TECHNICAL MANUAL

AuthentiMax[™] Software for GloMax[®]-Multi+

Instructions for use of Product **E8946**

Promega



TM403 Revised 9/13



AuthentiMaxTM Software for GloMax[®]-Multi+

All technical literature is available on the Internet at: www.promega.com/resources/protocols/ Please visit the web site to verify that you are using the most current version of this Technical Manual. Please contact Promega Technical Services if you have questions on the use of this product. Email: techserv@promega.com

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1. Introduction

1.A. Overview

AuthentiMaxTM Software for GloMax[®]-Multi+ is a Microsoft Windows[®]-based software that supports user authentication and document integrity, and creates an audit trail while applying electronic signatures to electronic records. AuthentiMaxTM Software for GloMax[®]-Multi+ does not change the data produced by the GloMax[®]-Multi+ instrument.

It is the responsibility of the user and his/her organization to ensure that the various functionalities provided by AuthentiMaxTM Software for GloMax[®]-Multi+ are used appropriately to achieve compliant operation of the system. AuthentiMaxTM Software for GloMax[®]-Multi+ can be operated only via a PC.

1.B. Product Components

| Product | Cat.# |
|--|-------|
| AuthentiMax™ Software for GloMax®-Multi+ | E8946 |

For Research Use Only. Not for Use in Diagnostic Procedures. Includes:

- CD containing AuthentiMax[™] Software for GloMax[®]-Multi+ (version 1.0.0), Technical Manual #TM358 and .NET Framework 2.0
- USB Cable

1.C. Inspection

Ensure that all the components listed in Section 1.B are included in your shipment. If any of the components are missing, contact Promega Technical Services (Tel: 800-356-9526 or email: techserv@promega.com).

1.D. Terminology

- Standard Operating Procedure (SOP): A written document or instruction detailing all steps and activities of a process or procedure.
- Electronic Signature: A computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.
- GMMP/GMM+: GloMax[®]-Multi+.
- **Checksum:** A special algorithm that generates a unique sequence of characters based on file content. Checksum warns users if file content has been modified or tampered with.
- GloMaxUser: Any user of the GloMax[®]-Multi+ with AuthentiMax[™] Software.
- GloMaxSuperUser: A user with administrative permissions within AuthentiMax[™] Software for GloMax[®]-Multi+. (A GloMaxUser with administrative permissions on the PC is effectively a GloMaxSuperUser.)



2. General Information

2.A. Connection to a PC

- AuthentiMax[™] Software for GloMax[®]-Multi+ must be installed on an external PC before connecting the instrument to the PC. Refer to Section 3.A of this manual for installation instructions. Note: Other GloMax[®] software, such as Instinct[™] Software and the External PC Connect Kit, does not have to be uninstalled before installing AuthentiMax[™] Software for GloMax[®]-Multi+.
- 2. When an external PC has control of the instrument, the GloMax[®]-Multi+ Detection System touch screen is disabled and the results files are stored directly on the hard drive of a PC. Note: When using the AuthentiMax[™] Software for GloMax[®]-Multi+, the files will only be saved on the external PC; files will not be saved on the instrument.
- 3. AuthentiMax[™] Software for GloMax[®]-Multi+ can be operated **only** via an external PC. Connecting directly to a Macintosh[®] computer is not currently supported.

2.B. System Requirements

- Windows®-based computer with a 32-bit operating system and Windows® 7 Professional. **Note:** To ensure that AuthentiMax[™] Software works as designed, the computer should be operating in English (United States) mode. AuthentiMax[™] Software has not been validated with any other Windows operating system. If you have questions about Windows® operating system, please contact Promega Technical Services (Tel: 800-356-9526 or email: techserv@promega.com).
- Microsoft .NET Framework, version 2.0 (see Section 2.D).
- USB cable (supplied).

2.C. File Locations

The files generated from AuthentiMax[™] Software for GloMax[®]-Multi+ are saved on the hard drive of the connected external PC. The files can be found in the following locations by default for users with Windows[®] 7 Professional edition. **Note:** The actual location may differ depending on the Windows[®] operating system used.

Data files: C:\ProgramData\Promega\AuthentiMax\Results\

Custom Protocol files: C:\ProgramData\Promega\AuthentiMax\Custom Protocols\

Preset Protocol files: <Installation Path>\Protocols

By default C:\Program Files\Promega\AuthentiMax Software for GloMax Multi+\

Audit Trail Logs: C:\ProgramData\Promega\AuthentiMax\AuditTrail

Event Logs: C:\ProgramData\Promega\AuthentiMax\Logs



2.D. Installing Microsoft .Net Framework (version 2.0)

The following steps are necessary only if Microsoft .Net Framework software is not already installed on the computer. Please check with your IT administrator if you are not sure whether Microsoft .Net Framework software has been installed. If Microsoft .Net Framework has not been installed, choose one of the options below to install.

