INSTRUCTION MANUAL

EVA-GXP-01

EVOM™ Auto GxP Module

CONTENTS

ABOUT THIS MANUAL

The following symbols are used in this guide:

⊘ This symbol indicates a CAUTION. Cautions warn against actions that can cause damage to equipment. Please read these carefully.

⚠ This symbol indicates a WARNING. Warnings alert you to actions that can cause personal injury or pose a physical threat. Please read these carefully.

NOTES and TIPS contain helpful information.

Fig. 1—The EVOM™ Auto GxP with 96 high throughput screening (HTS) electrode array simplifies transepithelial electrical resistance (TEER) measurement in 96-well HTS plates from MatTek, Corning, and Millipore multiwell plates. The system is also available for 24-well plates.

The EVOM™ Auto GxP automates measurements of TEER in epithelial or endothelial monolayers cultured on 24-well or 96-well high throughput screening (HTS) plates utilizing our innovative EVOM technology, qualitatively measuring cell monolayer health and quantitatively measuring cellular confluence by reaching an increase or a plateau in tissue resistance.

Automated measurement of tissue resistance in cell culture microplates provides the advantages of speed and precision, minimizes the chances of contamination, and ensures the rapid availability of measured resistance data. EVOM™ Auto GxP applies a 12.5 Hz square wave current with switching polarity, which mitigates the chances of charging the sample and nullifies the chances of measurement technique having any adverse effects on the sample. Therefore, it is considered non-invasive measurement. EVOM™ Auto GxP is designed for the non-destructive, high throughput screening of epithelial monolayer confluence and barrier function studies in cell cultures.

INTRODUCTION

The EVOM™ Auto GxP automates TEER measurements. The instrument is controlled through a web browser, and the measurements are stored in the instrument and downloaded to your computer (control device) through the web browser. At present, the instrument supports MatTek , Corning, and Millipore 96 HTS well plates using the

96-well electrode array, Corning 24 HTS plates using the 24C electrode array, and Millipore 24 HTS plates using the 24M electrode array. EVOM™ Auto GxP is controlled via Ethernet connectivity using an laptop (included with the system).

NOTE: When EVOM™ Auto is operated with the GxP module, the EVOM™ Auto GxP is restricted to work through the wired Ethernet connection on a laptop. The wireless connection is not allowed

GxP Compliance

The GxP module software has traceability features implemented to comply with FDA 21 CFR Part 11 regulations. To execute the required data traceability and data integrity functions, a dedicated software application (EVOM™ GxP Client) with direct access to invoke the EVOM™ Auto GxP interface completes the FDA compliant solution. The EVOM™ Auto GxP is accessed through the EVOM™ GxP Client application to ensure the proper credentials and user privileges are enforced in granting access to the instrument, as well as ensuring traceability of changes to data and settings. The EVOM™ Auto GxP module shows audit trails of a data file. Any actionable item to change the instrument settings and run experiments is implemented with user credentials. Verifiable data export is done with digital signatures. Thus, the EVOM™ Auto GxP module provides a compliant GxP standard software platform to operate the EVOM™ Auto unit and store data.

GxP Options

EVA-GXP-01-01 is option A, and it is recommended for those who wish to keep all their data, including the analysis of their data, within the EVOM™ Auto GxP module.

EVA-GXP-01-02 is option B, and it does not let you maintain any other data files in the EVOM™ Auto GxP platform other than the original data files generated by EVOM™ Auto instrument. The data files may be directed to your preferred secured location for further analysis.

Features

Features	Advantages	Benefits
Electrodes available for 24- and 96-well HTS plates	Measures wells one column at a time	Efficiency gains with automation
Easily switch between 24 and 96 plate types	Plug-n-play enables fast, easy switching between plate types and heads	Multi-plate compatibility utilizing only one instrument means cost and space savings
Automate your measurements	Streamline your workflow	Minimize human errors

Features	Advantages	Benefits
Three rinse locations	Rinse electrodes multiple times during a measuring sequence	Take control of protocol and define custom sequences
Disposable rinse station inserts available	Sterile disposable rinse station inserts fit in the base station	Convenient and fast for effective electrode disinfection options while reading a number of sample plates
Crash protection	Auto alignment detection pauses measurements, preventing equipment damage	Minimize electrode damage, avoiding costly repairs and down time
Auto-detection of electrode head	Auto electrode detection configures its position and software options for your plate	Simple hardware setup without configuration
Intuitive touchscreen user interface	User-friendly programming sequences with basic selection options	Easy-to-navigate system saves time when configuring sequences
Create custom plate profile	Adjust the programmed coordinates	Fine tune the programming as desired
Save up to three plate profiles per plate type	Multiple users can operate the instrument with individually saved settings	Ensures custom settings are saved, preserving data integrity
Store all your data or export to Microsoft® Excel	Analyze your data in a manner suitable to your workflow	Flexibility to manage your data
GxP for FDA 21 CFR Part 11 compliance	Uses the EVOM™ GxP Client tracking for clear documentation of user activity regarding data	Clear audit trail ensures data integrity

Notes and Warnings

WARNING: A BIOHAZARD LABEL IS ADDED ON THE AUTOSAMPLER UNIT SINCE IT MAY BE EXPOSED TO BIOLOGICAL SAMPLES WHILE BEING USED. IF YOU PROCESS POTENTIALLY HAZARDOUS SUBSTANCES ON THIS DEVICE, ENSURE PROPER HANDLING AND CLEANING PROCEDURES ARE FOLLOWED.

CAUTION: Never set anything (especially liquids) on top of the autosampler.

CAUTION: When you move or relocate the instrument, remove the front cover/lid, which can fall off. For example, you may move the system in and out of a cell culture hood. Always remove the EVOM™ Auto's front cover anytime the system is lifted and moved from one location in the lab to another and reinstall the cover after the system has been placed at a new location.

CAUTION: To safely change the electrode array, the software must be in offline mode OR the unit must be powered off. If one of these conditions is not met, DO NOT try to change the electrode array. Removing the electrode array when the system is in the fully active mode may put the system in an unresponsive, disrupted communication mode that may necessitate a return to the factory.

CAUTION: If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

CAUTION: Do not directly spray alcohol on the instrument.

CAUTION: WPI recommends that the electrode head be in the home position and any running experiments are finished before disconnecting the power.

TIP: Before you begin experimenting, verify the time zone setting is set correctly on your laptop controller. For instructions, visit the *support.apple.com page*.

Parts List

After unpacking, verify that there is no visible damage to the equipment. Verify that all items are included:

(1) Dell Laptop

(1) Configured USB to Ethernet Adapter

(1) EVOM™ Auto GxP Interface Unit

(1) Interface Unit Cable

(1) Power Supply Unit

(1) One-Year License Key provided by TotalLab

(1) Instruction Manual is available online at *www.wpiinc.com/manuals.*

NOTE: The GxP Module can only be used with an EVOM™ Auto system. The EVOM™ Auto system includes the autosampler and electrode array required for use with the EVOM™ Auto GxP Module. When using the GxP Module with the EVOM™ Auto, you will not need the interface unit or the iPad that come with the EVOM™ Auto system.

Unpacking

Upon receipt of this instrument, make a thorough inspection of the contents and check for possible damage. Missing cartons or obvious damage to cartons should be noted on the delivery receipt before signing. Concealed damage should be reported at once to the carrier and an inspection requested. Please read the section entitled "Claims and Returns" on page 75 of this manual. Please contact WPI Customer Service if any parts are missing at (941) 371-1003 or wpirms@wpiinc.com.

Returns: Do not return any goods to WPI without obtaining prior approval (RMA # required) and instructions from WPI's Returns Department. Goods returned

(unauthorized) by collect freight may be refused. If a return shipment is necessary, use the original container, if possible. If the original container is not available, use a suitable substitute that is rigid and of adequate size. Wrap the instrument in paper or plastic surrounded with at least 100mm (four inches) of shock absorbing material. For further details, please read the section entitled "Claims and Returns" on page 75 of this manual.

NOTE: Before shipping your system back to WPI, please contact *wpirms@wpiinc.com* for assistance to ensure proper packaging and avoid damage during shipping.

CAUTION: If the EVOM™ Auto GxP unit needs to be returned to WPI, it must be properly decontaminated prior to packing and shipping. Immerse the electrode tips in 70% ethanol or isopropanol for 20 minutes. Thoroughly wipe all the exterior surfaces of the EVOM™ Auto GxP (including the autosampler, the interface unit, and the exterior of the electrode array) with a paper towel or Kimwipe that was sprayed with 70% ethanol or isopropanol. Do not spray alcohol directly on the instrument. Allow the alcohol to evaporate for 20 minutes before packing the system for shipment to WPI.

INSTRUMENT DESCRIPTION

EVOM™ Auto GxP System

Fig. 2—The EVOM™ Auto GxP System, includes the laptop, the GxP interface unit, the power supply (not shown), a USB to Ethernet adapter, and an Ethernet cable that work with the EVOM™ Auto autosampler.

The EVOM™ Auto GxP consists of these major components:

- **Autosampler** – The robot contains the electrodes, a 3-compartment rinse station, and a well plate area. The autosampler may be placed inside an incubator for long term studies, if desired. It may also be used inside a cell culture laminar hood. This is NOT included in the GxP Module.

- **Interface Unit** – This unit connects through a cable to the autosampler. This unit facilitates communication between the control device and the autosampler. The standard EVOM™ Auto system uses a Wi-Fi access point on the interface unit to connect with the control device (laptop or iPad) . The GxP interface unit contains the EVOM™ Auto GxP software and connects with the laptop via Ethernet.

- **Power Supply** – The power supply provides power to the autosampler and the interface unit. The cable plugs into the interface unit power supply port and a standard wall outlet.

- **Laptop Computer** – The computer contains the EVOM™ GxP Client application and serves as the main access port to communicate with the EVOM™ Auto GxP.

NOTE: The interface unit, iPad, and Wi-Fi adapter that come with the EVOM™ Auto system are not necessary when you are using the GxP module.

World Precision Instruments

Autosampler

Electrode Array Head
(in the Home Position)
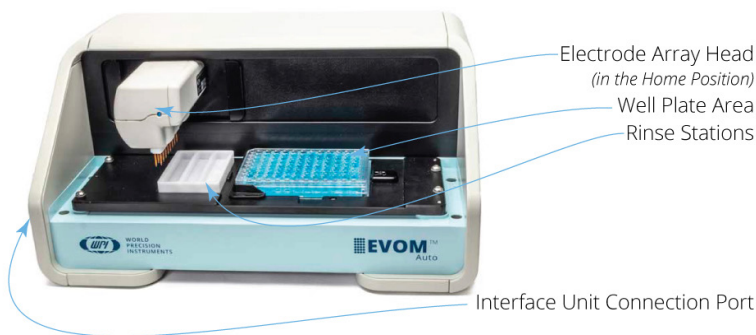Well Plate Area
Rinse Stations

Interface Unit Connection Port

Fig. 3—The autosampler takes the TEER measurements of the HTS well plate.

Here are the primary components of the autosampler.

Electrode Array Head – The electrode array rests in the home position (shown in Fig. 3), just to the left of the rinse stations. The LED on the electrode array will:
  • Flash blue when good measurements are being made.
  • Be a steady red on power up. This shows the unit has power but is not yet in communication with the interface unit.
  • Blink red when a bad measurement is made. (See "Online/Offline Toggle" on page 11.)
  • Be a steady blue when it is in communication with the interface unit.

Well Plate Area – The HTS well plates are positioned in the well plate area.

Rinse Stations – Three rinse stations are located on the left side of the autosampler. These may be used for stabilizing, cleaning or chloridizing. Place a sterile disposable rinse station insert in the base rinse station for a convenient way to disinfect and maintain your electrode. Simply discard the insert with the solutions when you change plates or need to change the solutions.

Fig. 4—(Left) Three rinse stations are available.
Fig. 5—(Right) Disposable inserts are used in the base rinse station for convenience to change solutions of the rinse stations.

Fig. 6—Place a sterile disposable rinse station insert in the base rinse station. Discard it and use a fresh rinse station insert before installing a different plate or running a different set of experiments.

Interface Unit Connection Port – One end of the autosampler cable connects here and the other end connects to the interface unit. The autosampler power and communications travel through this cable.

Looking at the autosampler measurement plate from the top, you can see the:
- Rinse Station Pocket where the rinse station slides into place. Sterile disposable rinse station inserts may be placed inside this base rinse station.
- Plate Positioner Sockets for installing the Plate Positioner used for positioning the well plate precisely.
- Spring loaded Well Plate Handle used to hold the well plate in place.
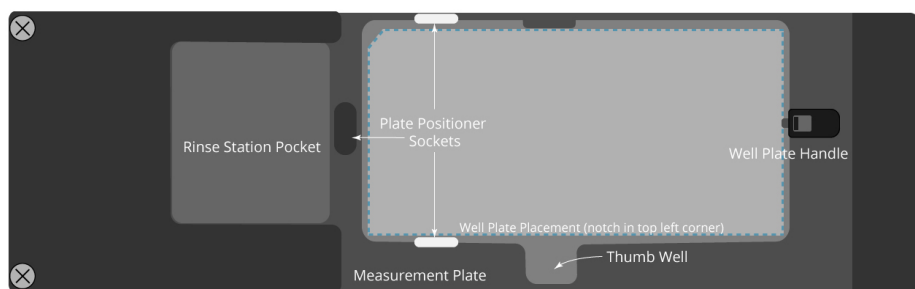- Thumb Well for ease of grasping a well plate.

Fig. 7—Top view of the measurement plate on the autosampler
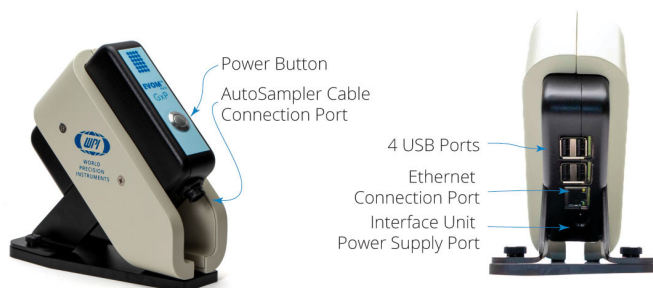
Interface Unit

Fig. 8—(Left) Side view of the interface unit, showing the front.
Fig. 9—(Right) Back view of the interface unit.

Power Button – Press the power button to turn on the interface unit and the autosampler. When it is powered on, a blue ring illuminates the button.

Autosampler Cable –This cable plugs into the autosampler cable connector on the interface unit and the interface unit connection port on the left side of the autosampler.

Interface Unit Power Supply Port – Plug the power supply cable into this port.

Ethernet Connection Port – This port is used to connect to the laptop using the standard Ethernet cable that comes with the GxP Module.

USB Ports (4) – These ports are not used with the GxP Module. When using the EVOM™ Auto basic system, one of these ports is used to connect the Wi-Fi adapter to communicate with the iPad.

CAUTION: WPI recommends that the electrode head be in the home position and any running experiments are finished before disconnecting the power.

Software

The EVOM™ Auto GxP software runs in a web browser and it is independent of operating system. The EVOM™ Auto GxP user interface is launched from within the EVOM™ GxP Client application. You must log into the EVOM™ GxP Client to have access to the launch button for the EVOM™ Auto GxP software.
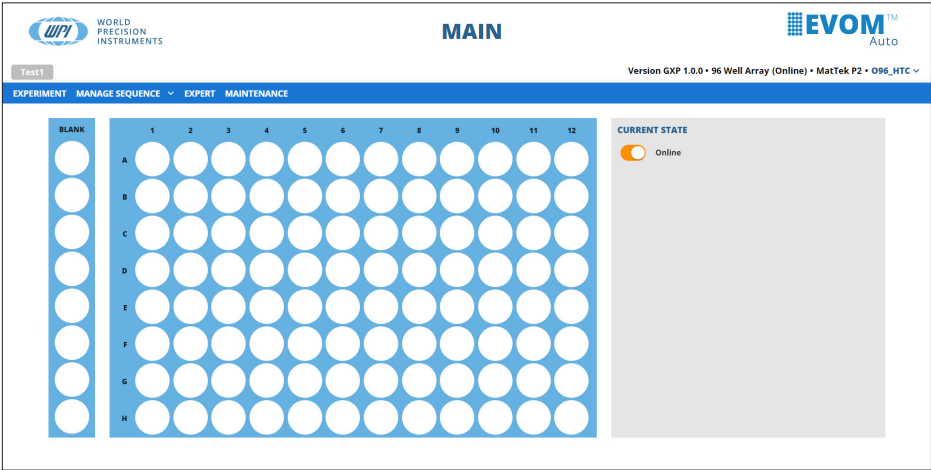

Fig. 10—The Main screen gives you access to all the main menu items and an overview of the selected plate. A 96-well plate is shown.
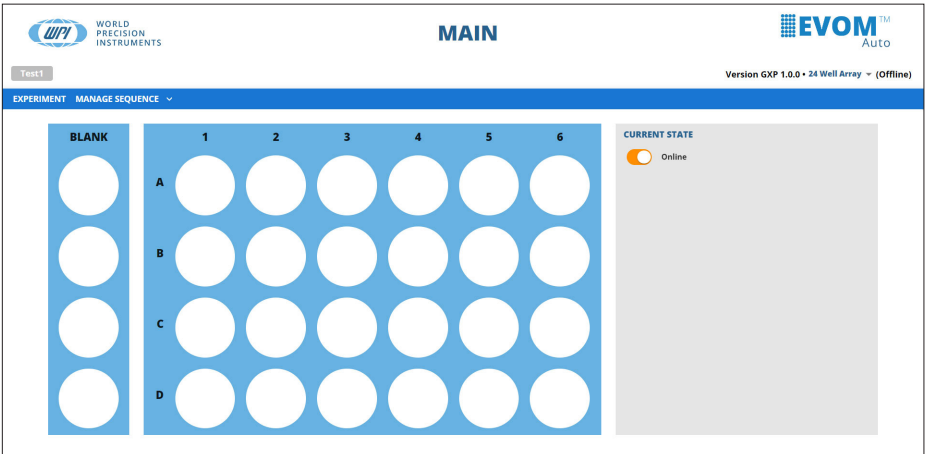

Fig. 11—The 24-well plate option for Millipore 24 is shown. EVOM™ Auto GxP system recognizes the electrode array and shows matching 24 or 96 plate option.

