GSI AMTAS Flex
4. Select Remove or 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



### **WARNING**

Check also 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 Flex 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 Flex 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 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 program operates in full screen, kiosk mode (no other program can be run and the desktop is not available). In order to exit the program and return the computer to the desktop, a password for the computer user is required if security has been enabled as part of the installation. A password is also required to enter the configuration from the GSI AMTAS program. GSI AMTAS checks the credentials against Windows authentication or user information set up in the GSI AMTAS Flex Config App depending on the security option selected at the time of the installation.

---

**NOTE:** The GSI AMTAS 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.

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### Launching and running GSI AMTAS

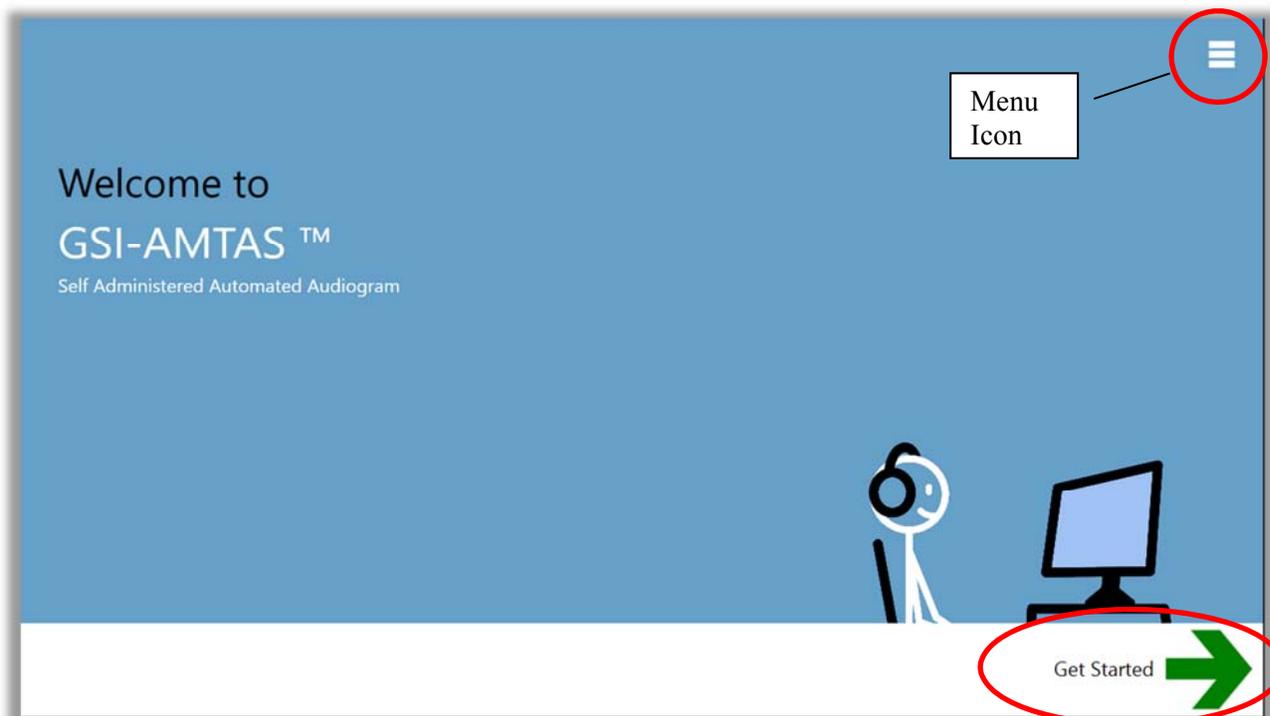


After installation of the program, a shortcut icon appears on the desktop. Double-click the desktop icon to open GSI AMTAS Flex. It is also possible to open this application from Start > All Programs > Grason-Stadler > GSI AMTAS Flex.

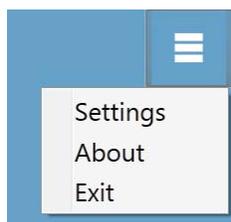
## User Interface – Screen Layout and Controls

### Opening Screen

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



### Menu



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

### Get Started Arrow

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

## Patient Information Screen

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

The screenshot displays the 'Patient Information' screen. At the top, the title 'Patient Information' is centered. Below the title is a form with the following fields: 'First Name', 'Last Name', 'ID', 'Gender' (with 'Male' and 'Female' radio buttons), and 'Birth Date' (with a date picker showing '5/1/2017' and a '15' day selector). A large green play button is centered below the form. At the bottom left of the screen is the 'gsi' logo with 'Grason-Stadler' underneath.

Once the required fields have been entered the arrow will change from black to green to indicate the test is ready to begin. Selecting the green arrow will move to the next screen and display the instructional video, if the instructions have been selected to play as part of the test setup (see the Setup and GSI AMTAS Flex Config App section of this manual for details). The test setup also determines the exams that will be performed. Available tests include diagnostic or screening air conduction thresholds.

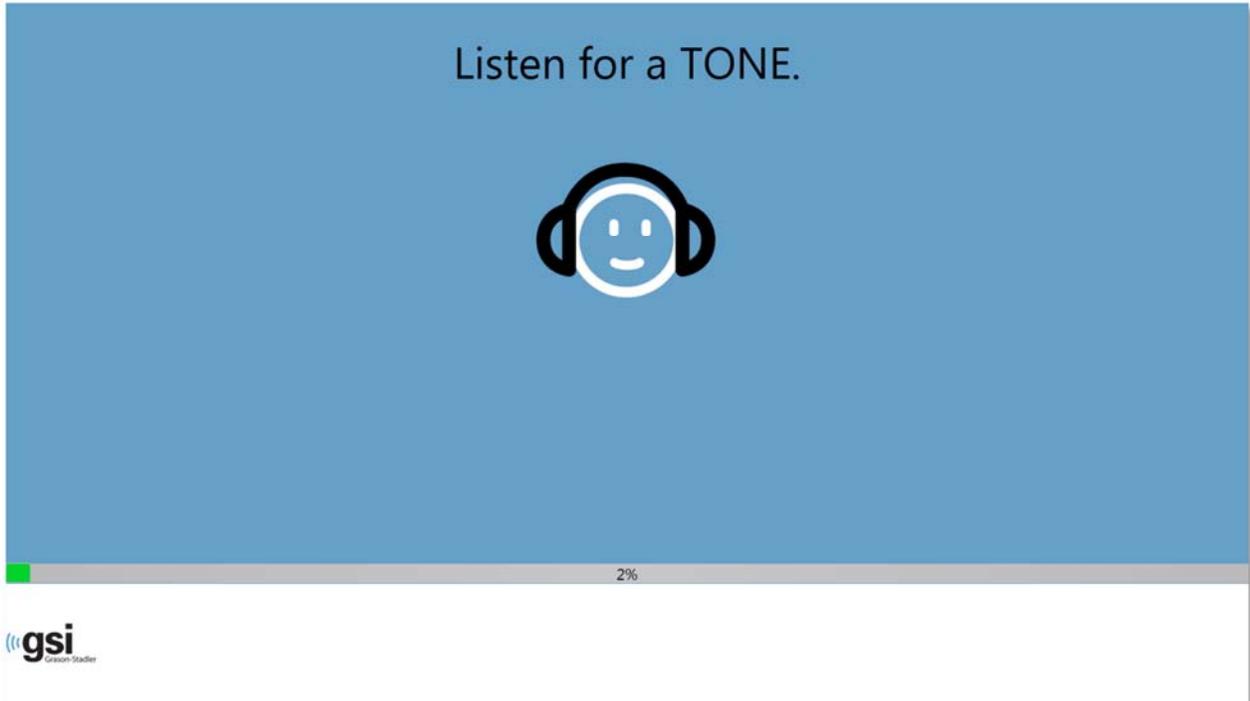
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**NOTE:** The GSI AMTAS Flex Config App provides an option to skip the patient information screen.