- 1. Microsoft.Net Framework is supplied on the AuthentiMax[™] Software CD. Double-click on the "dotnetfx.exe" file on the AuthentiMax[™] Software CD to install.
- 2. Download Microsoft.Net Framework from the web site: www.microsoft.com/downloads/

2.E. Features Not Supported by AuthentiMax[™] Software

AuthentiMaxTM Software does not support InstinctTM Software and associated InstinctTM Software features. If you have InstinctTM Software, you will need to close the InstinctTM application in order to use AuthentiMaxTM Software. The InstinctTM Software does not need to be uninstalled. Features not supported by AuthentiMaxTM Software are listed below:

- Ability to select multiple results/protocols for deleting/saving on USB.
- Ability to export/transfer protocols created using AuthentiMax[™] Software from PC to the GloMax[®]-Multi+ Instrument.
- Looping ability in protocol scripts.
- Ability to reorder protocols in protocol composer.
- Protocols requiring variable shaking.
- Ability to enter custom filter values (A and B) for Absorbance.
- Kinetics with fluorescence.
- Ability to program injector speed, for protocols requiring injectors.
- Ability to enter different volumes for both the pumps in protocols using dispensing.
- The option for setting an alarm at the end of incubation and shaking.
- Entering experimental notes.
- Ability to use multiple languages/local selection. AuthentiMax[™] Software is not supported for PC language settings other than English (USA).



3. Installing AuthentiMax[™] Software for GloMax[®]-Multi+

3.A. Installation Procedure

The AuthentiMax[™] Software uses Windows[®] permission structures. Therefore, to install AuthentiMax[™] Software you must have local administrator IT permissions. If you do not have such permissions, you will need to contact your local IT specialist to assist with the software installation.

- 1. Insert the AuthentiMax[™] Software CD into the computer CD drive. Installation will be initiated automatically.
- 2. If installation is not initiated automatically, navigate to the "setup.exe" file located on the CD. Right-click on the "setup.exe" file and choose "Run as an administrator".
- 3. Follow the prompts on the installer to install the software.

Step 1: Welcome Screen.

| 😸 AuthentiMax Software for GloMax Multi + | - • • |
|---|--|
| Welcome to the AuthentiMax Software for GloM Multi + Setup Wizard | lax 🕵 |
| The installer will guide you through the steps required to install AuthentiMax Soft Multi + on your computer. | ware for GloMax |
| WARNING: This computer program is protected by copyright law and internation Unauthorized duplication or distribution of this program, or any portion of it, may r or criminal penalties, and will be prosecuted to the maximum extent possible under | al treaties. esult in severe civil er the law. |
| Cancel < <u>B</u> ack | <u>N</u> ext > |



3.A. Installation Procedure (continued)

Step 2: Select Installation Folder.

Note: Select the "Everyone" radio button to allow others to use the software from this computer unless you will be the only user.

| 🖟 AuthentiMax Software for GloMax Multi + | - • 💌 |
|--|--|
| Select Installation Folder | |
| The installer will install AuthentiMax Software for GloMax Multi + to the follow To install in this folder, click ''Next''. To install to a different folder, enter it be | ing folder. Iow or click "Browse". |
| Eolder: C:\Program Files\Promega\AuthentiMax Software for GloMax Multi +\ Install AuthentiMax Software for GloMax Multi + for yourself, or for anyone | Browse Disk Cost who uses this computer: |
| ⊚ <u>E</u> veryone ⊙ Just <u>m</u> e | |
| Cancel < <u>B</u> ack | Next > |

Step 3: Confirm Installation.



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3.A. Installation Procedure (continued)

Step 4: Installation in Progress.

| 🛃 AuthentiMax Software for GloMax Multi + | - • • |
|---|--------------------|
| Installing AuthentiMax Software for GloMax Multi + | |
| AuthentiMax Software for GloMax Multi + is being installed. | |
| Please wait | |
| Cancel < B | ack <u>N</u> ext > |

Step 4a: GloMax® User Group and Audit Trail Settings Action (NO User Intervention Required).



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3.A. Installation Procedure (continued)

Step 5: Installation Complete.



Note: If you do not have local administrator privileges you will see a window indicating that the setup folders were not successfully created.



Once the AuthentiMax[™] Software installation is complete the following two groups are automatically added to the computer: GloMaxSuperUser and GloMaxUser groups. Follow the instructions in Section 3.B. to populate the groups.