Online/Offline Toggle

The system can only use the autosampler and collect data when it is in the *Online* state The toggle switch in the grey *Current State* area of the window determines the online status. Use that switch to change the status of the autosampler. The system can only use the autosampler and collect data when it is in the *Online* state.
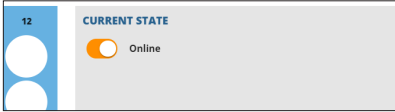

Fig. 12—Toggle this switch to take the autosampler online or offline.

The *Offline* state is used to access data from different head types without taking the risk of using the system with the wrong type of head installed. When in *offline* mode the drop-down menu in the status area allows you to select which head type for the system to simulate and allows access to its data.

If the system is *Offline*, click on the toggle switch to initialize the system and update the header area after initialization.

Resistance Value Display

The resistance values will always be displayed in ohms. There are three possible outcomes when displaying a measurement:

- Resistance values are within the set range.
  Example: 78568 = 78.568 KOhms

- Resistance values are higher than the selected range. This is considered an Overflow measurement and displays as OVF in the file and on screen.

- Resistance values are bad measurements and are displayed as a series of four dashes (––––). This indicates that a proper current could not be injected to accomplish a stable measurement. This is the case when there is no solution, or insufficient levels of fluid in the well being measured.

Emergency Stop

On any window where the electrode array can move, you can access the *Emergency Stop* button. It is the red stop icon located in the bottom right corner of the window.

Fig. 13—The emergency stop button is located in the bottom right corner of any window where the electrode array can move.

Press this button to disable the autosampler motors and stop movement immediately. The only valid option after this is *Go Home*. The autosampler needs to find the home position again to regain the reference to all movement. When you press the button, a message appears. Click the *Go Home* button to return to the home position.

Fig. 14—After pressing the emergency stop button, the message appears.

SETUP

Refer to the Install Guide for the hardware setup instructions.

Starting the EVOM™ Auto GxP Application from the EVOM™ GxP Client

1. Once all the components are properly connected, press the *Power* button on the interface unit to turn on the system. The blue ring around the button illuminates.

2. Allow the system to boot up. This may take up to 5 minutes. The electrode array will move to its home position as a self-test during this time.

3. On the laptop, double click on the EVOM™ GxP Client icon located on the desktop to start the application (Fig. 15). The EVOM™ GxP Client login window displays (Fig. 16).
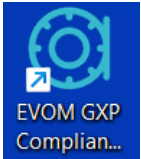

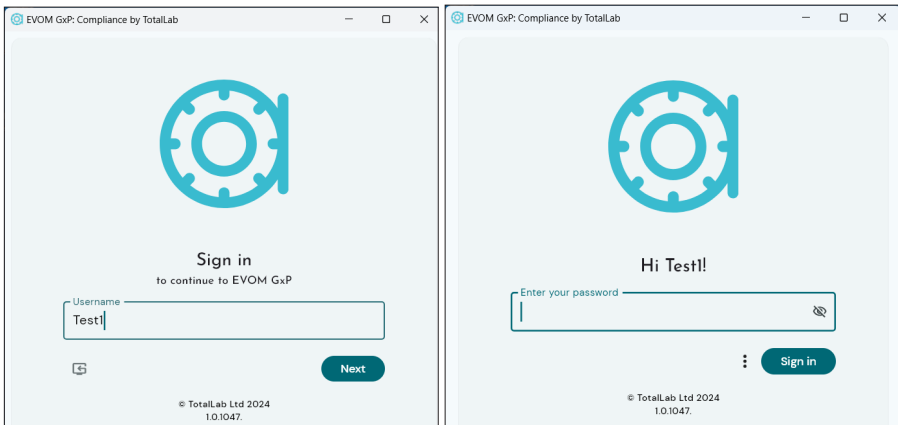*Fig. 15—EVOM GxP Client icon located on the laptop's desktop.*

Fig. 16—(Left) Enter your user name on the EVOM™ GxP Client sign in window.

Fig. 17—(Right) Enter your password on the EVOM™ GxP Client password window.

4. Enter your user name and press Next. The password prompt appears (Fig. 17). Enter your password and press the Sign In button. The Project window displays (Fig. 18).

Fig. 18—The EVOM™ GxP Client Project window.

5. Click on the hamburger icon ≡ in the upper left corner to select a project. The Project list displays (Fig. 19).

Fig. 19—The EVOM™ GxP Client Projects list.

6. Click on a project to select it. To create a new project you may click on one of the folder icons ⊞ ⊞ in the upper right corner. See "Creating a Project File" on page 32. The Project window appears (Fig. 20). The different versions of the project are displayed on the top.

    NOTE: If you have the GxP Option B, only the white new project icon will be present. Option A has both. The black icon allows you to create a project that is not empty. Option B new projects are always empty, since they do not contain any data files. The first original date file from the instrument is stored in Rev. 2.
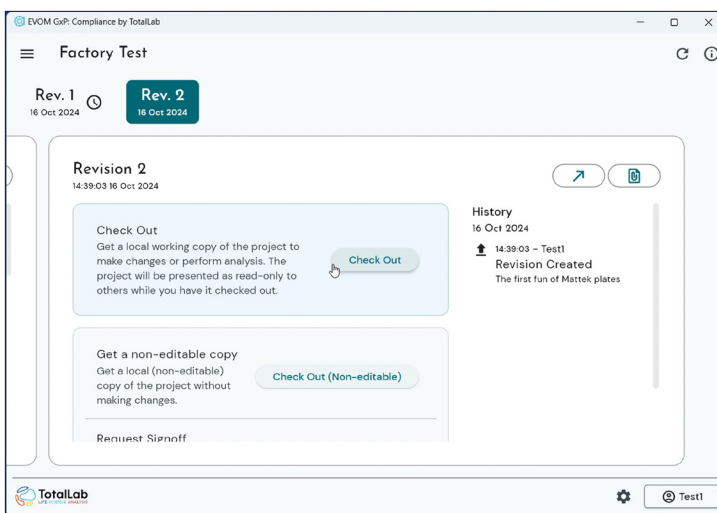
Fig. 20—The EVOM™ GxP Client Project window shows the selected revision at the top.

7. Select the revision you need to work on, and then press the *Check Out* button. Once the checkout is completed, the Revision history updates on the right side of the window. From here you may commit the changes to start a new revision, return the revision to checkout later, or access the EVOM™ Auto GxP software.

Click the WPI icon [image] (under the *Commit* and *Return* buttons) to access the EVOM™ Auto GxP software.

Fig. 21—The checkout screen lets you access the EVOM™ Auto GxP Software.

A *Check Out (Not-Editable)* button is available when a revision has not been returned by another user or when the revision has not been committed. When that user returns or commits the revision, then an editable version of the latest revisio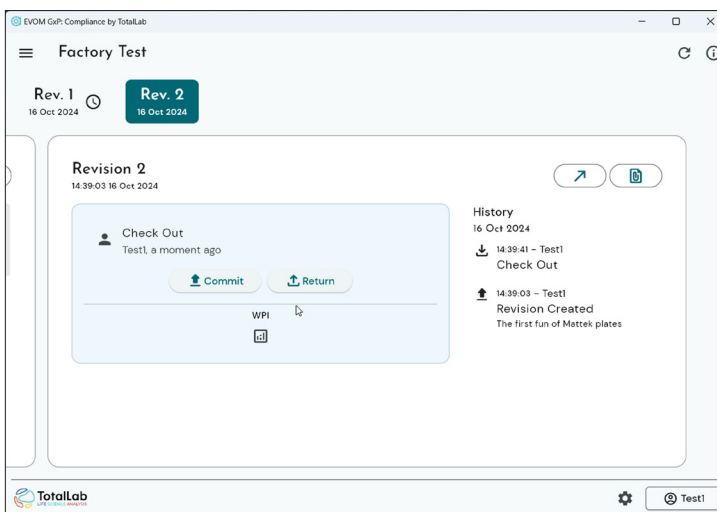n of the project may be checked out. When you click the *Check Out (Non-Editable* button, you may click on the inspection icon 👁️ to start the EVOM™ Auto GxP software (Fig. 22). If you check out a non-editable revision, you are not allowed to stage files for storage in the EVOM™ GxP Client. The non-editable revision is for review or inspection only.
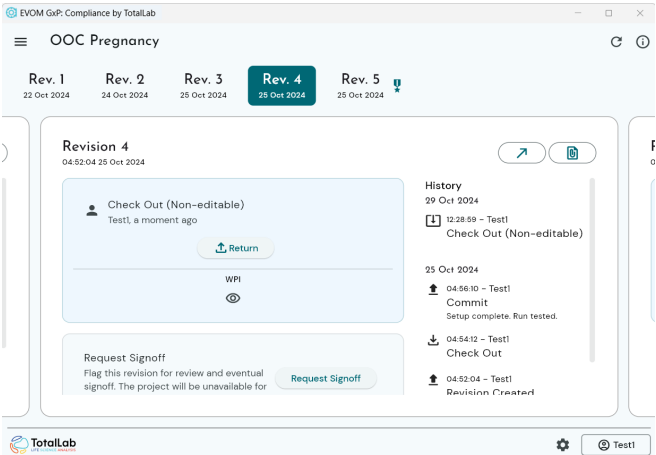

Fig. 22—Click the eye icon to checkout a non-editable version of the project revision.

8. The Initializing window displays (Fig. 23) showing the progress. The window briefly displays a ready message when the initialization is complete (Fig. 24). Then, the *Main* window appears (Fig. 25).

Fig. 23—Initialization screen.
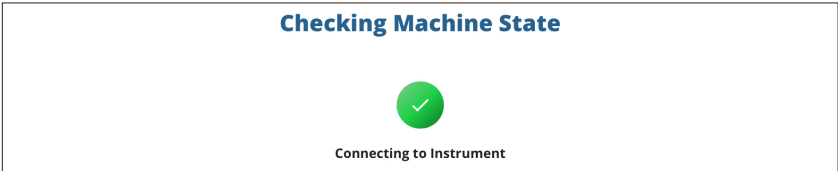
Fig. 24—Ready message displays briefly.
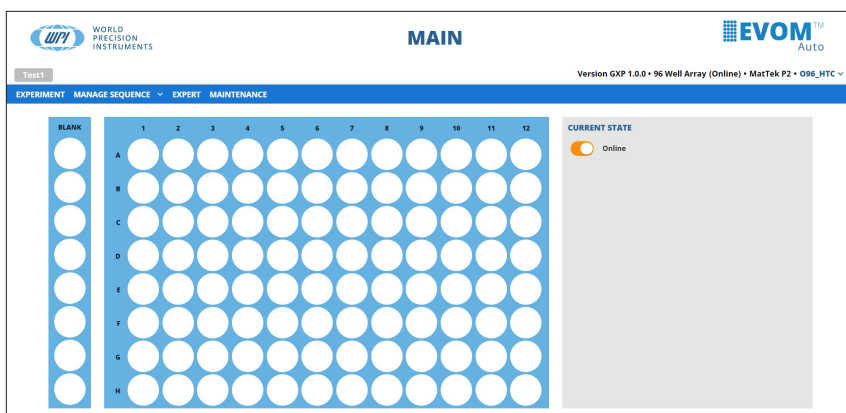
Fig. 25—Home screen showing a 96-well setup.
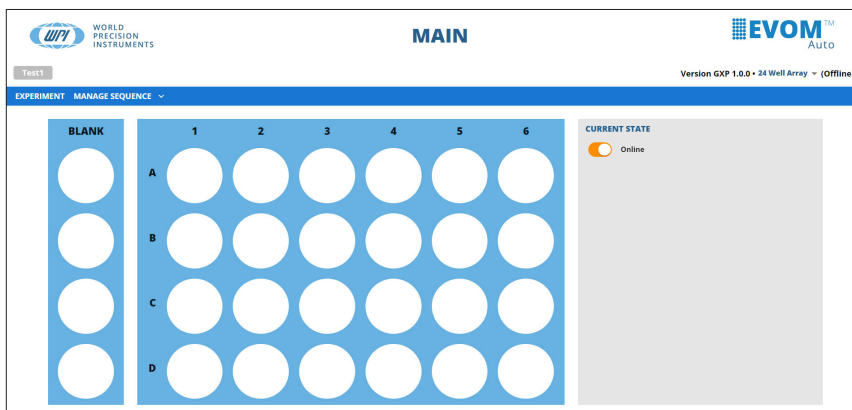
Fig. 26—Home screen showing a 24-well setup.

9. Click on the title MAIN in the center at the top of the screen to view the application in full screen mode. Notice that the user name is displayed above the action bar in the upper left corner.

If your connection between the laptop and the instrument is interrupted, you will see the greyed out screen with the *Instrument Disconnected* notice overlaid. This can happen if the unit loses power or the Ethernet cable is disconnected. Ensure your unit has power and the Ethernet adapter is correctly installed. Then, press the Cl*ick Here to Reconnect* button to re-establish your connection.
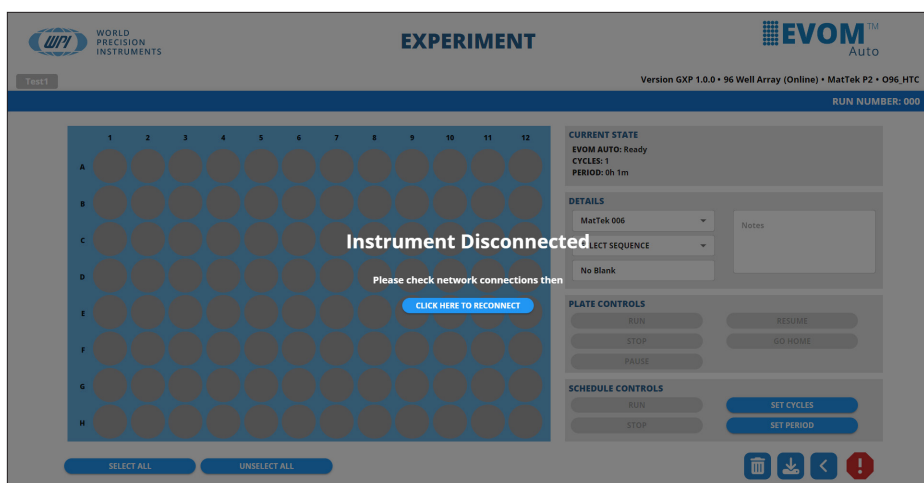
Fig. 27—The instrument connection with the control device was disrupted. Click the reconnect prompt to re-establish your connection.

CFR11 Error When Multiple Browser Windows Open

The EVOM™ Auto GxP software must always be started from within the EVOM™ GxP Client to preserve the synchronization between the two applications. If you press the Refresh button in the browser or an old browser tab is used to refresh, a CFR11 error message displays prompting you to close the browser tab and launch the software from within the EVOM™ GxP Client by clicking on WPI icon.
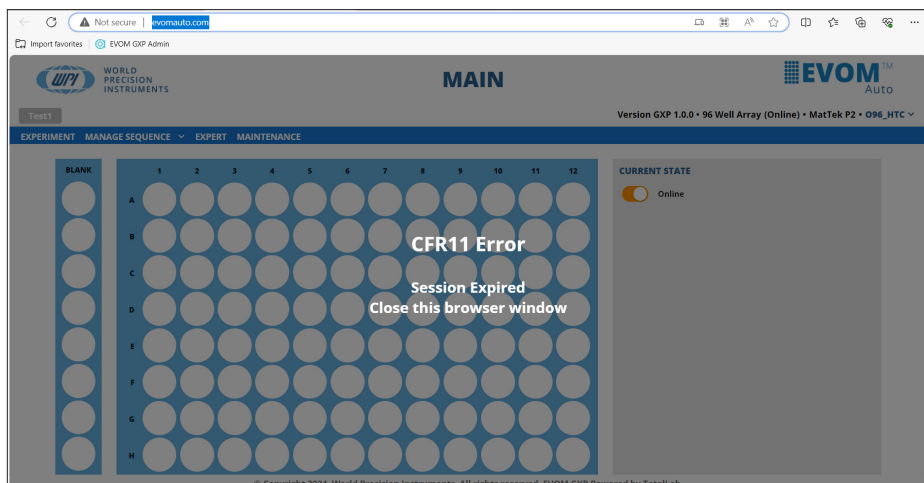
Fig. 28—If an old version of the application is running, this error displays. Start the EVOM™ Auto GxP software from within the EVOM™ GxP Client application.

