

Biotage® Extrahera™ HV-5000 GLP Software

User Manual



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Software Overview

This manual describes the features of the optional Biotage® Extrahera™ GLP Software license. The license is sold separately and must be installed and activated by an authorized Biotage service engineer.

Part No.	Description	Qty
417631	Biotage® Extrahera™ HV-5000 GLP Package - On Site Activation	1
415149	Handheld Bar code Scanner	1



Figure 1. The login view when using a Biotage® Extrahera™ HV-5000 system with the Extrahera GLP software license installed.

User Accounts and Access Levels

To protect the system against unauthorized usage, each user must log in to the system using a unique user account with an alpha-numeric, case sensitive, and time limited password (see Figure 1).

The user accounts are set up by a user with system administration access. Each user is provided a defined role which limits the capacity to interact with the system; see different access levels in Table 1 on page 6. Five user profiles are available: system administrator, power user, routine user, QA/QC, and monitor.

The system locks the screen after a set number of seconds of user inactivity. The screen must then be unlocked, either by the logged in user or a user with power user access. The latter is not possible when the logged in user has system administrator or

service user access. The time limit for inactivity is set for each user individually.

For more information, see “Manage User Accounts” on page 4.

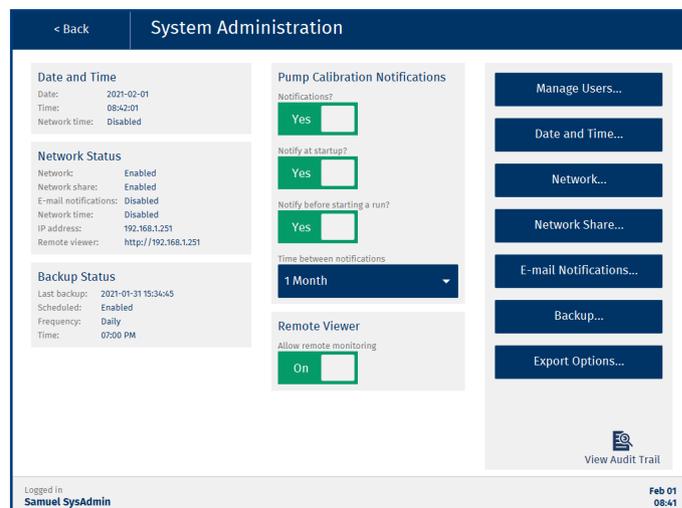


Figure 2. The System Administration view

E-mail Notifications

With the Extrahera system connected to an e-mail server, routine and power users can receive e-mail notifications when the following occurs during their run:

- » Scheduled pauses, i.e. pauses that are defined in the method.
- » Unscheduled pauses, e.g. when the system has run out of pipette tips or a clogged well/column has been detected.
- » The run is completed. If the **End of run comment** option is enabled in the method, the user is also notified when it is time to enter the comment.
- » The run is aborted.
- » The run failed.
- » System errors.

Users with power user or monitor access can get e-mail notifications for other users' runs. The notifications are enabled by a system administrator for each user individually.

For more information, see “Configure E-mail Notifications” on page 7 and “Manage User Accounts” on page 4.

Network Share

With the Extrahera system connected to the network, it is possible for a system administrator to give the system access to a network share folder. The share folder can be used for backups, import of methods and sample batch worklists, and export of methods, reports, audit trails, and system logs.

For more information, see “Configure Network Share” on page 8.

Biotage® Extrahera™ Remote Viewer

Biotage® Extrahera™ Remote Viewer allows the users to monitor their runs and download reports when away from the system. Power and monitor users can log in remotely at any time to a system allowing remote access, while routine and QA/QC users only can log in remotely (and stay logged in) when logged in locally on the system.

For more information, see “Remotely Monitor Runs and View Reports” on page 23.

Remote access has to be enabled by a system administrator. For more information, see “Enable/Disable the Remote Viewer” on page 7.

System Backup and Restore

A system backup contains all user accounts, methods, consumables, accessories, run reports, and audit trails registered on the system. It also contains all the system settings and configurations except for the settings for the DFE mode and the processing format.

Backups can be scheduled and started manually by a system administrator. Depending on which export options are enabled on the system, the backups can be stored on a USB memory device and/or in a network share folder.

A backup can be used to restore the system to the state it was at the time of the backup. Note that new entries, runs, and changes that occurred after the backup was performed will be lost.

For more information, see “Perform and Schedule Backups” on page 12.

Restricted USB Export and Locked PDF Files

The system offers the possibility to import and export both from/to a USB memory device and a network share folder (if configured). Whether both export destinations are allowed or not, and the export format used, are controlled by a system administrator; see “Set Export Options” on page 11.

All PDF files exported from the system are locked using automatically generated, non-recoverable passwords and cannot be edited.

Confirmation with Reason and Password

The following actions, that can only be performed by power users, require that the user enters a reason for the change and the user password:

- » Deleting an entry in the **Data Administration** view.
- » Locking a solvent to a specific solvent reservoir in position **5** on the working area.
- » Editing, locking, unlocking, and deleting a method; see page 17.
- » Deleting a report.

Editing and Locking Methods

When setting up a method, a timestamp in the footer displays when the method was last edited and by whom (see Figure 3). Check the method audit trail for detailed information.

Figure 3. A timestamp in the footer shows when the method was last edited and by whom.

Sample Batch Worklist (SBWL) and Identification Information

When setting up a run, sample information can be entered either manually or by importing a sample batch worklist (SBWL).

Biotage supplies SBWL Excel templates for all supported processing formats with color coded plate/rack map and 11 custom fields. You can also use tsv, csv, and txt files. For more information, see “Enter Sample Information” on page 19.

Identification (ID) information can be entered for all solvents, racks, plates, and pipette tips used in the run by pressing the corresponding positions in the **Prepare Run** view.

Clog Detection

Clog detection can be enabled for any load, wash, and/or elute step in SPE and SLE methods, and the collection step in Filtration+ methods.

The system can be set up to automatically try to clear clogged wells/columns by applying pressure up to three times. The pressure, time, and number of attempts are defined in the method. The plate/rack is scanned after each attempt and if the clogged wells/columns have been cleared, the run is immediately resumed.

If there are still clogged wells/columns when the maximum number of attempts have been made, or if that feature is not enabled, the **Clogged Wells/Columns Detected** dialog opens.

If enabled in the method, the user is given the option to apply pressure in the **Clogged Wells/Columns Detected** dialog.

For more information; see “Set Up Clog Detection” on page 14.

Dynamic Reporting

The contents of the report are set up in the method. The power user that sets up the method can enable/disable information for each operation individually and the details for the sample type, solvents, extraction media, sample plate/rack, carousel plates (only for DFE methods), and pipette tips used in the run.

It is also possible to let the operator add a comment to the report just before the report is generated by enabling the **End of run comment** option.

For more information; see “Set Up the Report” on page 16.

Audit Trails

Seven different audit trails log all changes and actions performed on the system together with date, time, and user ID (see Figure 4).

Audit trails can be exported either as a text file or a secure PDF. The format is set by a system administrator.

For more information, see “Set Export Options” on page 11 and “View and Export Audit Trails” on page 25.

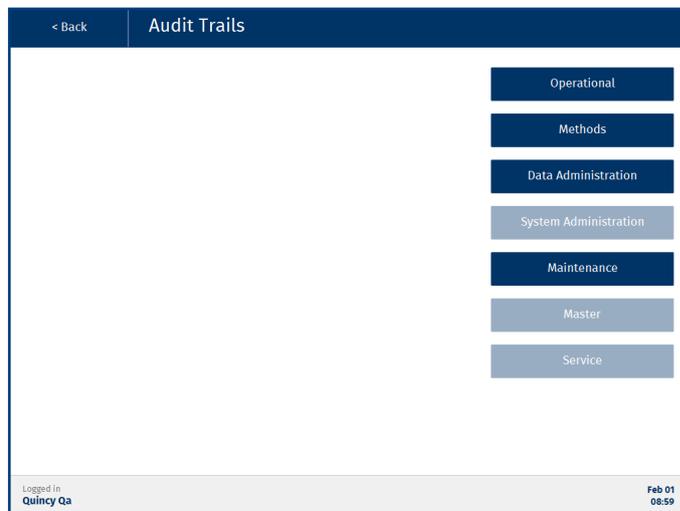


Figure 4. The Audit Trails view when logged in as a QA/QC user. For user access rights, see Table 1 on page 6.

Manage User Accounts

System Administration



User accounts can be created, edited, and deactivated in the **Manage Users** view (see Figure 6) by users with system administrator access.

Each user account has an access level that determines which functionality is available to the user; see Table 1 on page 6.

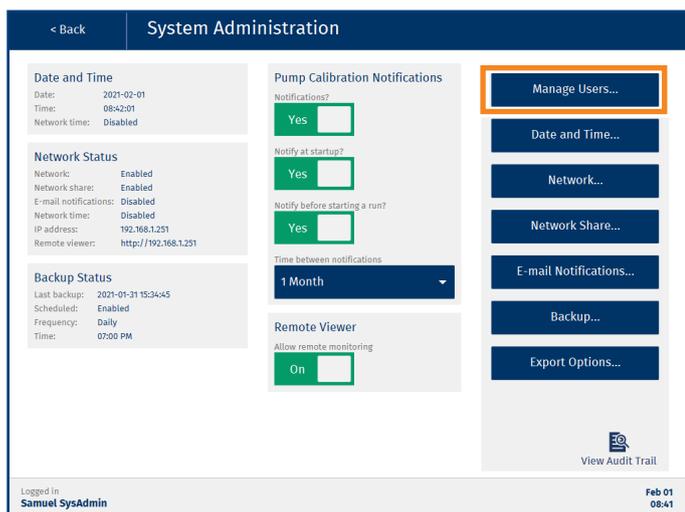


Figure 5. The Manage Users button in the System Administration view.

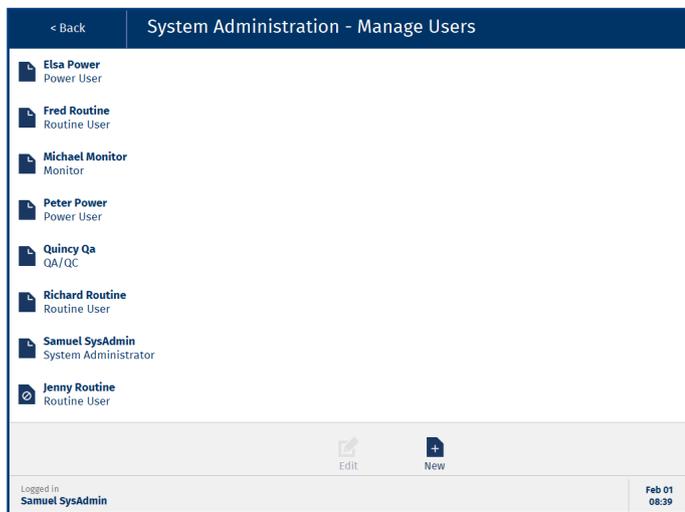


Figure 6. The Manage Users view. Jenny’s user account is deactivated.

User Parameters

The following user parameters are available in a user account (see Figure 7).

User

- » **User ID:** When a new user account is created, the system gives it a unique ID that is used in the audit trails.
- » **First name:** The user’s first name.
- » **Last name:** The user’s family name.
- » **Access level:** The user’s access level; see Table 1 on page 6.
- » **E-mail address:** The user’s e-mail address, which is used for e-mail notifications (see page 5).
- » **Activated account:** Whether the user account is activated or not. When deactivated, the user will not be able to log in to the system or the remote viewer (if enabled) but all reports on runs performed by the user will still be available to other users in the **Reports** view.