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## Listen for a Tone Screen

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



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

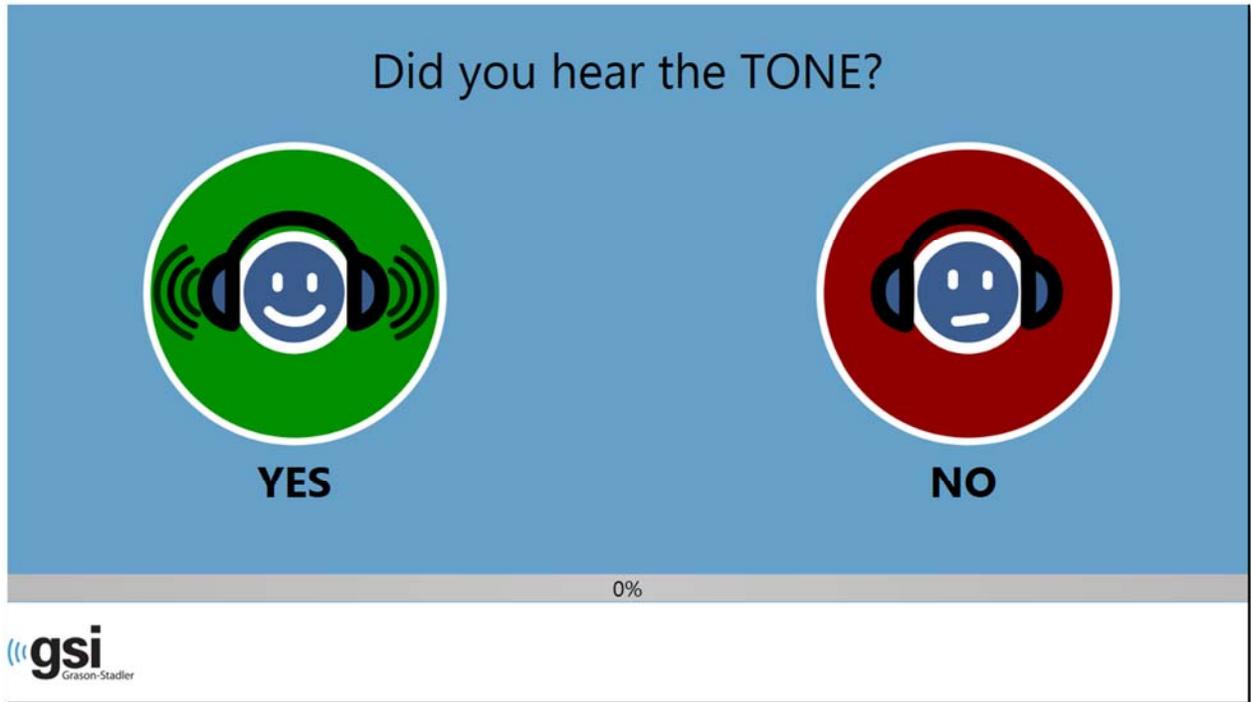
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**NOTE:** Because of the psychophysical procedure that is employed by the program, there may be times in which no stimulus is presented. In addition, if the patient does respond in a timely fashion, a warning message will be presented. The fourth non-response will result in the application ending the test and proceeding to the Finish screen.

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## Response to a Tone Screen

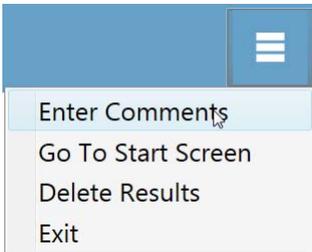
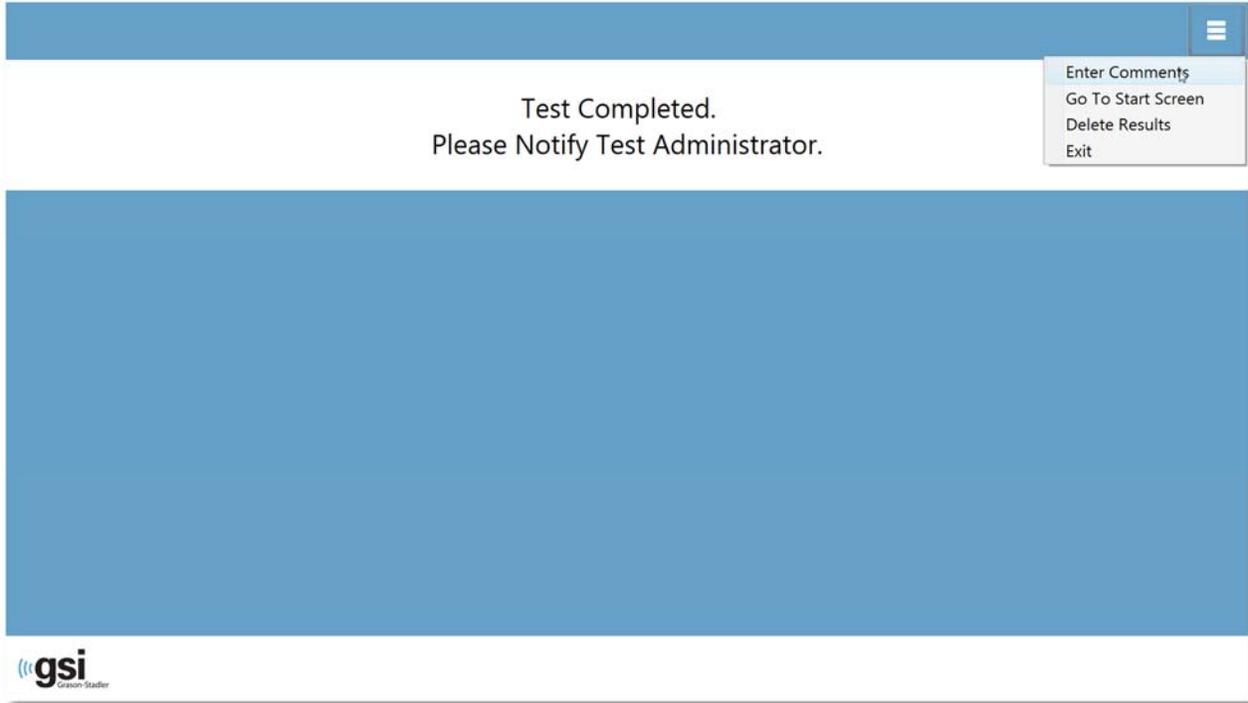
The response screen prompts the user with the question about hearing the tone and presents two icons. The patient indicates that they heard the tone by choosing the icon on the left and to indicate that they did not hear the tone by choosing the icon on the right.



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

When the tests have been completed, the screen that is displayed depends on the setting in the configuration. The program may display a report of the completed test or notify the user and wait at the “Test Completed” screen. Depending on the settings in the test configuration, there may be a menu at the top right of the screen. If any item in the sub menu is selected, a prompt for a password will appear if security has been enabled.



### Enter Comments

The “Enter Comments” sub menu item provides an option for the entry of free text. A dialog is presented for the user to enter the comments. This text is stored with the test results and printed as part of the report.

