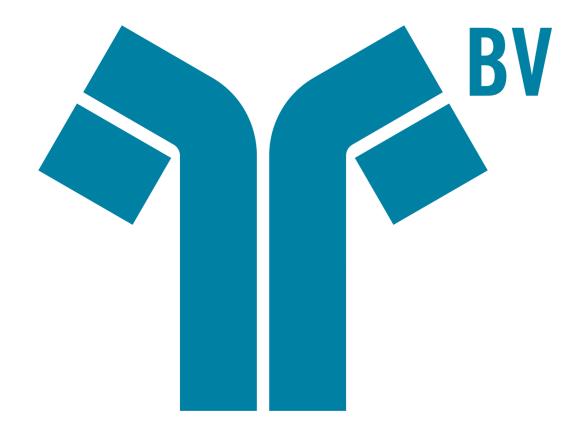


# **BioPharmaView<sup>™</sup> 2.1 Software**

**Release Notes** 



RUO-IDV-03-1798-D March 2017

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Introduction 1

The BioPharmaView<sup>™</sup> software is a post-acquisition processing software used for performing characterization and analysis of biologics. Use the software to complete the following tasks:

- Enter and update assay information
- Characterize standards
- · Batch process files
- Review batch results
- Create reports

The BioPharmaView<sup>™</sup> software processes data files generated by SCIEX TripleTOF<sup>®</sup> systems and the SCIEX X500 QTOF systems to support protein and peptide analysis during therapeutic drug development.

The BioPharmaView<sup>™</sup> software supports the following workflows:

- **Intact Protein Analysis**: Determines the molecular weight of intact proteins, based on the reconstruction of a charge series envelope resulting from LC-MS.
- **Peptide Mapping Analysis**: Determines the peptide sequences resulting from the enzymatic digestion of a protein from the mass-to-charge (*m/z*) ratio of TOF MS data.

Each workflow enables the user to characterize samples and store the results, perform automated batch analysis, and generate reports.

All of the BioPharmaView<sup>™</sup> software report templates, processing settings, and modifications can be customized.

### **Related Documentation**

- BioPharmaView<sup>™</sup> Software User Guide: Click Start > All Programs > AB SCIEX > BioPharmaView > BioPharmaView User Guide.
- BioPharmaView<sup>™</sup> Software Help: Click the Help icon in the bottom left corner of the BioPharmaView<sup>™</sup> software window, press F1 from any location in the software, or click Start > All Programs > AB SCIEX > BioPharmaView > BioPharmaView Help.

### Changes from Version 2.0 to Version 2.1

### Support for version 1.2 of the SCIEX OS

This version of the BioPharmaView<sup>™</sup> software integrates recent changes in data processing made as part of SCIEX OS, version 1.2. Version 2.1 of the software uses updated isotopic masses and abundances from: Coursey, J.S., Schwab, D.J., Tsai, J.J., and Dragoset, R.A. (2015), Atomic Weights and Isotopic Compositions (version 4.1). [Online] Available: http://physics.nist.gov/Comp. National Institute of Standards and Technology, Gaithersburg, MD.

### Support for data files generated by SCIEX X500B QTOF systems

This version of the BioPharmaView<sup>™</sup> software processes data files generated by the SCIEX X500B QTOF systems.

**Note:** Refer to Issues Fixed in Version 2.1 of the BioPharmaView Software on page 19 for a list of all of the previous issues that have been resolved with this release of the BioPharmaView TM software.

### **Contact Us**

### **SCIEX Support**

- sciex.com/contact-us
- sciex.com/request-support

### **Customer Training**

- In North America: NA.CustomerTraining@sciex.com
- In Europe: Europe.CustomerTraining@sciex.com
- Outside the EU and North America, visit sciex.com/education for contact information.

### **Online Learning Center**

SCIEXUniversity

### **Technical Support**

SCIEX and its representatives maintain a staff of fully-trained service and technical specialists located throughout the world. They can answer questions about the system or any technical issues that might arise. For more information, visit the Web site at sciex.com.