3.B. User Setup

 AuthentiMax[™] Software for GloMax[®]-Multi+ automatically creates the two user groups listed below at the time of installation. Since the software automatically creates these two groups, you will only need to populate these groups to access the AuthentiMax[™] Software. See Step 2 below for populating these groups:

GloMaxSuperUser (i.e., Administrator). GloMaxSuperUsers have the following capabilities:

- Ability to add/delete users to the GloMaxUser group
- Ability to create, modify, delete and save protocols from within the AuthentiMax™ Software
- Ability to delete result files from within the AuthentiMaxTM Software
- Ability to modify advanced instrument settings from within the AuthentiMax™ Software
- Ability to view audit trail logs

GloMaxUser. GloMaxUsers have the following capabilities:

- Ability to select and run predefined or user-defined protocols from the list of available protocols
- · Ability to activate PMT and injectors when required by the protocol

GloMaxUsers **do not** have the following:

- New Protocol button on the main screen
- Ability to create/modify/save/delete protocols from within the AuthentiMax[™] Software
- Ability to create/modify/save/delete protocol parameters from within the AuthentiMax[™] Software
- Ability to delete results from **within** the AuthentiMaxTM Software
- Ability to access advanced functionality of the instrument

2. Instructions for Setting up the GloMaxSuperUser Account

The system should be set up in accordance with Standard Operating Procedures (SOP) at the user's organization. It is the responsibility of the user's organization to control access for users.

Microsoft Windows[®] user configurations can be used to configure both GloMaxSuperUsers and GloMaxUsers.



Ensure that a user **does not** belong to both GloMaxUser and GloMaxSuperUser groups. If a user has been added to both user groups, then the GloMaxUser will have GloMaxSuperUser rights. Please follow your IT permissions procedure to ensure that this does not happen. For more information on setting permissions, visit:

www.windowsecurity.com/articles/Understanding-Windows-NTFS-Permissions.html



Add a User to the GloMaxSuperUser group as follows:

a. From the computer, navigate to Computer Management ->Local Users and Groups -> Groups->GloMaxSuperUsers. **Note:** The actual path may differ slightly depending on the Microsoft Windows[®] operating system used.

| ⊨ ⇔ <u>2</u> 📰 🗙 🗉 🕞 | 2 🗊 | | |
|--|--|--|---|
| Cle Acten Yiev Lebp Conputer Management (Local Conputer Management (Local Conputer Management Conputer Management Conputer and Groups Computer and Groups Company Comp | Annie Administrator Backup Operators Backup Operators Backup Operators Distributed COM Users Broth Configuration Operators Broth Star Brothers Operators Performance Koniter Users Performance Joy Users Rendet Desktop Users Brothers Desk | Description Administrators have complete an Beckup Operations can override ac Members with allowed to laurch, a Members are allowed to laurch, a Members are allowed to laurch, a Members in this group can read e Guids have the group can read e Members of this group can have s Members of this group can sche Members in this group can sche CoMPB Scheme Super Can fragment Members in this group can side a CoMPB Scheme Super Can fragment Members in this group can side a | Actions Groups More Actions GlobMasSupedIser More Actions |
| | | | |

b. Double-click on the GloMaxSuperUser Group.

| loiviaxsuperosei | Properties |
|------------------|--|
| General | |
| Glo M | axSuperUser |
| Description: | GMMP Software Super User Group |
| Members: | |
| | |
| | |
| | |
| | |
| | |
| | |
| Add | Changes to a user's group membership are not effective until the next time the user logs on. |

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c. Select the "Add" button, and enter the name(s) to be added in accordance with the organization's SOP.

| Select this object type: | |
|--------------------------------------|-----------------|
| Users, Service Accounts, or Group | Object Types |
| rom this location: | |
| PROMEGA COM | |
| | Locations |
| Enter the object names to select (av | nples): |
| Enter the object names to select (@ | nples): |
| Enter the object names to select (ex | pples): |
| Enter the object names to select (@ | <u>pples</u>): |

- d. Select "OK" to accept the GloMaxSuperUsers that were entered.
- e. Log out of the computer, and then log in again with appropriate credentials. This step is required to apply the changes to the software.

3. Instructions for Setting Up GloMaxUser Accounts

GloMaxSuperUsers and individuals with Local IT Administrator permission rights can add/delete users from the GloMaxUser group. Therefore, if a GloMaxUser is also a Local Administrator, they will also be able to add/delete users. Add a User to the GloMaxUser group as follows:

f. Log in to AuthentiMaxTM Software as a System Administrator.



- 3.B. User Setup (continued)
 - g. Navigate to Computer Management > Local Users and Groups > Groups > GloMaxUsers. Note: The actual path may differ slightly depending on the Microsoft Windows® operating system used.