### Go To Start Screen

The “Go To Start Screen” option returns the program to the Opening Screen ready to start the next test.

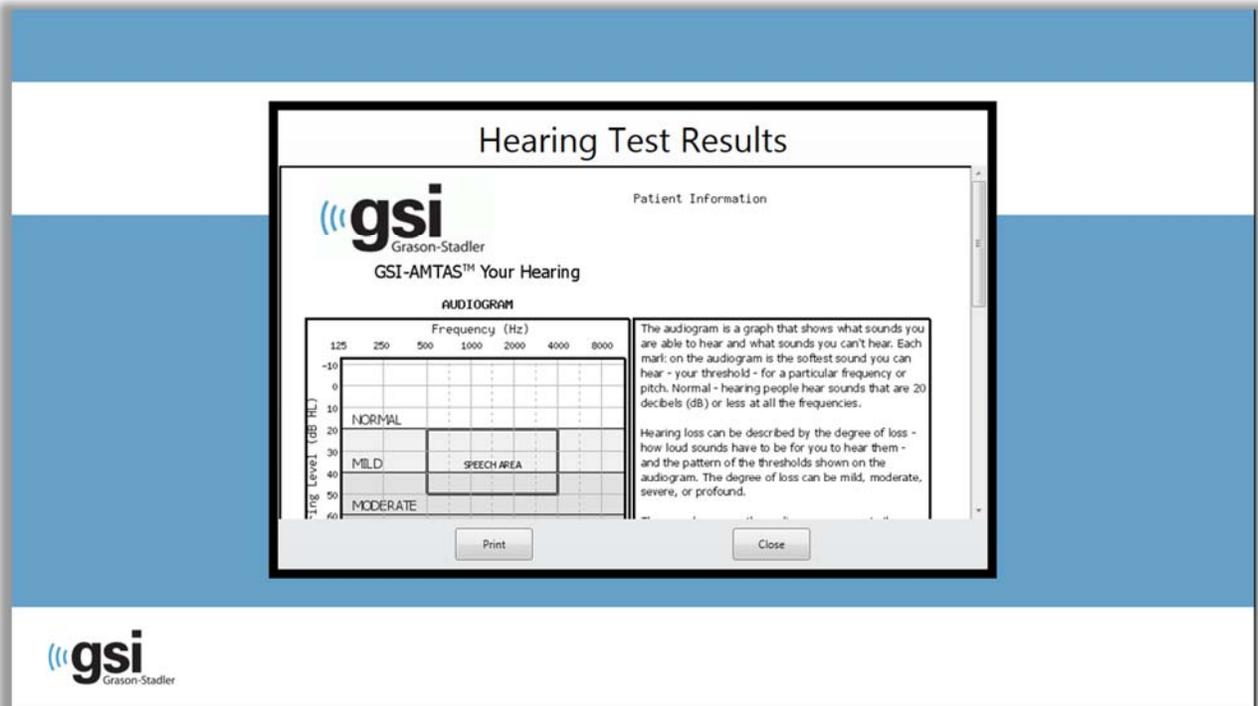
### Delete Results

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

### Exit

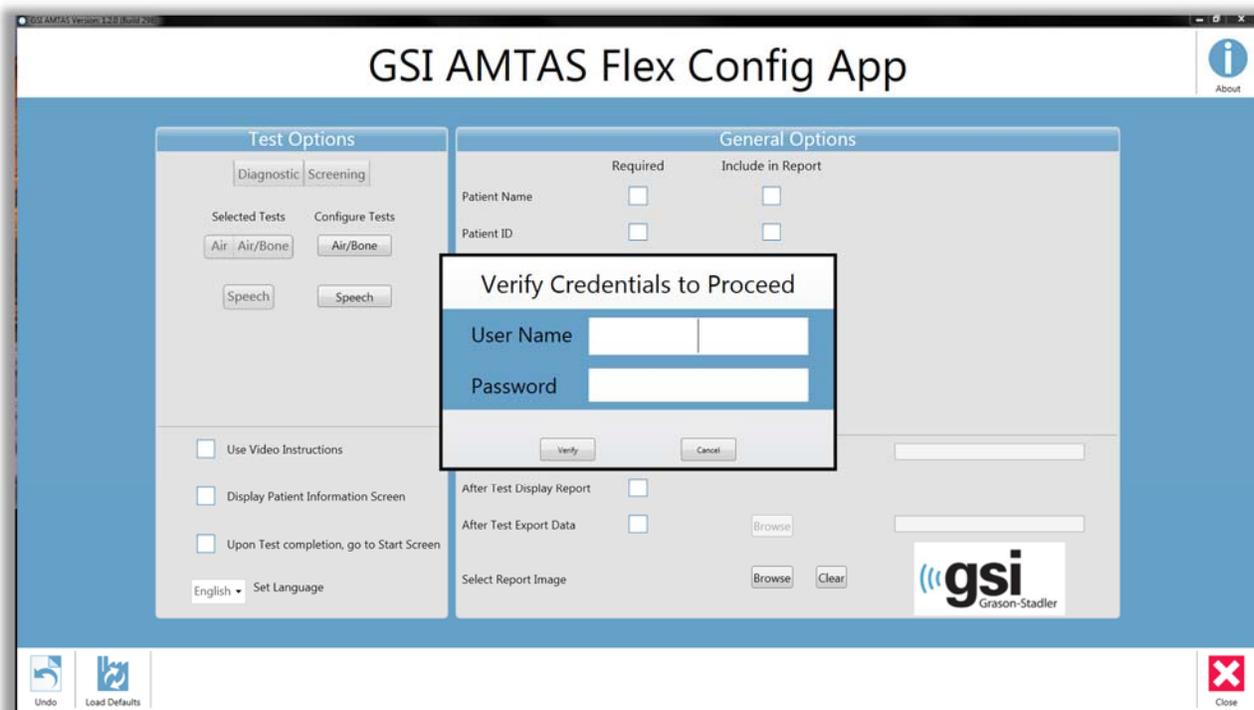
The exit option closes the program and returns the user to the PC desktop.

When the configuration is set to display the report, a window is presented with the report and an option to print the report.



## Settings and GSI AMTAS Flex Config App

The Settings option from the menu on the Opening 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. In order to configure users, the program must be in the Windows security mode and “Run as administrator” must be selected (right clicking on the desktop shortcut offers this option).



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

---

**NOTE:** There is a difference in the persistence of the changes made to the options that depends on how the Settings/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.

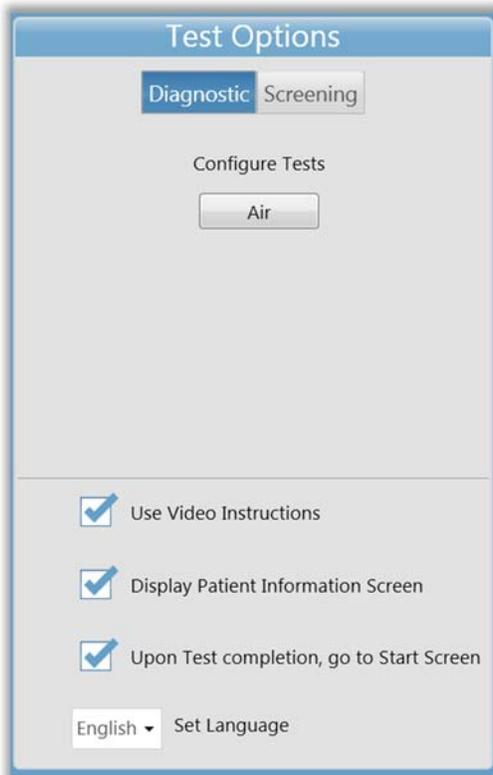
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The main Config App screen contains two main sections and a menu bar at the bottom. The sections are for General Options used in the program and the Test Options that are specific for the tests that will be conducted. The About icon in the top right of the screen displays information regarding the software version and patent and copyright information. The About dialog has an Export Log button 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.