CAUTION: Potential Data Loss. The BioPharmaView<sup>™</sup> software should not be installed on the acquisition computer. Software errors and data integrity issues can result if the BioPharmaView<sup>™</sup> software and acquisition software are used concurrently.

The workstation must be configured with the following applications:

- English version of Microsoft Windows 7 (32-bit or 64-bit) operating system with SP1
- Microsoft .NET Framework 4.6.2
- Adobe Reader

**Note:** Visit www.adobe.com and follow the instructions to install the latest version of Adobe Reader.

Microsoft Office 2010 or 2013.

**Note:** If a trial version of Microsoft Office is installed on the computer as a temporary measure, then the full version of the Microsoft Office software must be activated before the trial period expires. The license can be purchased from your regional division of Microsoft or from an authorized distributor in your region.

### **Supported Equipment**

- Dell OptiPlex 9010
- Dell OptiPlex XE2 computer with:
  - An Intel Core I5-4570S processor (Quad core, 2.90 GHz, 6 MB with HD Graphics 4600)
  - 32 GB DDR3 1600Mhz SDRAM
  - 2\*2Tb HDD (RAID1)
  - DVD+-RW

**Note:** Newer systems might become available. For more information, contact the local sales representative. Older computer models might be compatible. However, they have not been tested and might result in degraded performance.

Installation 3

### **Notes on Installation**

- The user must be logged on to the computer as a user with Administrator privileges.
- Any existing version of the BioPharmaView<sup>™</sup> software that is installed on the computer must be removed before this version of the software can be installed. Refer to Remove the BioPharmaView Software on page 17.
- For BioPharmaView<sup>TM</sup> 1.0 software users only: Before installing this version of the BioPharmaView<sup>TM</sup> software on a system configured with the Microsoft Windows 7 64-bit operating system that previously had version 1.0 of the BioPharmaView<sup>TM</sup> software installed, the user must remove the installed version of the AB SCIEX Reporter Template Suite 3.2 through the Control Panel > Programs > Uninstall a program option. (BPV-335)
- If using a .zip file that contains the BioPharmaView<sup>™</sup> software installer, then extract all of the files from the .zip file before running the installer from the location containing the extracted files. Errors will occur if the installer is run from within the .zip file.
- During installation of the BioPharmaView<sup>™</sup> software, the system might determine that Microsoft .NET Framework 4.6.2 is not installed. If this occurs, then the system must be connected to the Internet to download additional components for the Microsoft .NET Framework 4.6.2 installation process. If the system fails to install the Microsoft .NET Framework 4.6.2, then the BioPharmaView<sup>™</sup> software installation also fails. Resolve the situation by connecting the workstation to the Internet or contacting your local IT department to install the Microsoft .NET Framework 4.6.2, and then install the BioPharmaView<sup>™</sup> software again.

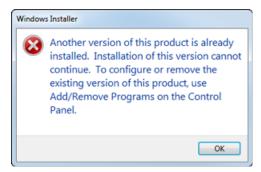
## Install the BioPharmaView<sup>™</sup> Software

CAUTION: Potential Data Loss. The BioPharmaView<sup>TM</sup> software should not be installed on a computer used for acquisition. Software errors and data integrity issues can result if the BioPharmaView<sup>TM</sup> software and acquisition software are used concurrently.

- 1. Log on to the computer as a Microsoft Windows user with administrator privileges.
- 2. Remove any existing version of the BioPharmaView<sup>™</sup> software. Refer to Remove the BioPharmaView Software on page 17.

**Note:** If any version of the BioPharmaView<sup>™</sup> software is already installed on the computer, then a Windows Installer error dialog opens before the installation starts. Click **OK** and then remove the software.

**Figure 3-1 Windows Installer Error Dialog** 



- 3. Make sure that all of the applications are closed.
- 4. Install the BioPharmaView<sup>TM</sup> software as described in Table 3-1.