Password

- » **Password:** The user’s password for logging in to the system and the remote viewer (if enabled). The password must contain between 8 and 40 characters, at least one upper case and one lower case character, and at least one number.
- » **Lock screen timeout (in seconds):** Number of seconds of inactivity before the system locks the screen. The screen must then be unlocked, either by the logged in user or a user with power user access. The latter is not possible when the logged in user has system administrator or service user access.
- » **Password expiry (in days):** The number of days the password is valid. When the password has expired, the user will be prompted to change it.
- » **Number of failed login attempts:** When a user fails to log in five times, the user account is locked. If e-mail notifications are allowed on your system (see page 7), all users with system administrator access (and an e-mail address registered) will be notified that the account has been locked. A user with system administrator access can unlock the account by pressing **Reset** (see Figure 7).

E-mail Notifications

When your system is connected to a network and has e-mail notifications enabled, it is possible for users with routine or power user access to receive the following e-mail notifications for their runs:

- » **Aborted runs:** The user is notified when a run is aborted.
- » **Errors:** The user is notified if a system error occurs during a run. The error message is included in the e-mail.
- » **Scheduled pauses:** The user is notified when a scheduled pause occurs, i.e. a pause that is defined in the method.
- » **System pauses:** The user is notified when an unscheduled pause occurs, e.g. when the system has run out of pipette tips or a clogged well/column has been detected.
- » **Failed runs:** The user is notified when a run fails.
- » **Completed runs:** The user is notified when a run is completed. If the **End of run comment** option is enabled in the method, the user is also notified when it is time to enter the comment.

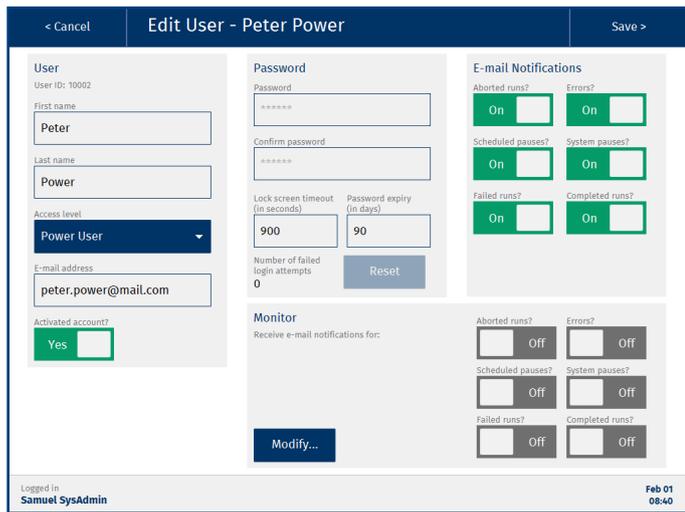


Figure 7. Editing a user with power user access.

Monitor

Users with power user or monitor access can get e-mail notifications for other users' runs. Available notifications are the same as the ones listed above. To define which users to monitor, press **Modify...** (see Figure 8), select the user(s) in the **Monitor – Add/Remove Users** view (see Figure 9), and press **Save** in the top pane.

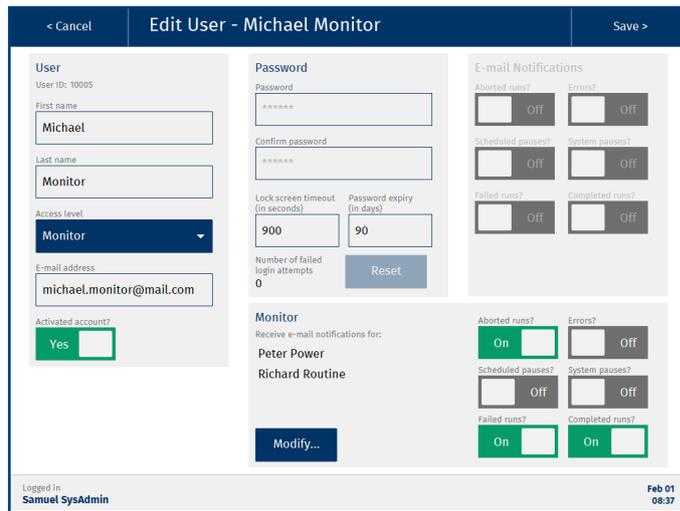


Figure 8. Editing a user with monitor user access.



Figure 9. Only users that can perform runs on the system (routine or power users) are listed in the Monitor - Add/Remove Users view.

Feature	 Routine	 Power	 QA/QC	 Admin.	 Monitor	 Service	Comment
Login to the System	✓(1)	✓(1)	✓(1)	✓	✗	✓	(1) Overridable by a power user when the screen is locked.
Run Methods							
Locked Methods	✓	✓	✗	✗	✗	✗	
Unlocked Methods	✗	✓	✗	✗	✗	✗	
Biotage Methods	✗	✓	✗	✗	✗	✗	
Get E-mail Notifications	✓	✓	✗	✗	✓	✗	
Reports							
Delete	✗	✓	✗	✗	✗	✗	If the reports are only saved in a network share folder, the Reports view is disabled to all users.
View and Export as PDF	✓	✓	✓	✗	✗	✗	
Manage Methods							
Create, Import, Export, Edit, and Lock	✗	✓	✗	✗	✗	✗	A method can only be unlocked by the same user that locked it.
View and Export as PDF	✓	✓	✓	✗	✗	✗	
Data Administration							
Create and Delete Entry, and Lock Solvent	✗	✓	✗	✗	✗	✗	Solvents, sample types, extraction media, sample plate and racks, and pipette tips.
View Entry	✗	✓	✓	✗	✗	✗	
System Administration							
Configure Pipette Pump Notifications	✗	✗	✗	✓	✗	✓	
Enable the Remote Viewer	✗	✗	✗	✓	✗	✓	
Manage User Accounts	✗	✗	✗	✓	✗	✓	
Set Date and Time	✗	✗	✗	✓	✗	✗	
Network Services	✗	✗	✗	✓	✗	✗	
Perform and Schedule Backup	✗	✗	✗	✓	✗	✗	
Export Options	✗	✗	✗	✓	✗	✗	
Maintenance							
System Settings	✓	✓	✓	✗	✗	✗	System settings: alarm, lights, processing format, PPT/PLD mode, and headers for SBWL.
Calibrate Pipette Pump	✗	✓	✓	✗	✗	✗	
Manual Control	✓	✓	✗	✗	✗	✗	
Flush Solvent Inlets	✓	✓	✗	✗	✗	✗	
Export Logs	✓	✓	✗	✗	✗	✗	
Re-initialize the System	✓	✓	✗	✗	✗	✗	
View and Export Audit Trails							
Operational	✓	✓	✓	✗	✗	✗	If the reports are only saved in a network share folder, the operational audit trails are not accessible on the system.
Methods	✓	✓	✓	✗	✗	✗	
Data Administration	✗	✓	✓	✗	✗	✗	
System Administration	✗	✗	✗	✓	✗	✓	
Maintenance	✓	✓	✓	✗	✗	✗	
Master	✗	✗	✗	✓	✗	✓	
Service	✗	✗	✗	✗	✗	✓	
Access Remote Viewer (if enabled)	✓(2)	✓	✓(2)	✗	✓	✗	(2) When logged in to the system.

Table 1. User access rights.

Connect the System to Your Network

System Administration



Network configurations can be done in the **System Administration** view (see Figure 10) by users with system administrator access.

With the Extrahera system connected to your network, it is possible to get e-mail notifications, monitor the run and download reports through a remote viewer, use a network share folder, and synchronize the system with a network time server (see page 10).

To get an overview of which network features are enabled on your system, see the **Network Status** field in the **System Administration** view (see Figure 10).

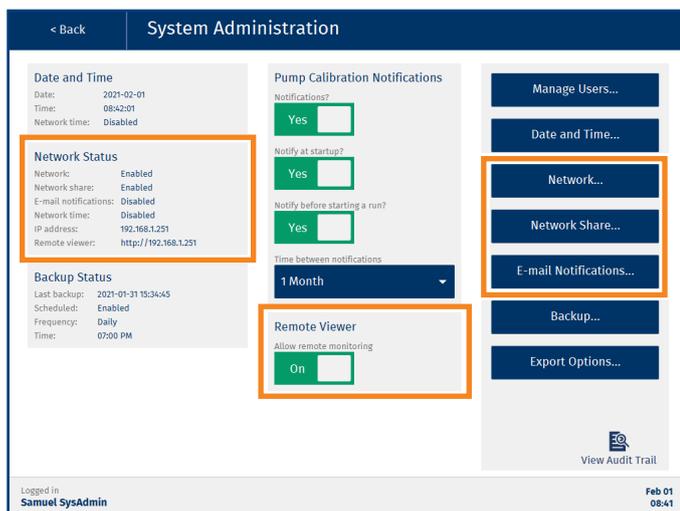


Figure 10. The network features in the System Administration view.

Configure Network Connection

To enable network share, remote monitoring, and/or e-mail notifications, start by setting up a network connection for your Extrahera system as described below.

Note: Any change to the network settings will require a restart of the system.

Note: If you disable the network connection, the latest network settings are saved until enabled again.

1. Connect the system to your network via the LAN port located on the right hand side of the system.
2. In the **System Administration** view, press **Network....** (see Figure 10).
3. In the **Network** view (see Figure 11), enable the **Network** option.

4. Enter the required network settings. Please contact your IT department for help with entering the correct settings for your network.

Note: The **Host name** will be used to identify the system in the network and it is also displayed in the remote viewer (see Figure 41 on page 23), if enabled.

5. When done, press **Save** in the top pane and restart the system when prompted.

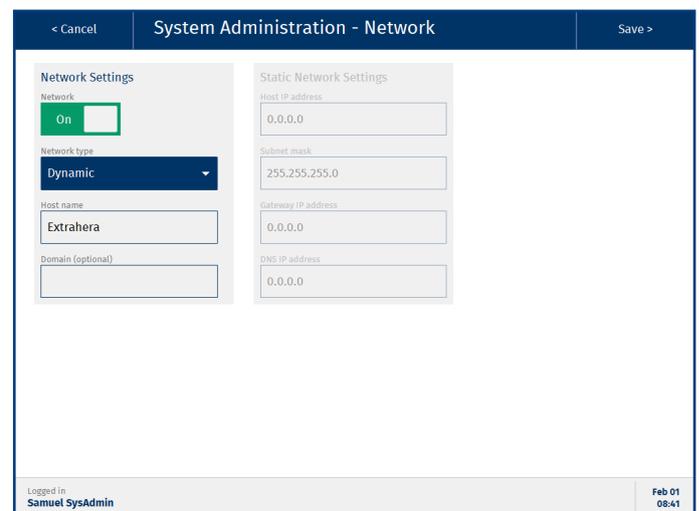


Figure 11. The Network view.

Enable/Disable the Remote Viewer

The remote viewer allows the user to monitor the run and download reports when away from the system; see “Remotely Monitor Runs and View Reports” on page 23.

The remote viewer is enabled/disabled using the **Allow remote monitoring** option in the **Remote Viewer** field; see Figure 10.

The IP address of the remote viewer is displayed in the **Network Status** field. It is also displayed in the upper right corner in the **Running** view; see Figure 40 on page 23.

Note: The remote viewer is supported on Microsoft Edge, Mozilla Firefox, and Google Chrome.

Configure E-mail Notifications

During a run, the system can send out e-mail notifications to the user that started the run and to users that monitor the user’s runs. For more information, see “E-mail Notifications” on page 5.

1. Ensure that you have an e-mail address registered in your user account.
2. In the **System Administration** view, press **E-mail Notifications...**
3. In the **General** and **SMTP Security** fields (see Figure 12), enter the required information. Please contact your IT department to get the correct settings for your e-mail server.
4. When done, send a test e-mail to the e-mail address registered to your user account by pressing **Test Configuration**.
5. If you receive a test e-mail, press **Save** in the top pane.
6. If you do not receive a test e-mail, check that the correct e-mail address has been registered. For help troubleshooting, please contact your IT department.

