Biotage® Extrahera™

Release Notes

What's New in Biotage® Extrahera™ 2.0.1

Biotage® Extrahera software version 2.0.1 includes the following enhancement:

Possible to have up to 100 rinse cycles in SPE methods. Rinsing is used for removing the last residual sample from the sample plate/rack and transferring the liquid to the extraction media.

What's New in Biotage® Extrahera™ 2.0

Biotage® Extrahera software version 2.0 includes the following new features and enhancements:

- » Biotage° Extrahera GLP software license; see page 2.
- » Run individual samples. When setting up a run by pressing Run Individual Samples in the main menu, up to 3 or 7 samples (depending on the format) can be processed per run. The samples must be loaded in the first plate/rack column.

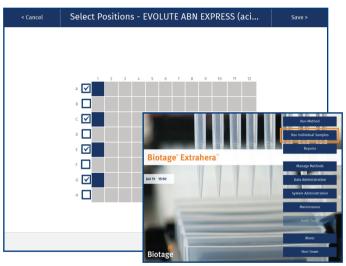


Figure 1. The main menu when using a system without the GLP software license installed (in the front) and the Select Positions view for when running individual samples (in the back).

- » Hydro DME+ method. Use this method to perform dual mode extraction with in-situ hydrolysis.
- Support for 48 positions column racks with the following accessories added to the database: Column Rack 48 x 3 mL (P/N 415556SP) and Sample/Collection Rack 12 x 75 mm 48 Positions (P/N 415555SP). With this new format, the system has four possible configurations: 1) 96 Positions, Plate/Columns; 2) 48 Positions, Plate; 3) 48 Positions, Columns; and 4) 24 Positions, Columns.

- Sample pipette tip type is now defined in the method.
- » Any conditioning, equilibration, wash, and elution step can be repeated up to 100 times.
- » Premix of sample is by default set to three times.
- Improved naming of two method parameters.
 "Reuse sample tips" is changed to "Reuse tips for pretreatment mix and sample load" and all "Volume" fields for sample are changed to "Sample volume".
- » All predefined entries in the Data Administration view are locked and cannot be edited or deleted.
- Possible to lock a solvent to a specific solvent reservoir in position 5 on the working area. As long as the solvent is locked to the reservoir, no other solvent can be used in that reservoir.

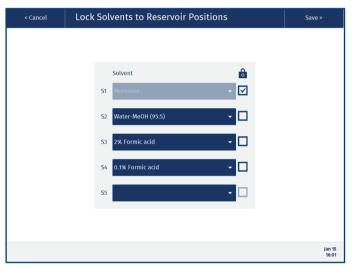


Figure 2. The Lock Solvents to Reservoir Positions view with methanol locked to reservoir S1.

- Improved settings for the following predefined solvents: Acetonitrile, DCM, Ethyl Acetate, Heptane, Hexane, IPA, Methanol, MTBE, and Water.
- » A new predefined Biotage pipette tip; 1000 μL Wide Bore, Clear (P/N 416444).
- Possible to set the tip conditioning frequency for solvents; once before the first aspiration, before each step, or before every aspiration.
- » Possible to set the flow rate and volume that will be used when aspirating a solvent/sample post dispense.
- » Height setting for sample plates and racks. This setting is important when clog detection is used on a GLP system.



Solvents can be defined as highly volatile. When a solvent defined as highly volatile is assigned to the solvent rack in position 5 on the working area, the reservoir is filled just before the solvent is used for the first time in the run.

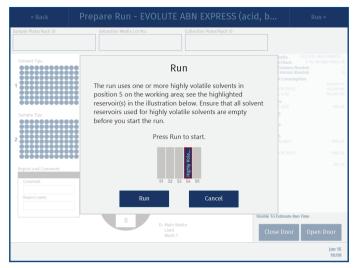


Figure 3. The Run dialog when using a highly volatile solvent in reservoir S4 on the working area.

- » Visible and audible alarm. The system's visual and audible alarm is triggered by non-user-initiated pauses, scheduled pauses (defined in the method), and system errors:
 - When a non-user-initiated or scheduled pause occurs, the software background flashes in blue and an alarm with short beeps sounds.
 - » If a system error occurs, the software background flashes in red and an alarm with longer beeps sounds.

The alarm stops when the touch screen is pressed. The audible alarm can be disabled in the software's Maintenance view.