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Changing the Electrode Array Head

1. Place the electrode array head in the home position by pressing the *Go Home* button on the *Experiment* window.

2. Navigate to the main window by using the *Back* button at the bottom of the screen.

3. Toggle the *Online/Offline* switch in the *Current State* section on the right side of the window to offline to set the autosampler in offline mode

4. Remove the electrode array by depressing the button on the left side of the array with your thumb and pull it straight out of the connection port. (Fig. 29)

CAUTION: To safely change the electrode array, the software must be in offline mode OR the unit must be powered off. If one of these conditions is not met, DO NOT try to change the electrode array. Removing the electrode array when the system is in the fully active mode may put the system in an unresponsive, disrupted communication mode that may necessitate a return to the factory.

NOTE: The electrode array needs to be installed before trying to power up the unit, otherwise the software will not recognize the device and will not connect.
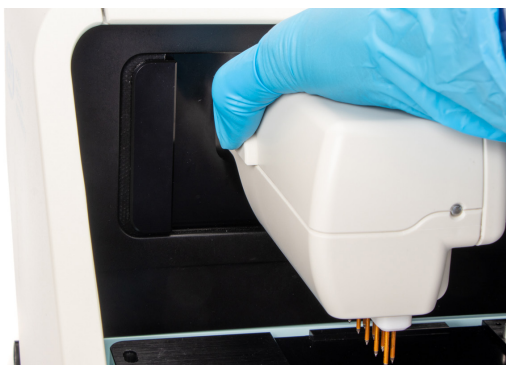
Fig. 29—Depress the button on the left side of the electrode array until you hear a click. Then, pull the array out to remove the electrode array. No light on the electrode array indicates the unit is off, and a red light on the electrode array indicates you are in offline mode. In either case, it is safe to remove the electrode array.

5. To install the new head, line up the connector, and push the new head in firmly until it clicks. Then, give it a little tug to bring it forward as much as possible.
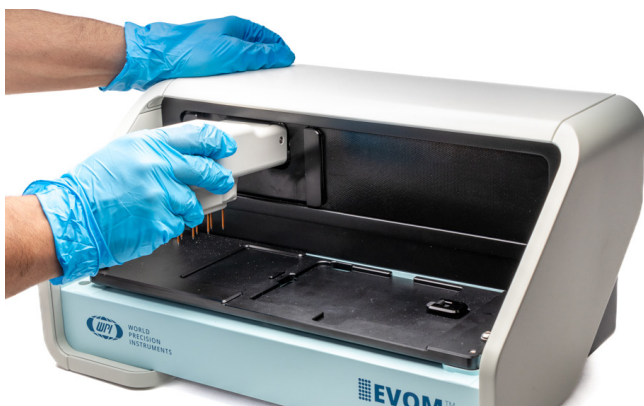
Fig. 30—Hold the top of the autosampler with one hand, line up the electrode array with the connection port and press the electrode array into the connection port until it clicks.

6. After the electrode array is installed, toggle the *Online/Offline* switch to online mode. This will read the head information and initialize the autosampler accordingly.

Using a Different Plate

1. First, install the matching electrode array. For example, if you want to use a Corning 24 HTS plate, install a 24C electrode array. See "Starting the EVOM™ Auto GxP Application from the EVOM™ GxP Client" on page 13.

2. Insert the appropriate plate positioning adapter key. In our example, use the C24/M24 adapter key.

3. Insert the chosen well plate on the measurement plate. In this example, insert the Corning 24 HTS plate.

    The software will automatically recognize the Corning 24 electrode array when it is plugged in and will only show the options for Corning 24 HTS plate option to run experiment.

NOTE: In the offline mode you can see the data for other plate/electrode types, but you can make no measurements.

OPERATING INSTRUCTIONS

After your system is set up and configured, you may use the browser on the laptop to control the autosampler.

It is important to note that the Plate Name ties the elements together in the EVOM™ Auto GxP software. The measurement options and date are attached to the Plate Name. Sequences are attached to a plate to define the measurement options and parameters. For example, parameters include number of rinses, each well measurement time, etc.

TIP: The same sequences may be used on multiple plates.

Full Screen Mode

By default the system will display navigation controls and URL bar when initially launched from the EVOM™ GxP Client. After the interface launches, you will want to put the system into full screen mode, because the software is easier to operate when it runs in full screen mode.

On a Windows® compatible browser, simply click on the Main headline in the center of the header at the top of the window to enter full screen mode. To exit full screen mode, press the Main headline again.

TIP: Pressing the WPI logo or the EVOM™ logo in the header will always return you to the Main window.

TIP: Avoid using the browser forward and back buttons to navigate the web page. Use the icons on the bottom right of the various screens. This ensures that the web page and the instrument are always synchronized.

Re-initializing the Instrument

If it becomes necessary to re-initialize the instrument because it becomes non-responsive, close the active web page and use the WPI icon in the EVOM™ GxP Client to access the web page. This will re-establish communications with the instrument and re-initialize it. The autosampler will finish its run and store the data for the plate it was reading, even if the connection between the web browser and the autosampler was lost. If you relaunch the software web browser, it will not be able to re-establish the connection until the previous plate reading finishes. Allow the last plate or experiment to finish. Then, launch the software to establish the connection again.

If relaunching the software does not re-establish proper connectivity between controlling device and the autosampler, turn OFF the power button of the interface unit, and power it ON again by pressing the power button.

User Types and Permissions

Each user who logs into the EVOM™ GxP Client to access the EVOM™ Auto instrument has a user level associated with their account. This level is assigned during user account creation in Auditsafe. There are user permissions assigned in the EVOM™ Auto GxP instrument depending on the EVOM™ user level.

EVOM™ GxP Client Group Levels

There are also groups in the EVOM™ GxP Client that determine the permissions inside the EVOM™ GxP Client application in addition to setting the EVOM™ Auto GxP instrument user level. The default groups are setup as follows.

Client Permissions	EVOM™ GxP Client Groups				Administrators
	EVOM™ GxP Maintenance	EVOM™ GxP Standard	EVOM™ GxP Advanced	EVOM™ GxP Admin	
Check out	✅	✅	✅	✅	
Check out (non-editable)	✅	✅	✅	✅	
File Export	✅	✅	✅	✅	
Add Project	✅	✅	✅	✅	
[EVOM] Maintenance	✅				
[EVOM] Standard		✅			
[EVOM] Advanced			✅		
[EVOM] Admin				✅	
Admin					✅
Server Logs					✅
Lock					✅

In the EVOM™ GxP Client platform, the Client features like File export, Server Logs, etc. are linked to a user type by default, but those can be easily changed by the Client superadmin while creating user accounts by selecting and adding the options.
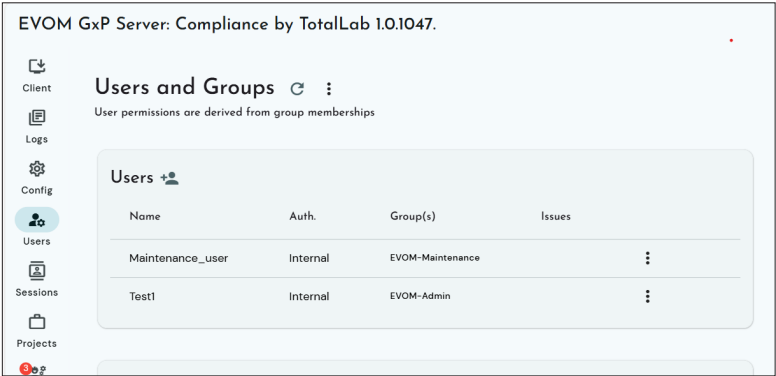

Fig. 31—The superadmin can create and manage users and groups.

Fig. 32—(Left) The superadmin can add a new group.
Fig. 33—(Right) The superadmin can add new users and assign them to a group.

EVOM™ Instrument Level Permissions

EVOM™ Auto GxP privileges (for the control of the EVOM™ Auto instrument) for each user type are fixed. Not all users can exercise all functions of the instrument. The features not available to a user type, will not be displayed to them. For example, if an EVOM™ Standard user is selected, they will not have access to instrument logs.

EVOM GxP Instrument Permissions	EVOM™ Auto GxP User Level			
	Maintenance	Standard	Advanced	Admin
Create Sequences			✅	✅
Modify/Save Sequences			✅	✅
Run Experiments	✅	✅	✅	✅
Export Experiment Results to EVOM™ GxP Client	✅	✅	✅	✅
Expert Screen	All Functions	Home Sensor Head Only	All Functions	All functions
Maintenance Screen	All Functions	Home Sensor Head Only	All Functions	All functions
Instrument Logs	View Only	No Access	View Only	View/Export

Actionable Items

Any EVOM™ Auto GxP operation that can affect the outcome of the instrument's measurements requires the assurance that it is being performed by authorized personnel. These are called actionable items. EVOM™ Auto GxP actionable items include:

Maintenance Window	Experiment Window	Manage Plate Window	Expert Window
Chloridize	New Plate	Create New Sequence	Save Changes
Stabilize	Run/Resume/Stop	Save Changes	Restore Factory Settings
Calibrate	Delete Plate	Delete Sequence	
Sync Time	Export Plate		
Export Logs			

A user who is logged into the EVOM™ GxP Client and opens the EVOM™ Auto GxP software will enter his/her password to perform the action. The user name is displayed in the password prompt. In Fig. 34 "Test1's password" displays. When the user attempts to execute one of these actions, a dialog appears requiring them to complete a comment (reason for the action) and the user's credential to certify that an authorized person is performing the action.

Run Experiment

Comment: _____ Trial 7
43 characters left

☐ No comment

"Test1's" password: _____ ·········

CANCEL   RUN

Fig. 34—Before you can run an experiment, you must enter a comment and your password. The logged in user's user name appears in the password prompt. Here the user is Test1.

The comment section is required. You may click the *No Comment* check box if you do not wish to enter a comment. The software enters "No comment provided by user" text in the *Comment* field. The comment can be 50 characters long and a message below the comment line will count down indicating how many characters remain available for the comment.

Run Experiment

Comment: _____ No comment provided by user

☑ No comment

"Test1's" password: _____

CANCEL   RUN

Fig. 35—If you select the No Comment checkbox, default text is entered into the Comment field automatically.

When the user password is entered, the action button (in this case, *Run*) is activated (turns blue) allowing you to perform the action.
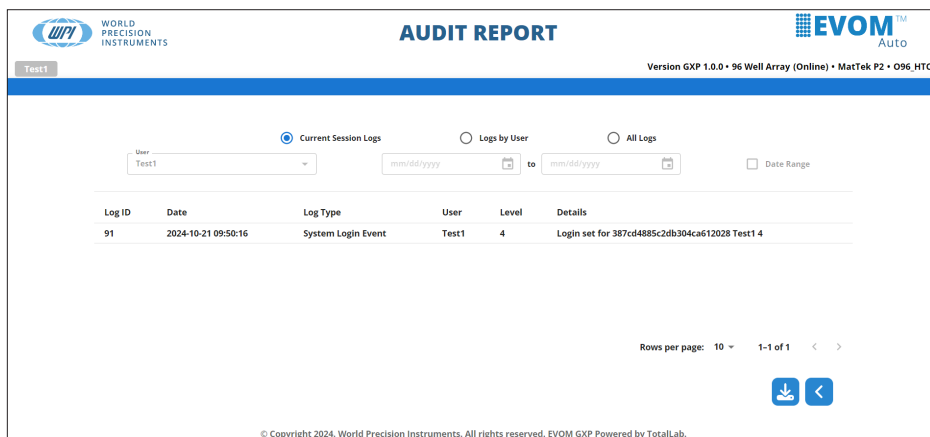
> **CAUTION:** Be aware that each time an incorrect password is entered, the EVOM™ GxP Client counts it as a failed login attempt. If a number of attempts greater than the allowed limit is reached, you will be locked out of the Client, preventing you from accessing the project and the Client. Your system administrator must reset your password before you will be granted access again. The number of tries is configured by the system administrator when setting up the system.

EVOM™ GxP Client Logs
Audit Trail Log

The EVOM™ Auto GxP keeps a log of actions taken during the operation of the system. These events are logged in the background and require no user intervention. You can create an Audit Report listing the events that can be exported and incorporated to the project for audit purposes. To generate the report, navigate to the Maintenance screen and press the report icon [icon]. The Audit Report displays (Fig. 36).

Fig. 36—The Audit Report shows a log of all the actions taken during the system's operation.

From the Audit Report you can access all logged events by all users. The logs can be filtered by different criteria by selecting the desired radio button on the top of the window. The filters are as follows:

Current Session Logs – This option only displays events logged since the EVOM™ Auto GxP was launched for this session.

Logs By User – When selecting this option, the *User* drop down list becomes active and a list of the users in the log records becomes available. Click on the desired user to show only the records for that user. When using this filter, the data range selection box becomes active and selecting it allows you to select a data range to further narrow the selection of records displayed. Set the *From* and *To* dates to determine the date range. Click inside these boxes to reveal a graphical date selection assistant

All Logs – This selection displays all the logs in the instrument. Entries are displayed with the most recent ones on top. The *Data Range* selection box is available to narrow the selection of records displayed.

Rows Per Page – This dropdown menu at the bottom of the window allows you to select the number of records per page to display. When the number of records per page cannot the displayed in one page, you may scroll up or down to view the results in that page. The range is 10 to 500 entries per page.

Exporting the Logs

1. In the Audit report page, press the export icon .

    NOTE: This icon may not be present if the logged-in user does not have the proper permissions.

    After pressing this icon, a file is created and a message in the lower right corner of the window displays indicating the export was successful (Fig. 37).

Fig. 37—When the data is exported, a green message appears at the bottom of the window.

    If you attempt to export the logs with no open and checked out session, an error dialog displays.

Export Plate "Scheduler Test Oct 2"

Data cannot be exported when Checkout is not active
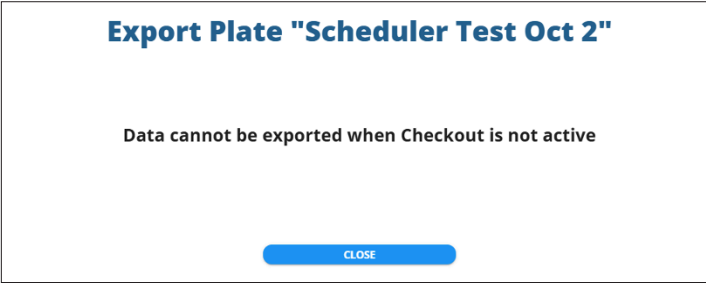
CLOSE

Fig. 38—An error displays if you export logs with no open and checked out session.

    Once the project is committed in the EVOM™ GxP Client, the files are brought into the version currently open, and the files can be accessed by checking out the project's newly created revision. First, return to the EVOM™ GxP Client and commit the revision by pressing the *Commit* button.
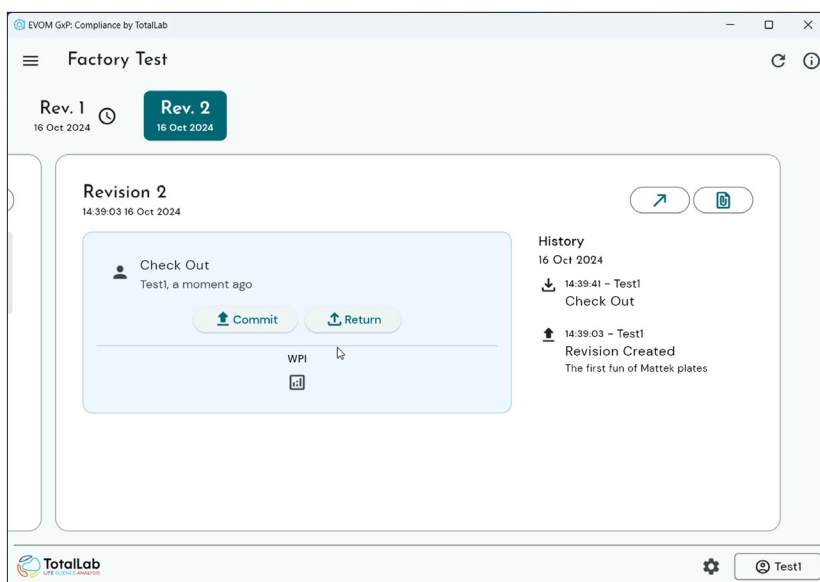
Fig. 39—Press the Commit bottom to commit the changes for the revision and create a new revision.

NOTE: The file export process is identical when exporting experiment data.