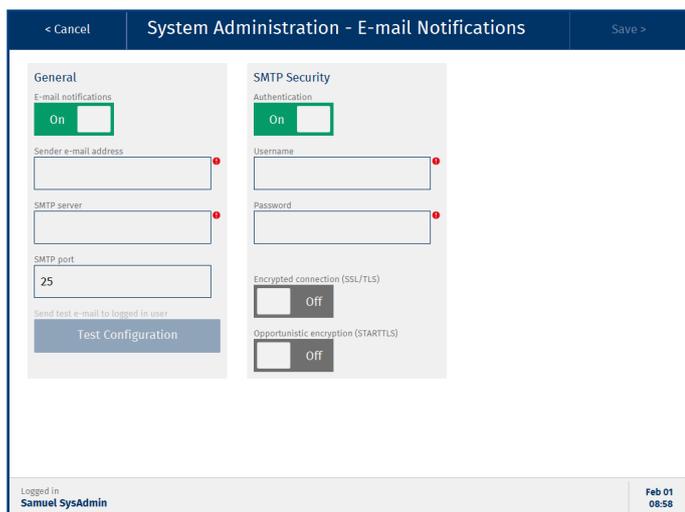


Figure 12. The E-mail Notifications view.

Configure Network Share

Note: For help configuring network share, please contact your IT department.

A system administrator can give the system access to a share folder on the network. The share folder can be used for backups, import of methods and sample batch worklists, and export of methods, reports, audit trails, and system logs.

The system will create a sub folder in the share folder with the name Extrahera and the system’s serial number (**extrahera_serialnumber**). In this way the share folder can be used by several Extrahera systems.

Example on How to Create a Share Folder Using a Windows 10 Computer

Note: This procedure requires administrator permission on the Windows 10 computer.

1. Create or select a folder that you want to share. The folder can be located anywhere on the computer.

2. Right-click the folder and select **Properties** from the right-click menu.
3. In the **Properties** dialog, select the **Sharing** tab (see Figure 13).
4. In the **Sharing** tab, click **Advanced Sharing** (see Figure 13).
5. In the **Advanced Sharing** dialog, select the **Share this folder** check box and click **Permissions** (see Figure 13).
6. Add the users that you want to give access to the folder and give them at least the permission to Change and Read.
7. When done, click **OK** twice to close the **Permissions** and **Advanced Sharing** dialogs.
8. Click **Close** in the **Properties** dialog.

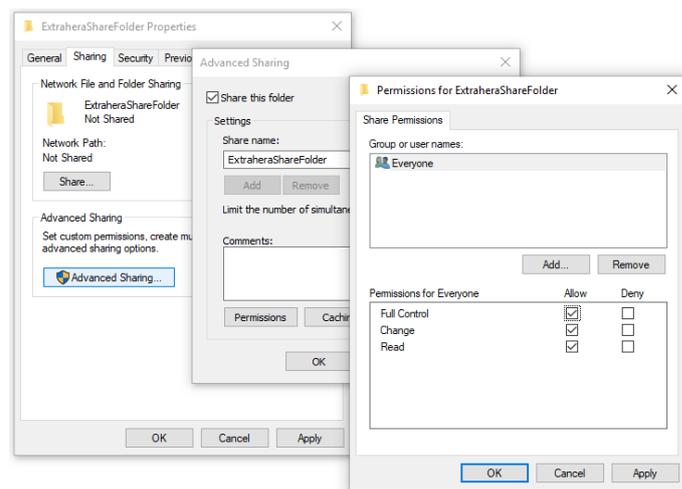


Figure 13. Creating a share folder on a Windows 10 computer. In this example the user group Everyone has been given full control of the share folder “ExtraheraShareFolder”.

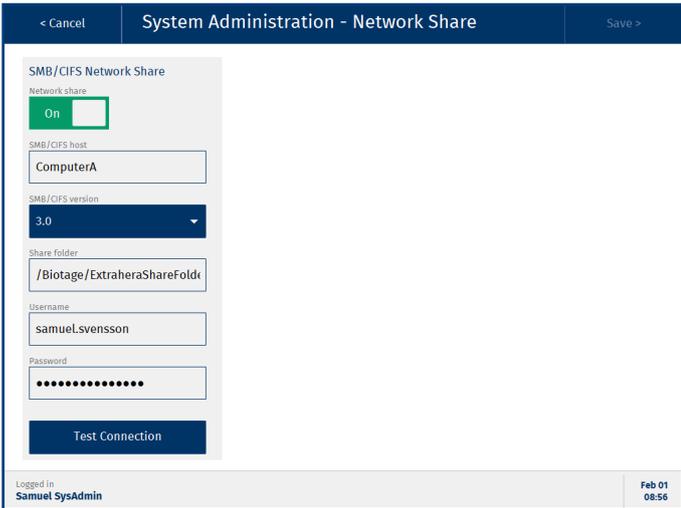
Give the Extrahera System Access to the Share Folder

1. In the **System Administration** view, press **Network Share...**
2. In the **Network Share** view (see Figure 14), enable the **Network share** option.
3. Enter the host name or IP address of the computer sharing the folder in the **SMB/CIFS host** text box. When using a Windows 10 computer, the host name is the **Computer name** that can be found in the Control Panel (Control Panel\System and Security\System).
4. In the **SMB/CIFS version** drop-down list, select the correct version for the computer sharing the folder, e.g. modern Windows computers need at least version 2.0.
5. Enter the network share path to the share folder in the **Share folder** text box. Replace any backslashes (\) in the path with frontslashes (/). In Windows 10, the network path can be found by right-clicking the share folder and selecting **Properties** from the right-click menu.

Note: The folder must exist before the network share is configured on the system.

6. Enter the username and password for a user with read/write access to this folder. This can be skipped if the folder is set up to be accessed by anyone that has access to the network.
7. Press **Test Connection**. The system will try to access the share folder and create an **extrahera_serialnumber** sub folder.
8. If the test is successful, press **Save** in the top pane.
9. If the test fails, please contact your IT department for help troubleshooting.

Note: Export to the network share folder has to be enabled in the **Export Options** view; see page 11.



The screenshot shows a configuration window titled "System Administration - Network Share". The window has a dark blue header with "< Cancel" on the left and "Save >" on the right. The main content area is titled "SMB/CIFS Network Share" and contains the following fields and controls:

- Network share:** A green "On" toggle switch.
- SMB/CIFS host:** A text input field containing "ComputerA".
- SMB/CIFS version:** A dropdown menu set to "3.0".
- Share folder:** A text input field containing "/Biotage/ExtraheraShareFolder".
- Username:** A text input field containing "samuel.svensson".
- Password:** A password input field with 12 dots.
- Test Connection:** A blue button.

At the bottom of the window, there is a status bar showing "Logged in Samuel SysAdmin" on the left and "Feb 01 08:56" on the right.

Figure 14. The Network Share view. In this example, the host name of the computer sharing the folder is "ComputerA" and the share folder path is "/Biotage/ExtraheraShareFolder".

Set Date and Time

System Administration



The date and time can be set in the **Date and Time** view (see Figure 16) by users with system administrator access.

Either enter the date and time manually or, if your system is connected to a network, synchronize the system with an NTP time server:

1. In the **System Administration** view, press **Date and Time...** (see Figure 15).
2. Enable the **Network date and time** option.
3. Enter the address to the time server in the **NTP time server** text box (see Figure 16). Please contact your IT department for more information.
4. Press **Synchronize**.
5. If the synchronization is successful, press **Close** in the **Synchronizing** dialog and then **Save** in the top pane.
6. If the synchronization fails, please contact your IT department for help troubleshooting.

The synchronization is performed every 10 minutes and cannot be changed.

Select the time zone from the **Time zone** drop-down list. Changing the time zone requires a restart of the system. Daylight savings adjustments is not supported.

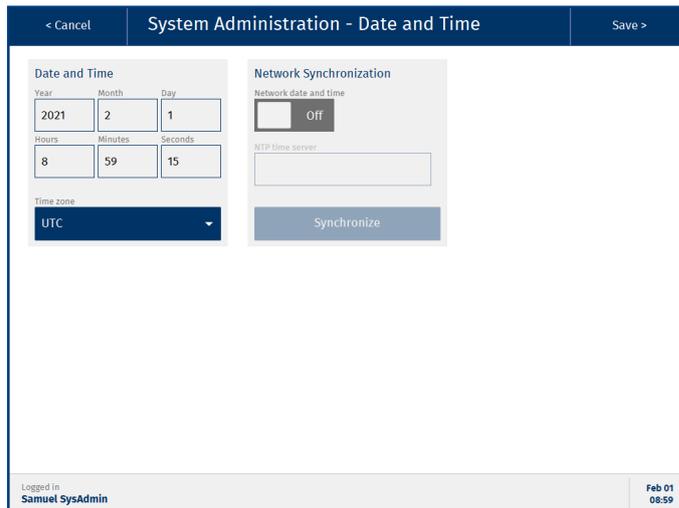


Figure 16. The Date and Time view.

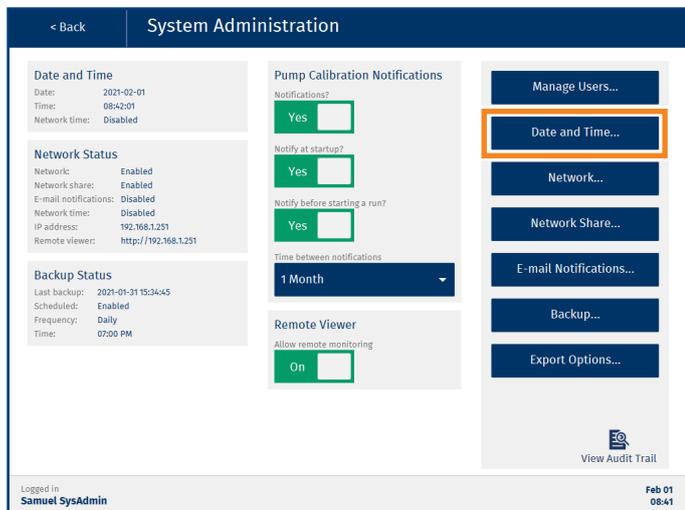


Figure 15. The Date and Time button in the System Administration view.

Set Export Options

System Administration



The system offers the possibility to import and export both from/to a USB memory device and a network share folder (if configured). Whether both export destinations are allowed or not, and the export format used, are controlled in the **Export Options** view (see Figure 18) by users with system administrator access.

In the **Export Options** view, it is also possible to enable auto-export of reports to a network share folder and, if desired, auto-delete of reports from the system when they have been auto-exported.

Note: The export options for network share can only be enabled when network share is configured (see page 8).

- In the **System Administration** view, press **Export Options...** (see Figure 17).
- In the **Export Destination** field (see Figure 18), enable the desired option(s):
 - » **Allow export to USB:** The USB ports on the system can be used for backups and export of methods, reports, audit trails, and system logs.
 - » **Allow export to network share:** The network share folder can be used as the destination for backups and export of methods, reports, audit trails, and system logs.
- In the **Report Auto-Features** field (see Figure 18), enable the desired option(s):
 - » **Auto-export reports to network share:** Reports and operational audit trails are automatically saved in the network share folder.

Note: If the system fails to export a report (e.g. when the network is down), the system will retry every 15 minutes until the report is successfully exported. If the system is turned off, it will retry within 5 minutes after startup. The system will pop up a notification each time the auto-export fails.
 - » **Auto-delete reports from system:** Reports and audit trails are permanently deleted from the system after they have been exported to the network share folder (see the option above). The **Report** view will be disabled to all users.
- In the **Export Format** field (see Figure 18), select the format (PDF or TXT) to be used when exporting an audit trail.
- When done, press **Save** in the top pane.