**Table 3-1 Installation Instructions** 

To install from a file downloaded from the SCIEX Web site	To install from the BioPharmaView <sup>™</sup> software installation DVD	
Download the .zip file from sciex.com/products/software/biopharmaview-software.	Load the BioPharmaView <sup>™</sup> software installation DVD in the DVD drive.	
<b>Tip!</b> To prevent potential installation issues, we recommend that the file is saved to a location other than the computer desktop.		
After the download is complete, right-click the <b>BioPharmaView_2.1.zip</b> .	Navigate to the DVD and then double-click setup.exe.  Tip! If the Reporter Software 3.2 is not installed on the system, then click Accept on the Reporter Software v3.2 End User License Agreement dialog.	
	The BioPharmaView™ Software Setup  Welcome to the BioPharmaView™ Software Setup Wizard  The Setup Wizard will install BioPharmaView™ Software on your computer. Click Next to continue or Cancel to exit the Setup Wizard.  We recommend that you do not install or run BioPharmaView™ Software on a computer used for acquisition. Running BioPharmaView™ Software while performing acquisition will adversely affect data acquisition.	
Click Extract All.	Click <b>Next</b> .	
<b>Note:</b> By default, the files are extracted to the BioPharmaView_2.1 folder in the same location where the <b>BioPharmaView_2.1.zip</b> was saved.		

**Table 3-1 Installation Instructions (continued)** 



**Table 3-1 Installation Instructions (continued)** 

To install from a file downloaded from the SCIEX Web site	To install from the BioPharmaView <sup>™</sup> software installation DVD
On the End-User License Agreement dialog, click the laccept the terms in the License Agreement check box and then click Next.	
On the Destination Folder dialog, click <b>Next</b> .	—
<b>Tip!</b> The user can change the software installation locations and the data folders before clicking <b>Next</b> .	
Click Install.	_

- 5. After the installation is complete, click **Finish**.
- 6. Continue with License the BioPharmaView Software on page 11.

## License the BioPharmaView<sup>™</sup> Software

The BioPharmaView<sup>™</sup> software is a licensed product. If a valid 2.0 license is not installed, or if the license has expired, then the processing and saving functions are not available.

- 1. Open the BioPharmaView<sup>™</sup> software.
- 2. View the software title bar.
  - If a valid license file exists, then the title bar only contains the software name.



• If a valid license file does not exist, then the title bar contains the software name and a message indicating that there is an issue with the license.



3. If there is a licensing issue, then click **About** in the lower left corner of the software.



The About BioPharmaView<sup>™</sup> Software and Software License Activation dialog opens.

Figure 3-2 About BioPharmaView<sup>™</sup> Software and Software License Activation Dialog



Any of the following conditions can result in the "This software is not licensed" message being shown:

- A valid 2.0 license is not installed.
- The computer network connection is not available. The licensing components used by BioPharmaView<sup>™</sup> software require that the computer's network adapter be enabled, although a physical connection to the network is not required.

### 4. Click Software Activation.

The BioPharmaView  $^{\text{TM}}$  Software Activation dialog opens.

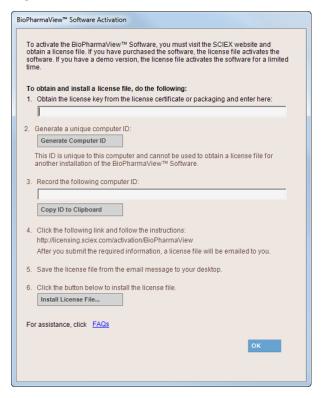


Figure 3-3 BioPharmaView<sup>™</sup> Software Activation Dialog

5. Type the license key in the appropriate field.

If a license key is not available, then contact sciex.com/request-support.

6. Click Generate Computer ID.

This creates a unique identifier for the workstation.

- 7. Click Copy ID to Clipboard.
- 8. Click the http://licensing.sciex.com/activation/BioPharmaView link.
- 9. Follow the instructions to obtain the license.

After the required information is submitted, a license file is sent to all of the e-mail addresses provided.

- 10. When the e-mail containing the license file is received, copy the license file to the workstation desktop.
- 11. Click **Install License File** on the BioPharmaView<sup>™</sup> Software Activation dialog.

The Select the new license file to be installed dialog opens.

12. Browse to and select the license file and then click **Open**.

Both the Select the new license file to be installed and the BioPharmaView<sup>TM</sup> Software Activation dialogs close.