- » Barcode and QR scanner support. The barcode and QR scanner (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.
- » Modified Maintenance view. The controls for manually moving the extraction waste collector and pipette head have been moved into the Manual Control view.
- » Reminders for pipette pump calibration can be enabled in the new System Administration view. It is possible to select how often the pipette pump should be calibrated (once a month, once every third month, once every sixth month, or once a year) and when the user is notified that the calibration has expired (at startup and/or before a run is started).

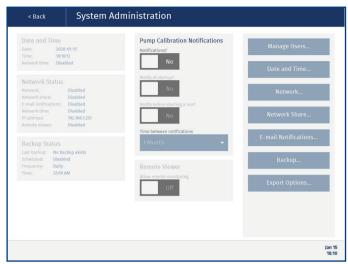


Figure 4. The System Administration view with only access to set up reminders for pipette pump calibration. To get access to all features in this view, the GLP software license has to be installed.

Biotage® Extrahera GLP Software License

The license is sold separately and must be installed by an authorized Biotage service engineer. The following features are available with the GLP software license:

Wser accounts. Each user must log in to the system using a unique user account with an alpha-numeric, time-sensitive, password. The user is provided a defined role which limits the capacity to interact with the system; see Table 1 on page 5. Five user profiles are available: system administrator, power user, routine user, QA/QC, and monitor.



Figure 5. Editing a user with power user access.



- E-mail notifications. With the Extrahera system connected to an e-mail server, 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.
 - 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 for each user account individually.

- » Network share. With the Extrahera system connected to a network, it is possible 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.
- » Restricted USB export. Export to a USB memory device and a network share folder (if configured) can be enabled/ disabled individually. Import is always allowed.
- » Clog detection. Clog detection can be enabled for any load, wash, and elute step in SPE, SLE, and 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.

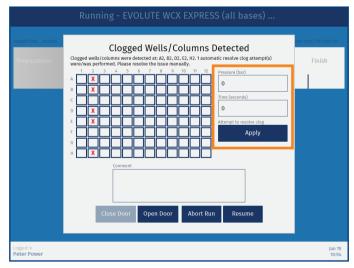


Figure 6. If there are still clogged wells/columns when the maximum number of attempts have been made by the system, or if that feature is not enabled, the "Clogged Wells/Columns Detected" dialog opens. If enabled in the method, you can try to clear the clogged well(s)/column(s) by applying pressure (see the highlighted section).

Note: The following Biotage and competitor consumables are currently not supported when using clog detection: ISOLUTE® PPT+, ISOLUTE® PLD+, ISOLUTE® FILTER+ Plate, Waters Oasis µElution Plates, Tecan NBE and Cerex Columns, and 1 mL Columns, 24 and 96 Positions Configuration.

- » Method timestamps. When setting up a method, a timestamp inside the method displays when it was last edited and by whom. Check the method audit trail for detailed information.
- » Lock methods. Methods that contain all information required to be run can be locked. Locked methods cannot be modified or deleted, and can only be unlocked by the same user.
- » Dynamic reporting. The contents of the report is set up in the method with the possibility to enable/disable the settings for each method operation individually, and 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.
- » Sample Batch Worklist (SBWL). 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 plate/rack formats with color coded plate/rack map and 11 custom fields. You can also use tsv, csv, and txt files.

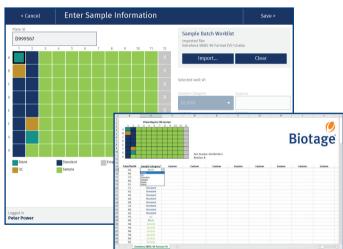


Figure 7. Once a SBWL has been imported, the user cannot edit the information on the system.

Identification (ID) information. Identification 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.



» Biotage® Extrahera™ Remote Viewer. With the Extrahera system connected to a network, it is possible to allow the users to monitor their runs and download reports when away from the system.

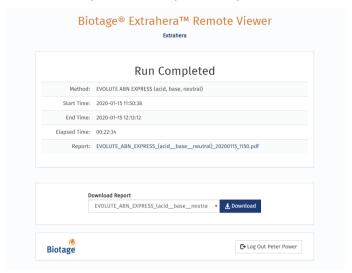


Figure 8. The reports are listed in chronological order with the newest at the top.