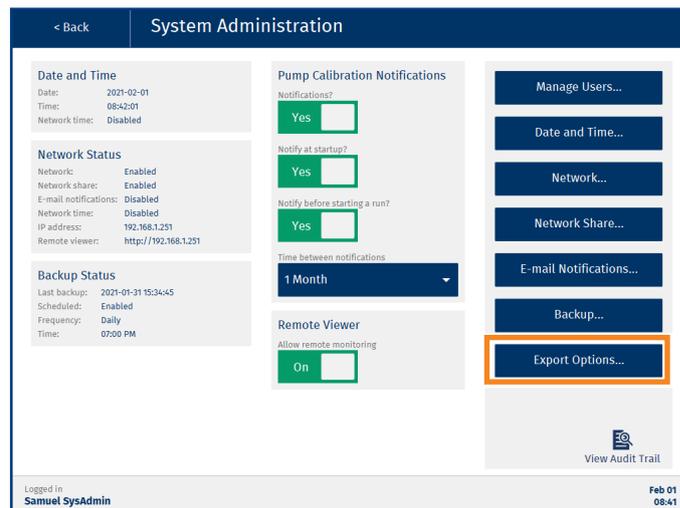


Figure 17. The Export Options button in the System Administration view.



Figure 18. The Export Options view.

Locked PDF Files

All PDF files exported from the system are locked using automatically generated, non-recoverable passwords and cannot be edited.

Perform and Schedule Backups

System Administration



Backups can be scheduled and started manually in the **Backup** view (see Figure 20) by users with system administrator access.

Depending on which export options are enabled on your system (see page 11), backups can be stored on a USB memory device and/or in a network share folder.

To get a quick overview of the backup setup and when the last backup was performed, see the **Backup Status** field in the **System Administration** view (see Figure 19).

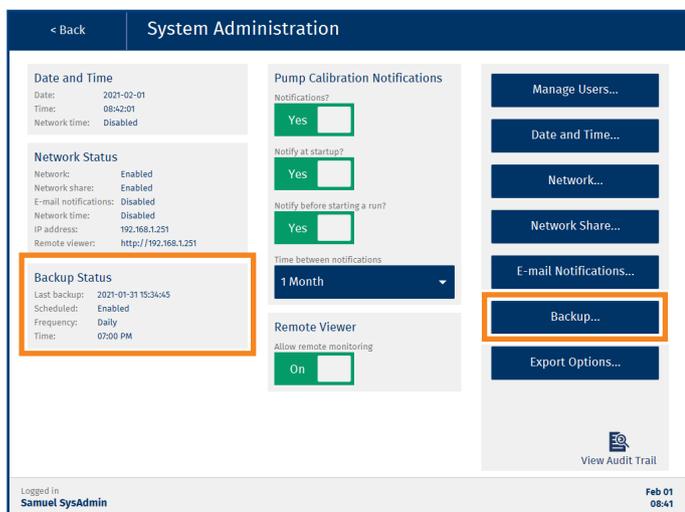


Figure 19. The backup features in the System Administration view.

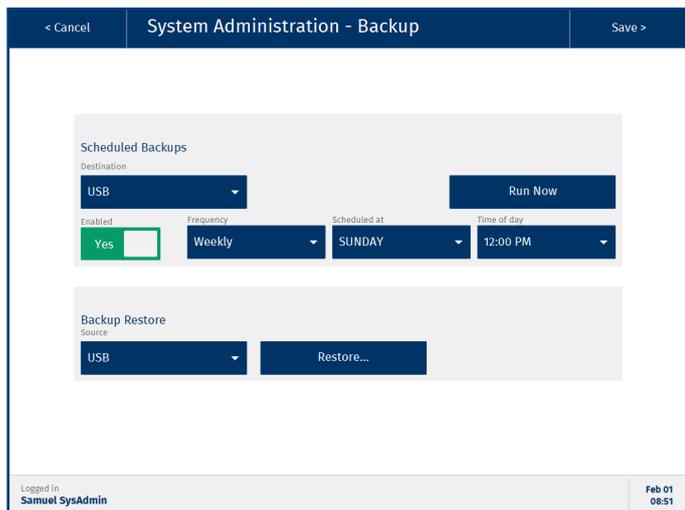


Figure 20. The Backup view.

Backup Contents

The following information is included in a backup:

- » User accounts.
- » Methods.
- » Consumables and accessories in the **Data Administration** view.
- » Run reports.
- » Audit trails.
- » System settings and configurations in the **Maintenance** and **System Administration** views except for the settings for the DFE mode and the processing format.

Schedule Backups

Note: If the system is turned off, the power goes out during a backup, or the backup destination is not accessible at the time of a scheduled backup, the backup fails and has to be performed manually. The system will pop up a notification asking a system administrator to perform a manual backup.

Note: Scheduled backups can be performed during runs.

1. In the **System Administration** view, press **Backup...** (see Figure 19).
2. If the system has both network share and USB export enabled, select where you want the backup to be stored from the **Destination** drop-down list (see Figure 20).
3. For USB backup, connect a USB memory device to one of the USB ports on the touch screen frame.
4. Enable the **Enabled** option.
5. Select how often the backups shall be performed (daily, weekly, or monthly) from the **Frequency** drop-down list.
6. If applicable, select the weekday or the day of month to perform the scheduled backup from the **Scheduled at** drop-down list.

Note: If the day of month is set to 31, a backup will not be scheduled for months with less than 31 days.
7. Select the time of day to perform the scheduled backups from the **Time of day** drop-down list.
8. Press **Save** in the top pane.

Perform a Manual Backup

1. In the **System Administration** view, press **Backup**.
2. If the system has both network share and USB export enabled, select where you want the backup to be stored from the **Destination** drop-down list.
3. For USB backup, connect a USB memory device to one of the USB ports on the touch screen frame.
4. Press **Run Now**. The file name for backups is based on the system's serial number and the date and time of the backup.

Restore the System Database

Note: All the current data on the system will be erased and replaced with the data in the used backup file.

1. In the **System Administration** view, press **Backup...** (see Figure 19).
2. Perform a safety backup; see “Perform a Manual Backup” above.
3. If restoring the database using a backup file on a USB memory device, connect it to one of the USB ports on the touch screen frame.
4. If the system has both network share and USB export enabled, select the location of the backup file from the **Source** drop-down list (see Figure 20).
5. Press **Restore...**
6. In the **Select Backup File to Restore** dialog (see Figure 21), browse to the file location (if necessary) and select the backup file to be used. The file name for backups is based on the system's serial number and the date and time of the backup.

Note: Do not use a backup file from another Extrahera system, or any other Biotage system. To verify that the file comes from the system, check the system's serial number (press **About** in the main menu) and compare it to the serial number in the backup file name.
7. Press **Restore...** and confirm that the system is restarted and the database is restored in the **Confirm Restore** dialog.

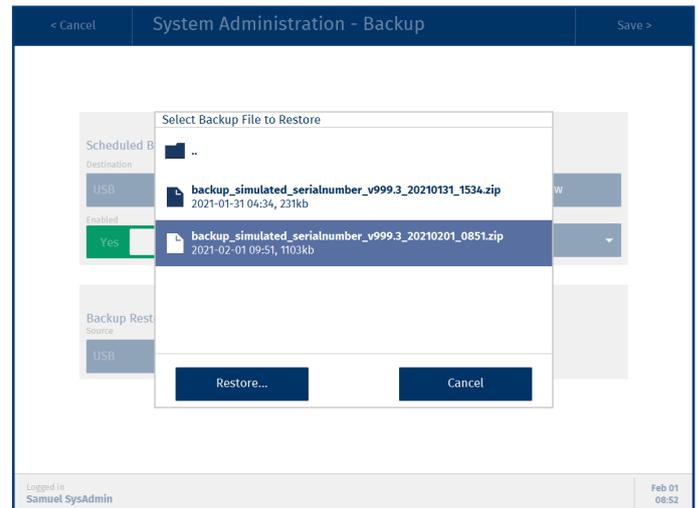


Figure 21. The Select Backup File to Restore dialog.

Set Up Clog Detection

Manage Methods



Clog detection can be enabled for any load, wash, and/or elute step in SPE and SLE methods, and the collection step in Filtration+ methods. by power users; see Figure 22.

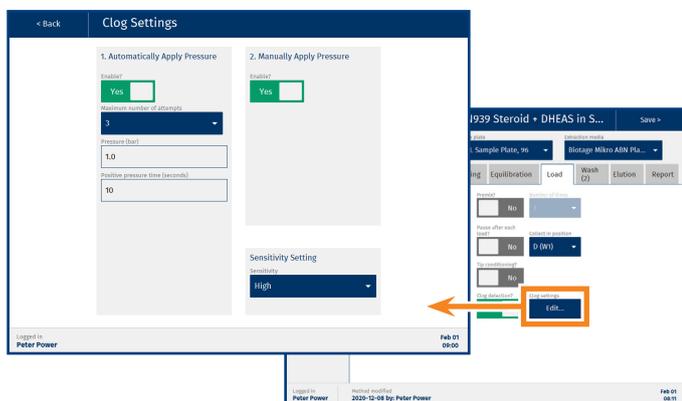


Figure 22. The Clog Settings view.

Clog Settings

The clog settings have to be set up for each step using clog detection; press the **Edit...** button next to the enabled clog detection option to open the **Clog Settings** view (see Figure 22).

Automatically Apply Pressure

When **Automatically Apply Pressure** is enabled (see Figure 22), the system will attempt to clear clogged wells/columns by applying pressure up to three times. Select the desired number of attempts from the **Maximum number of attempts** drop-down list. Enter the pressure and time settings for each attempt in the **Pressure** and **Positive pressure time** text boxes.

The system scans the wells/columns after each attempt. If the clogged wells/columns have been successfully cleared, the run is immediately resumed.

If there are still clogged wells/columns when the maximum number of attempts have been made, or **Automatically Apply Pressure** is disabled, the run is paused and the **Clogged Wells/Columns Detected** dialog opens; see Figure 23.

Manually Apply Pressure

If **Manually Apply Pressure** is enabled (see Figure 22), the user will be given the option to apply pressure in the **Clogged Wells/Columns** dialog as shown in Figure 23.

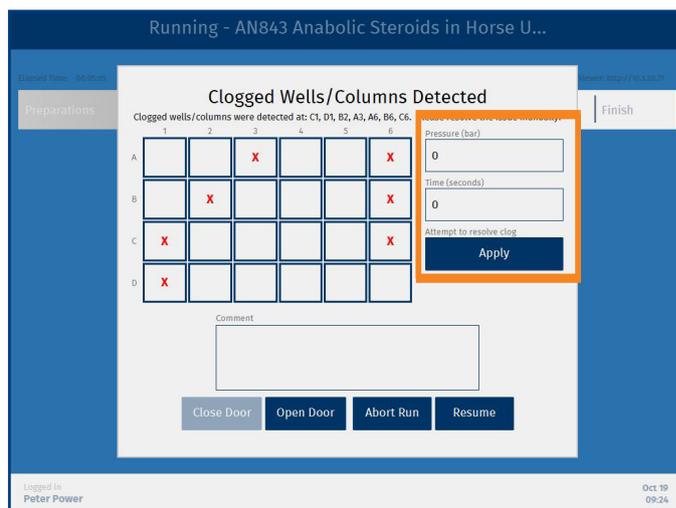


Figure 23. The Clogged Wells Detected dialog. If enabled in the method, you can try to clear the clogged well(s) by applying pressure (see the highlighted section).

Scans and Sensitivity Setting

The following scans are performed when clog detection is enabled:

- » **Height scan:** In the preparation phase, the system scans the height of the extraction plate/rack and compares it with the height defined for the used sample plate/rack. The scan is used to determine a safe scan height.
- » **Reference scan:** In the preparation phase, the system measures the distance to the bottom of the extraction well/column.
- » **Clog scan:** After a load/wash/elute step has been completed, the system measures the distance to the bottom of the extraction well or column.