All files committed come directly from the EVOM™ Auto GxP instrument to the EVOM™ GxP Client platform. An additional safety measure is the fact that the EVOM™ software tags all transferred data files as "Original-data."

2. Next enter the desired revision notes and press the *Commit* button (Fig. 40). When the files are committed, a new revision is created. A badge is displayed next to every revision that contains at least one original data file (Fig. 41). Rev. 1 was created as an empty project file with no files, so it has no badge. Rev. 2 has at least one data file from the EVOM™ Auto GxP and a badge.
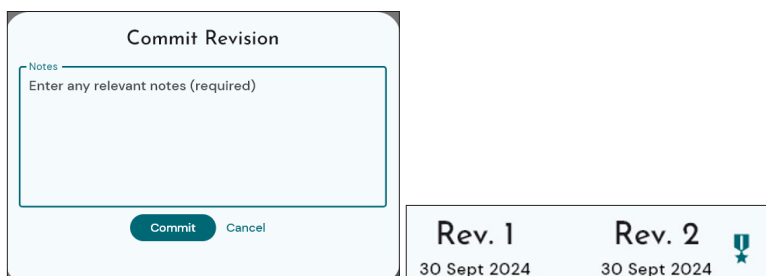

Fig. 40—(Left) Enter any notes and press the Commit button to finalize the revision.
Fig. 41—(Right) Revision 2 has a badge, because there is an original data file associated with it.

3. From the EVOM™ GxP Client window, you may click on the Export icon ⬀ in the upper right corner to view the version contents. The Export Files popup window displays.

Export Files

×

Export individual files from this revision

Local Testing Pi – New Test 10K – R079.csv   [original-data] ⬀

Local Testing Pi – New Test 10K – R079.sha   [original-data] ⬀

Local Testing Pi – New Test 10K – R080.csv   [original-data] ⬀

Fig. 42—The Export Files popup window shows the different data files. Click the arrow to access an individual file.

> **NOTE**: Data file names are appended with a numerical value in the form of R079 to indicate which run of the data it contains. R079 contains all runds from1 up to 79 , the number appended. It represents the last run in the file.

4. To export an individual file, Click the export arrow ⬀ located to the right of the data file you want to view. (The Original-Data indicator signifies that the file came directly from the EVOM™ Auto GxP instrument.) A popup appears allowing you to browse to a location where you want to save the data file.

> **NOTE**: The "Original-Data" stamp displays next to all the files that were transferred directly from the EVOM™ Auto GxP Instrument. Imported or modified files will not have the "Original-Data" stamp.
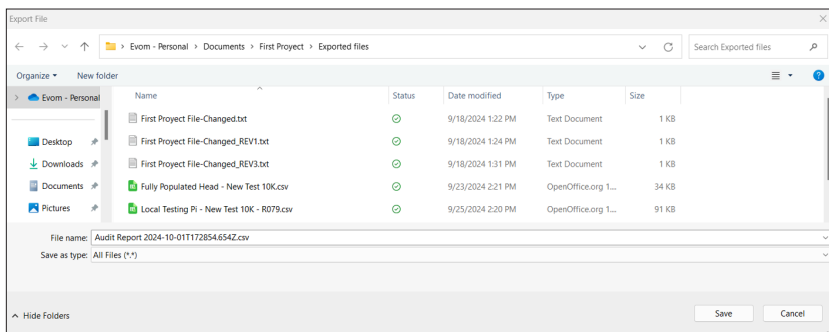

Fig. 43—Select the location on the computer where you want to save the data file.

NOTE: A .sha file is created with each exported file. The content of this file contains the calculated hash signature (SHA256 format) that is used to verify that the

accompanying file has not changed in any way. This file can be used with various tools to verify that the SHA256 HASH calculated for the data file matches the contents of the .sha file.

Fig. 44 shows a sample Audit Trail Log report CSV file.

Export Date:	Fri Aug 23 2024 08:17:09 GMT-0400 (Eastern Daylight Time)				
Log ID	Date	Log Type	User	Level	Details
7329	8/1/2024 10:46	System Login Event	user1	2	Experiment started Comment: No comment provided by user
7330	8/1/2024 10:46	E-Stop	user1	2	Experiment stopped Comment: No comment provided by user
7331	8/1/2024 11:06	System Login Event	user1	2	Experiment started Comment: First Run
7332	8/1/2024 11:06	E-Stop	user1	2	Experiment stopped Comment: Well A7 has low level
7333	8/1/2024 11:47	System Login Event	user2	2	Machine E-Stop triggered.

Fig. 44—Sample Audit Trail report in CSV format.

It includes the following columns:
- **Log ID** – Unique number assigned by the EVOM™ GxP Client every time that credentials are entered
- **Date** – Date that the action took place
- **Log Type** – Event Type logged
- **User** – User name
- **Level** – Level defining the privileges for the user logged it at the time
- **Details** – Activity performed plus user comments

NOTE: There is no restriction on how many times the WPI button is pressed to open a new browser window. It is recommended that you close any previous windows to limit the number of tabs open in the browser. However, every time a new browser tab is opened, the previously opened tab is considered obsolete. If an obsolete tab is opened a CFR 11 Error message displays.
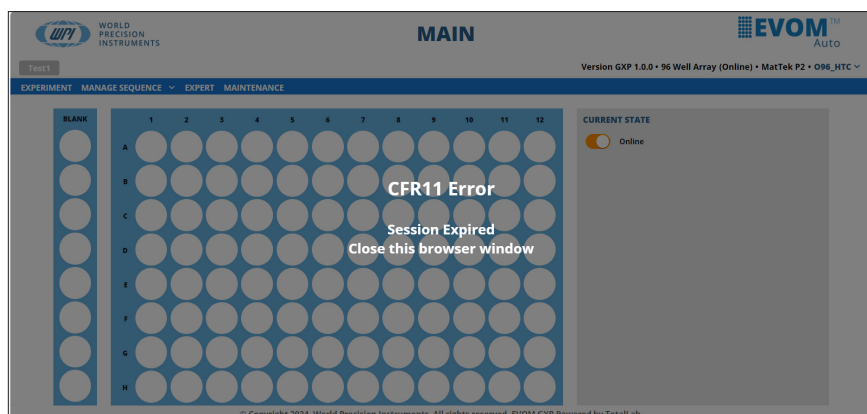

Fig. 45—A CFR11 error message displays in the first browser window when the EVOM™ Auto GxP software is restarted so that you know which browser is loaded with the most recent revision.

NOTE: It is a best practice to commit or return checked out projects before logging out of the EVOM™ GxP Client.

Accessing Files within the EVOM™ GxP Client
System Options

The EVOM™ GxP Client is available with EVOM™ Auto GxP in two versions that require different license activations.

- **EVA-GXP-01-01** is Option A, and it is recommended for those who wish to keep all their data, including the analysis of their data, within the EVOM™ Auto GxP module.

- **EVA-GXP-01-02** is Option B, and it does not allow you to maintain any other data files in the EVOM™ Auto GxP platform other than the original data files generated by EVOM™ Auto instrument. The data files can be directed to a desired secured location that you select for further analysis.

Option A

1. If you select Option A, you have a working folder icon ⬛ in the Checkout area that allows you to access the working folder (Fig. 46). Selecting that icon displays a list of the available files in the current version of the project (Fig. 47).
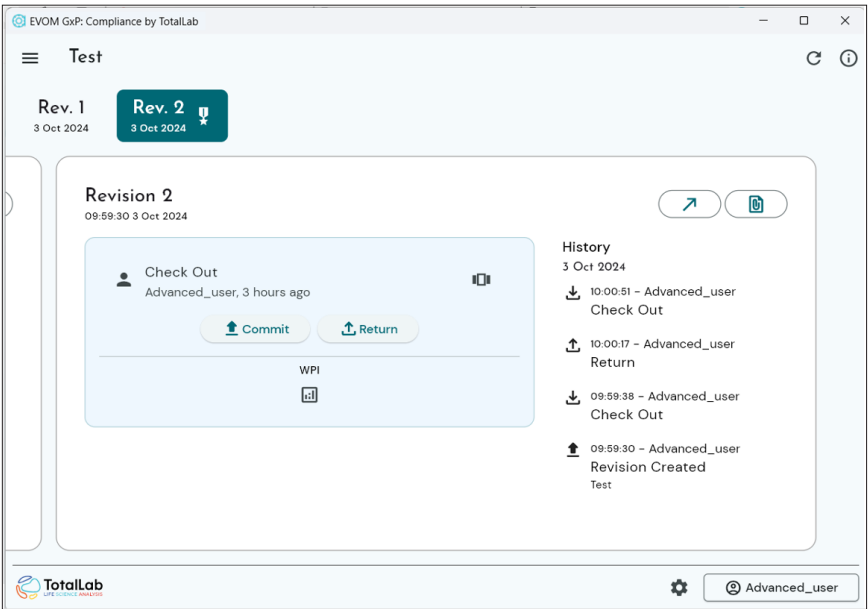

Fig. 46—For Option A, the checkout area in the center of the screen has a working folder icon that allows you to access all the files in the current version.

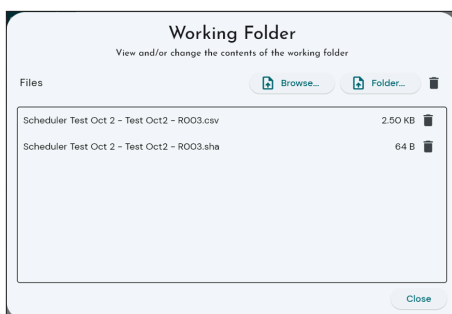World Precision Instruments

Fig. 47—From the working folder, you may import files or directories into the folder.

2. Press the *Browse* button to upload a file into the working folder, or press the *Folder* button to upload an entire directory. When either of the import buttons is clicked, a popup appears (Fig. 48) allowing you to browse to a location where your file or folder is stored. Your selected file or folder is imported into the working folder and shown in the working folder window (Fig. 49).
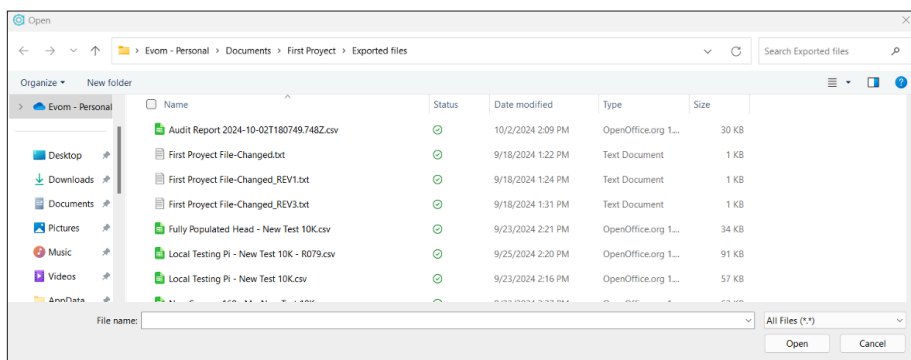

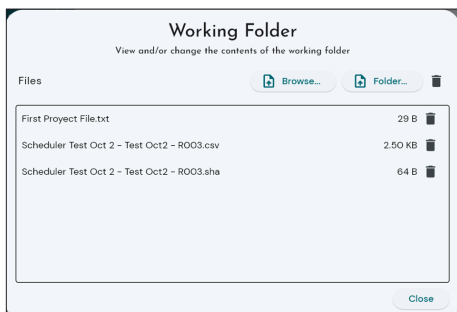Fig. 48—Select the file or folder you wish to upload to your working folder.

Fig. 49—The working folder list updates with the imported files.

3. Trash can icons to the right of each file allow you to remove the file from the working directory.

   NOTE: It is important to note that no files are ever truly deleted since they are always available in the previous version of the project.

Option B

In Option B you cannot import any files into the folder or delete any files from this working folder. In Option B, you can only view the contents of the working folder. Option B only lets you maintain the original files from the EVOM™ Auto instrument in the working folder. Other files are directed to your designated secured storage location for further data processing.

Creating a Project File

Creating a project file works the same way in both Option A and Option B versions. However, you may only create a project with files in the EVOM™ Auto GxP Option A software.

Option A has two new project icons ., a black one for creating a project with files in it and a white for creating a project that is empty and ONLY contains EVOM™ Auto GxP data files. The black folder is only visible in Option A software. Option B has only the white folder.

NOTE: For Option B all new projects will be empty, since they will not contain any data files. The first original date file from the instrument is stored in Revision 2.

1. To create a new project, log in to the EVOM™ GxP Client, and click on the hamburger icon ☰ in the upper left corner to display the project list.

Projects My Projects ▾ Q C   ⊞ ⊡

⤓ Build_912_Project   19 hours ago by user1

⤓ My First Project   20 hours ago by user1

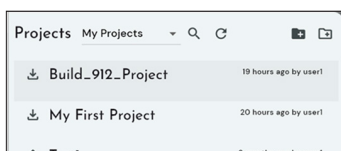⤓ Test   2 months ago by user1

Fig. 50—The New Project icons are located in the upper right corner of the Projects List.

2. Click on one of the new project icons in the upper right corner to create a new project. The black icon, only in Option A, allows you to create a project that is not empty. If you selected the black new project icon, the New Project window displays (Fig. 51), and if you selected the white icon, the New Empty Project window displays (Fig. 52).

Fig. 51—(Left) If you click on the black new project icon, the New Project window allows you to add files or folders to the project.
Fig. 52—(Right) If you select the white new project icon, you may only enter a name and notes.

3. Enter a name for your project into the *Project Name* field. If you desire, you may also add a description in the *Notes* field.

4. If you have Option A and selected the black icon, you may click the *Browse* button to load an external file into the project, or you may click the *Folder* button to add a directory to the project.

5. After you enter a project name the New Project button becomes active. Press the New Project button to create your project. The project window appears showing Rev. 1 (Fig. 53).

Fig. 53—The EVOM™ GxP Client Project window shows the revision 1.

Selecting a Plate Brand and Plate Profile

The plate brand selected displays in the upper right corner of the window. Selecting a brand loads the geographical coordinates for the specific plate you choose. The electrode array is configured to support various 24 or 96 HTS well plates. Three different brands of plates are supported by the 96-electrode array:

- **MT96_HTC** – MatTek 96 Well Plate
- **C96_HTC** – Corning 96 Well Plate
- **M96_HTC** – Millipore 96 Well Plate

Corning 24 HTS plates are supported by 24C electrode array, and Millipore 24 HTS pates are supported by 24M electrode array.

Three plate profiles per plate brand are allowed. For example, the Corning 24 has three plate profile options that may be saved. The plate profile names are editable. Each plate profile is tracked with the last date and time of change. Three different EVOM™ Auto GxP users can set their own plate profiles. Using the plate profile option with date and time stamp, you can track when any changes were made in the plate-electrode coordinate or positioning. Thus, plate profile options allow multiple users to operate the instrument without affecting each other's plate profile settings/data.

TIP: The last used plate profile is stored as the default for your convenience.

NOTE: Only plate profiles for the electrode array that is plugged into instrument are shown when you are in the online mode. To see all the data for other electrode array options, switch to offline mode.

1. To select the desired brand and plate profile, click on the brand name under the EVOM™ Auto logo in the upper right corner of the Main window (Fig. 54). A dropdown menu displays (Fig. 55).

   NOTE: On the *Expert* window, you may also select the brand from the displayed drop-down list.
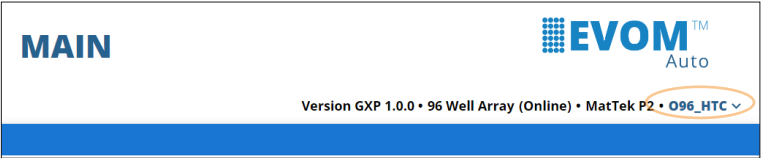

Fig. 54—Click on the brand in the upper right corner under the EVOM™ Auto logo to access the plate brand and plate profile menu.
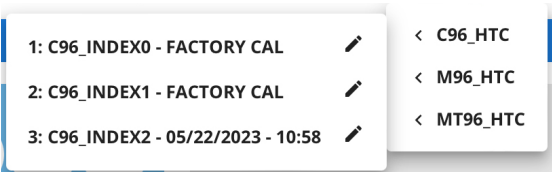

Fig. 55—The plate brand and profile menu displays. In offline mode, you can see all the plate brand options. In online mode, only the available option displays.

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2.   Select the desired brand (in offline mode), and then click on the profile choice.

3.   If you want to rename an existing profile, click on the pencil icon and enter the new name.

Online Status Definition and Use

The online status is displayed next to the electrode array type in the header under the EVOM™ Auto logo. The system automatically displays the head type for the electrode array that is plugged into the system. This field is not editable (Fig. 56). The system can only use the autosampler and collect data when it is in the *Online* state.
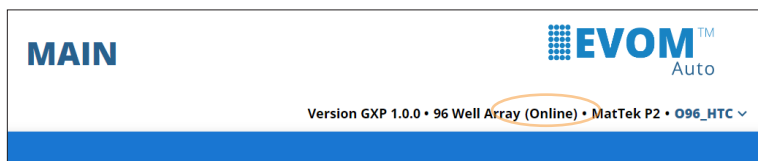

Fig. 56—The online/offline state of the system displays next to the electrode array type in the header on the right side of the window.