## Test Options

The Test Options section controls the type of testing that will be performed by the program.



### Diagnostic/Screening Option

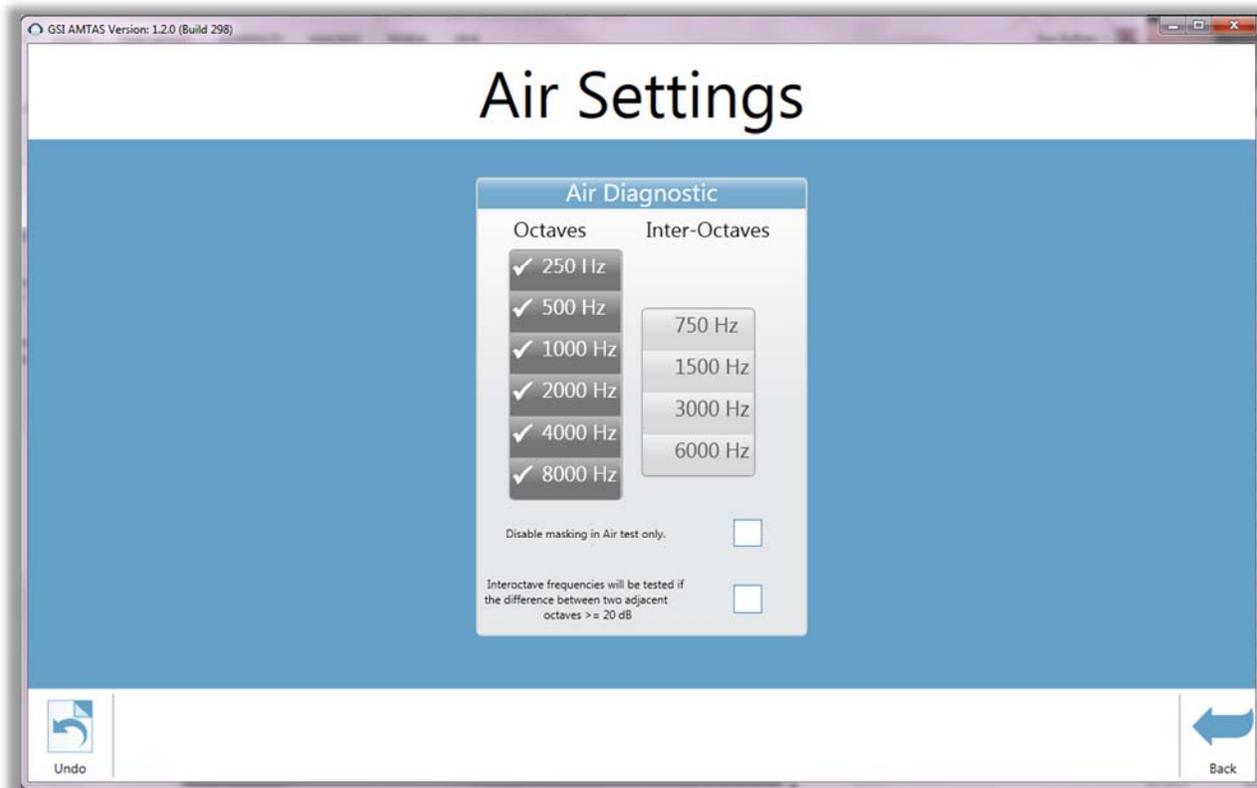
The Diagnostic and Screening buttons control the type of pure tone testing that will be performed. The Diagnostic option is used to identify hearing threshold levels of the patient. The Screening option presents the pure tones at a fixed level (upper limits of normal hearing) and records the results as pass/fail for the frequencies that are tested. The parameters that are used for the testing are set in the Configure Tests, Air option.

### Configure Tests – Air

When the Configure Tests Air button is selected, a new screen is presented with the options for performing the pure tone test. The display and the parameters that may be configured depend on the test type; diagnostic or screening.

### Diagnostic Configure Tests – Air

When the Configure Air button is selected and the Diagnostic test type is selected, a new screen is presented with the options for performing the pure tone diagnostic threshold tests.