The system compares the clog scan value with the reference scan value to determine if the well/column is clogged. The allowed difference is set by the **Sensitivity** setting:

- » **Low:** >4 mm = clog.
- » **Medium:** >3 mm = clog.
- » **High:** >2 mm = clog.

Supported Solvents

Solvent/Solvent Combination	Clog Detection Compatibility
0.05 M Ammonium acetate, pH 6 (aq)	Excellent
0.05 M Ammonium acetate, pH 7 (aq)	Excellent
0.05 M pH7 Amm Ac/MeOH [9:1]	Excellent
Acetone	Good
Acetone/Hexane [20:80]	Poor
Acetonitrile	Excellent
Ammonium acetate, pH 7 in MeOH [95:5]	Excellent
Dichloromethane	Poor
Diethyl ether	Poor
Ethanol	Excellent
Ethyl acetate	Good
Heptane	Good
Hexane	Good
Ethyl acetate/Hexane [70:30]	Poor
H2O/MeCN [60:40]	Excellent
H2O/MeOH [95:5]	Excellent
H2O/NH4OH [95:5]	Excellent
Isopropanol (IPA)	Excellent
MeOH/Formic Acid [98:2]	Good
MeOH/H2O [10:90]	Excellent
MeOH/H2O [40:60]	Excellent
MeOH/H2O [50:50]	Excellent
MeOH/H2O [80:20]	Excellent
MeOH/NH4OH [95:5]	Good
MeOH/NH4OH [98:2]	Good
Methanol	Excellent
Toluene/Acetone [95:5]	Excellent
Water *	Excellent
Methyl tert-butyl ether (MTBE)	Poor
Phosphatebuffer pH 6.2	Excellent
0.1% Ammonium hydroxide (aq)	Excellent
0.5 M Ammonium hydroxide (aq)	Excellent
0.1% Formic acid (aq)	Excellent
1% Formic acid (aq)	Excellent
2% Formic acid (aq)	Excellent
4% Phosphoric acid (aq)	Excellent
Acetic acid 1 M	Excellent
DCM/IPA [90:10]	Poor
DCM/MeOH [90:10]	Poor
DCM/MeOH/NH ₄ OH [78:20:2]	Poor

* Includes aqueous based buffers.

Table 2. Supported solvents.

Currently Not Supported Consumables

The following Biotage and competitor consumables are not supported when using clog detection:

- » ISOLUTE® PPT+
- » ISOLUTE® PLD+
- » ISOLUTE® FILTER+ Plate
- » Tecan NBE and Cerex Columns
- » 1 mL Columns, 24 Positions Configuration

Troubleshooting

- » If the plate/rack height scan fails, check that there is an extraction plate or column rack in position **3** on the working area.
 - » If the reference scan fails; check that the extraction plate/rack is supported with clog detection (see “Currently not Supported Consumables” above).
- » If the clog detection fails/gives false results:
 - » Check that your extraction plate/rack is supported with clog detection; see “Currently not Supported Consumables” above.
 - » Check that the solvent or solvent combination is compatible with clog detection; see Table 2.
 - » Change the clog sensitivity setting; see “Scans and Sensitivity Setting” on page 14.
- » If the pipette head collides with the sample tubes during the clog detection scan, check that the sample rack has the correct height setting. For more information, see the user manual supplied with the system.

Set Up the Report

Manage Methods



The contents of the report are set up in the method's **Report** tab by a power user; see Figure 24.

You can enable/disable information for each operation individually and the details for the sample type, solvents, extraction media, sample plate, and pipette tips used in the run.

It is also possible to let the operator add a comment to the report just before the report is generated by enabling the **End of run comment** option.

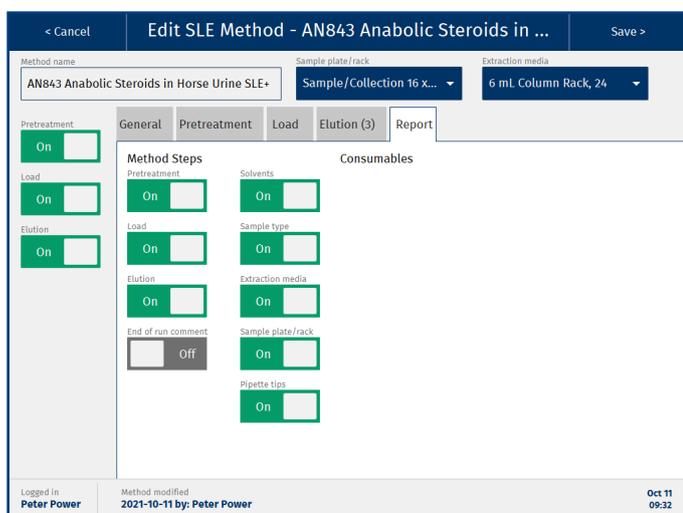


Figure 24. The Report tab in an SLE method.

End of Run Comment

If the method has the **End of run comment** option enabled, the **End of Run** dialog opens when the run has been completed but before the report is generated (see Figure 25). If desired, enter a comment that will be added to the report and press **Finish**.

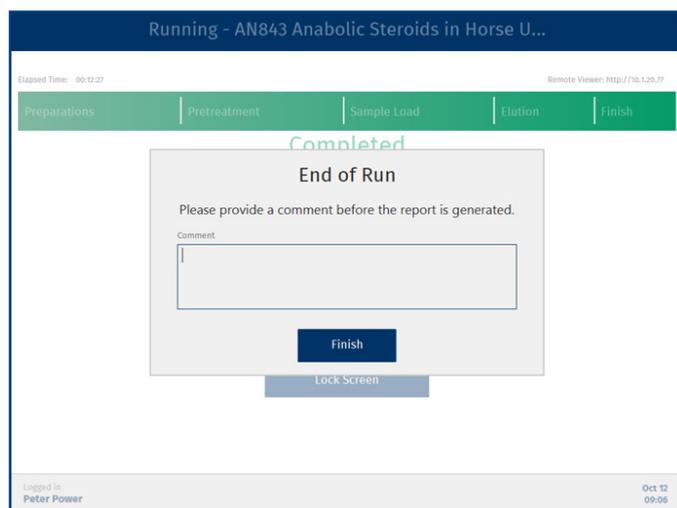


Figure 25. The End of Run dialog.

Lock/Unlock, Export/Import, and Delete Methods

Manage Methods



Lock and Unlock a Method

Methods that contain all required information can be locked by a power user. To lock a method, select the **User methods** folder, select the method, and press **Lock**. The lock action has to be confirmed by entering a comment and your password (see Figure 26). The method is then moved to the **Locked methods** folder and cannot be modified or deleted while locked. It can be unlocked by the same user (see Figure 26).

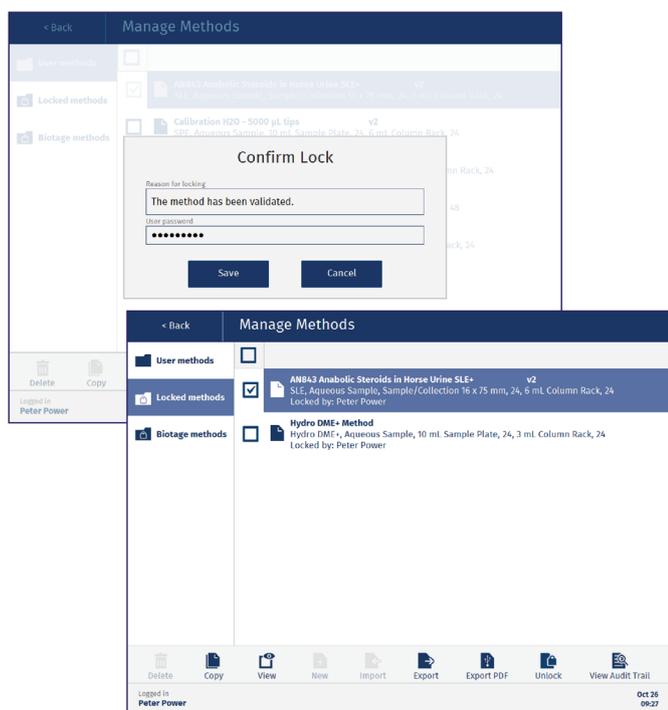


Figure 26. The Confirm Lock dialog (in the back). In the Locked methods folder, you can see which user locked a method (in the front).

Export and Import Methods

The system offers the possibility to import and export both from/to a USB memory device and a network share folder (if configured). Whether both export destinations are allowed or not is controlled by a system administrator; see “Set Export Options” on page 11.

For instructions, see the user manual supplied with your system.

Delete a Method

When using the Extrahera GLP software, only one method at a time can be deleted by power users. Before the method and its operational audit trail can be deleted, the user has to export the audit trail and enter a reason for deleting and the user password:

1. Press **Manage Methods** in the main menu. Select the **User methods** folder.
2. Select the method and press **Delete**. The **Export Audit Trail and Delete** dialog opens; see Figure 27.
3. For USB export of the audit trail, connect a USB memory device to one of the USB ports on the touch screen frame and press **Export**.
4. If the **Export Destination** dialog opens, select the export destination (USB or Network Share) and press **Continue**.
5. When the export is completed, press **Close** in the **Exporting Audit Trail** dialog.
6. Enter the reason for deleting and your password, and then press **Delete**.

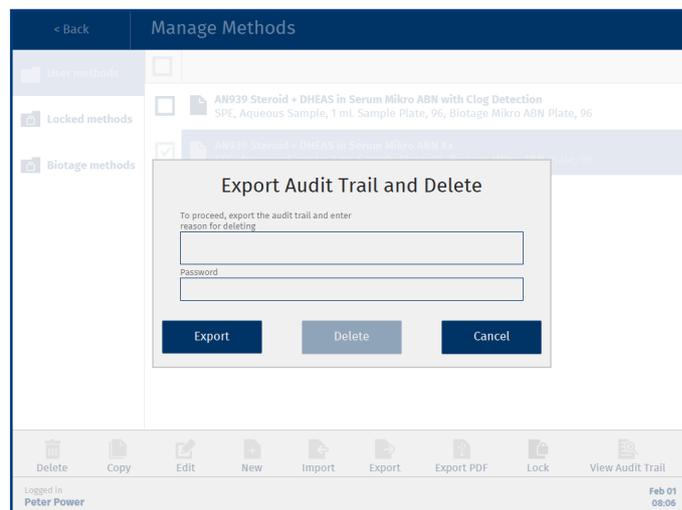


Figure 27. The Export Audit Trail and Delete dialog.

Enter IDs for Pipette Tips and Solvents

Prepare Run



With the GLP software, power and routine users can enter IDs not only for the extraction, sample, and carousel plates and racks but also for the pipette tip racks and solvent reservoirs.

To enter the ID for the pipette tip racks, press the illustration of the pipette tips in the **Prepare Run** view (position 1 and 2). See Figure 28 and Figure 29.

To enter the IDs for the solvent reservoirs, press the illustration of the reservoirs in the **Prepare Run** view (position 5 and 6). See Figure 28 and Figure 30.

The barcode and QR scanner supplied by Biotage (sold separately) can be connected to one of the two USB ports on the touch screen frame and be used instead of the touch keyboard to enter information.

