

Release Notes

BioPharmaView™

Software for Biologics Characterization
Version 1.0

Introduction

Thank you for using the BioPharmaView software.

Carefully read the Release Notes for information on the software features, workflow, known issues and limitations, and notes on use.

The BioPharmaView software is post-acquisition processing software to use for performing characterization and analysis of biologics. The software processes data files generated by AB SCIEX TripleTOF® systems to support protein and peptide analysis during therapeutic drug development. The BioPharmaView software supports the following tasks:

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

The BioPharmaView software facilitates the following workflows:

- **Intact Protein Analysis:** Determining the molecular weight of intact proteins, based on the deconvolution of a charge series envelope resulting from LC/MS.
- **Peptide Mapping Analysis:** Determining the mass-to-charge ratio m/z (from TOF MS) or sequence (from MS/MS) of peptides resulting from enzymatic digestion of a protein.

Requirements

Operating System

The following operating systems are supported:

- Windows 7 Professional x64 Service Pack 1
- Windows XP Professional x86 (32 bit) Service Pack 3

Software Requirements

- **Microsoft .NET Framework 4.0:** If not currently installed, the BioPharmaView software installation automatically installs it. An Internet connection is required.
- **Adobe Reader:** Required to read documentation supplied with BioPharmaView software. If it is not already installed, it is available at <http://www.adobe.com>. Click **Get Adobe Reader** and follow the instructions.
- **Microsoft Word (2010 or 2013):** Required to generate and open the BioPharmaView software reports.

Hardware Requirements

CAUTION! Potential Data Loss. Running the BioPharmaView software while performing acquisition can adversely affect data acquisition. It is recommended that you do not install or run the BioPharmaView software on a computer used for acquisition.

The system must be able to display 32-bit graphics to launch the BioPharmaView software.

Security Requirements

To install the BioPharmaView software, Administrator privileges are required.

To install the license, Administrator privileges with the ability to write files under the Program Files (x86) folder are required.

After the BioPharmaView software is installed and registered, you must be a Windows XP Limited or a Windows 7 Standard user and have permission to write files to the computer's hard drive (for example, C:\AB SCIEX\BioPharmaView Data and its subfolders).

Tested Configurations

The following configurations were used for testing the BioPharmaView software and similar configurations are recommended:

Dell Optiplex 9010
Window 7 Professional, SP1 64-bit Operating System
Intel Core i7-2600 CPU @3.40GHz, 3.40 GHz
4.00 GB of RAM
240 GB HDD

Dell Precision T3500
Windows XP SP3
Intel® Xeon® CPU E5630 @ 2.53 GHz, 2.53 GHz
3.00 GB of RAM

Dell Optiplex XE2
Window 7 Professional, SP1 64-bit Operating System
Intel® Core™ i5-4570S CPU @ 2.90 GHz, 2.90 GHz
8.00 GB of RAM

The BioPharmaView software 1.0 has been successfully tested with data from the AB SCIEX TripleTOF systems.

Installation Instructions

Install the BioPharmaView Software

NOTE: If using a .zip file that contains the BioPharmaView software installer, first extract all files from the .zip file before beginning installation. Do not run the installer from within the .zip file.

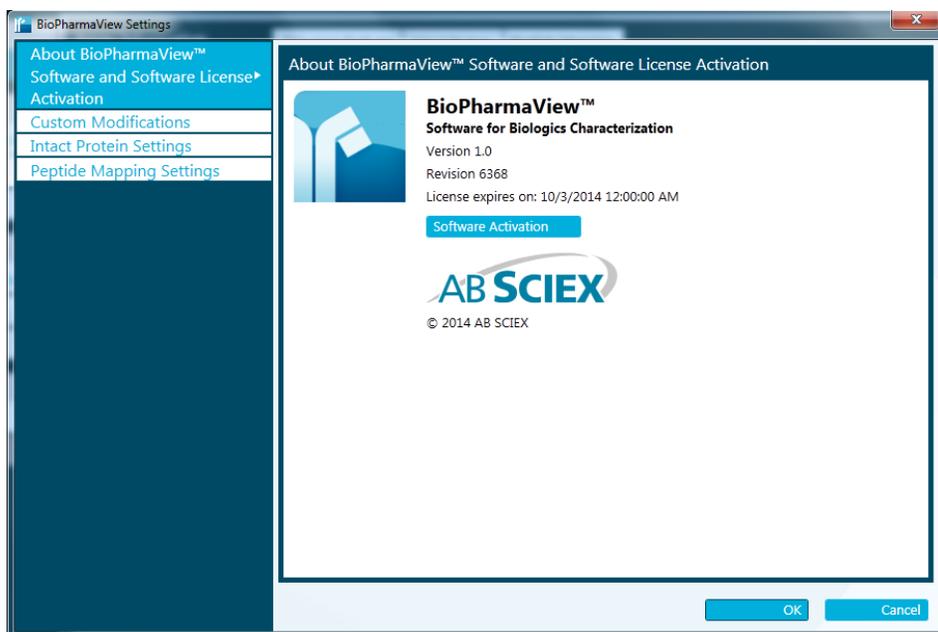
1. Open the *BioPharmaView™ Software QuickStart Installation* document.
2. Double-click **setup.exe** to start the BioPharmaView™ Software installer. The Installation script launches and the **Welcome Screen** opens.
NOTE: If Microsoft .NET Framework 4.0 and AB SCIEX Reporter Template Suite are not currently installed, the BioPharmaView software installation automatically installs them.
3. Click **Next**. The **End-User License Agreement** opens.
4. Select the **I accept the terms in the License Agreement** check box, and then click **Next**.
5. Accept the default installation and data directories, or optionally choose different directories, and then click **Next**.
6. Click **Finish**.
7. Review the *BioPharmaView™ Software Tutorial Video*.