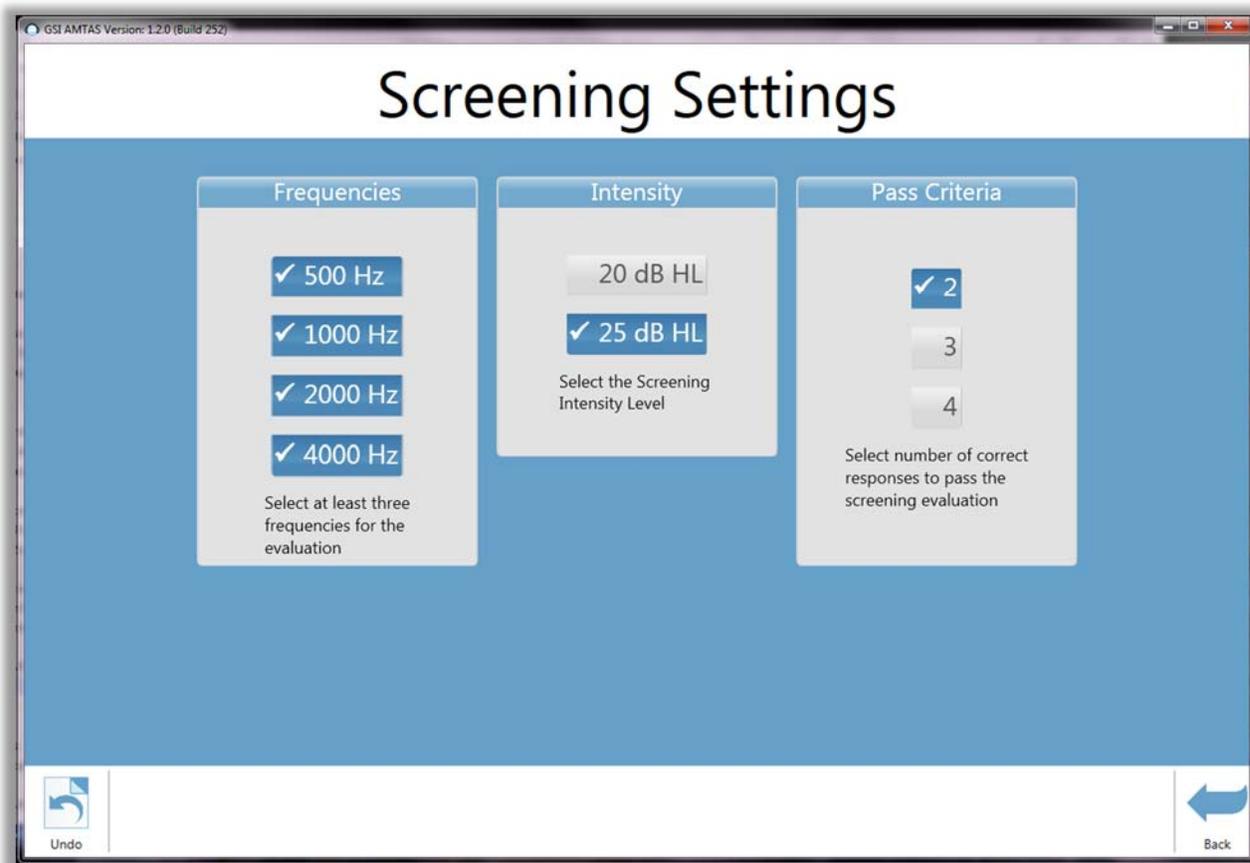


The Air Diagnostic section shows the octave frequencies that will be tested. The octave frequencies are always tested and not configurable. The inter-octave frequencies may be configured by selecting the desired frequency – a check mark will be displayed to indicate that the frequency has been selected for testing. The check box at the bottom of the section allows the user to select when the inter-octaves are tested. When the box is checked, the selected inter-octave frequencies are only tested when the difference between the adjacent octaves are 20 dB or greater. If the box is not checked, the selected inter-octave frequencies will always be tested. The Disable Masking check box allows you to turn off the masking to the opposite ear during the test. Normally masking is presented in the opposite ear.

The menu bar at the bottom of the window has two options; Undo and Back. The Undo button reloads the settings that were enabled when the screen was presented. This allows you to revert back to the previous settings. The Back button saves the settings and closes the window returning to the main window.

### Screening Configure Tests – Screening

When the Configure Tests button is selected and the Screening test type is selected, a new screen is presented with the options for performing the pure tone screening tests.



There are three sections in the screening settings that control the parameters used for the screening test. The Frequencies section controls the pure tone frequencies (500, 1000, 2000 and 4000 Hz) that are presented in the test. Three of the four frequencies are required in order to perform the test. The Intensity section determines if the output level for the test is at 20 or 25 dB HL. The Pass Criteria section determines the number of presented frequencies where a response is required in order to pass the screening test. The menu bar at the bottom has the options to undo any changes (and retain the previous setting) or go Back to the previous screen (settings are saved).

### **Use Video Instructions**

The Use Video Instructions check box determines if the video instructions for the test are presented. If the box is checked, instructions describing the pure tone test is presented prior to the test beginning.

### **Display Patient Information Screen**

The Display Patient Information Screen check box determines if the patient demographic dialog is presented. If the box is checked, there is a dialog that prompts for the patient information. If the box is unchecked, a patient information dialog is not presented prior to the test beginning.

### **Upon Test completion, go to Start Screen**

The Upon Test completion, go to Start Screen check box determines if upon completion of the test, the program returns to the Start screen or remains at the Finished test screen. If this option is checked, the program proceeds to the Test start 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 or exit the program. When an option is selected from the menu, the program prompts for a password in order to proceed with the menu choice if security is enabled. If comments are entered, these comments are stored as part of the test results report.

### **Set Language**

The currently selected language of the GSI AMTAS Flex Config App is shown in the text box. When the arrow on the right side of the text box is selected, a dropdown menu is displayed containing the options for the language of the GSI AMTAS Flex Config App program.

## General Options

The General Options top section determines the required fields for the patient information entry. This section also determines the fields that are included in the report.

General Options			
	Required	Include in Report	
Patient Name	<input type="checkbox"/>	<input type="checkbox"/>	
Patient ID	<input type="checkbox"/>	<input type="checkbox"/>	
Patient DOB	<input type="checkbox"/>	<input type="checkbox"/>	
Patient Gender	<input type="checkbox"/>	<input type="checkbox"/>	
Date Time		<input type="checkbox"/>	
Generate PDF Report	<input checked="" type="checkbox"/>	<input type="button" value="Browse"/>	C:\ProgramData\Grason-Stadler\GSI-AMTAS\Re
After Test Display Report	<input type="checkbox"/>		
After Test Export Data	<input type="checkbox"/>	<input type="button" value="Browse"/>	C:\ProgramData\Grason-Stadler\GSI-AMTAS\
Select Report Image		<input type="button" value="Browse"/> <input type="button" value="Clear"/>	

The “Generate PDF Report” check box determines if the reports are generated after the test is completed. The location where the reports are stored may be set by using the Browse button to navigate to the location where the reports will be stored. The “After Test Display Report” check box determines, if upon completion of the test, the patient report is presented. If the patient report is presented, a dialog is displayed with the report and an option to print the report is available. The “After Test Export Data” determines if the data is automatically exported after the test has been completed. The location where data is exported is specified by using the Browse button to navigate to the location. The data is exported in an XML format. The “Select Report Image” section allows you to select the graphic that will be used on the reports. Use the Browse button to locate and select the graphic and the Clear button to remove the graphic.

## Menu Bar

The Menu Bar at the bottom of the screen provides options to save or cancel the changes that have been made in the Test Options and General Options sections. The menu bar contains an option to import the calibration levels for the headphones, set up administrative users of the system, transfer the data, add the license information and view the reports.



### Undo

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



### Load Defaults

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



### Calibration

The Calibration File button is used to display the transducer calibration information and to import the calibration file for the headphones. The calibration file is needed if the PC or tablet was not purchased from a GSI distributor and is required for the correct headphone calibration. The calibration file is specific to an individual pair of headphones.



### Security

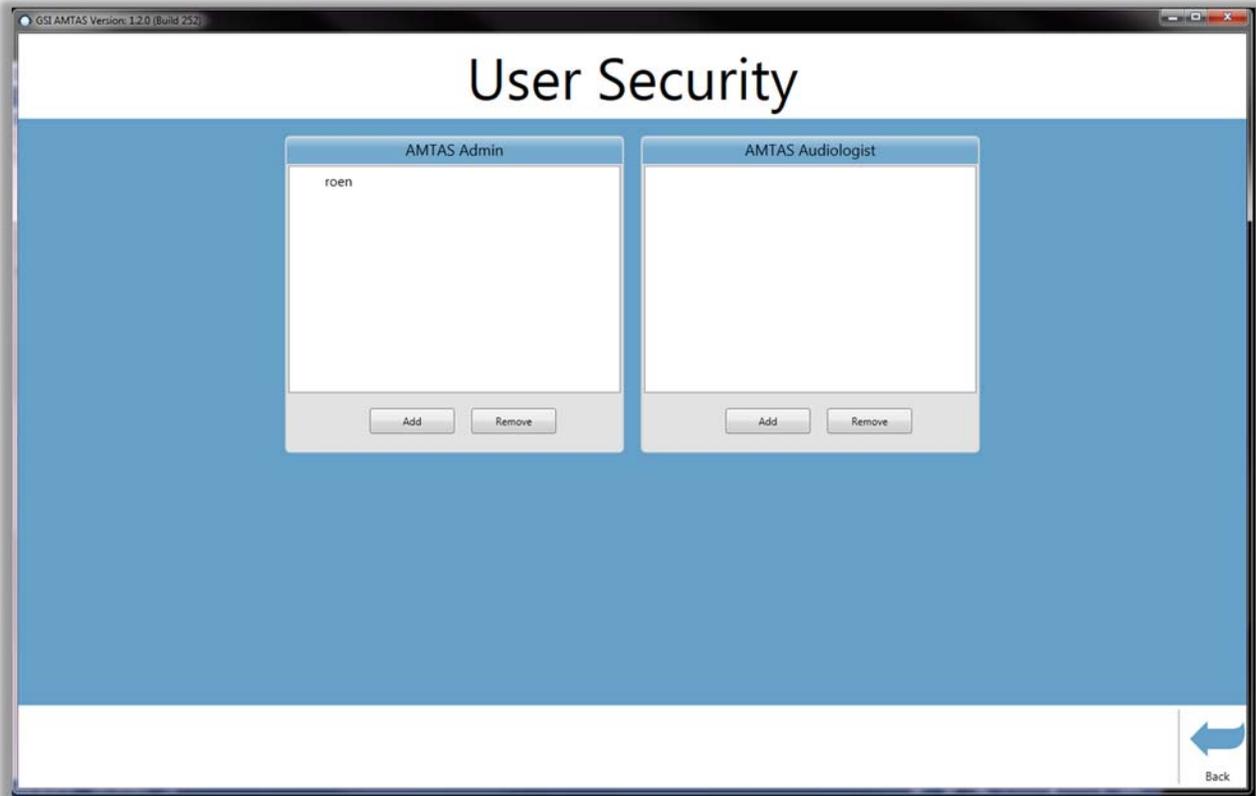
The Security button on the menu bar allows you to configure the users of the GSI AMTAS program. This button will only appear if security has been enabled at the time of installation. There are two types of security options available in GSI AMTAS; Windows and Single Password. The single password security has a single user "admin" and a password for the user that may be changed using the security button.