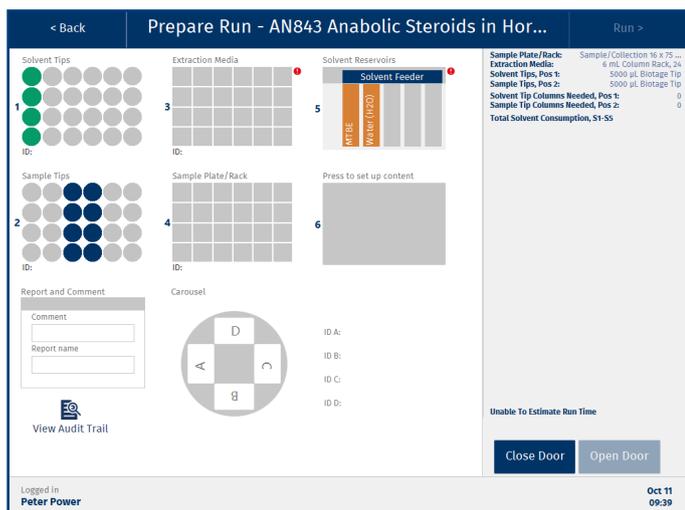


Figure 28. The Prepare Run view.

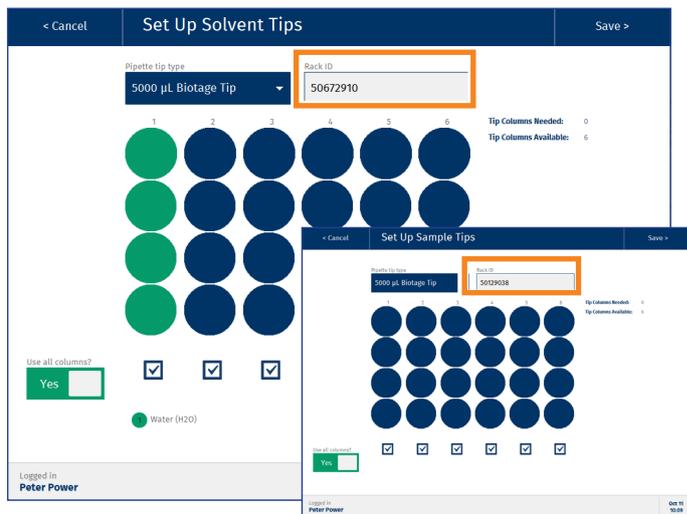


Figure 29. The Set Up Solvent Tips view (in the back) and the Setup Sample Tips view (in the front).

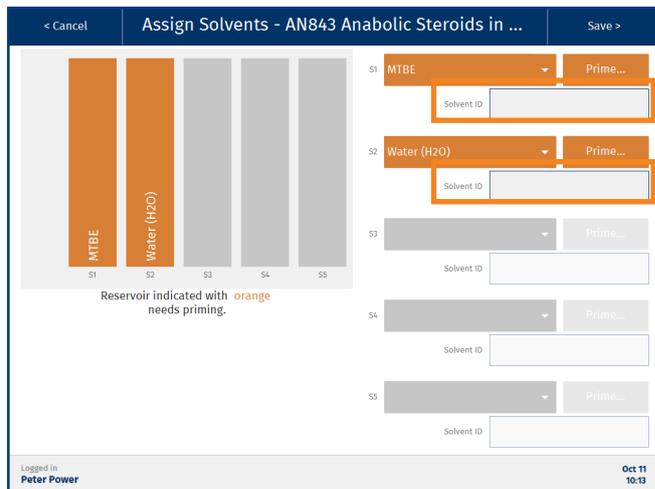


Figure 30. The Assign Solvents view for position 5 on the working area.

Enter Sample Information

Prepare Run



Power and routine users can enter custom information for the individual samples in the **Enter Sample Information** view (see Figure 33) during the setup of a run. There are two ways to do this, manually or by importing a sample batch worklist.

Configure Headers

The headers in the **Enter Sample Information** view (Custom Field 1 to 11) can be setup by pressing **Headers...** in the **Maintenance** view (see Figure 31). This can be done by power, QA/QC and routine users.

Note: If the headers in the imported sample batch worklist differ from the configured headers, the headers in the imported worklist will be used.

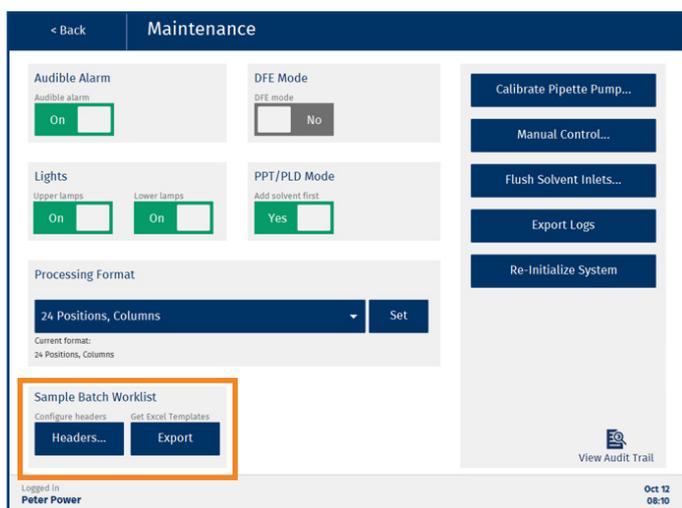


Figure 31. The Headers button in the Maintenance view.

Enter Sample Information Using the Touch Screen

1. Press the illustration of the sample plate/rack in the **Prepare Run** view (position 4); see Figure 32.
2. In the **Enter Sample Information** view, do the following for each sample to be processed:
 - a. Select a position in the sample plate/rack by pressing it; see Figure 33. Wells/columns that are not enabled in the extraction plate/rack are disabled and marked with an X.
 - b. Select the sample category from the drop-down list; see Figure 33. Each category has its own color; see the color legend below the plate/rack.

- c. Enter the desired information for the selected position in the **Custom Field** text boxes.
3. Enter the sample plate/rack ID in the **Plate ID** text box in the **Enter Sample Information** view; see Figure 33.
 4. When done, press **Save** in the top pane.

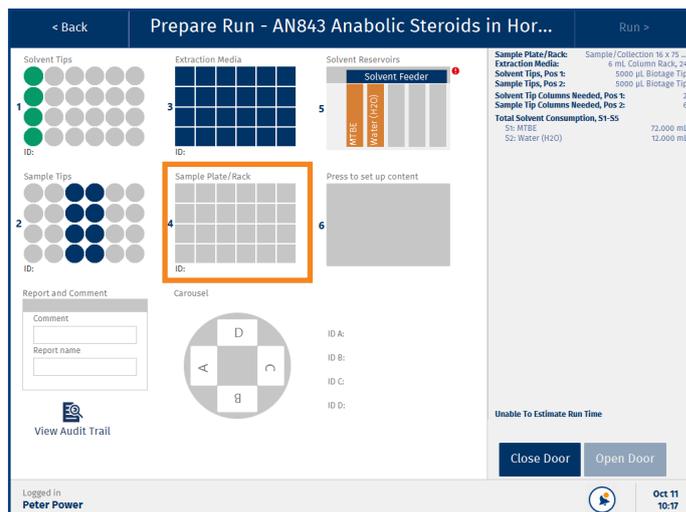


Figure 32. The Enter Sample Information view is reached by pressing position 4 in the Prepare Run view.

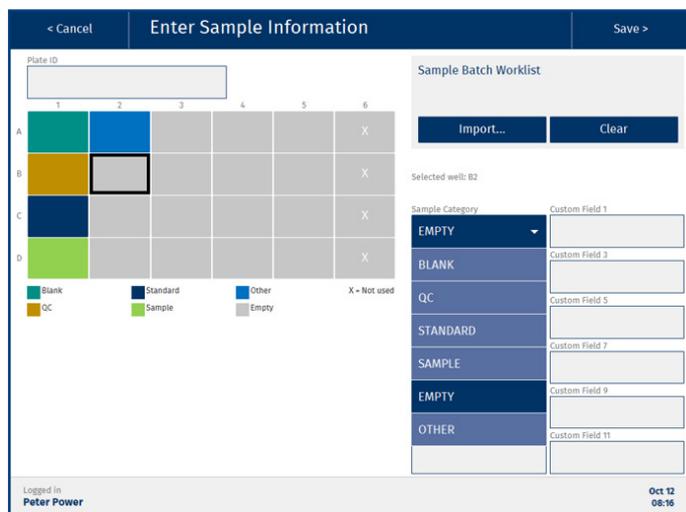


Figure 33. The Enter Sample Information view. Wells/columns that are not enabled in the extraction media are disabled and marked with an X (see A6-D6).

Enter Sample Information Using a Sample Batch Worklist

A sample batch worklist (see Figure 34) can be used to import custom information for individual samples in the **Enter Sample Information** view; see Figure 366.

Rules

The following rules must be applied when creating a sample batch worklist:

- » The file must contain a column with the tube/well position (A1, A2, etc).
- » The file must contain a column with the sample category.
- » The file can contain up to eleven columns with custom values and their headers.
- » The headers for the tube/well position column must contain a hash tag, e.g. “Tube/Well#”. This must be the only hash tag in the headers.
- » The headers for the sample category column must contain a star, e.g. “Sample Category*”. This must be the only star in the headers.
- » The file must contain at least one row in addition to the header row.
- » The sample category is case sensitive and must be set to one of the following values: Blank, QC, Standard, Sample, Empty, or Other.
- » The tube/well position must be unique and be valid for the rack/plate that will be used.
- » Each row in the file must contain the same amount of values/separators. A field can be left empty but the separator must be entered.

Create a Sample Batch Worklist Using a Excel Template from Biotage (.xlsx)

The SBWL Excel templates supplied by Biotage (see Figure 34) follow the rules that must be applied when creating a sample batch work list for Extrahera. Enter your data in the template presets.

Note: It is not possible to create your own SBWL Excel template.

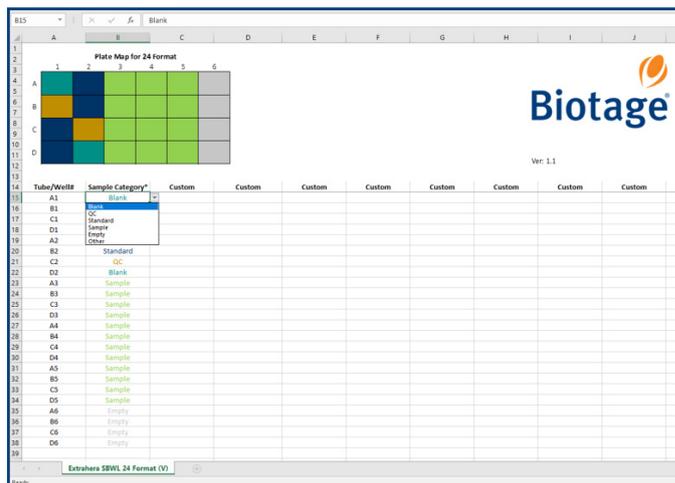


Figure 34. A SBWL Excel template supplied by Biotage.

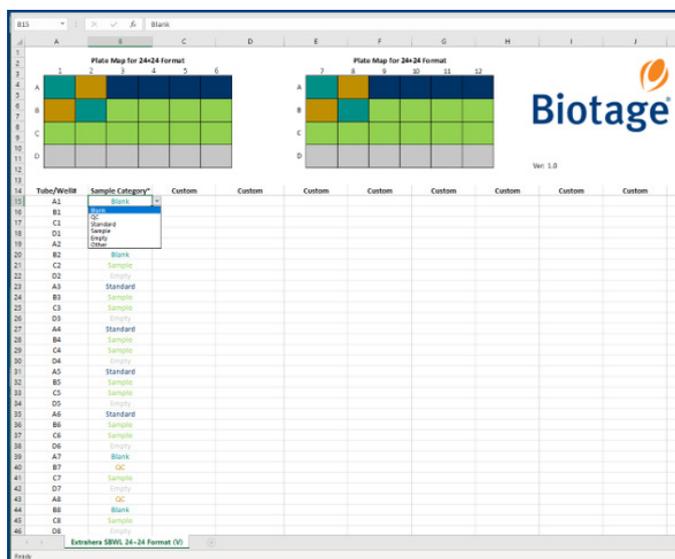


Figure 35. A SBWL Excel template for mixed format supplied by Biotage.