| 🔿 🖄 📅 🗙 🖹 🔒 🛛 | ? 🖬 | | | |
|----------------------------|------------------------------------|-------------------------------------|--------------|--|
| Computer Management (Local | Name | Description | Actions | |
| Tack Scheduler | Administrators | Administrators have complete an | Groups | |
| Event Viewer | Backup Operators | Backup Operators can override se | More Actions | |
| Shared Folders | Cryptographic Operators | Members are authorized to perfor | GloMaxilizer | |
| a 🜆 Local Users and Groups | Se Distributed COM Users | Members are allowed to launch, a | Giowiaxosei | |
| Users Groups | Se Event Log Readers | Members of this group can read e | More Actions | |
| | A ne nicoc | Guests have the same access as m | | |
| Performance | Me IIS_JUSKS | Built-in group used by Internet Inf | | |
| Device Manager | Servetwork Configuration Operators | Members in this group can have s | | |
| Storage | Se Performance Log Users | Members of this group may sche | | |
| Disk Management | Deves lieses | Deves Users on this group can acces | | |
| Services and Applications | Power Osers | Members in this group are grante | | |
| | Benlicator | Supports file replication in a dom | | |
| | D Ilrar | literr are prevented from making | | |
| | ConfinMar Remote Control Liters | Members in this group can view a | | |
| | GloMarSuperLiser | GMMP Software Super User Group | | |
| | A GloMaxUser | GMMP Software User Group | | |
| | Differ Remote Assistance Helpers | Members in this group can offer | | |
| | - | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

h. Double-click on the GloMaxUser Group.

| General | |
|--------------|--|
| GloM | laxUser |
| Description: | GMMP Software User Group |
| Members: | |
| | |
| | |
| | |
| | |
| | |
| Add | Changes to a user's group membership are not effective until the next time the user logs on. |

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i. Select the "Add" button, and enter the names to be added in accordance with your organization's SOP.

| Select this object type: | |
|---|-------------------|
| Users, Service Accounts, or Groups | Object Types |
| From this location: | |
| PROMEGA.COM | |
| THOMEGA.COM | Locations |
| Enter the object names to select (<u>example</u> | <u>L</u> ocations |
| Enter the object names to select (<u>example</u> | s): |
| Enter the object names to select (<u>example</u> | s): |
| Enter the object names to select (<u>example</u> | s): |

- j. Select "OK" to accept the GloMaxUsers that were entered.
- k. Log out of the computer, and then log in again with appropriate credentials. This step is required to apply the changes to the software.
- 4. Once the GloMaxSuperUsers and GloMaxUsers are set up, the software is ready for use. If a user is not added to a user group (GloMaxSuperUsers or GloMaxUsers), the following error message is displayed when trying to open the AuthentiMax[™] Software.





5. If the computer is not on a network or domain, the process for adding users to the GloMax groups is different. You must first create a computer user before adding them into the GloMax groups. Computers that are networked or on a domain typically have users already setup within their IT systems.



- 1. From the Computer Management window select the User tab.
- m. Right-click to add a "New user".
- n. Add the user credentials by assigning a user name and password. Click Create.

| Full name: | | | |
|----------------------------|------------------------|----|--|
| Description: | | | |
| | | | |
| Password: | | | |
| <u>C</u> onfirm password: | | | |
| User <u>m</u> ust chang | password at next logon | U. | |
| User cannot cha | ge password | | |
| Password never | xpires | | |
| | d | | |
| Account is disa <u>b</u> l | | | |
| Account is disa <u>b</u> l | | | |

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o. Once the user is created select the Groups tab from the Computer Management window then and double-click the GloMaxSuperUser or GloMaxUser groups, as appropriate, to add this user into the group.

| Select this object type: | |
|-------------------------------------|-----------------|
| Users, Service Accounts, or Group | ps Object Types |
| From this location: | |
| PROMEGA.COM | Locations |
| Enter the object names to select (e | examples): |
| | Check Names |

- p. Type the name you assigned in the previous step.
- q. Click the Locations button and change the location to the local computer.
- r. Click Check Names, then click OK.
- s. The new user will then be added to the GloMax group.

| Glo M | laxUser |
|--------------|--|
| Description: | GMMP Software User Group |
| Members: | |
| 💻 New Authe | entiMaxUser |
| - | |
| | |
| | |
| | |
| | |
| Add | Changes to a user's group membership Bemove are not effective until the next time the |

t. Log out of the computer and then log in again with the appropriate credentials. This step is required to apply the changes to the software.



4. Authentication, Authorization and User Functionality

4.A. Authorization and Authentication

Access to AuthentiMax[™] Software for GloMax[®]-Multi+ is controlled through Microsoft Windows[®] user administration functions via an account login, which requires a username and password. The software functionality access is controlled by the System Administrator, who provides privileges to individual users or a group of users. Section 4.F of this manual provides recommendations on username and password creation.

4.B. Connecting to a PC Using a USB Cable

- 1. Turn on the instrument and computer.
- Connect the GloMax[®]-Multi+ Detection System to the computer using the supplied USB cable via the USB port on the **back** panel of the instrument. **Note:** The USB port on the front of the instrument is used only for data transfer. Refer to the *GloMax[®]-Multi+ Detection System with Instinct™ Software Technical Manual* (#TM340, Section 16.E; 1) for details on installing drivers for the GloMax[®]-Multi+ instrument.
- 3. From the Home screen on the GloMax[®]-Multi+ instrument, go to the Instrument Control screen and touch the "Tools" button.
- 4. Touch the "External PC Control" button.