13. Click **OK** to close the About BioPharmaView<sup>™</sup> Software and Software License Activation dialog.

**Known Issues and Limitations** 

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Everyone should read this section of the Release Notes. This section applies specifically to issues that are known in the BioPharmaView<sup>TM</sup> software, version 2.1.

**Note:** The numbers in brackets are reference numbers to each issue or feature in our internal tracking system.

#### **Performance Issues**

• When the peptide list contains a large number of theoretical peptides, the BioPharmaView<sup>TM</sup> software might become slow to respond or indicate that it is not responding. No user action is required. The requested task will be completed. We recommend that the user consider the complexity of the sample being used for characterization to make sure that the BioPharmaView<sup>TM</sup> software is being used as efficiently as possible and to make sure that the best results are achieved without compromising the performance of the software. (BPV-67, BPV-110, BPV-670)

#### **Filtering Issues**

 Occasionally, the BioPharmaView<sup>™</sup> software does not apply the active filters when alternating between the different tabs in the Intact Protein—Review Results workflow. To resolve this issue, close and then open the project again. (BPV-850)

#### **Reporting Issues**

- When the batch contains mean ratio to protein information, and a report is requested, the Detailed Modifications
  section of an Intact Protein Single Sample Report or the Intact Protein Batch Results Report does not contain
  the multiplicity data. However, the multiplicity data is included at the beginning of the Modification Summary
  section. (BPV-846)
- When saving a report to the C:\Program Files folder, an error message is shown and the report is not created.
   Reports must be saved to a different location, preferably to a folder on the D:\ drive.
- When editing a report template for the first time, the message "Are you sure you want to install this
  customization?" might be shown. To resolve the issue, close any open report templates and then close any
  open copies of Microsoft Word. Navigate to the C:\Program Files\AB SCIEX\ReporterOfficeAddins\
  TemplateContentControlManager folder, double-click the TemplateContentControlManager.vsto file,
  and then install the component.
- After installing the MasterView<sup>™</sup> software on a 64-bit workstation where the BioPharmaView<sup>™</sup> software is installed, an error might occur when editing a BioPharmaView<sup>™</sup> software report template. To resolve the issue, close any open report templates and then close any open copies of Microsoft Word. Navigate to the C:\Program Files\AB SCIEX\ReporterOfficeAddins\TemplateContentControlManager folder, double-click the TemplateContentControlManager.vsto file, and then install the component.

- When attempting to open a report template for the first time on a system with Microsoft Office 2010 Professional installed, a message "Exception from HRESULT: 0x8004063E", a Microsoft Office Document Customization error message might open. This occurs because the Visual Studio 2010 Tools for Office Runtime is missing from the system. To resolve this issue, download the component from the Microsoft Web site using the following URL: https://www.microsoft.com/en-us/download/details.aspx?id=48217, and then double-click the vstor\_redist.exe file and follow the installation prompts. (BPV-137)
- If the ClearType option in Microsoft Windows is turned on, then the text in the generated reports might be
  fuzzy. We recommend that this option is turned off. Refer to Turn ClearType Option in Microsoft Windows Off
  on page 18.

### **Labeling Issues**

- Occasionally, in the Peptide Mapping—Characterize Standard and the Peptide Mapping—Review Results
  workflows, the chromatogram label for a selected peptide in the BPC graph is slightly different than the RT
  value listed for the peptide in the Peptide Results table. (BPV-695)
- In the MS/MS Graph pane of the Peptide Mapping—Characterize Standard workflow, the Experiment numbers included in the labels of the graph are the Information Dependent Acquisition (IDA) experiment numbers and not the experiment number selected in the Characterize Standard for Peptide Mapping pane. (BPV-701)