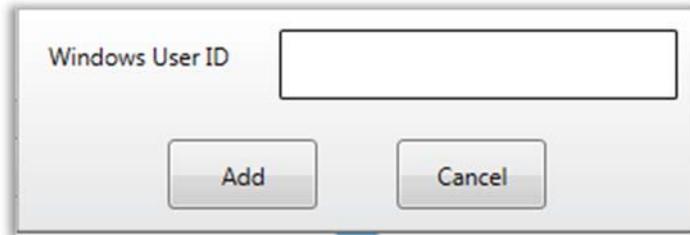
To change the password you must enter the old password, then enter the new password and a confirmation of the new password. Press the finish button to save the new password, then the Back button to return to the main screen.

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

The AMTAS Windows Security screen contains two sections; Admin and Audiologist user that correspond to the types of users defined in GSI AMTAS.



For each user type section there are buttons to add and remove users. To add a new admin or user press the add button and the add dialog is presented.



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

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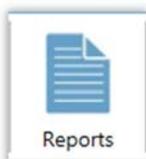
**NOTE:** GSI AMTAS uses Windows authentication for the user IDs and passwords. The user names entered in the GSI AMTAS setup should be the same as those used for the computer login. When a new user is added, the program will authenticate the user and indicate a successful authentication by placing the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

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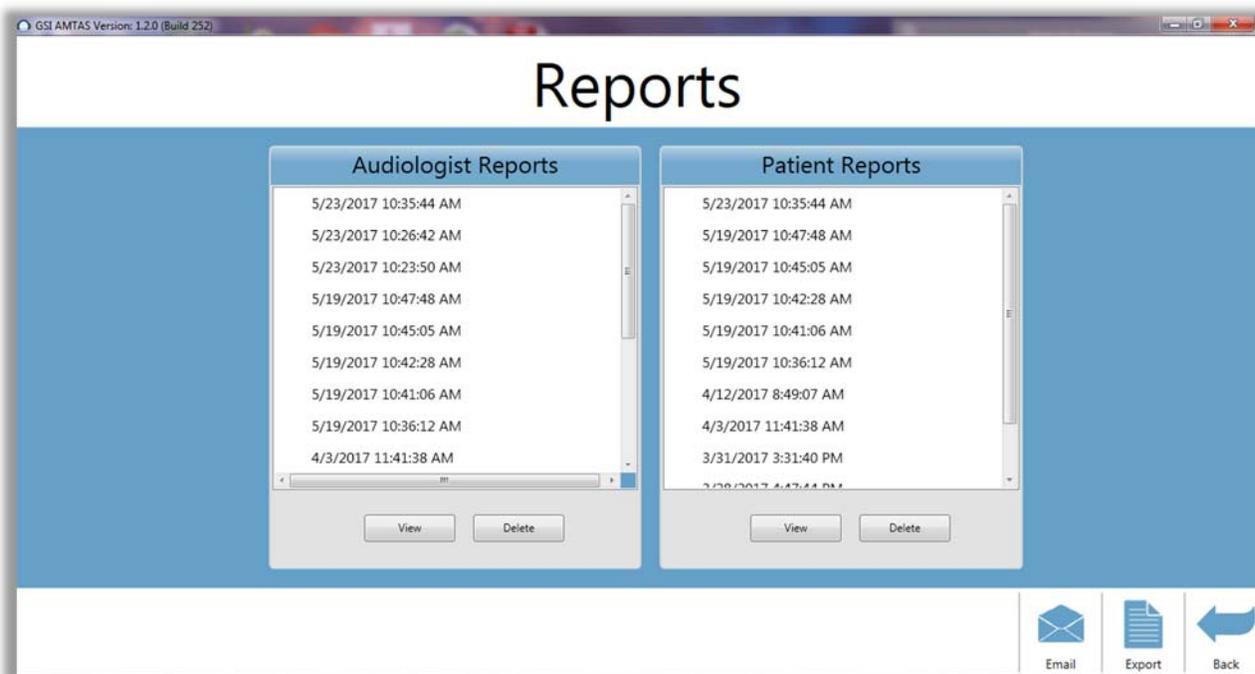
### Licensing

The Licensing button provides management of the AMTAS license. In order to run GSI AMTAS Flex, a software license is required. This license provided and installed with the Tablet/PC if the computer was purchased from GSI. If the Tablet/PC was not purchased from GSI the key is obtained from the GSI distributor. To obtain a key, the hardware license key should be exported or emailed to the GSI distributor. The distributor will provide a new key that is then imported. The license button displays a dialog that has the hardware license key and options to export, import or email the license key.



### Reports

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



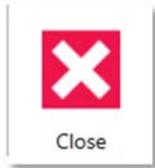
The menu bar at the bottom of the screen has buttons that are used to send the report to an email address or to export the report to another location. Sending a report by email requires that an email client is installed on the PC. When the Email button is selected, the default email client displays its send dialog where you enter

the email address, subject line and any message. When the Export button is pressed, the program displays a dialog to allow the selection of a location to send the report file. The reports and the exports file are pdf formatted files. The Back button returns to the previous screen.



**Start Test**

The Start Test icon saves any changes that have been made in the configuration and starts the GSI AMTAS testing. The GSI AMTAS Flex Config App is closed and the main GSI AMTAS screen is presented.