Creating a Plate File and Setting up Measurements

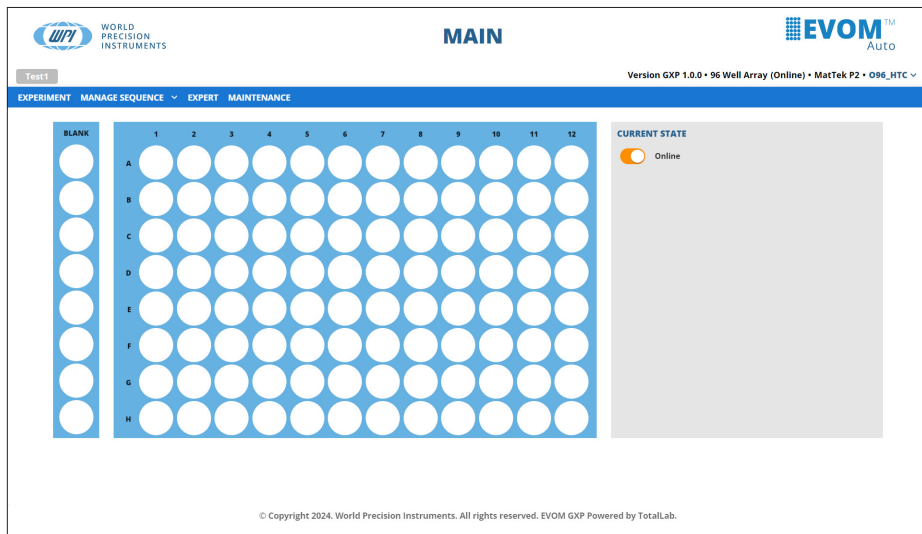When the system starts, the *Main* window displays.

Fig. 57—The Main Window appears.

1.   To create a measurement sequence, select the *Manage Sequence* menu. A list of the existing sequences displays (Fig. 58), and you can open and edit any existing sequence or select *New Sequence* to create a new one.

Fig. 58—The Manage Sequence menu lists the existing sequences.

If you select *New Sequence*, a popup allows you to name the sequence (Fig. 59). Enter a name, your comment, and your EVOM™ GxP Client password. If you don't want to add a comment, you may select the *No Comment* checkbox. If you do, default text appears in the comment line. Then, press the *Save* button to continue or the *Cancel* button to return to the main window without saving. The *Sequence* window appears (Fig. 60). The new sequence name is displayed on top of the window.

Fig. 59—Use this popup to name your sequence.

Fig. 60—The Sequence window lets you define a sequence.

2. You may choose to display the measured resistance values or the TEER measurement. TEER is a calculated value based on the surface area of the well and the measured resistance. Select the *Mode* menu. Options include *Resistance and TEER*.
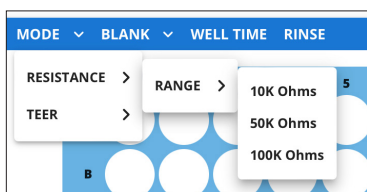

Fig. 61—The mode menu lets you select your options.

3. When you select the *Mode>Resistance>Range*, you can choose the resistance range for making measurements. Options include *10K Ohms*, *50K Ohms* and *100K Ohms*. The *Current State* area on the right side of the window updates accordingly.

   When you select *Mode>TEER*, you may choose the resistance range and the well area. The well area defines the surface area of a well on your plate. You may select the default surface area of the well or manually enter the value.

4. Select your blank option. This option measures the resistance of the first column (Wells A1, B1, C1... H1), and this value is used as a baseline for each row. Each value on the *Blank Value* table measures the resistance of the specific electrode pair used to measure each column on a well containing only buffer or media. (See the column highlighted in blue in Fig. 62.) These values (Value 1 ... Value 8) are subtracted from the measurements on the corresponding row (Red Rectangles) to obtain the change from the baseline well (the well with no cell growth) to omit any offset or background values.
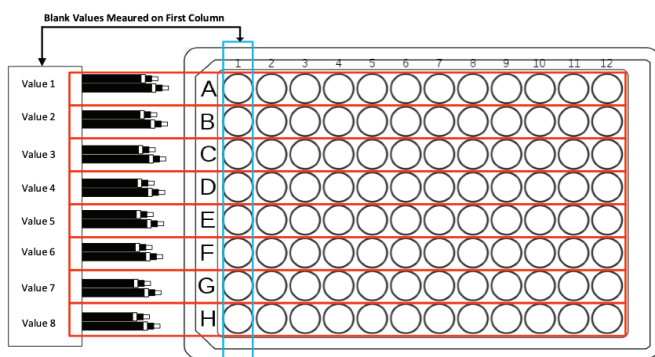

Fig. 62—The values of the blanks are measured to determine the baseline resistance without any cells. This figure shows an array of 96 wells.

   To start the blank setup, select the *Blank* menu and choose *Load Blank*, and then *New Blank* (Fig. 63) to create a blank baseline data file. A popup asks for a name for your new blank file or data set (Fig. 64).

NOTE: You may select previously created blank data sets, which will load previously measured values for the first column.
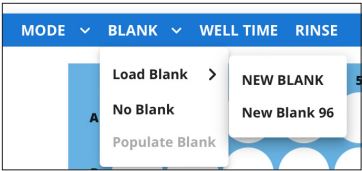

Fig. 63—The blank menu lets you create a new blank or load a previous set of data for blank wells.

Fig. 64—Enter the name of your new blank data set.

6. Enter a name and press *Save*, or press *Cancel* to abort the action. After the sequence is saved, the container is created with a default value of zero shown. The blank name is updated on the *Current State* area.

7. Load a well plate with media or buffer in the first column of wells and place it in the well plate area on the autosampler.

8. To measure the blanks and load that information into the blank data set, select the *Blank* menu and choose *Populate Blank*. A message appears indicating that the EVOM™ Auto GxP is about to measure the resistance values of the first column and that a well plate with the desired level of buffer or media solution must be placed in the well plate area to be measured (Fig. 65). Press *Continue* to begin or *Cancel* to abort the action. A message displays briefly at the bottom of the screen to indicate the population of the blank will begin.

Fig. 65—An informational message appears to make sure you have positioned your well plate on the autosampler and filled the first column of wells with media.

The autosampler moves the electrode array to Column 1 and measures all eight values consecutively. The values are shown in the *Blank* area on the window as they are populated.

9. After the measurement is completed, a message appears (Fig. 66). Press *OK* to complete the sequence. You may re-sample the blanks as many times as desired, now or in the future.
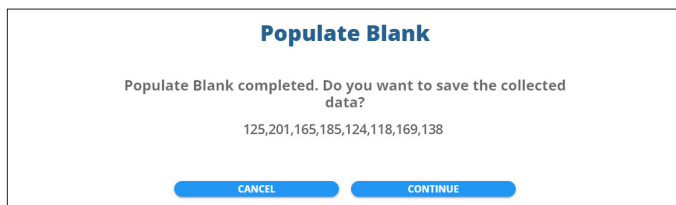

Populate Blank

Populate Blank completed. Do you want to save the collected data?

125,201,165,185,124,118,169,138

CANCEL   CONTINUE

Fig. 66—The message indicates that the blank measurements have completed.

10. Setup the well time by selecting the *Well Time* menu. The well time is the number of seconds the electrodes are held immersed in a well before measurements are taken. The *Well Time* popup appears (Fig. 67). Enter the desired time in seconds and press *Save*. The updated value displays in the *Current State* area of the window.
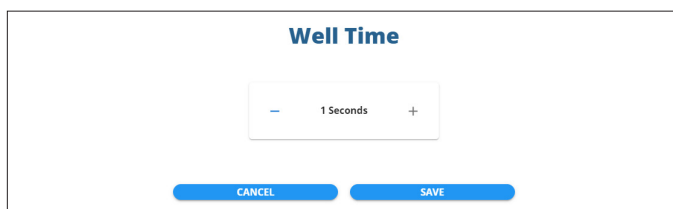

Well Time

−   1 Seconds   +

CANCEL   SAVE

Fig. 67—Set the desired amount of time that the electrodes will be immersed in a well before taking measurements.

11. The three rinse stations may be used for rinsing, disinfecting, stabilizing or any other function desired. Configure the rinse schedule by selecting *Rinse* from the menu. The *Rinse Time* window appears (Fig. 68). You can set the rinse time and the wait time in each rinse station using the toggle controls on each field. Three toggle buttons in the *Rinse Options* section on the right side of the window let you set when the rinse and wait parameters are implemented.

The rinse time is the duration of time that the electrode array stays immersed in the rinse station. The wait time is the duration the electrode array waits above the rinse station to drip any remaining liquids. You may choose any combination of these options:
  - Between measurements
  - At the beginning of a sequence
  - At the end of a sequence

NOTE: If none of the check boxes are selected, measurement will be taken with no rinsing operations.

Fig. 68—The Rinse Time window lets you configure the rinse schedule.

For example, the following rinse schedule will run as shown in Fig. 70.

Fig. 69—This is an example of a rinse schedule.
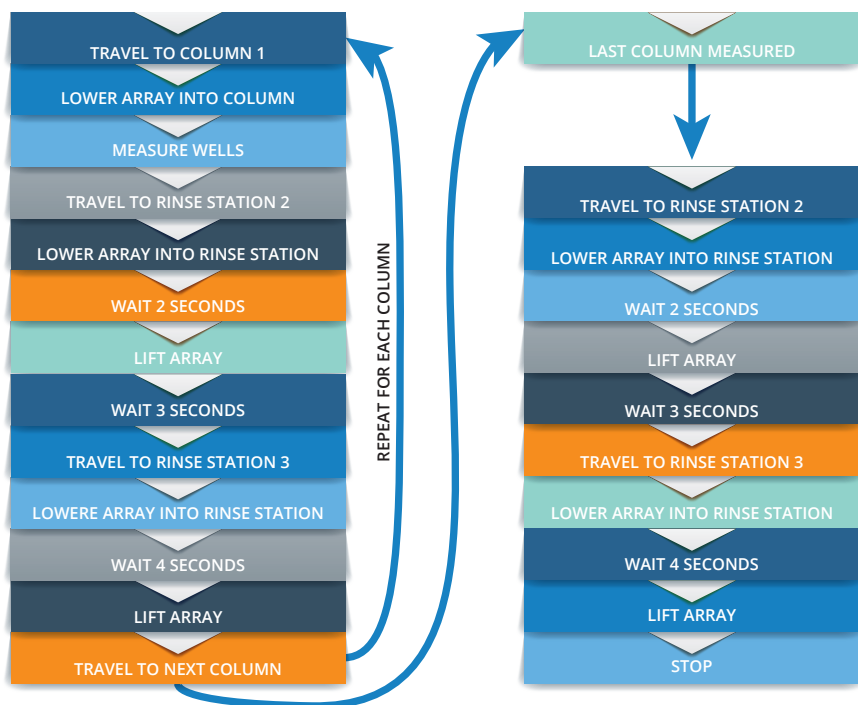
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Fig. 70—This is the sequence of events that happens based on the example program above.

12. After the schedule is set in the *Rinse Time* window, press *Save* to save the changes, and then return to the *Sequence* window. Press *Cancel* to abort without saving the changes.

13. Press the *Save* icon ⬛ in the bottom right corner of the *Sequence* window to save the sequence. In the popup window (Fig. 71), enter your comment, and your EVOM™ GxP Client password. If you don't want to add a comment, you may select the *No Comment* checkbox. If you do, default text appears in the comment line. Then, press the *Save* button to continue or the *Cancel* button to return to the main window without saving.

Fig. 71—Enter your comment and password to save the sequence.

A brief message displays indicating the sequence was saved.

Now that we have defined the sequence, we can use it in a plate. For example, you can run an experiment with a saved protocol. Press the *Back* button to return to the *Main* window and select the *Experiment* menu to begin taking measurements.

NOTE: If you press the *Back* button without saving, a confirmation message appears (Fig. 72) asking if you want to proceed without saving. Press *Cancel* to return to the screen and save your changes or *Continue* to proceed to the main window without saving the changes.
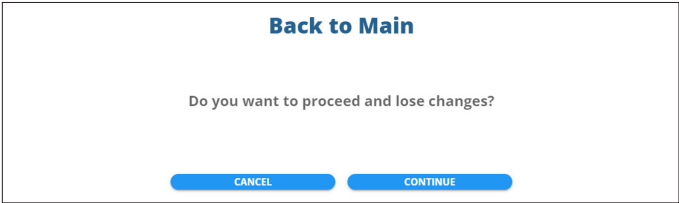
Fig. 72—To save the sequence, press Cancel and return to the previous window.

Deleting a Sequence

1. To delete a measurement sequence, select the *Manage Sequence* menu. A list of the existing sequences displays (Fig. 73), and you select the sequence you want to delete. The Sequence window displays.

Fig. 73—The Manage Sequence menu lists the existing sequences.

2. Click on the delete icon in the bottom right corner of the window. A popup displays (Fig. 74).

Fig. 74—Use this popup to name your sequence.

3. Enter your comment, and your EVOM™ GxP Client password. If you don't want to add a comment, you may select the *No Comment* checkbox. If you do, default text appears in the comment line. Then, press the *Delete* button to continue or the *Cancel* button to abort the delete action.

Running an Experiment

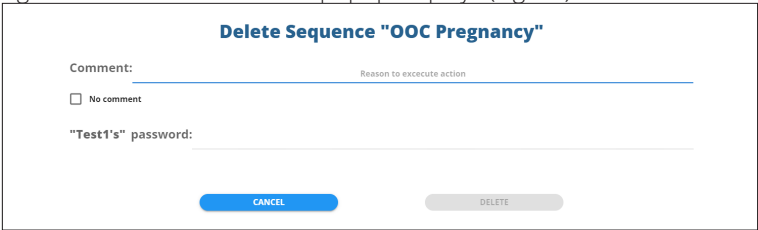After you have defined a sequence, you can begin running an experiment. The *Experiment* window shows a representation of the plate on the left side of the window. On the right side of the window, you see these areas:

- *Current State* region shows the status of the autosampler and remaining time. It also shows the schedule settings.
- *Details* area lets you set your plate name, choose a sequence, select your blank and make notes.
- *Plate Controls/Schedule Controls* areas have all the buttons for controlling an experiment or scheduling an experiment.
- *System Controls* area has the buttons to manage the data files and the emergency shut off for the autosampler.
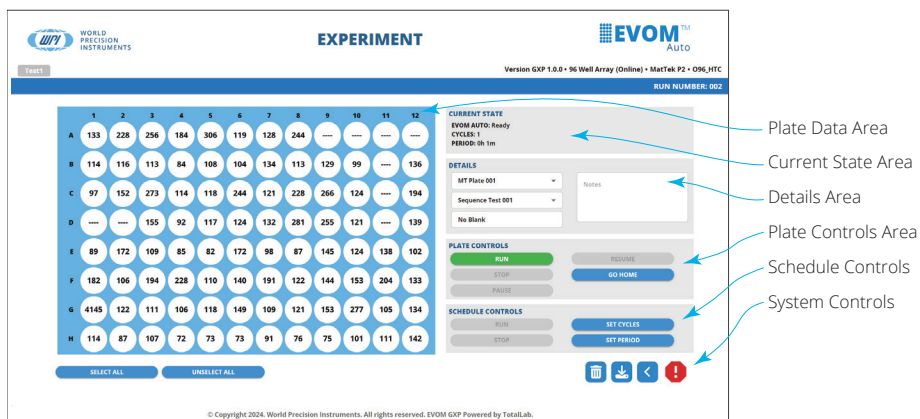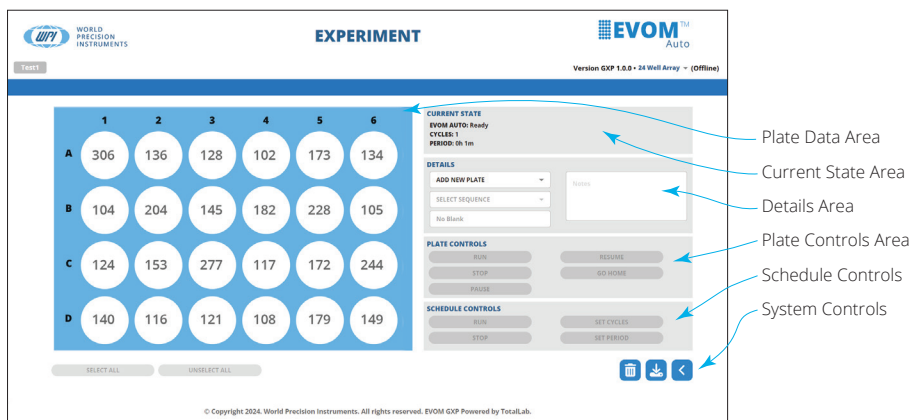

Fig. 75—The experiment window has several important areas.