### **Error Messages**

- "The assay information has been modified and no longer matches the Intact Protein [Peptide Mapping] characterization results. You must reprocess and update the assay information before saving the project."
  - In the Intact Protein—Characterize Standard and the Peptide Mapping—Characterize Standard workflows,
    if the user clicks Process and then clicks Cancel before the processing is completed, the software incorrectly
    instructs the user to reprocess and update the assay information before the project can be saved. To resolve
    this issue, click Process and then click Update Assay Information before saving. (BPV-119)
- Chain N: The following modification has changed since the project was created. You must reprocess: Modification<....>
  - If the message "Chain N: The following modification has changed since the project was created. You must reprocess: Modification <....>" is shown, then delete the modification and add it again. (BPV-1478)
- "The parameters have changed. Before saving the project, update the assay information.
   If the update option is not available, then open a data file."
  - If the message "The parameters have changed. Before saving the project, update the assay information. If
    the update option is not available, then open a data file." is shown, then click Update Assay Information.
    This might need to be done in the workflow that is not currently active. For example, when working in the
    Peptide Mapping workflow, the Intact Protein workflow assay information might need to be updated.
    (BPV-2011)

#### Miscellaneous Issues

 When adding Position or Maximum Mods per Chain information to the Modifications table, users must double-click inside the appropriate cell to move the focus from the previous cell. (BPV-83)

#### **Known Issues and Limitations**

- The values shown in the XIC Area column of the Peptide Results table in the Characterize Standard for Peptide Mapping workflow are determined by the processing functionality and are used by the BioPharmaView software for evaluation purposes. The peptide values are also shown in the Area column of the XIC Peaks tab in the BPC/TIC/XIC pane. However, because there might be slight differences in the values, the values in the XIC Peaks tab should be used for information purposes only. (BPV-868)
- Because version 2.0 is not fully compatible with previous releases of the BioPharmaView<sup>™</sup> software, version 2.0 is unable to determine the MS/MS tolerance that was used for processing in 1.5 projects. As a result, the information in the MS/MS fragments table cannot be recalculated and populated. The Basic tab shows the theoretical fragments, without any green highlighting. The Advanced tab shows the error message "No data available for display". To resolve this issue, the information must be reprocessed. However, this can result in difference between the original (1.5) values and the new (2.0 values). (BPV-1321, BPV-1327)
- If the .dad.scan file or the .dad.sidx file is missing when a corresponding .wiff file is submitted in a batch, the processing of the batch completes but the results cannot be opened. Make sure that all required files are present when submitting a batch. (BPV-1986)
- A sample that is being used in the Characterize Standard workflow should have a minimal Retention Time window. For example, if a peptide is eluting at multiple times within the gradient, then the BioPharmaView<sup>TM</sup> software might use multiple potential matches for the abundance ratio calculation and users might be required to make changes to the chromatography used. (BPV-2081)
- For position-less modifications or disulfide bonds, occasionally the MS/MS Fragment tab shows the Basic view instead of the Advanced view. The Basic view shows b- and y-ion MS/MS evidence for the peptide assignment. For peptides with disulfide bonds, we recommend that the Advanced view be used. If internal fragmentation or neutral loss ions are of interest, then we recommend that the Advanced view be used. (BPV-2133, BPV-2929)
- Occasionally, disulfide bonded cysteines are incorrectly modified during digestion. (BPV-2141)
- If the .wiff file or .wiff.scan file is corrupt or missing, then the BioPharmaView<sup>™</sup> software stops responding and the following error is shown: BioPharmaView has encountered an unexpected error. (BPV-2164)
- The software might become slow to respond when creating a batch from .wiff2 files. (BPV-2165)
- Occasionally, the BioPharmaView<sup>™</sup> software signal processing functionality does not detect all of the peaks that are detected by other SCIEX software products. (BPV-2356)

# Remove the BioPharmaView<sup>™</sup> Software

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- 1. Log on to the computer as a Microsoft Windows user with Administrator privileges.
- 2. Click Start > Control Panel > Programs and Features.

**Tip!** If the control panel components are shown by **Category**, then click **Start > Control Panel > Programs > Programs and Features > Uninstall a program.** 

3. Select BioPharmaView<sup>™</sup> Software and then click **Uninstall**.

The software is removed, with no user intervention required.

During the removal, the software name is removed from the Installed Programs list, the shortcut to the BioPharmaView<sup>TM</sup> software is removed from the desktop, and the shortcuts to the software and the user documentation are removed from the Start menu.