Once GloMaxSuperUsers and GloMaxUsers have been setup, you can launch AuthentiMax[™] Software for GloMax[®]-Multi+ by navigating to Programs>Start>Promega>AuthentiMax[™] Software for GloMax[®]-Multi+. **Note:** The actual path may differ slightly depending on the Windows[®] operating system used.

- 5. Launch AuthentiMax[™] Software for GloMax[®]-Multi+ from the computer. (For AuthentiMax[™] Software installation instructions, refer to Section 3.A of this manual.)
- Check the "Instrument Status" bar of the AuthentiMax[™] Software for GloMax[®]-Multi+ for connectivity. When the connection is successful, the word "Ready" will display on the "Instrument Status" bar.
- 7. If the "Instrument Status" bar does not display "Ready", select the "Tools" button of the Instrument Control screen on the computer and confirm that the "Instrument Port" setting is "USB".
- From this point, all instrument control will be done from the computer. To return control to the GloMax[®]-Multi+ Detection System touch screen, follow the instructions in Section 16.H of the GloMax[®]-Multi+ Detection System with Instinct[™] Software Technical Manual, #TM340.



4.C. GloMaxSuperUser Functionality

d.

- 1. Log in as the GloMaxSuperUser.
 - a. Perform a test run to generate some results by using the Select Protocol button on the Home Screen and choosing a Preset protocol from the protocol list.
 - b. To demonstrate the GloMaxSuperUser functionality, run a protocol several times. This will generate several results files to use for demonstration.

| Touch an option on | this screen to select it | |
|--------------------|---|--|
| New Protocol | Protocol Wizard for creating and storing a new protocol | |
| Select Protocol | Protocol Wizard for selecting a stored protocol | |
| Instrument Control | Instrument Set Up, Read, Results, and Tools | |
| Help Topics | View all Help Topics | |

c. From the Results tab click Files to select a results file.

| _ AuthentiMax™ Softwar | e for GloMax® Multi+ Detection System | × |
|---|--|----|
| | Read Results Tools | ?) |
| testrun1:Cyt Friday, December 1 | oTox-Fluor(Fluorescence) | 5 |
| 1 A 2.986 e4 B 2.974 e4 C 2.960 e4 D 2.964 e4 E 2.957 e4 F 2.958 e4 G 2.954 e4 H 2.966 e4 | testcustom1_customprotocol_12-16-2011_11-24-51 AM testcustom3_customprotocol_12-16-2011_11-26-25 AM testcustom2_customprotocol_12-16-2011_11-25-53 AM testrun3_CytoTox-Fluor_12-16-2011_11-21-35 AM testrun3_CytoTox-Fluor_12-16-2011_11-21-35 AM testrun1_CytoTox-Fluor_12-16-2011_11-21-34 AM | |
| | No instrument control | |

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4.C. GloMaxSuperUser Functionality (continued)

- e. A window will appear to confirm that you want to delete the file.
- f. If you click OK, the file is then deleted.

| Confirm Delete |
|---------------------------------------|
| Permanently delete result |
| 'testrun2 CytoTox-Fluor 12-16-2011 11 |
| -21-10 AM' ? |
| |
| OK Cancel |
| |

Note: Only GloMaxSuperUsers and personnel with Local Administrator permissions can delete files from AuthentiMax[™] Software. GloMaxUsers **are not** able to delete results, provided they are not also Local Administrators.

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g. To demonstrate that a GloMaxSuperUser can **create a new protocol**, click the New Protocol button from the Home screen menu.

| AuthentiMax™ S | oftware for GloMax® Multi+ Detection | i System | |
|----------------|---|--|-----------|
| M W | elcome to the Authen etection System | tiMax™ Software for GloMa | x® Multi+ |
| | Touch an option or | n this screen to select it | |
| | New Protocol | Protocol Wizard for creating and storing a new protocol | |
| | Select Protocol | Protocol Wizard for selecting a stored protocol | |
| | Instrument Control | Instrument Set Up, Read, Results, and Tools | |
| | Help Topics | View all Help Topics | |
| | | | |
| | | | |



4.C. GloMaxSuperUser Functionality (continued)

h. Navigate through the setup wizard to create your custom protocol



i. Save the new protocol.



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4.C. GloMaxSuperUser Functionality (continued)

j. Type a reason for creating the protocol.

Note: Only a GloMaxSuperUser and personnel with Local Administrator permissions can create a new protocol. A GloMaxUser cannot, provided they are not also Local Administrators.

| Welcome Measuremer | Finish ? |
|------------------------------|---|
| Luminescence | |
| Multiple R | Electronic Signature Id will be |
| Injectors | Edit Reason for Creation |
| Reading | |
| Integration 0.5 | ОК |
| Plate Forn | |
| Plate Wells Partial Plate | |
| Einish | |
| | Select Finish to go to the Instrument Control screen. |
| 12 | C Back Einich Cancel |

k. If you want to **run a custom protocol** from the Home screen click the Select Protocol button. Then choose the User tab and select the protocol of interest.