The selected wells appear white in color and unselected wells appear grey in color. In order for the *Run* button and other options to be active, at least one well needs to be selected. Also, a sequence file needs to be selected in order to measure a plate.

Fig. 76—The Experiment window has a 24 well plate window with readings for a 24 Millipore HTS plate, shown in offline mode.

NOTE: In offline mode the *Run* and other options are unavailable. Only previous collected data for a plate may be viewed.

The buttons in the *Plate Controls* Area function as follows:

Run – Starts the data acquisition sequence.

Stop – Finishes the data collection on the present column and lifts the electrode array out of the well plate. The data acquisition is halted.

Pause – Finishes the data collection on the active column and lifts the electrode array out of the well plate. Continue the data acquisition run by pressing the *Resume* button.

Resume – Restarts the data collection at the point it left off when you pressed the *Pause* button.

Go Home – This places the electrode array in the home position away from the well plate and rinse stations. This option is only available after pressing the *Stop* button.

The buttons in the *Schedule Controls* area function as follows:

Run – The *green* button starts the first scan. The time and cycle counters become active, counting down one by one until they reach zero, when the measurement stops. Every time a scan finishes, the data is saved, and the plate run number increments. When the scheduled operations are not being used, the counters are displayed in grey. When active, the buttons are green.

Stop – The *red* button stops the scheduler. The current scan will continue until you press the *Stop* button.

Set Cycles – Brings up a popup to set the number of scans to be performed using the current sequence.

Set Period – Brings up a popup to set the length of time in between well plate scans.

In the *Plate Controls* area, available options are shown in color. If an option is not available, the button will be grey. For example, at the beginning of data acquisition, the *Run* and *Go Home* buttons will be the only valid options.
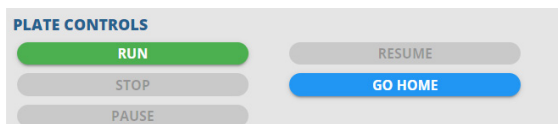

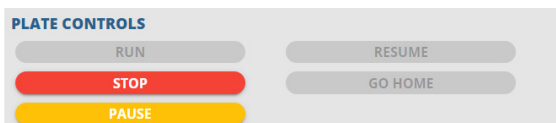*Fig. 77—Controls at the beginning of data acquisition.*
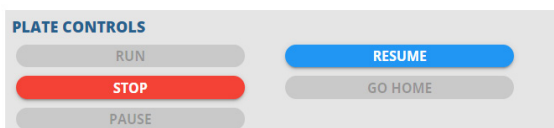

Fig. 78—Controls when a sequence is running.

Fig. 79—Controls when a sequence is paused.

The *System Controls* area has four buttons as follows:

Delete   Download   Back   STOP

Fig. 80—System Control buttons.

Delete – Deletes the current data file. This option is not valid during data acquisition.

Download – Downloads the current data file. This option is not valid during data acquisition.

Back – Returns you to the previous window (*Main* page). If you press this during data acquisition, a popup asks if you wish to discard the collected data. Press *Yes* to discard the data and return to the previous window or *No* to all the data collection to finish normally.

Stop – This emergency stop button is always active. If you press this button, the autosampler will immediately stop, no matter where it is in a sequence. All measurement will be suspended.

NOTE: When a plate file finishes a run, a message window opens, giving you the option to save the data.

To begin running an experiment:

1. Select *Experiment* from the main menu. The *Experiment* window appears (Fig. 81).
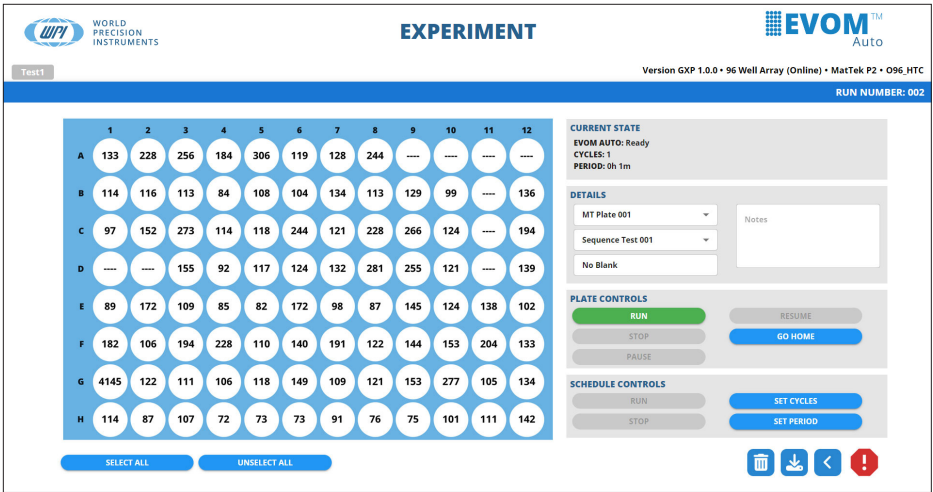

Fig. 81—The Experiment window appears. This example shows a 96-well plate option.
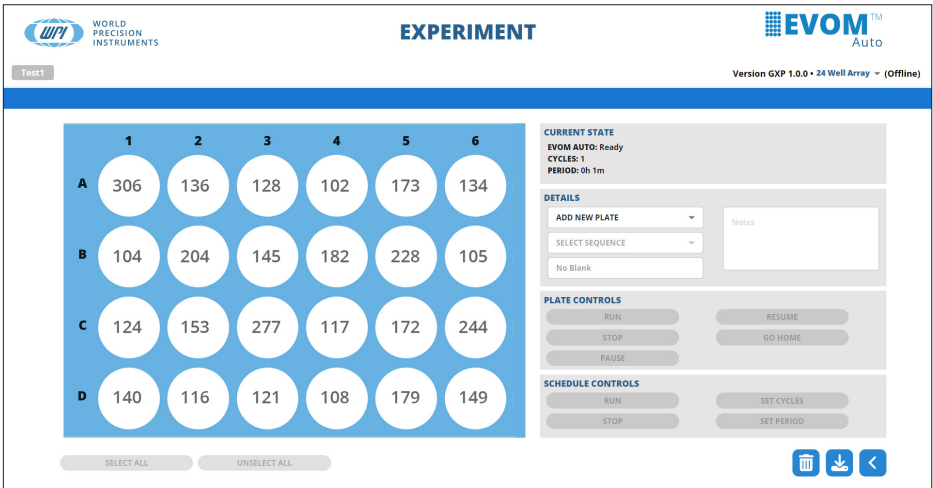
Fig. 82—This example shows a 24-well plate option, in offline mode.

2. Select the *Plate Name* drop-down in the *Details* area on the right side of the screen. Choose from the list of existing plates or select *Add New Plate* to define a new plate. A popup appears so you can enter a name for the plate, your comment, and your EVOM™ GxP Client password. If you don't want to add a comment, you may select the *No Comment* checkbox. If you do, default text appears in the comment line (Fig. 83).

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NOTE: The plate name refers to the CSV output file name where data is saved. If the same plate name is used to read multiple plates, readings for different plates are saved as different run numbers 01, 02 (as different tables) under the same file. Each table would have its date and time stamps and any additional notes you add.

Fig. 83—Plate name popup.

3. Press the *Save* button. A green confirmation message appears briefly in the bottom left corner of the window indicating that the plate was successfully created (Fig. 84). This indicates that this is the first data set for this plate when measurements are taken. The run number displays in the menu bar and indicates the number of times you have run the plate sequence.

Fig. 84—Confirmation message displays briefly in the bottom left corner of the window.

4. Select the *Sequence Name* drop-down, the second drop-down in the *Details* area on the right side of the screen. A list of existing sequences appears. Select the appropriate sequence that you created earlier.

    A blank data table with no data values displays in the window. At this point, select which wells you want to measure. Press the *Select All* button below the data table to select all the wells. The selected wells change color as you select them. You may also select or unselect wells by clicking on them directly. Selected wells are white, and unselected cells are grey.

    Select rows and columns by double clicking on the arrows to the left of rows or on the top of columns in the Experiment window that appear when you hover over the column or row numbers. This is only available when you are running the software revision 3.0.0 or higher. (Fig. 85)
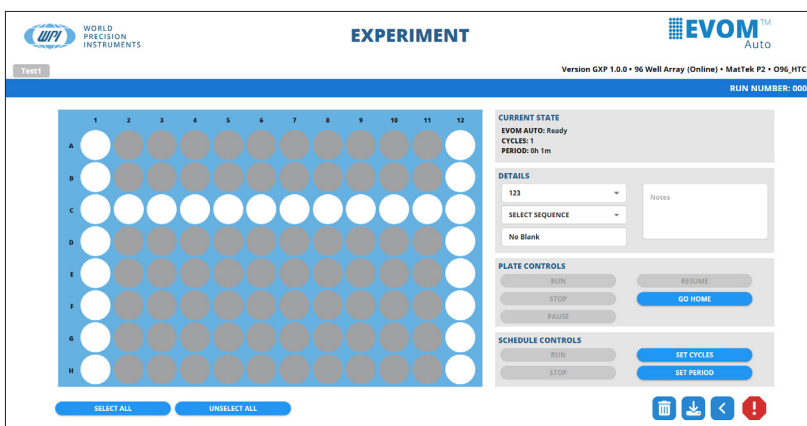
Fig. 85—Double click the arrow on the top of a column or beside a row to select the column or row of the well plate to read in the experiment screen.

NOTE: The status line below the table indicates the EVOM™ autosampler is ready.

5. Press the *Run* button located in the *Plate Controls* area on the right side of the window. A popup window appears (Fig. 86) where you can enter your comment, and your EVOM™ GxP Client password. If you don't want to add a comment, you may select the *No Comment* checkbox. If you do, default text appears in the comment line. Then, press the *Run* button to continue or the *Cancel* button to return to the previous window.

Fig. 86—Enter your comment and password and click Run to run the experiment.

The sequence is executed. A brief message in the lower left corner indicates that the experiment has started. If you defined the blank container, the data displayed represents the difference between the baseline and the actual value measured.

NOTE: If the blank values have overflow values, the calculated values on the *Experiment* window are also invalid and will show a --- or *OVF*. Therefore, ensure your blank values are valid.

7. At any time, you may add comments for the data run being collected. Click inside the *Notes* text block in the *Details* section on the right side of the screen to attach notes to the plate run. All your comments must be added before you click the *Run* button.

TIP: Select only the wells containing samples. Reading empty wells takes longer to

finish reading the sample plate. Click any selected well to disable it, and then read the sample plate.

8. You may pause or stop the experiment, if necessary. If you pause or stop the experiment, you will be prompted for a comment and your password.

- If you stop an experiment (Fig. 87), the autosampler finishes the data collection on the present column and lifts the electrode array out of the well plate. The data acquisition is halted. The sequence may be restarted.
- If you pause the experiment (Fig. 88), it finishes the data collection on the active column and lifts the electrode array out of the well plate. Continue the data acquisition run by pressing the *Resume* button. You will again be prompted to enter a comment and your password (Fig. 89).

Fig. 87—To stop an experiment, you need to enter a comment and your password.

Fig. 88—To pause an experiment, you need to enter a comment and your password.

Fig. 89—To resume an experiment, you need to enter a comment and your password.

Downloading the Plate File

Once a data acquisition run is completed, the data can be "staged." This process prepares all the runs performed on a plate into a downloadable, comma-delimited (CSV) file which can be read by Microsoft® Excel. The downloaded file will be available from the EVOM™ GxP Client after the project is committed.

1. To stage a data file, press the *Download* button in the *System Controls* area in the bottom right corner of the Experiment window.

   NOTE: The data may also be staged from the Audit Report window which is accessed from the Maintenance window. Press the report icon in the bottom right corner of the window to access the Audit Report. Then, you may press the *Download* button to stage the data.

2. Return to the EVOM™ GxP Client and login if necessary.

3. Follow the instruction found in "Exporting the Logs" on page 26 to download the data file you want to view.

   NOTE: Data file names are appended with a numerical value in the form of R001 to indicate which run of the data it contains. R001 is the first run.

4. Open the file with Microsoft® Excel. The first line of the file indicates when the data was exported.

Fig. 90—The CSV file shows the export date of the file in the first line.

For each run there is a header section. The first run at the top of the file is the most recent. A sample file is shown in Fig. 91.
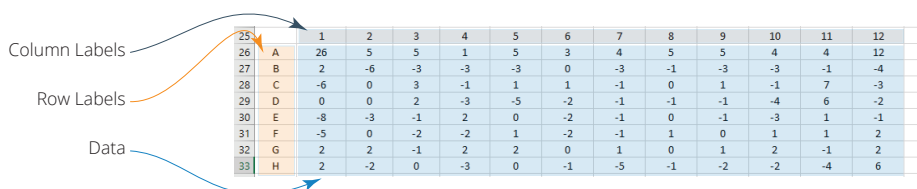

Fig. 91—Sample data file.

Following the header is the data table. See Fig. 92.

Column Labels

Row Labels

Data

Fig. 92—Sample data table in CSV format.

Plates files may be downloaded at any point after a data acquisition run is completed.

Deleting a Plate File

Plates files may be deleted using the *Delete* button in the *System Controls* area in the bottom right corner of the window. When a plate is deleted, all data runs are deleted. The sequences are not deleted since other plates may be referencing the same sequences. If you choose to delete a file, a confirmation popup appears asking you to verify that you want to delete the selected plate file (Fig. 93). Select the *Delete* button, and then enter your comment and your EVOM™ GxP Client password. If you don't want to add a comment, you may select the *No Comment* checkbox. If you do, default text appears in the comment line. Then, press the *Delete* button to delete the file or the *Cancel* button to abort the deletion.

Delete Plate "MatTek 006"

Comment: Reason to execute action

☐ No comment

"Test1's" password:

CANCEL   DELETE

Fig. 93—Confirmation popup to verify the deletion of a plate file.

Scheduling Operations

The data acquisition functions of the EVOM™ Auto GxP may be repeated at a user-defined time interval when multiple scans of a plate are needed. The scheduled operations are displayed on the right side of the *Experiment* window in the *Current State* area (Fig. 94). The control buttons for scheduling are in the *Schedule Controls* area on the right side of the window (Fig. 95).
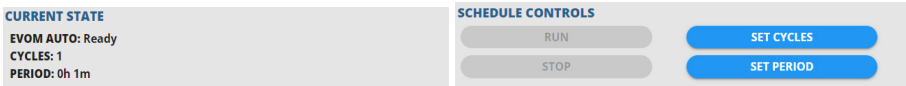
CURRENT STATE	SCHEDULE CONTROLS	
EVOM AUTO: Ready	RUN	SET CYCLES
CYCLES: 1	STOP	SET PERIOD
PERIOD: 0h 1m		

Fig. 94—(Left) Current State area of the window when a schedule is running.
Fig. 95—(Right) Plate Controls area of the window for running a schedule.

Running a Scheduled Measurement Sequence

1. Press the *Set Period* button to set the length of time in between well plate scans. A popup displays (Fig. 96). Enter into the field a four-digit number (HHMM) to set the hours and minutes or click on the clock icon to reveal a graphical helper (Fig. 97). Use the spinner to select the hours. You may select from 1 to 23 hours. The first 12 hours are on the outside of the spinner, and the inner spinner is used to set 13 – 23 hours. After you make that selection, the spinner displays minutes and you may use the dial to set the number of minutes in the period (Fig. 98). Then, press the *SAVE* button to save the changes.

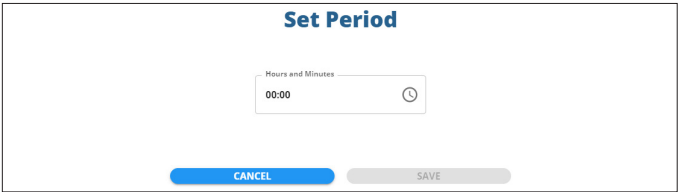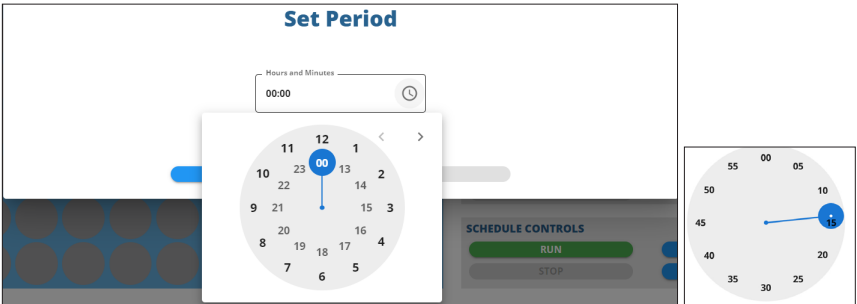*Fig. 96—Tap the numbers in the hours and minutes field to set the period.*

Fig. 97—(Left) Click the clock icon to reveal the graphical helper. Then, use the spinner to set the number of hours and minutes for which you want the schedule to run.
Fig. 98—(Right) If you used the spinner to set the hours of the period, then the display changes to allow you to set the minutes of the period.