- Set date and time. Either enter the date and time manually or, if your system is connected to a network, synchronize the system with an NTP time server.
- System backup and restore. Backups can be scheduled (monthly, weekly, or daily) and started manually. Depending on which export options that are enabled on the system, the backups can be stored on a USB memory device and/or in a network share folder.
- » Password required when editing, locking/unlocking, and deleting. The following actions require that the user enter 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.
 - » Editing, locking, unlocking, and deleting a method.
 - » Deleting a report.
- » Audit trails. Seven different audit trails log all changes and actions performed on the system together with date, time, and user ID. The audit trails can be exported either as a text file or a secure PDF depending on the system export settings.

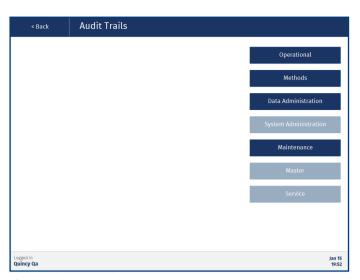


Figure 9. The Audit Trails view when logged in as a QA/QC user.

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

Bug Fixes

Biotage® Extrahera software version 2.0 includes the following bug fixes:

- Improved scanning of the solvent reservoirs in position 5 on the working area.
- » Improved handling of the static solvent reservoirs in position 6 on the working area.
- » New improved ultra sonic sensor, which is used for measuring distances.
- » Rinsing is now performed in aliquots when necessary.

Notes

- » Run of multiple methods is no longer supported. The Run Single Method button has been renamed to Run Method.
- » It is no longer possible to lock/unlock methods unless the new GLP software license is installed.
- » It is no longer possible to enable/disable the settings for the method operations in the report when setting up a run. With the GLP software license installed, the contents of the report can now be set up in each method (see page 3).



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 and Export as PDF	~	~	~	×	×	×	view is disabled to all users.
Manage Methods							
Create, Import, Export, Edit, and Lock	×	/	×	×	×	×	A method can only be unlocked by
View and Export as PDF	~	/	/	×	×	×	the same user that locked it.
Data Administration							
Create and Delete Entry, and Lock Solvent	×		×	×	×	×	Solvents, sample types,
View Entry	×		~	×	×	×	extraction media, sample plate and racks, and pipette tips.
System Administration	• •	•	•	• • •	• •	• • •	
Configure Pipette Pump Notifications	×	×	×		×		
Enable the Remote Viewer	×	×	×		×		
Manage User Accounts	×	×	X		×		
Set Date and Time	×	×	×		×	×	
Network Services	×	×	×		×	×	
Perform and Schedule Backup	×	×	×		×	×	
Export Options	×	×	×		×	×	
Maintenance				•			
System Settings	_			×	×	×	System settings: alarm, lights,
Calibrate Pipette Pump	×		*	×	×	×	instrument type, PPT/PLD mode,
Manual Control			×	×	×	×	and headers for SBWL.
Flush Solvent Inlets			×	×	×	×	
Export Logs			×	×	×	×	
Re-initilize the System			×	X	×	×	
	*	*					
View and Export Audit Trails				×	×	~	If the reports are only saved
Operational Methods		×	/	×	×	×	If the reports are only saved in a network share folder, the operational audit trails are not accessible on the system.
	×	×	×	×	×	×	
Data Administration	×	×	×		×	· ·	The state of the s
System Administration Maintenance	- Ç	- Ç	~	×	×	×	
Master	×	×	×	ŷ	×		
Service	×	×	×	×	×		
		^			^	•	(2) 144
Access Remote Viewer (if enabled)	(2)	✓	(2)	×	~	×	(2) When logged in to the system.

Table 1. User access rights.



What's New in Biotage® Extrahera™ 1.5.5

Biotage® Extrahera software version 1.5.5 includes the following enhancements and bug fixes:

- Improved pressure head control now used to reduce pressure head blockages. The gas flow remains on after the pressure head has been lifted from the extraction plate or column rack. Previously, the gas flow remained off as the pressure head was lifted.
- Air Push option is now available at the end of pressure gradients when using SLE methods. When using SLE, the "Plate Dry" option has been renamed "Air Push." This feature is located under the "Advanced pressure settings" under the SLE "Load" step. When using the "Air Push" option, positive pressure is applied with a gas flow of approximately 10 mL/min for an amount of time set by the user.
- » Additional information added to "Export Methods" for SLE based methods. In this release, parameters for both pretreatment and pressure gradients are included in the SLE method export.