Note: The default view will display the Preset protocols. You must click the User tab to view the user-created custom protocols.

| Welcome Measurement Protocol Finish | Protocol Preset User New protocol MB | ? |
|--|--------------------------------------|------|
| | < Back Next > Ca | ncel |

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4.D. GloMaxUser Functionality

- 1. GloMaxUsers are not allowed to delete results files or create custom protocol within the AuthentiMax Software. To demonstrate this, log into the computer as a GloMaxUser.
 - a. Click Instrument Control button, then click Results tab.

Note: The "Delete" button (the red X) is grayed out to indicate that it is not functional; the GloMaxUser cannot delete a file from within the AuthentiMaxTM Software.



b. Try to create a user-defined custom protocol.

Note: The New Protocol button is grayed out to indicate that it is not functional; the GloMaxUser cannot create new protocols.

c. A GloMaxUser may only choose a protocol from the Preset or User-defined protocol lists, provided they are not also Local Administrators.

| AuthentiMax ^{**} | Software for GloMaxo Multi- Det elcome to the Authen etection System Touch an option or | ection System tiMax™ Software for GloMa> n this screen to select it | ® Multi+ |
|---------------------------|--|---|----------|
| | New Protocol | Protocol Wizard for creating and storing a new protocol | D |
| | Select Protocol | Protocol Wizard for selecting a stored protocol | |
| | Instrument Control | Instrument Set Up, Read, Results, and Tools | |
| | Help Topics | View all Help Topics | |
| | | | 0000TTA |



4.E. Viewing files from Windows® Explorer

 Since AuthentiMax[™] Software is operated only from the PC, the results generated are automatically saved to the PC hard drive. The results files are not saved to the instrument and therefore do not need to be exported. Results files can be accessed from the Results tab within the AuthentiMax[™] Software and by using Windows[®] Explorer.

The Results are located in the C:\Program Data\AuthentiMax folder, but may be located in a slightly different location depending on your Windows® version.

You can use the search function within Windows[®] Explorer to locate the AuthentiMax[™] Results if necessary.

| • | « | Local Dis | k (C:) | Pro | gramData | • | Prom |
|-----|----|-----------|--------------|-----|----------|-----|------|
| Vie | ew | Tools | <u>H</u> elp | | | | |
| - | I | nclude i | h library | • | Share w | ith | - |
| Na | me | | | ^ | | | |
| | Au | ditTrail | | | | | |
| | Cu | stom Pro | otocols | | | | |
| | Lo | gs | | | | | |
| | Re | sults | | | | | |
| ø | Co | nfigSetti | ngs.xml | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

a. Once generated and automatically saved to the PC, the Results files are **outside of the** AuthentiMax[™] Software and outside of the control of AuthentiMax[™] Software.

It is recommended that GloMaxSuperUsers and GloMaxUsers copy their original/unmodified results files and save them to a different folder in order to maintain an unaltered backup of the results.

Since the files are outside of the AuthentiMax[™] Software they can be viewed, manipulated and changed by both GloMaxSuperUsers and GloMaxUsers. It is the user's responsibility to have and adhere to their institution's procedures for electronic records at this point.



4.E. Viewing files from Windows® Explorer (continued)

b. If a customer changes a Result File, Custom Protocol or Event Log by accessing the file through Windows[®] Explorer, the AuthentiMax[™] Software will detect that the file has been altered, if the file is opened within the AuthentiMax[™] Software. The following images are examples of prompts/messages that will appear in the AuthentiMax[™] Software when trying to view an altered result file or protocol.



c. Audit Trail files are also automatically saved to the PC.

A GloMaxSuperUser is able to open and view the Audit Trail. The GloMaxSuperUser is also able to change the Audit Trail since they have Local Administrator permissions. Again, at this point the file is outside of the AuthentiMax[™] Software control.

d. GloMaxUsers are not able to view or change an Audit Trail file, provided they are not also Local Administrators. A GloMaxUser would see the following window when trying to open the Audit Trail file.





4.F. Account Security/Protection

Access to AuthentiMax[™] Software for GloMax[®]-Multi+ is controlled through the Microsoft Windows[®] operating system user administration functions. All software functionality for AuthentiMax[™] Software for GloMax[®]-Multi+ is controlled through the privileges and controls assigned to GloMaxSuperUsers and GloMaxUsers groups. The GloMaxSuperUser determines the levels of access depending on SOPs governing the user site.