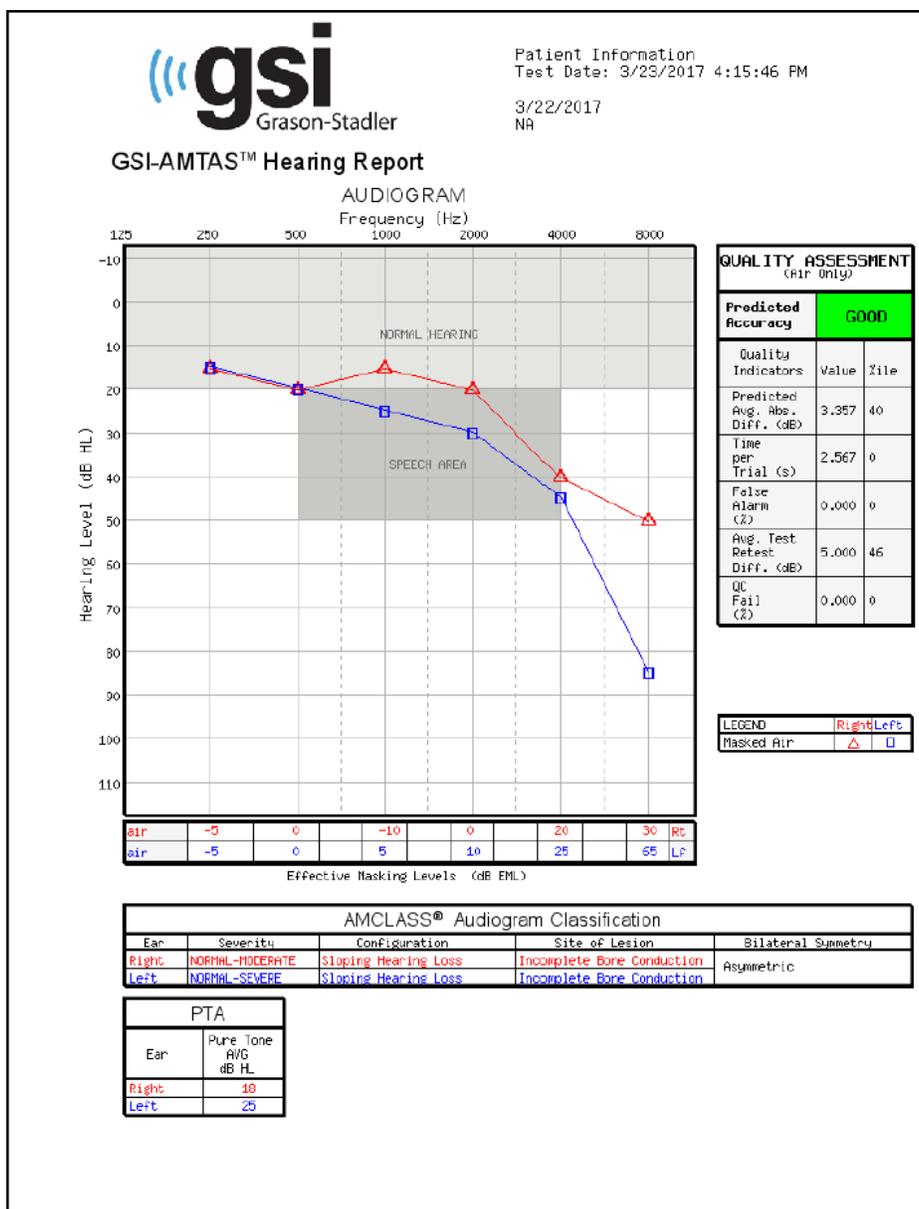
**Close**

The Close icon saves any changes that have been made in the configuration and closes the GSI AMTAS Flex Config App program.

# GSI AMTAS Reports

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

## Audiometric Report



The report is automatically generated at the completion of the test and is accessed from the GSI AMTAS 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 Table
- Comments

### **Patient Information**

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

### **Audiogram**

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

### **Masking Level Table**

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

### **Quality Assessment Table**

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

#### *Predicted Accuracy*

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

#### *Predicted Average Absolute Difference*

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

#### *Time per Trial*

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

#### *False Alarm Rate*

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

#### *Average Test-Retest Difference*

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

*Quality Check Fail Rate*

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

**Audiogram Classification Table**

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

*Configuration*

Describes the shape of the hearing loss with one of the following descriptors:

- Normal Hearing
- Flat Hearing Loss
- Sloping Hearing Loss
- Rising Hearing Loss
- Trough-shaped Hearing Loss
- Peaked Hearing Loss
- Other

*Severity*

Describes the degree of hearing loss with one or a combination of the following descriptors:

- Normal
- Mild
- Moderate
- Severe
- Profound

*Site of Lesion*

Describes the type of hearing loss with one or a combination of the following descriptors:

- Conductive
- Sensorineural
- Mixed

For the GSI AMTAS Flex this will be labeled as “Incomplete Bone Conduction” since bone conduction is required in order to determine the site of lesion

*Bilateral Symmetry*

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

**Pure Tone Average Table**

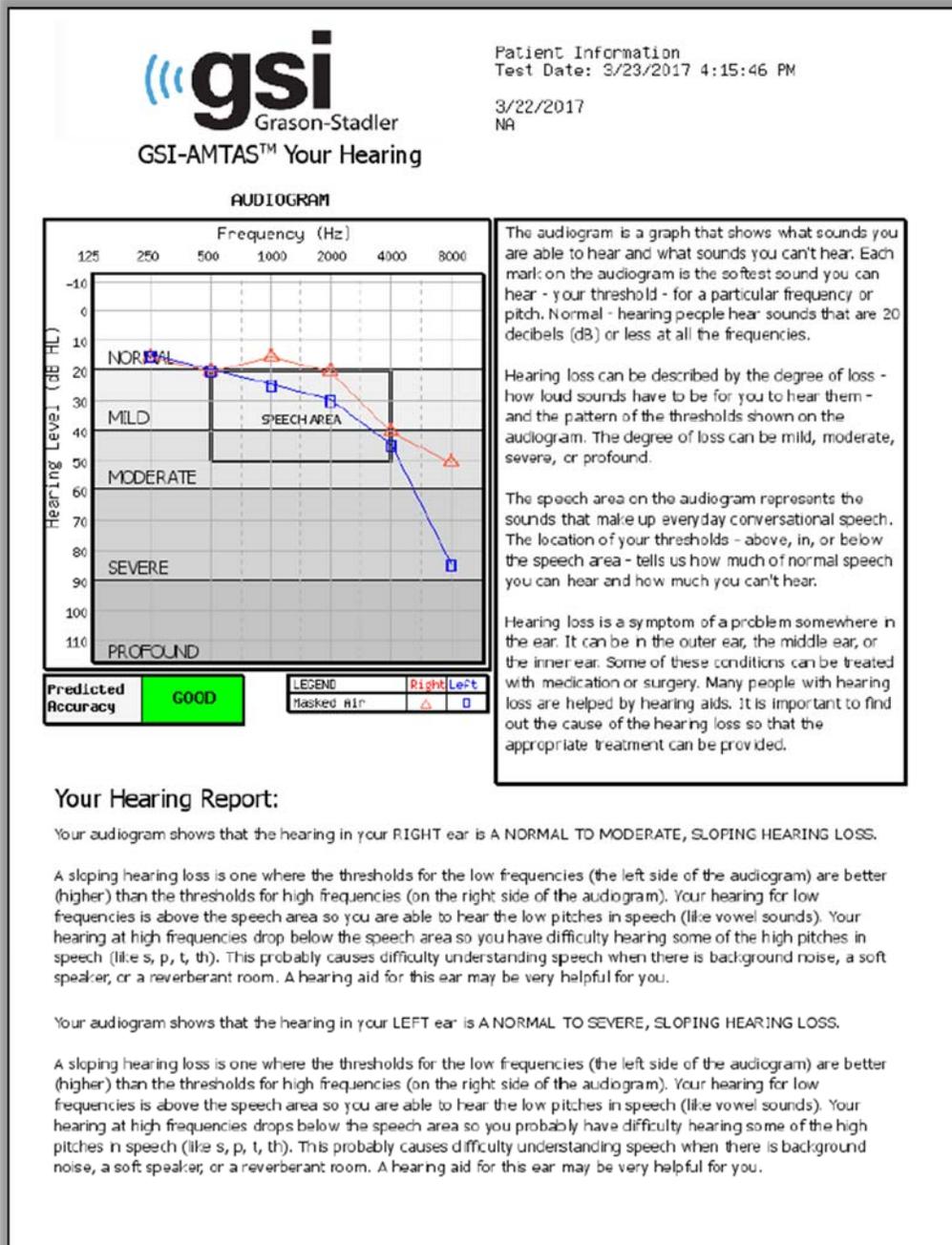
The pure tone average is the average air conduction threshold at 500, 1000 and 2000 Hz for a given ear. When there is a difference of  $\geq 20$  dB between any two frequencies the pure tone average is the average of the better two thresholds.