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2. Press the *Set Cycles* button to set the number of scans to be performed according to the current sequence. A popup displays (Fig. 99). Use the + and – buttons to increment or decrement the number of scans. Then, press the *OK* button to save the changes.
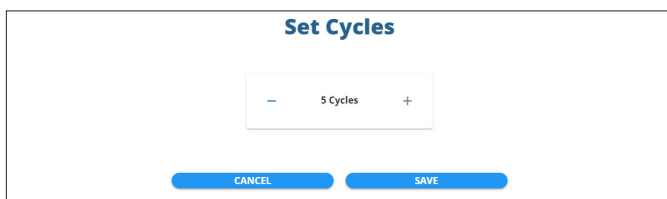

Fig. 99—Use the buttons to set the number of scans to be performed.

3. Press the *Run* button in the *Schedule Controls* area to start the first scan. After that scan, the *Time* and *Cycle* counters become active in the *Current State* area on the right side of the window (Fig. 100). They will continue counting down until they reach zero. Then, measurements stop. When a scan is finished, the data is saved, and the plate number (run number) increments. When the scheduled operations are dormant, the counters display grey. When the schedule is active the counters turn green.

    NOTE: A minimum of two cycles need to be selected in order for the Schedule Controls options to be active.

Fig. 100—The counters display when the schedule is active, and it only appears when it is actually counting down.

Stopping a Running Scheduled Sequence

Press the *Stop* button in the *Schedule Controls* area to stop the schedule. Enter your comment and your EVOM™ GxP Client password. If you don't want to add a comment, you may select the *No Comment* checkbox. If you do, default text appears in the comment line. Then, press the *Stop* button. The current scan will continue until it completes the cycle. The *Stop* and *Pause* buttons become active in the *Plate Controls* area.

Fig. 101—Enter your comment and password and press the Stop button to abort a scheduled run.

If you need to stop the scan, you must also press the *Plate Controls Stop* button. Enter your comment or select the *No Comment* checkbox and enter your EVOM™ GxP Client password. Then, press the *Stop* button. Measurements continue until the scan reaches the end of the active column. The data is automatically saved, and the saved data includes all the collected data, including the last active row scanned.

Fig. 102—Enter your comment and password again to stop the experiment.

MAINTENANCE

The electrodes require regular maintenance to keep them performing optimally.

Chloridizing – To replenish the chloride on the surface of the electrodes, the electrode tips need to be submerged in a bleach solution (3–6% sodium hypochlorite) for at least 10 minutes, followed by a rinse with distilled water.

Stabilization – Once chloridized, the electrodes need to be stabilized by being submerged in buffer solution or media.

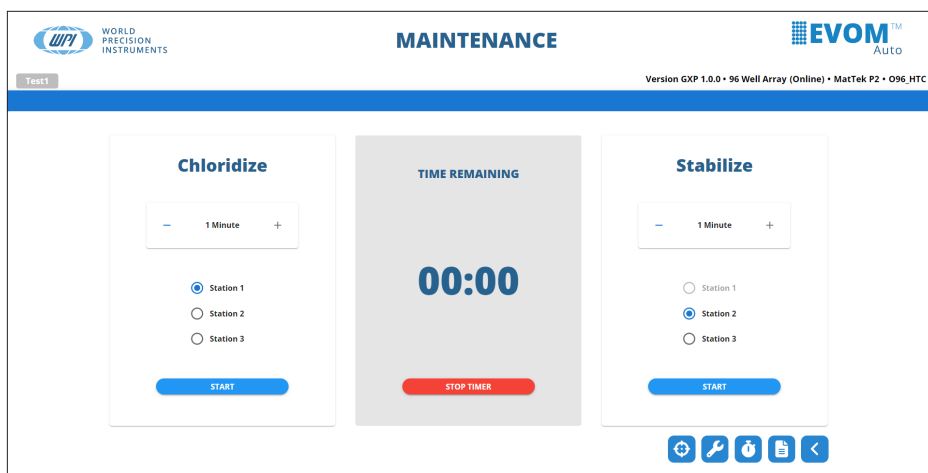The *Maintenance* window allows for a timed soaking for each operation.

Fig. 103—Maintenance window.

Four control buttons are located at the bottom of this window:

- - Go home button positions the electrode array in the home position.
- - Calibrate takes a few moments to calibrate the sensor head using the internal reference resistor. Nothing involving the motor movement happens. The icons show the animation until the process is completed.
- - Set/Read Time allows you to synchronize the date and time of the EVOM™ Auto GxP system to the laptop. This date is used to time stamp data when acquiring data and when exporting it.
- - Back returns you to the previous window.
- - Audit trail allow you to download a report of he project.

Cleaning the Electrode Array

You can use 70% ethanol or isopropanol to disinfect the electrodes. Insert sterile disposable rinse station inserts in the base rinse station and add solutions to the rinse station inserts. For convenience and to maintain sterile conditions, add a fresh or new sterile disposable rinse station for effective and fast electrode disinfection. You can include a rinsing option in the sequence. For example, your rinse protocol could include:

- Rinse station 1– 70% Ethanol
- Rinse station 2 – Sterile water, media, or buffer
- Rinse station 3 – Sterile media

1. Select *Manage Sequence* from the main menu and then choose *Rinse* to access the Rinse Time window.

Fig. 104—The Rinse Time window lets you configure the rinse schedule

2. Select your options:
   - Select the *Rinse Between Measurements* option so that the electrode gets quickly disinfected during analysis. Rinse stations 2 and 3 will remove the alcohol before the electrodes go into samples.
   - You can set the rinse time, but you may or may not need to select a wait time. This option allows the electrodes to dry or drip any remaining liquid.
   - For longer disinfection at the end of the day, use the *Maintenance* window and keep the tips in ethanol or isopropanol for 15-20 minutes followed by a rinse with distilled water.

Bleach maintenance is intended for chloridizing the electrode for proper functionality, this will also act as a disinfectant. Ten minutes of chloridizing is recommended every 1-2 weeks. Make sure the bleach is washed off with distilled water. See "Chloriding the Electrode Array" on page 57.

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NOTE: Only the electrode tip may be immersed in liquids (for example, ethanol). The remaining parts of the electrode may be disinfected by wiping them with a paper towel or Kimwipe sprayed with alcohol.

Cleaning the Autosampler and Interface Unit

Spray 70% ethanol or isopropanol on a paper towel and wipe the instrument.

(!) **CAUTION:** Do not directly spray alcohol on the instrument.

Chloriding the Electrode Array

1. Select *Maintenance* on the main menu. The *Maintenance* window appears.

Fig. 105—The Maintenance window.

2. To chloridize, press the + or – buttons to set the timer to the desired time in minutes in the *Chloridize* frame.

3. Select the radio button for the rinse station containing the chloridizing solution.

4. Fill the appropriate rinse station with a bleach solution.

5. Press the *Start Timer* button. The Start Chloridize popup displays. Enter your comment and your EVOM™ GxP Client password. If you don't want to add a comment, you may select the *No Comment* checkbox. If you do, default text appears in the comment line. Then, press the *Start* button. The time interval displays on the counter in the center of the window. The title changes to *Chloriding Time Remaining*.

Fig. 106—Enter your comment and password and press the Start button to begin the chloridizing process.

6. The electrode array moves to the selected rinse station, and the counters start counting down to zero.

7. When the count reaches zero, the electrode array retracts.

8. At any point, you may stop the counter by pressing the *Stop Timer* button. This resets the counter to zero and retracts the electrode array.

Decontaminating the Unit

If the EVOM™ Auto GxP unit needs to be returned to WPI, it must be properly decontaminated prior to packing and shipping.

1. Decontaminate the electrodes by immersing the electrode tips in 70% ethanol or isopropanol for 20 minutes.

2. Decontaminate the exterior surfaces of the autosampler, the interface unit, and the exterior of the electrode array.
    - Spray 70% ethanol or isopropanol on a paper towel or Kimwipe.
    - Thoroughly wipe all the exterior surfaces of the EVOM™ Auto GxP, including the autosampler, the interface unit, and the exterior of the electrode array.
    - Allow the alcohol to evaporate for 20 minutes before packing the system for shipment to WPI.

CAUTION: Do not directly spray alcohol on the instrument.

Stabilizing the Electrode Array

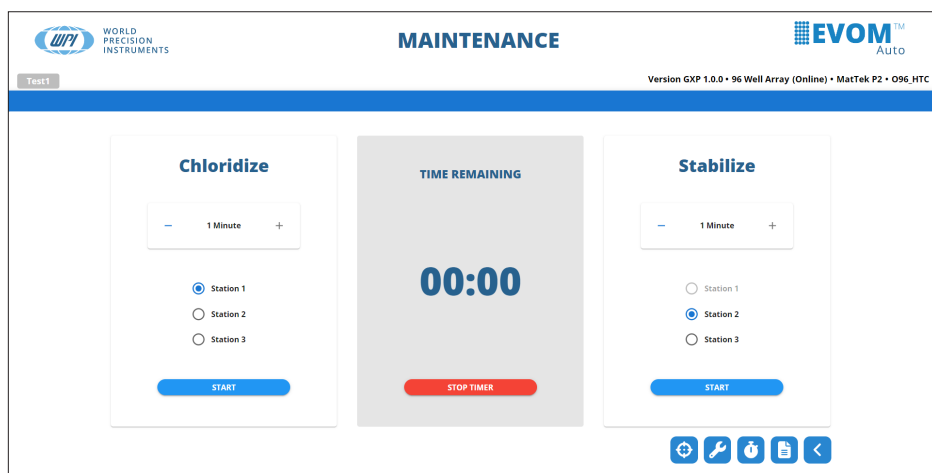1. Select *Maintenance* on the main menu. The *Maintenance* window appears (Fig. 105).

2. To stabilize, press the + or – buttons to set the timer to the desired time in minutes in the *Stabilize* frame.

3. Select the radio button for the rinse station containing the buffer solution.

4. Fill the appropriate rinse station with distilled water.

5. Press the *Start Timer* button. The Start Stabilize popup displays. Enter your comment and your EVOM™ GxP Client password. If you don't want to add a comment, you may select the *No Comment* checkbox. If you do, default text appears in the comment line. Then, press the *Start* button. The time interval displays on the counter in the center of the window. The title changes to *Stabilizing Time Remaining*.
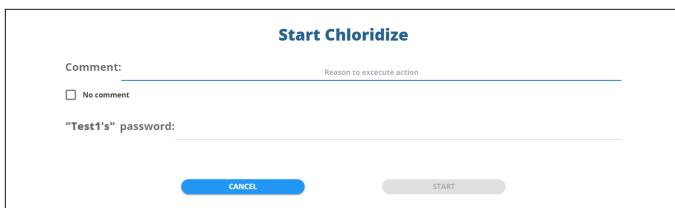

Start Stabilize

Comment: _____ Reason to excecute action

☐ No comment

"Test1's" password: _____

CANCEL   START

Fig. 107—Enter your comment and password and press the Start button to begin the stabilization process.

6. The electrode array moves to the selected rinse station, and the counter starts counting down to zero.

7. When the count reaches zero, the electrode array retracts.

8. At any point, you may stop the counter by pressing the *Stop Timer* button. This resets the counter to zero and retract the electrode array.

9. In the third rinse station, you may perform another rinse in distilled water.

NOTE: The radio button selection requires different rinse stations to be used for chloriding and stabilizing.

ACCESSORIES/SERVICES

Part Number	Description
EVA-GXP-01-01	EVOM™ Auto GxP Compliance Module Powered by TotalLab
EVA-GXP-01-02	EVOM™ Auto GxP Compliance Module Powered by TotalLab
EVA-GXP-01-03	EVOM™ Auto GxP Yearly Renewal Powered by TotalLab
EVA-GXP-01-04-UPGR-S	EVOM™ Auto Upgrade to GxP Module (Standard) Powered by TotalLab
EVA-GXP-01-04-UPGR-R	EVOM™ Auto Upgrade to GxP Module (Restricted) Powered by TotalLab
EVA-MT-03-INS	EVOM™ Auto On-Site Installation & Training
EVA-MT-03-IOQ	EVOM™ Auto Instrument IQ/OQ
EVA-GXP-01-05-IOQ-V	EVOM™ Auto GxP IQ/OQ Virtual by TotalLab
EVA-GXP-01-05-IOQ-O	EVOM™ Auto GxP IQ/OQ On Site by TotalLab

TROUBLESHOOTING

Issue	Possible Cause	Solution
Reading displays as dashes	You may not have adequate apical or basolateral liquid volumes.	Increase the liquid volumes.
	Readings may be out of range.	Make sure 100 KΩ maximum range is selected.
Unable to launch EVOM™ Auto GxP from the EVOM™ GxP Client	Connectivity Issue	1. Make sure the Ethernet cable is properly secured on the port of the interface unit side and properly secured onto the USB adapter. 2. Restart the interface unit. 3. If the issue persists, go to the Wiindows settings, click Network & internet, and then click Ethernet to verify that Ethernet is connected. Otherwise, Ethernet connectivity needs to be re-established. See "Appendix E: Configuring the Ethernet Adapter" on page 68.

NOTE: If you have a problem/issue with that falls outside the definitions of this troubleshooting section, contact the WPI Technical Support team at (941) 371-1003 or wpirms@wpiinc.com.
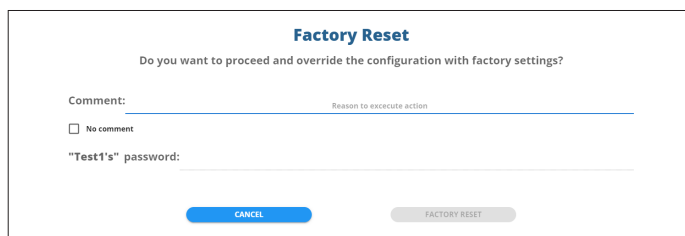
SPECIFICATIONS

This unit conforms to the following specifications:

Autosampler Dimensions (W×D×H)...16×10×8.4"
Autosampler Weight ....15.5 lbs.
Interface Unit Weight.. 1 lb.
CE Certified...Yes
UL/CSA Certified ....Yes
Compatibility... 96-well HTS Plates (Corning, Millipore, MatTek)
.... 24-well HTS Plates (Corning, Millipore)
Resistance Range.. 10KΩ, 50KΩ, 100KΩ
Number of Rinse Stations 3
Electrode Array for 96 HTS Plate ....Array of 8 pair of (1.2mm Φ) electrodes
Electrode Array for 24 HTS Plate ....Array of 4 pair of (1.2 mm Φ) electrodes
Minimum Sample Reading Time ....1 Second
Device Connectivity .... Wi-Fi
Wi-Fi Range...25 ft./7 m
Software Type...Web browser
Control Device for Running Software ....Laptop running EVOM™ GxP Client
Output Data ....CSV/Microsoft® Excel
Equipment rating.. 12 VDC 1.67 A
Operating Temperature Range (Autosampler) .... 15°C (59°F) to 40°C (104°F)
Humidity Rating (Autosampler) ....10% to 98% RH, non-condensing
Operating Temperature Range (Interface Unit).........................15°C (59°F) to 35°C (95°F)
Humidity Rating (Interface Unit)...10% to 90% RH, non-condensing
Maximum Altitude: Standard Commercial Electronics.......................Up to 2000 m (6562')
IPX rating.. IPX0; No protection against water
Pollution Degree 1
    Definition...............................No pollution or only dry, non-conductive pollution occurs
    Typical Environment.............................Clean rooms, laboratories, and other controlled
        environments where dust and moisture are minimal
    Impact on Insulation ....Pollution does not affect the insulation of the equipment
Specification for intermittent operation limits (duty cycle if applicable).......No minimum.
    The equipment can operate continuously (100% duty cycle).

APPENDIX A: RESTORE FACTORY DEFAULTS

If you need to restore the factory default parameters, press the *Restore icon* ⚙ at the bottom of the *Expert* window. A popup window opens asking you to verify whether you want to restore factory settings for that plate profile. In the popup window (Fig. 108), enter your comment, and your EVOM™ GxP Client password. If you don't want to add a comment, you may select the *No Comment* checkbox. If you do, default text appears in the comment line. Then, press the *Factory Reset* button to continue or the *Cancel* button to return to the *Expert* window without performing a reset.

Factory Reset

Do you want to proceed and override the configuration with factory settings?

Comment:

Reason to excecute action

☐ No comment

"Test1's" password:

CANCEL   FACTORY RESET

Fig. 108—Click continue to restore the factory settings.

APPENDIX B: SYNCHRONIZING THE READ TIME

The Set/Read Time function on the *Maintenance* window allows you to synchronize the date and time of the EVOM™ Auto GxP system to the computer. This date is used to time stamp data when acquiring data and when staging it for export.