**Note:** The following components remain on the computer:

- The C:\AB SCIEX\BioPharmaView\Data folder, which might contain BioPharmaView<sup>™</sup> software project data.
- If the product is licensed, the C:\Program Files\AB SCIEX\BioPharmaView folder, which contains the license file.
- The C:\ProgramData\AB SCIEX\BioPharmaView folder, which contains the Intact Protein and Peptide Mapping report templates.
- The AB SCIEX Reporter Template Suite 3.2.
- Microsoft .NET Framework.

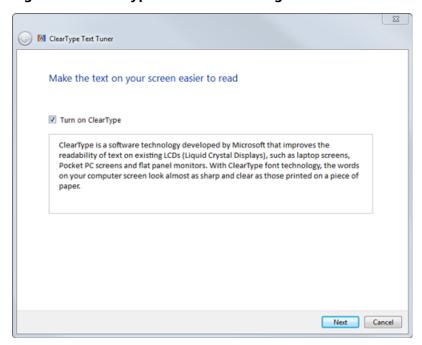
# Turn ClearType Option in Microsoft Windows Off



- 1. Click Start.
- 2. In the Search field, type **ClearType**.
- 3. Click Adjust ClearType text.

The ClearType Text Tuner dialog opens.

Figure A-1 ClearType Text Tuner Dialog



- 4. Clear the **Turn on ClearType** check box.
- 5. Click **Next** and then follow the on-screen instructions.

# Issues Fixed in Version 2.1 of the BioPharmaView<sup>TM</sup> Software

B

**Note:** The following issues have been fixed with the release of version 2.1 of the BioPharmaView<sup>™</sup> software.

- The columns of information being imported into the Peptides table or the Characterized Proteins table had to
  be arranged in the same order as the default column order in the BioPharmaView<sup>™</sup> software. In addition, all
  of the columns had to be present and visible. If the user had modified the column order in the .txt file, removed
  columns from the .txt file, or had hidden a column and then attempted to import peptides or characterized
  proteins, the import failed. (BPV-1468)
- If a peptide sequence was added in the Assay Information—Sequence Features tab and the user neglected to type a Protein Name, then when the user clicked Peptide Mapping an error icon was shown in the Protein Name field and an error message opened prompting the user to correct errors before navigating away from the page. When the user typeed a valid Protein Name and pressed Enter, the error icon remained, the error message prompting the user to correct the errors was shown again, and the valid Protein Name was removed. To resolve this issue, the user had to shift the focus to another field on the Sequence Features tab before attempting to navigate away from this page. (BPV-2049)
- Occasionally, when importing peptides, the BioPharmaView<sup>™</sup> software only validated that the XIC Area and the Retention Time columns were populated. The software did not always validate the information in the Mono. Mass column. (BPV-2094)
- In version 2.0 of theBioPharmaView<sup>™</sup> software, exception conditions were generated when:
  - the Revert Calibration option was clicked on the Optimize Matching Parameters dialog (BPV-2134)
  - the Copy All option was selected from the right-click menu in the Peptide Results table (BPV-2135)
  - an invalid modification was added (BPV-2136, BPV-2140)

# **Revision History**

Revision	Reason for Change	Date
А	First release.	July 2015
В	Updated the list of Related Documentation. Added the list of changes from version 1.5 to version 2.0. Updated the installation and activation procedures. Updated the list of known issues and limitations. Added the procedure to turn off the ClearType Option in Microsoft Windows. Moved the Fixed Issues to an Appendix.	June 2016
С	Updated software version. Added the list of changes from version 2.0 to version 2.0.1. Updated the installation and activation procedures. Updated the download link for Visual Studio 2010 Tools for Office Runtime. Updated the title of Appendix B and added a note to clarify that the issues listed were fixed in the version 2.0 release.	October 2016
D	Updated software version. Added the list of changes from version 2.0 to version 2.1. Removed list of changes from version 2.0 to version 2.0.1. Updated list of Known Issues and Limitations. Removed fixed issues from this list and created an Appendix listing all of the issues fixed in version 2.1. Removed Appendix listing all of the issues fixed in version 2.0. Updated the installation and activation procedures.	March 2017