Create Your Own Sample Batch Worklist Using Other formats (.tsv, .csv or .txt)

File Formats

- » .tsv for tab separated data.
- » .csv for comma separated data.
- » .txt for tab, semicolon, comma or | separated data. The software will detect the separator by reading the first row (the headers). The separator is tested in the following order: tab, semicolon, comma, and then |.

Import a Sample Batch Worklist

The sample batch worklist (SBWL) will be included in the operational audit trail. It can also be included in the report by enabling the **Sample Plate** report option in the method (see page 16).

1. To import the SBWL file using a USB memory device, save the file in a **sample_batch_worklists** folder on the memory device and connect it to one of the USB ports on the touch screen frame.
2. To import the SBWL file from the network share folder (if configured); save the file in a **sample_batch_worklists** folder in the share folder. Get the location of the folder from a user with system administrator access.
3. In the **Enter Sample Information** view, press **Import...** (see Figure 366).
4. If the **Import Source** dialog opens, select the location of the SBWL file and press **Continue**.
5. In the **Select File** dialog, browse to the file location (if necessary), select the SBWL file, and press **Select**.
6. When the data has been imported, press **Close** in the **Import Completed** dialog and verify that the headers and the information in the text boxes are correct in the **Enter Sample Information** view. Wells/tubes that will not be processed are marked with an X (see Figure 366).

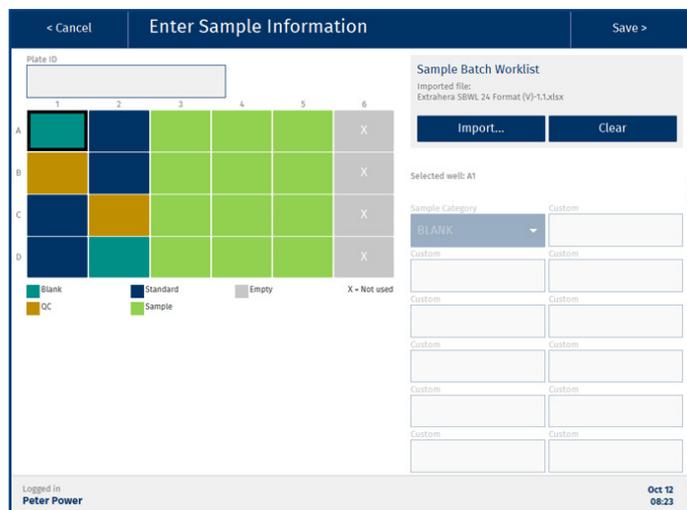


Figure 36. Imported Sample Batch Worklist. Wells/tubes that will not be processed are marked with an X.

7. Enter the sample plate/rack ID in the **Plate ID** text box in the **Enter Sample Information** view.
8. Press **Save** in the top pane. The illustration of the sample rack in the **Prepare Run** view shows the color of the selected sample category for each well/tube; see Figure 377.

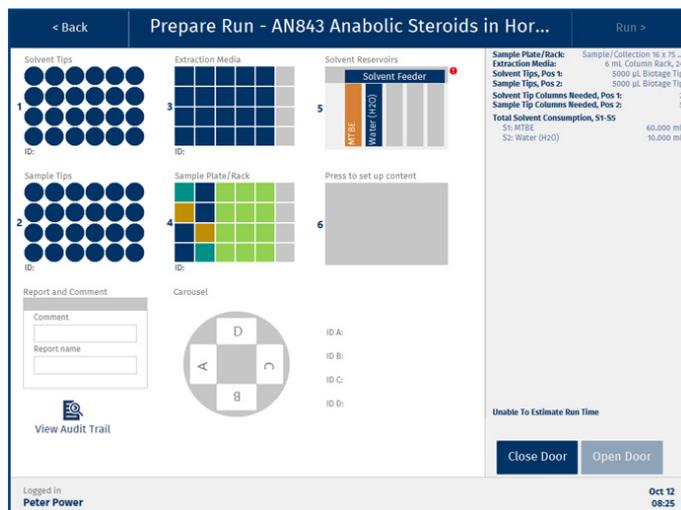


Figure 37. The Prepare Run view.

View, Export, and Delete Reports

Reports



The **Reports** view can be accessed by power, QA/QC, and routine users. Only power users can delete reports.

Reports that are stored on the system can be viewed, exported, and deleted in the **Reports** view; see Figure 38. The reports are organized in folders by month of creation, and can be sorted in chronological or alphabetical order within a folder by pressing the **Run Date** or **Report Name** header.

To display a report, select it and press **View**.

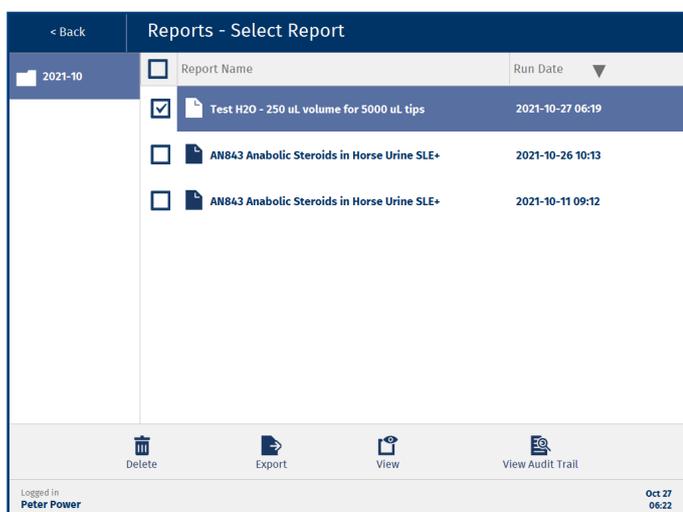


Figure 38. The Reports view. The reports can be sorted in chronological or alphabetical order.

View Reports in Network Share Folder

If your system has been set up to only store the reports in a network share folder, you will not be able to access the reports from the system (the **Report** button is disabled). Get the location of the network share folder from a user with system administrator access.

Export a Report

The system offers the possibility to import and export both from/to a USB memory device and a network share folder (if configured). Whether both export destinations are allowed or not is controlled by a system administrator; see “Set Export Options” on page 11. For export instructions, see the user manual supplied with your system.

Reports can also be downloaded from the remote viewer (if enabled); see page 43.

Locked PDF Files

All PDF files exported from the system are locked using automatically generated, non-recoverable passwords and cannot be edited.

Delete a Report

Note: Deleted reports cannot be recovered.

Before the report and its operational audit trail can be deleted by a power user, the user has to export the audit trail and enter a reason for deleting and the user password:

1. Select the report and press **Delete**. The **Export Audit Trail and Delete** dialog opens; see Figure 39. Note that only one report at a time can be deleted.
2. For USB export of the audit trail, connect a USB memory device to one of the USB ports on the touch screen frame and press **Export**.
3. If the **Export Destination** dialog opens, select the export destination (USB or Network Share) and press **Continue**.
4. When the export is completed, press **Close** in the **Exporting Audit Trail** dialog.
5. Enter the reason for deleting and your password, and then press **Delete**.

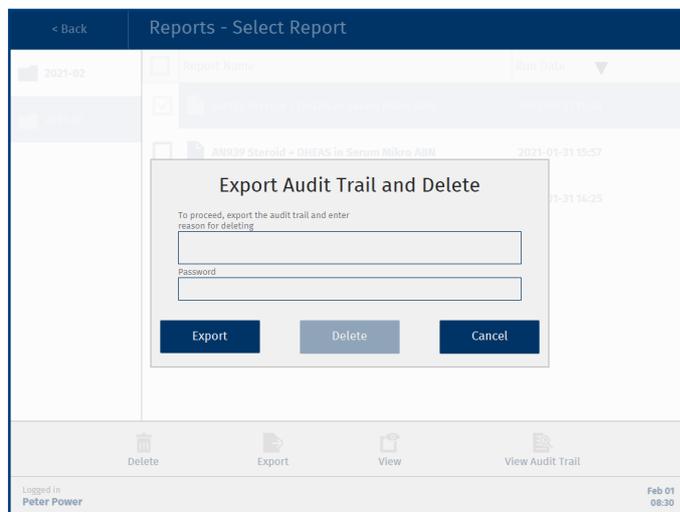


Figure 39. The Export Audit Trail and Delete dialog.

Remotely Monitor Runs and View Reports

Biotage® Extrahera™ Remote Viewer



The remote viewer allows power, routine, and monitor users to monitor runs and download reports when away from the system. QA/QC users can use the remote viewer to download reports.

Note: The remote viewer can only be accessed when the system is connected to your network and the remote viewer option is enabled; see page 7.

Note: The remote viewer is supported on Microsoft Edge, Mozilla Firefox, and Google Chrome.

Log In to the Remote Viewer

Enter the IP address displayed in the upper right corner when in the **Running** view (see Figure 40) into a web browser. You can also get the address from a user with system administrator access.

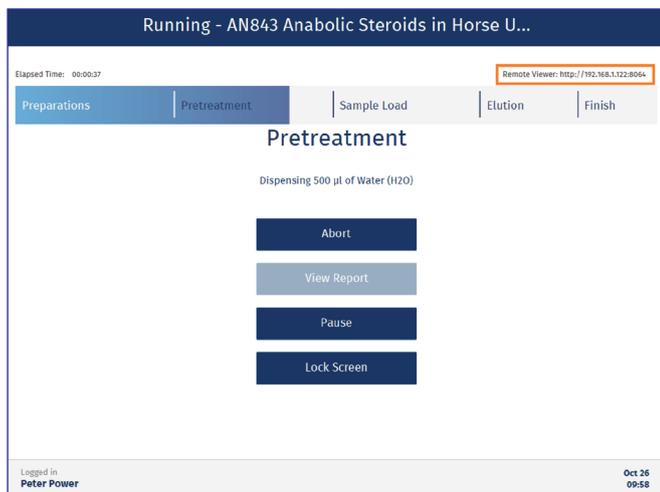


Figure 40. The Running view with the remote viewer address in the top right corner.

Log in to the remote viewer using the same user name and password as on the system; see Figure 41. Power and monitor users can log in at any time to a system allowing remote access, while routine and QA/QC users only can log in remotely (and stay logged in) when they are logged in locally on the system.

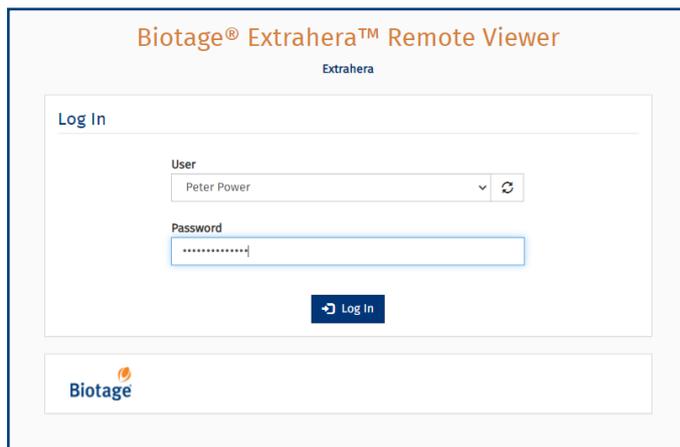


Figure 41. Log in to the remote viewer using the same user name and password as on the system. "Extrahera" in blue is the host name that the system administrator entered in the network settings for this system.

Monitor the Run

During the run, the same run progress information is displayed in the remote viewer as on the system (see Figure 42).