What's New in Biotage® Extrahera™ 1.5.4

Biotage® Extrahera software version 1.5.4 includes the following new features and enhancements:

- » A pressure gradient can now also be created in the SLE load step.
- » Three new predefined extraction media: ISOLUTE® SLE+ 400 μl columns (P/N 820-0055-B), ISOLUTE® SLE+ 1 mL columns (P/N 820-0140-CG), and ISOLUTE® FILTER+ plate 25 μm/0.2 μm (P/N 120-2000-P25).
- Improved solvent reservoir scanning with higher accuracy when using high volatile solvents and no scanning when the solvent rack (in position 5 on the working area) is not used.

What's New in Biotage® Extrahera™ 1.5.3

Biotage® Extrahera software version 1.5.3 includes the following new features, enhancements, and bug fixes:

- Two new methods. Filtration and Filtration+:
 - » Use the Filtration method to apply pressure to a filter plate with preloaded sample. The method has an adjustable collection height.
 - » Use the Filtration+ method for sample load and filtration preceded by an optional pretreatment.
- Three new sample/collection racks with 24 positions for 12 x 75 mm, 16 x 75 mm, or 18 x 75 mm test tubes (P/N 415491, 415585, and 415492).
- Support for a new solvent rack for the 100 mL reservoirs. With the new solvent rack (P/N 415560SP) it is possible to use the 100 mL reservoirs with both well plates and column racks. The old 100 mL solvent rack (P/N 414215SP) can only be used with well plates.

- Aspirate post dispense. An option to aspirate air into the pipette tip after dispensing sample or solvent. This is defined when setting up solvents and sample types.
- » Conditioning volume for solvents. It is now possible to define the conditioning volume, in percentage of the pipette tip that will be filled with solvent. This is defined when setting up solvents.
- » Zero pipetting volume is allowed to increase the flexibility in the method setup.
- Moveable pretreatment step. The pretreatment step can now be moved to take place immediately before the load step, i.e. after conditioning and equilibration. SPE only.
- Pretreatment mixing. It is now possible to mix the sample and added solvent in the sample well/tube immediately after pretreatment.
- » Tip conditioning before sample load. An option to condition the sample pipette tip with solvent. SPE only.
- » Rinsing of the sample wells or test tubes. An option to remove the last residual sample from the sample plate/ rack by rinsing the wells or test tubes with solvent, and then transferring the liquid to the extraction media. SPE only.
- » More flexible reuse of sample pipette tips. The reuse of sample pipette tips is enabled or disabled for each method individually and is no longer a global system setting. Besides the possibility to reuse sample pipette tips when loading sample in aliquots, it is now also possible to reuse the tips when mixing following pretreatment.
- A pressure gradient can now also be created in the collection step. (PPT/PLD, Filtration, and Filtration+.)
- Estimated remaining time in the Running view. When a method has been run at least once before, an estimated remaining time is displayed in the Running view. The calculation is based on all previous runs using the method. Note that if the method is changed, the algorithm calculating the estimated time is reset.
- Door controls in more views. Buttons for opening and closing the door are now also available in the Manual Control and Prepare Run views.
- » Abort option available in the Pause dialog.
- The reports are organized in folders by month of creation.
- Improved behavior of the solvent reservoir refill routine. In previous versions of the software, there were situations where the system incorrectly reported a refill error in the middle of a run with no possibility to resume the run.
- Corrected behavior of the pickup of the inner pipette tips when using a 24-format system.
- The software is updated to Java 8.

Note: The possibility to attach a LIMS file to the report and define the sorbent load for extraction plate and column rack have been removed in this version of the software.



What's New in Biotage® Extrahera™ 1.5.2

Biotage® Extrahera software version 1.5.2 includes the following new features, enhancements, and bug fixes:

- >> Two new methods, Filtration and Filtration+:
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Compatibility Information

- In order to have dual flow, systems produced before 20160201 must be upgraded with the Dual Flow Upgrade Kit (P/N 415039). With dual flow, the gas flow when processing is between o and 10 mL/min during all operations except for plate dry, where it is approximately 600 mL/min.
- In order to use the 12 x 75 mm and 18 x 75 mm collection rack options, your system must have the updated extraction waste collector that was released in 2015 (P/N 414565SP).
- In order to use the 100 mL solvent reservoirs in the 1.5.4 software, the new solvent rack has to be used (P/N 415560SP).

For more information, please contact your local Biotage representative. See contact information on our website www.biotage.com.

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