Open the Maintenance window by selecting it from the main menu. Press the Set/Read Time icon 🕐 located in the lower right corner of the window. A popup window opens (Fig. 109). Enter your comment, and your EVOM™ GxP Client password. If you don't want to add a comment, you may select the *No Comment* checkbox. If you do, default text appears in the comment line. Then, press the *Synchronize* button to continue or the *Cancel* button to return to the *Maintenance* window without performing a reset.
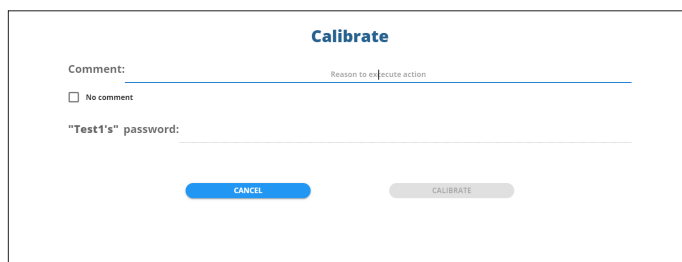
Fig. 109—Click synchronize to match the EVOM™ Auto GxP to the laptop system time.

APPENDIX C: CALIBRATE THE ELECTRODE

You may calibrate the electrode array head using the internal reference resistor. Nothing involving the motor movement happens. Open the Maintenance window by selecting it from the main menu. Press the Calibrate icon 🔧 located in the lower right corner of the window. A popup window opens (Fig. 110). Enter your comment, and your EVOM™ GxP Client password. If you don't want to add a comment, you may select the *No Comment* checkbox. If you do, default text appears in the comment line. Then, press the *Calibrate* button to continue or the *Cancel* button to return to the *Maintenance* window without performing an electrode array calibration. The icon shows the animation until the process is completed.

Fig. 110—Click synchronize to match the EVOM™ Auto GxP to the laptop system time.

APPENDIX D: USING EXPERT MODE

In Expert mode, you can adjust the positions of the first column in the X direction and the depth of measurement (Z direction). If the position of the electrodes needs to be adjusted, select the *Expert Mode* menu. When entering the Expert mode, a warning displays indicating that potential damage to the instrument is possible (Fig. 111). Use caution. Once you have read the instructions on how to use this mode, press *Continue* to continue.
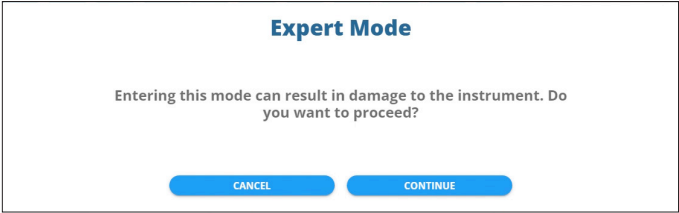

Fig. 111—Select Continue to continue.
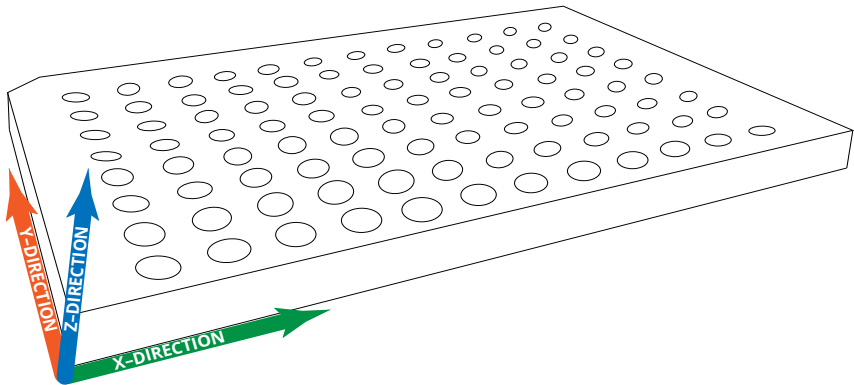
Fig. 112—You may make adjustments to the X and the Z directions.

There are two sections in the expert screen:
- Well Plate adjustments
- Rinse Station Adjustments

See Fig. 113.

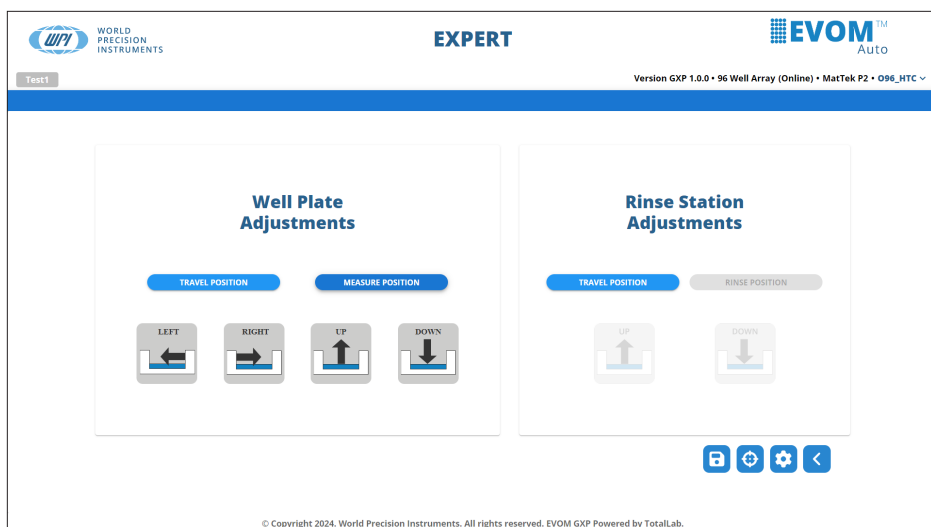Refer to the installation guide for instructions on making these adjustments.

Fig. 113—The Expert window has two sections: well plate adjustments and rinse station adjustments.

Saving a Profile Setting

To save a profile, click on the Save button ⬜ at the bottom of the window. A popup window opens asking you to verify whether you want to save the profiles settings for that plate profile. Enter your comment, and your EVOM™ GxP Client password. If you don't want to add a comment, you may select the *No Comment* checkbox. If you do, default text appears in the comment line. Then, press the *Save* button to continue or the *Cancel* button to return to the *Expert* window without saving.
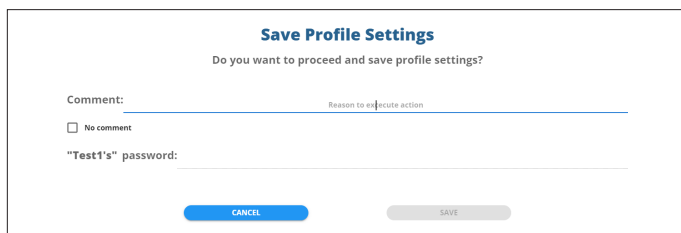

Fig. 114—Save the new plate profile settings once you have adjusted.

APPENDIX E: CONFIGURING THE ETHERNET ADAPTER

The Ethernet-to-USB adapter provided with your system has been configured to address the proper IP address range to ensure communications with the EVOM™ Auto GxP. If the adapter is lost or damaged a generic adapter cannot be used until it is configured correctly. The procedure is as follows:

1. Connect the USB-to-Ethernet adapter to a USB port on the laptop.

2. Go to the search bar and enter "Network Connections" and click on the *View Network Connections Result.*

3. A list of networks displays. Right click on the connection corresponding to the USB Network adapter and select *Properties* from the drop down menu.

4. On the *Networking* tab scroll to *Internet Protocol Version 4* entry and double click on it (Fig. 115).
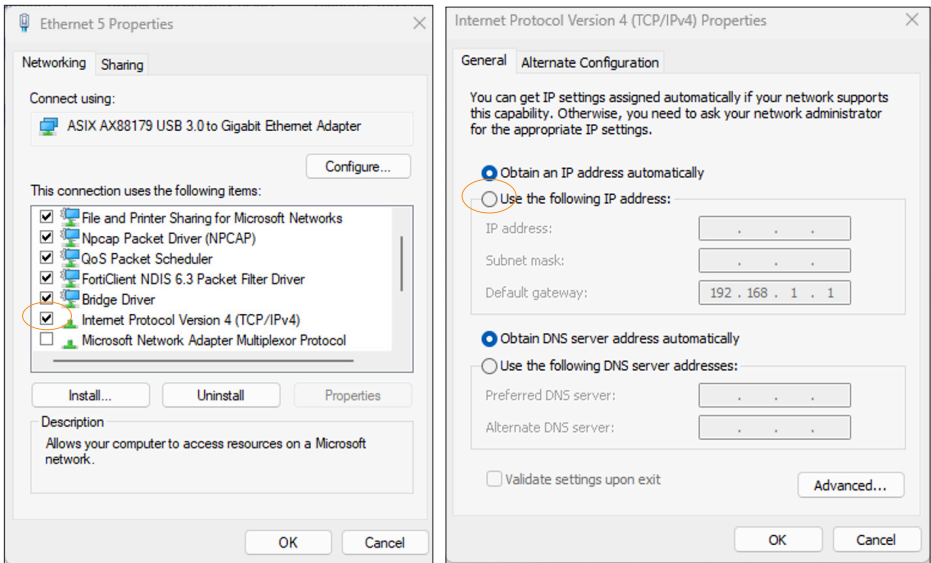

Fig. 115—Double click the Internet Protocol Version 4 (TCP/IPv4) entry.
Fig. 116—Select the Use the following IP address radio button.

5. On the *General* tab of the resulting window click on the *Use the following IP Address* radio button (Fig. 116).

6. On the IP entry box enter *10.10.10.1* and then press *Tab*. The other values are automatically set (Fig. 117).
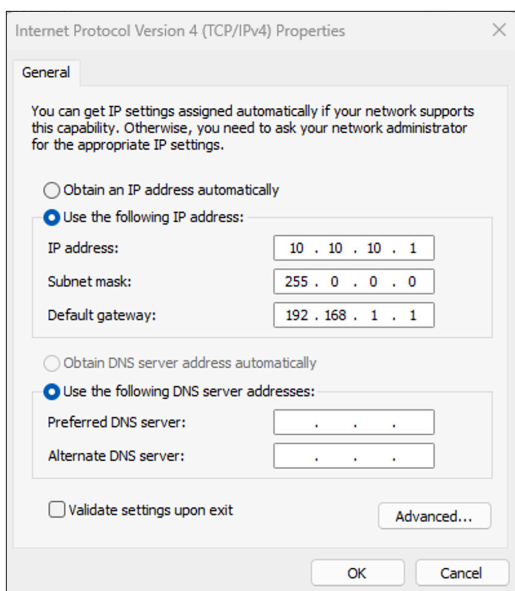
World Precision Instruments

Fig. 117—Subnet mask and gateway are set automatically.

7. Click OK to accept the changes. At this point the Ethernet adapter has been setup to be able to access the EVOM™ Auto GxP through the Ethernet port.

APPENDIX F: CONFIGURING THE BROWSER TO ALLOW ACCESS TO THE EVOM™ GXP CLIENT

The EVOM™ GxP Client client needs access to the EVOM™ GxP Client Server. The server is an application that runs automatically but needs to be considered as a trusted site with the proper SSL certificate. Your laptop has been configured as such from WPI. However, it is possible that after putting the laptop into your company's IT infrastructure this configuration may undergo changes. This usually results in the inability to launch the EVOM™ Auto GxP interface. To allow the EVOM™ GxP Client client to work properly complete the following steps.

1. Open the Edge Browser.

2. Using the URL bar navigate to "edge://flags" and press the *Enter* button on your keyboard.

3. A list of options displays. Scroll down until you find "*Allow invalid certificates for resources loaded from localhost.*"

4. Click on the selection drop down and change from disable to enabled.
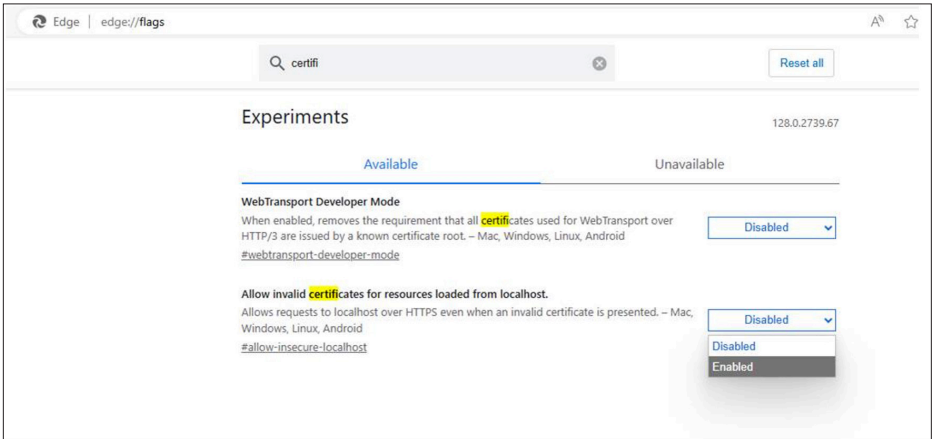

Fig. 118—Change the setting from Disabled to Enabled.

5. Close the browser and restart the laptop for the change to take effect.

APPENDIX G: EVOM™ GXP CLIENT ADDITIONAL RESOURCES

The following links may be helpful in learning to use the EVOM™ GxP Client, which is referred to by TotalLabs as AuditSafe.

Admin Walkthrough -- 1.0

Client Guide -- 1.0

VIDEO: EVOM™ GxP Client 21 CFR Part 11/GMP-Compliance Software Client Guide

Regulatory Compliance Guide -- 1.0

Install Guide

How to Configure the EVOM™ GxP Client

User Account Creation in the EVOM™ GxP Client

Excel and the EVOM™ GxP Client

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DECLARATION OF CONFORMITY

WORLD PRECISION INSTRUMENTS, LLC.

175 Sarasota Center Boulevard
Sarasota, FL 34240-9258 USA
Telephone: (941) 371-1003 Fax: (941) 377-5428
E-mail: wpi@wpiinc.com

DECLARATION OF CONFORMITY CE

We: World Precision Instruments
                      175 Sarasota Center Boulevard
                      Sarasota, FL 34240-9258 USA

As the **manufacture/distributor** of the apparatus listed, declare under sole responsibility
that the product(s):
WPI PN: EVOM AUTO

To which this declaration relates is/are in conformity with the following standards or
other normative documents:

Low Voltage:
  EN 61010-1:2010+A1:2019
EMC:
  EN 61326-2-3:2013, EN 61326-1:2013
  EN IEC 61000-3-2:2019+A1:2021
  EN61000-3-3:2013+A1:2019+A2:2021

And therefore conform(s) with the protection requirements of Council Directive
2014/30/EU relating to electromagnetic compatibility and Council Directive 2014/35/EU
relating to safety requirements and Council Directive 2011/65/EU relating to hazardous
substances:

Issued on:	**August 10, 2022**

_____
President of WPI

F-QC-006   Rev C

WARRANTY

WPI (World Precision Instruments) warrants to the original purchaser that this equipment, including its components and parts, shall be free from defects in material and workmanship for a period of one year* from the date of receipt. WPI's obligation under this warranty shall be limited to repair or replacement, at WPI's option, of the equipment or defective components or parts upon receipt thereof f.o.b. WPI, Sarasota, Florida U.S.A. Return of a repaired instrument shall be f.o.b. Sarasota.

The above warranty is contingent upon normal usage and does not cover products which have been modified without WPI's approval or which have been subjected to unusual physical or electrical stress or on which the original identification marks have been removed or altered. The above warranty will not apply if adjustment, repair or parts replacement is required because of accident, neglect, misuse, failure of electric power, air conditioning, humidity control, or causes other than normal and ordinary usage.

To the extent that any of its equipment is furnished by a manufacturer other than WPI, the foregoing warranty shall be applicable only to the extent of the warranty furnished by such other manufacturer. This warranty will not apply to appearance terms, such as knobs, handles, dials or the like.

WPI makes no warranty of any kind, express or implied or statutory, including without limitation any warranties of merchantability and/or fitness for a particular purpose. WPI shall not be liable for any damages, whether direct, indirect, special or consequential arising from a failure of this product to operate in the manner desired by the user. WPI shall not be liable for any damage to data or property that may be caused directly or indirectly by use of this product.

Claims and Returns

Inspect all shipments upon receipt. Missing cartons or obvious damage to cartons should be noted on the delivery receipt before signing. Concealed loss or damage should be reported at once to the carrier and an inspection requested. All claims for shortage or damage must be made within ten (10) days after receipt of shipment. Claims for lost shipments must be made within thirty (30) days of receipt of invoice or other notification of shipment. Please save damaged or pilfered cartons until claim is settled. In some instances, photographic documentation may be required. Some items are time-sensitive; WPI assumes no extended warranty or any liability for use beyond the date specified on the container

Do not return any goods to us without obtaining prior approval and instructions from our Returns Department. Goods returned (unauthorized) by collect freight may be refused. Goods accepted for restocking will be exchanged or credited to your WPI account. Goods returned which were ordered by customers in error are subject to a 25% restocking charge. Equipment which was built as a special order cannot be returned.

Repairs

Contact our Customer Service Department for assistance in the repair of apparatus. Do not return goods until instructions have been received. Returned items must be securely packed to prevent further damage in transit. The Customer is responsible for paying shipping expenses, including adequate insurance on all items returned for repairs. Identification of the item(s) by model number, name, as well as complete description of the difficulties experienced should be written on the repair purchase order and on a tag attached to the item.

Electrodes, batteries and other consumable parts are warranted for 90 days only from the date on which the customer receives these items.