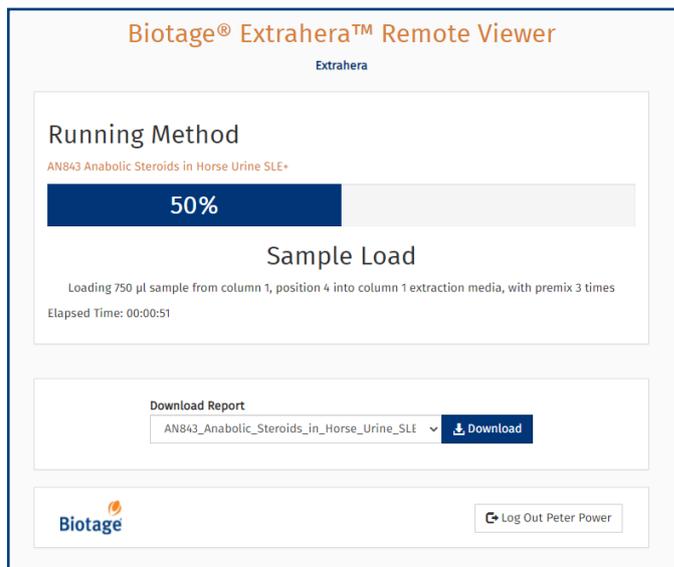


Figure 42. The run can be monitored using the remote viewer.

Download Reports

When the run is completed, the report can be downloaded to the **Downloads** folder on your computer as a PDF file. The file is locked using an automatically generated, non-recoverable password and cannot be edited.

You may also download any of the other reports that are stored on the system. The reports are listed in chronological order with the newest at the top. The file name is based on the report name, run date, and start time; see Figure 43.

Note: If your system has been set up to only store the reports in a network share folder, you will not be able to access the reports from the remote viewer.



Figure 43. The reports are listed in chronological order with the newest at the top.

View and Export Audit Trails

Audit Trails



The audit trails can be accessed from the **Audit Trails** view (see Figure 44). For user access rights, see Table 1 on page 6.

The audit trails log all changes and actions performed on the system together with date, time, the system's serial number, and user ID.

Note: A method/operational audit trail is deleted when the corresponding method/report is deleted. The audit trail has to be exported before deletion can be approved.

Note: Methods created and reports generated before the GLP software license was installed do not have audit trails. The first time a method is edited after the license has been installed, a method audit trail is created.

View an Audit Trail

All audit trails can be accessed from the **Audit Trails** view (see Figure 44). The audit trails, except for the master, can also be accessed by pressing  in the lower right corner in the corresponding view (see Figure 45).

The following audit trails are available:

- » **Operational Audit Trail:** Logs run data. Each run has its own audit trail that contains more detailed information than the report that is generated at the end of the run.
- » **Method Audit Trail:** Logs all changes in a method. Each method has its own audit trail.
- » **Data Administration Audit Trail:** Logs all creations and deletions of custom solvents, sample types, plates, racks, and pipette tips, and locking and unlocking of solvents.
- » **System Administration Audit Trail:** Logs all logins and logouts on the system and actions performed in the **System Administration** view.
- » **Maintenance Audit Trail:** Logs all changes and actions performed in the **Maintenance** view.
- » **Master:** Logs all backup, restore database, import, export, and delete actions performed on the system, and all downloads of reports from the remote viewer.
- » **Service Audit Trail:** Logs all changes and actions performed in the **Service** view.

For more detailed information, see Table 3 on page 26.

For user access rights, see Table 1 on page 6.

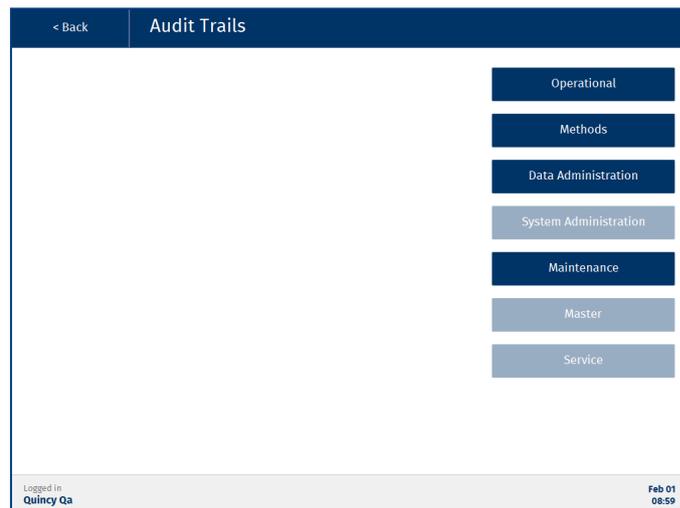


Figure 44. The Audit Trails view when logged in as a QA/QC user. For user access rights, see Table 1 on page 6.

Export an Audit Trail

A user that can view an audit trail can also export it. The audit trail can be exported either as a PDF or plain text file to a USB memory device or a network share folder. The file format and available export destinations are set up in the **System Administration** view (see page 11). Note that the PDF file is locked using an automatically generated, non-recoverable password and cannot be edited.

1. For USB export, connect a USB memory device to one of the USB ports on the touch screen frame.
2. Open the audit trail and press **Export** (see Figure 45).
3. If the **Export Destination** dialog opens, select the export destination and press **Continue**.

The audit trails are exported to an **audit_trails** folder, with one sub folder for methods and one for operational audit trails.

Audit Trail	Contents
Operational	<ul style="list-style-type: none"> » Date and time when the audit trail was created, and the system's serial number. » Method database ID and name. » Instrument ID. » User that started the run with user ID, name, e-mail address, and access level. » Run started at date and time. » Date, time, and user for the last edit of the method. » Solvent pipette tips setup and the rack ID entered at the run setup. » Sample pipette tips setup and the rack ID entered at the run setup. » Used extraction media with all information entered in the Data Administration view and the ID entered at the run setup. » Used sample plate/rack with all information entered in the Data Administration view and the ID entered at the run setup. » Used sample type. Only the name and the database ID. » Used method with all settings. » Used sample batch worklist. » Used solvents with reservoir positions, all information entered in the Data Administration view, and the ID entered at the run setup. » The IDs for the used collection plates entered at the run setup. » System software and firmware versions. » Execution log, e.g. <i>Closing door, Docking pressure unit, Measured volume in reservoir #TWO, was 21.0 ml, Pause triggered by user.</i> Each entry has a date and timestamp.
Methods	<p><u>Created:</u></p> <ul style="list-style-type: none"> » All method settings and the database ID. » Date, time, system's serial number, user ID, user access level, and username. <p><u>Changes:</u></p> <ul style="list-style-type: none"> » The old values, e.g. <i>DELETED: Starting sample volume in plate/rack (uL): 300.0.</i> » The new values, e.g. <i>ADDED: Starting sample volume in plate/rack (uL): 500.0.</i> » Change ID. » Reason for changing. » Date, time, system's serial number, user ID, user access level, and name.
Data Administration	<ul style="list-style-type: none"> » Navigation in the view, e.g. <i>Enter Page "Manage Sample Plates and Racks"</i> and <i>Exit (Save) "New Sample Plate/Rack"</i>. » Pressed buttons, e.g. <i>Button Pressed "New"</i>. » Changes to database/configuration. » All settings for the new entry are logged. » Reason for deleting an entry or locking/unlocking a solvent to a specific reservoir. » Each entry includes date, time, system's serial number, user ID, and name.
System Administration	<ul style="list-style-type: none"> » Navigation in the view, e.g. <i>Enter Page "Backup"</i> and <i>Exit (Save) "Backup"</i>. » Pressed buttons, e.g. <i>Button Pressed "Run Now"</i>. » Changes to database/configuration. In most cases all the settings in the view are logged with the change(s) highlighted either with an asterisk (*) or by having the old value in brackets behind the new value. » User logins (including failed attempts) and logouts. » Each entry includes date, time, system's serial number, user ID, and name.

Audit Trail	Contents
Maintenance	<ul style="list-style-type: none"> » Navigation in the view, e.g. <i>Enter Page "Flush Solvent Inlets"</i> and <i>Exit (Save) "Calibrate Pipette Pump"</i>. » Entered values, e.g. <i>S1 Volume (mL): 20.</i> » Pressed buttons, e.g. <i>Button Pressed: "Flush S1"</i>. » Changes to database/system configuration, e.g. <i>Audible alarms: Disabled.</i> » Each entry includes date, time, system's serial number, user ID, and name.
Master	<ul style="list-style-type: none"> » All backup, restore, import, export, and delete actions performed on the system, and downloads of reports from the remote viewer » Reason for deleting an entry. » Each entry includes date, time, and system's serial number. Export and import of methods and deletion of an entry also includes user ID and name.

Table 3. Audit trail contents.

The screenshot shows the 'Reports - Select Report' interface. It features a search bar for 'Report Name' and a dropdown for 'Run Date'. A report titled 'AN843 Anabolic Steroids in Horse Urine SLE+' is selected, with a run date of '2021-10-11 09:12'. Below this, there is a section for 'Operational Audit Trail' with an 'Export' button. A red arrow points to a 'View Audit Trail' button in the bottom right corner of the interface.

Figure 45. There is one operational audit trail for each run.

The screenshot shows the 'Method Audit Trail' interface. It displays details for a method with ID [10001]. The method name is 'AN939 Steroid + DHEAS in Serum Mikro ABN with Clog Detection'. The audit trail text includes: '2021-01-31 21:56:53 simulated_serialNumber ** Log file created **', 'Method ID: [10001]', 'Type: SPE', 'User: [10002] [Power User] Peter Power', 'Creation Type: Copy from [63] AN939 Steroid + DHEAS in Serum Mikro ABN', 'Name: "AN939 Steroid + DHEAS in Serum Mikro ABN with Clog Detection"', 'Sample plate/rack: "1 ml Sample Plate, 96"', 'Extraction media: "Biotage Mikro ABN Plate, 96"', 'Sample pipette tip type: "200 µl Biotage tip"', 'Position 1 solvent pipette tip type: "200 µl Biotage tip"', 'Sample type: [24] Aqueous Sample', 'Starting sample volume in plate/rack (µl): 500.0', 'Reuse sample tips? Yes', 'Method comment: Application note AS939. Steroids (including DHEAS) in serum. Use Mikro ABN. Condition and Pre-treatment steps are -', 'Pre-treatment: enabled: No', 'Pre-treatment: Pause after each step: No', 'Pre-treatment: Dispose tips after each step: No', 'Pre-treatment: Number of steps: 1', 'Pre-treatment: Step #1: Solvent: -', 'Pre-treatment: Step #1: Volume(µl): 0'. The interface also shows 'Logged in Peter Power' and the date 'Feb 01 08:04'.

Figure 46. Example of a method audit trail.

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EUROPE

Main Office: +46 18 565900
Toll Free: +800 18 565710
Fax: +46 18 591922
Order Tel: +46 18 565710
Order Fax: +46 18 565705
order@biotage.com
Support Tel: +46 18 56 59 11
Support Fax: +46 18 56 57 11
eu-1-pointsupport@biotage.com

NORTH & LATIN AMERICA

Main Office: +1 704 654 4900
Toll Free: +1 800 446 4752
Fax: +1 704 654 4917
Order Tel: +1 704 654 4900
Order Fax: +1 434 296 8217
ordermailbox@biotage.com
Support Tel: +1 800 446 4752
Outside US: +1 704 654 4900
us-1-pointsupport@biotage.com

JAPAN

Tel: +81 3 5627 3123
Fax: +81 3 5627 3121
jp_order@biotage.com
jp-1-pointsupport@biotage.com

CHINA

Tel: +86 21 68162810
Fax: +86 21 68162829
cn_order@biotage.com
cn-1-pointsupport@biotage.com

KOREA

Tel: +82 31 706 8500
Fax: +82 31 706 8510
korea_info@biotage.com
kr-1-pointsupport@biotage.com

INDIA

Tel: +91 11 45653772
india@biotage.com

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