**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 Config App.

## Patient Report

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



## 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 come in contact with 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 considered to be 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

### **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 instructed.

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

When a tone 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 instructed 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 with Windows security uses Windows authentication for the user IDs and passwords. The user names entered in the GSI AMTAS setup should be the same as those used for the computer login. 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 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 program can be accessed.

### **The username or password was incorrect.**

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

## 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

Level Range: 10 dB to 80 dB HL

Masking: Narrow band 250 Hz to 8000 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: Sennheiser HD 280 Pro

### Headphone HD 280 PRO

Acoustic principle: dynamic, closed

Impedance: 64  $\Omega$

Ear coupling: circumaural

Frequency response: 8 - 25,000 Hz

Ambient noise attenuation:  $\leq 32$  dB

THD:  $< 0.1\%$  (@ 1 kHz, 100 dB SPL)

Weight: (w/o cable) approx. 285 g

Contact pressure: approx. 6 N

Length of coiled cable:  $\geq 1.3$  m /  $\leq 3$  m

Operating temperature:  $-10$  °C to  $+55$  °C

Storage temperature:  $-20$  °C to  $+70$  °C

Relative humidity:  $\leq 90\%$  @  $40$  °C

## 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

Transducer	HD 280 Pro
Impedance	64 Ω
Coupler	318-1
	RETSPL
125 Hz	37.2
250 Hz	13.5
500 Hz	6.8
750 Hz	1.8
1000 Hz	1.4
1500 Hz	3.7
2000 Hz	1.9
3000 Hz	-3.9
4000 Hz	2.2
6000 Hz	13.9
8000 Hz	22.8

Artificial ear uses IEC60318-1 coupler with type 1 adaptor and RETSPL comes from ANSI S3.6 2010 and ISO 389-8 2004. Force 9N ±0.5N

HD280 Pro RETSPL from “Audiometric Properties of Three Circumaural Earphones”  
 Brandon M. Madsen and Robert H. Margolis. 2014 American Academy of Audiology  
 Poster Presentation

## Narrow Band Noise

Frequency (Hz)	RETSPL (pure tone + correction)	Correction factor from IEC Std
125	41.2	4
250	17.5	4
500	10.8	4
750	6.8	5
1000	7.4	6
1500	9.7	6
2000	7.9	6
3000	2.1	6
4000	7.2	5
6000	18.9	5
8000	27.8	5

# GSI AMTAS Testing Protocol

## Psychophysical Method

GSI 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. 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 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 overmasking or undermasking 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, 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, 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.

## Config App Default Settings

### Test Options

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

### General Options

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

### Air/Bone Settings

#### Air Diagnostic

- Octave frequencies: All tested (not configurable)
- Inter-Octaves: Not tested
- Inter-Octave testing if  $\geq 20$  dB between octaves: No

### Screening Settings

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

## AMTAS Publications and Patents

### AMTAS PUBLICATIONS

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4. Margolis, R.H., Saly, G.S. Toward a standard description of hearing loss. Int. J. Audiology 46, 746-758, 2007.
5. Margolis, R.H., Morgan, D.E. The Value of Automated Audiometry. Insights in Practice for Clinical Audiology, January 2008.
6. Margolis, R.H., Saly, G.L. Prevalence of hearing loss types in a clinical population. Ear and Hearing, 29, 524-532, 2008.
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8. Margolis, R.H., Saly, G.L. Asymmetrical Hearing Loss: Definition, Validation, Prevalence. Otolology & Neurotology, 29, 422-431, 2008.
9. 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.
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11. Margolis, R.H., Frisina, R., Walton, J.P. (2011). Automated method for testing auditory sensitivity: II. Air Conduction Audiograms in Children and Adults. *Int J Audiology*, 50, 434-439, 2011.
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13. 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.

### AMTAS PATENTS

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

## 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, with the exception of 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.

### Warning



- 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 is in compliance 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 with regard to EMC can be found in the general maintenance section in this instruction. No further steps required.

## Electrical Safety, EMC and Associated Standards

1. ES 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety
2. IEC/EN 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety
3. CAN/CSA-C22.2 No. 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety Electrical Equipment for Laboratory Use
4. IEC/EN 60601-1-1: Collateral Standard, Safety Requirements for Medical Electrical Systems
5. IEC/EN 60601-1-2: Medical Electrical Equipment, Part 1 - Electromagnetic Compatibility - Requirements and Tests
6. Essential Requirements of the current European Union Medical Device Directive 93/42/EEC
7. RoHS (Restriction of the use of certain Hazardous Substance)
8. WEEE (Waste Electrical & Electronic Equipment) Legislation

<b>Guidance and Manufacturer's Declaration Electromagnetic Emissions</b>		
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.  The GSI AMTAS Flex is suitable for use in all commercial, industrial, business, hospital, and residential environments.
RF Emissions CISPR 11	Class B Limits	
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 $d = 2.23\sqrt{P}$
<b>0.01</b>	0.12	0.12	0.23
<b>0.1</b>	0.37	0.37	0.74
<b>1</b>	1.17	1.17	2.33
<b>10</b>	3.70	3.70	7.37
<b>100</b>	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
<b>Electrostatic Discharge (ESD)</b>  <b>IEC 61000-4-2</b>	±6 kV contact  ±8 kV air	±6 kV contact  ±8 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%.
<b>Electrical Fast Transient/Burst</b>  <b>IEC 61000-4-4</b>	±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.
<b>Surge</b>  <b>IEC 61000-4-5</b>	±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.
<b>Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Lines</b>  <b>IEC 61000-4-11</b>	<5% <b>UT</b> (>95% dip in <b>UT</b> ) for 0.5 cycle <b>40% UT</b> (60% dip in <b>UT</b> ) for 5 cycles <b>70% UT</b>	<5% <b>UT</b> (>95% dip in <b>UT</b> ) for 0.5 cycle <b>40% UT</b> (60% dip in <b>UT</b> ) for 5 cycles <b>70% UT</b>	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,

	(30% dip in <i>UT</i> ) for 25 cycles <b>5% <i>UT</i></b> (>95% dip in <i>UT</i> ) for 5 sec	(30% dip in <i>UT</i> ) for 25 cycles <b>5% <i>UT</i></b> (>95% dip in <i>UT</i> ) for 5 sec	it is recommended that the GSI AMTAS Flex be powered from an uninterrupted power supply.
<b>Power Frequency (50/60 Hz)</b>  <b>IEC 61000-4-8</b>	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.

### 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 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	<p>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.</p> <p>Recommended separation distance</p> $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 1.17\sqrt{P} \text{ 800 MHz to 2.5 GHz}$ <p>where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> 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:</p> 

**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
HD280 Pro Audiometric Headset	Sennheiser	HD280 Pro

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	2.5m	Unscreened
HD280 Pro Audiometric Headset	2.0m	Screened