- 1. **Username and Password:** The user is ultimately responsible for creating the usernames and passwords in compliance with the governing IT procedures and security policies at his/her organization.
- 2. **Prevention of Duplicate Passwords:** The Microsoft Windows[®] operating system user management prevents creation of duplicate usernames and passwords. It is the responsibility of the end user to create usernames and passwords in compliance with the governing IT procedures and security policies for his/her organization.
- 3. **Password Aging:** The Microsoft Windows® operating system user management can be configured to automatically and periodically revise passwords as well as to prevent users from creating duplicate passwords. The user is responsible for resetting their password within the specified time. Please contact your System Administrator if your password has expired or you cannot log in to the system.
- 4. Automatic Timeout After Inactivity: The Microsoft Windows[®] operating system user management can be configured to timeout to prevent unauthorized users from accessing AuthentiMax[™] Software. To change the time period for lockout, refer to the Microsoft Windows[®] lockout functionality feature on your PC.



5. Document Integrity

AuthentiMaxTM Software for GloMax[®]-Multi+ ensures document integrity by protecting a wide array of files (e.g., protocols, results and configuration files) via a proprietary checksum algorithm. AuthentiMaxTM Software for GloMax[®]-Multi+ automatically creates a checksum that is validated when the file is subsequently opened. If the checksum validation fails, the following software error messages are displayed for various files:

Configuration File: If the configuration file is corrupted or has been tampered with, the message below will be displayed at the time of access to the application. If the user selects "Yes", access to the application will be allowed. If the user selects "No", the application will exit.

| Docι | ument Integrity | / Failed for C | onfig file | |
|------|--|--|----------------------------------|--|
| Ċ, | The ConfigSettings.xm software or is corr | nl file has been modii upted. Do you want | fied outside the to continue? | |
| | | Yes | No | |

Protocol File: If a protocol file is corrupted or has been tampered with, the message below will be displayed. If the user selects "Yes", the application will load the selected protocol file. If the user selects "No", the application keeps the previously selected protocol (if any).

| Docur | ment Integrity Failed for Protocol file |
|-------|---|
| | The Absorbance Protocol.csv file has been modified outside the software or is corrupted. Do you want to continue? |
| | Yes No |

Results File: If the results file is corrupted or has been tampered with, the message below will be displayed. If the user selects "Yes", the application will load the selected results file. If the user selects "No", the application keeps the previously selected result file (if any).

In the event of a failed validation, it is up to the user to decide whether to use the modified file in accordance with the policies of the organization.





5. Document Integrity (continued)

Once result files, logs or custom protocols have been generated in the AuthentiMax[™] Software they can be accessed from the PC using Windows[®] Explorer. However, the files are considered outside of the control of AuthentiMax[™] Software and subject to the institution's procedures for electronic records.

Simply opening the saved Result file (.CSV file) and re-saving it with the same name will change the file and disable it from being used or viewed within the AuthentiMax[™] Software in order to prevent the unauthorized use of tampered files in the AuthentiMax[™] Software.

Both GloMaxUsers and GloMaxSuperUsers may change result files, log files and custom protocols from within Windows[®] Explorer because these files are now outside of the AuthentiMax[™] Software. Any modification to the files using Windows[®] Explorer may cause them to be corrupted and even GloMaxSuperUsers may not be able to restore them using AuthentiMax[™] Software.

Therefore, once a results files is generated, it is recommended that the file be copied and saved to another location on the PC. This allows an unmodified copy of the results file with its original document integrity to be maintained.



6. Audit Trails

Both user and instrument actions are recorded by AuthentiMax[™] Software for GloMax[®]-Multi+ using a secure, computer-generated, time-stamped audit trail. Additionally, AuthentiMax[™] Software for GloMax[®]-Multi+ protects the audit trail files from edits, deletion and unauthorized access using the Microsoft Windows[®] operating system user permissions. The AuthentiMax[™] Software for GloMax[®]-Multi+ audit trail logs detail the username and privilege level, action performed, details of the actions and the timestamp when the action was performed. The audit trail files are stored in a secure location that is accessible only by a GloMax^SuperUser or personnel with administrative rights to that location. Audit trails are created and stored by AuthentiMax[™] Software for GloMax[®]-Multi+ at: C:\ProgramData\Promega\AuthentiMax\AuditTrail

Audit trail files are created on a daily basis, and are easily searchable and retrievable by the GloMaxSuperUser. Audit trail files are text (.txt) files that can be opened, copied and printed by the GloMaxSuperUser using any document that reads text files (e.g., Notepad, Microsoft Word[®], etc.).

AuthentiMax[™] Software for GloMax[®]-Multi+ does not automatically back up audit trail files and records. It is the responsibility of the end user and the organization to establish standard operating procedures for ensuring proper archiving of electronic records.

Errors and exceptions generated by the software or the instrument are logged in the event log files. Event log files are created and stored at: C:\ProgramData\Promega\AuthentiMax\Logs

7. Electronic Signatures

AuthentiMaxTM Software for GloMax[®]-Multi+ allows users to electronically sign records. Only a GloMaxSuperUser is allowed to modify and/or sign new or modified protocols. AuthentiMaxTM Software for GloMax[®]-Multi+ provides the following content for electronic signatures:

- Full username
- Date and time the signature was applied
- The reason or meaning provided at the time of the signature
- An encrypted code generated by the user certificate

AuthentiMaxTM Software for GloMax[®]-Multi+ uses the Microsoft Windows[®] authentication mechanism to control user credentials and link those credentials to the user's electronic signature. AuthentiMaxTM Software for GloMax[®]-Multi+ uses the Full Name and Date plus Time of creation/modification of a file combination in the electronic signature feature. AuthentiMaxTM Software for GloMax[®]-Multi+ ensures electronic signature integrity. Any changes or modifications to the electronic signature record results in an invalid checksum and the data can no longer be used for viewing or processing. When a protocol is created or modified, AuthentiMaxTM Software for GloMax[®]-Multi+ provides a means to enter a reason for signing the changed or created record as shown below.

If the modified record has been previously signed, it has to be signed again. The user will be prompted to enter a reason for change upon modification.



8. System Information

8.A. Accessing System Information

For more information about AuthentiMax[™] Software for GloMax®-Multi+, select the "Instrument Control" button on the Home screen, then select the "Tools" tab and the "Information" button.

| AuthentiMax™ Software for GloMax® Multi+ Detection System | | |
|---|---------|--|
| Read Results Tools | -? | |
| Wednesday, July 06, 2011 | 1:33 PM | |
| Activate Heater 20 °C C | Port | |
| | | |
| | | |
| No instrument control | | |

The following system information is provided:

| AuthentiMax™ Software for GloMax®-Multi+ | SN:931001109020 | |
|--|------------------------|----|
| User Interface | 1.0.0 (Rev 6407) | |
| Controller (LLC) | | |
| Firmware | mod384 (Rev 04.13.0) | |
| FPGA | 01.52 | |
| NVRAM | 04.13.0 | |
| PMT Luminometer | SN:CF0000001111E12D | |
| Fluorometer | SN:CA000000BE1FFB2D | |
| Optical Kit | SN:32000001143E42D Red | |
| Absorbance | SN:EE000000BB83DC2D | |
| | | ОК |

8.B. Updating Software

Contact Technical Services for more information on how to obtain the most current version of AuthentiMax[™] Software for GloMax[®]-Multi+ Instrument: Toll-Free Phone: (800) 356-9526 or (608) 274-4330. Email: techserv@promega.com

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| Error Message | Description | Resolution |
|---|--|---|
| Cannot open audit trail files | Only GloMaxSuperUsers can open audit trail files | • Ensure that the user is added to the GloMaxSuperUser group. |
| Access to AuthentiMax [™] Software denied | User cannot access AuthentiMax™ Software | Ensure that the user is added to one of the user groups, i.e., GloMaxUser or GloMaxSuperUser. |
| | | • If the user was recently added, log out of the computer, and then log in again with appropriate credentials to apply changes to the software. |
| Cannot connect instrument to PC Software | User cannot connect the GloMax [®] Multi+ instrument to AuthentiMax [™] Software | • Please refer to Section 3.B of this technical manual and the instrument technical manual for additional information. |

9. Troubleshooting

10. Frequently Asked Questions

Question: As a GloMaxUser will I be able to change results files from within Windows® Explorer?

- **Answer:** Yes. The file is outside of the AuthentiMax[™] Software and therefore outside of its control. The file would not be usable by the AuthentiMax[™] Software.
- **Question:** If a results file, custom protocol or event log file has been modified how can I restore the file?
- Answer: If a file has been changed or manipulated in any way, which may include simply opening and re-saving the file with the same file name, the file will be corrupted. A corrupted file cannot be fixed and can no longer be viewed or used by the AuthentiMax[™] Software.

The user must rely on the institution's procedures for electronic records to maintain integrity of the document once the file is in Windows[®] Explorer. Once a file is on the PC it is outside of the AuthentiMaxTM Software control.

- Question: If I need to change a protocol, how can I do this?
- **Answer:** To change a protocol you must be a GloMaxSuperUser and make any changes within the AuthentiMax[™] Software. The software will require an electronic signature to maintain the integrity of the protocol.



10. Frequently Asked Questions (continued)

Question: The data results are being incorrectly added to the results files.

- **Answer:** Confirm the PC language pack is set to English (USA). Non-English language settings are incompatible.
- Question: What is meant by a file (results, protocol, or audit trail) being outside of the control of AuthentiMax[™] Software?
- Answer: Files are saved to the hard drive of a PC. The files can be accessed using Windows[®] Explorer and opened in various programs (Excel, Notepad, etc). Therefore, it is possible to view, modify and re-save the files using a program other than AuthentiMax[™]. In this way, the files are outside the control of the AuthentiMax[™] Software. Any file modified in any way outside of the AuthentiMax[™] Software may not be viewed or used by the AuthentiMax[™] Software. The user must rely on their institution's procedures for electronic records to maintain integrity of the document once the file is in Windows Explorer.

11. References

1. GloMax[®]-Multi+ Detection System with Instinct[™] Software Technical Manual, #TM340, Promega Corporation.

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