NOTE: If you uninstall the BioPharmaView Software, uninstalling does not remove the data folders which might contain BioPharmaView Software project data (e.g. C:\AB SCIEX\BioPharmaView Data\). If the product is licensed OR if any other file is in the installation folder, uninstallation will not remove the installation folder. The software does not uninstall the AB SCIEX Reporter Template suite or the Microsoft .NET Framework 4 (if installed as part of the BioPharmaView software installation).

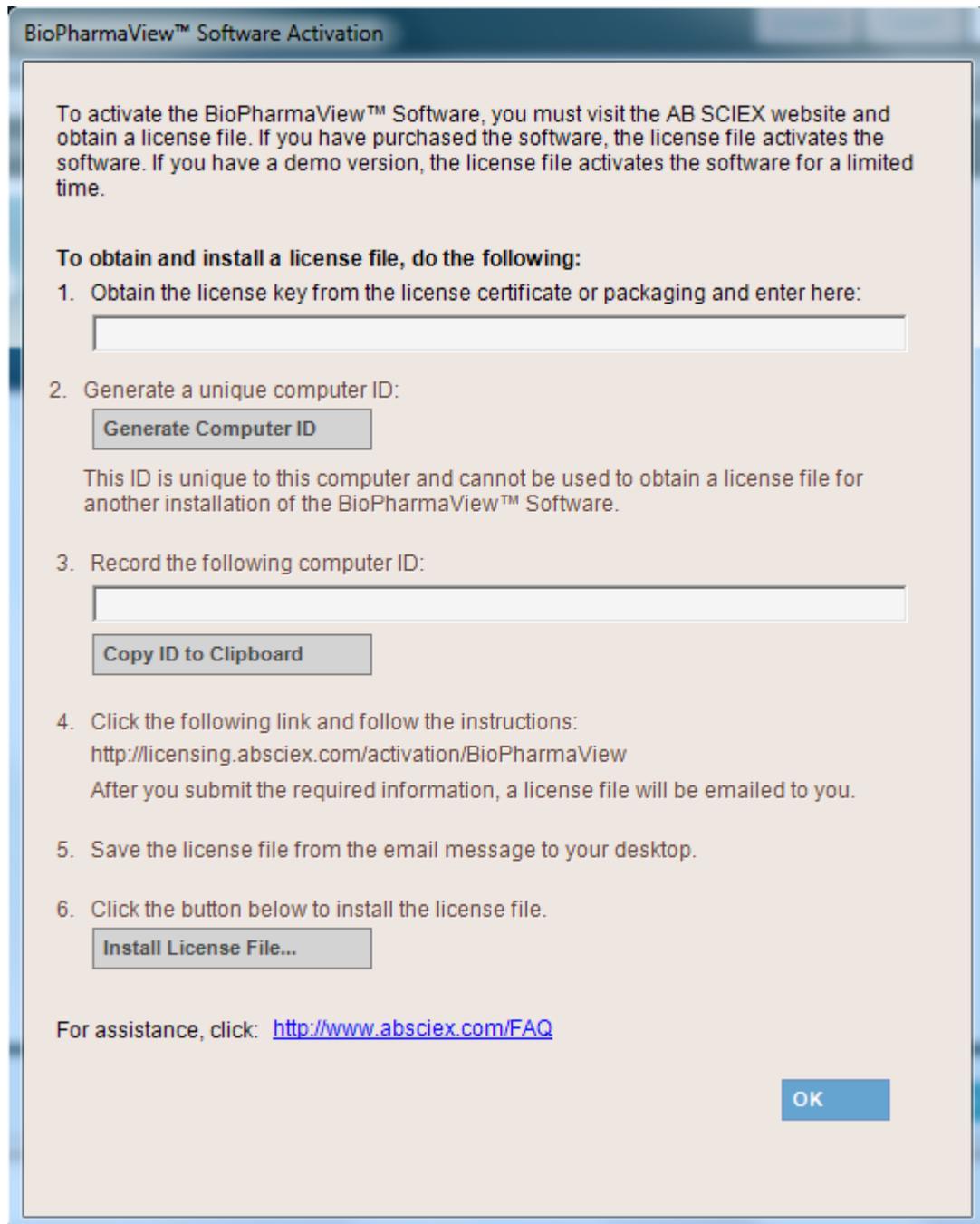
Install the BioPharmaView Software License

The BioPharmaView software is licensed. If you do not have a current license installed, processing and saving functions are not available.

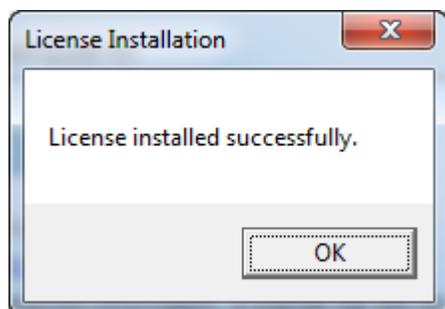
1. Open the BioPharmaView software.
2. If the **BioPharmaView Activation** dialog does not automatically open, click **Settings**, and then in the **BioPharmaView Settings** dialog, click **Software Activation**.



3. In the **BioPharmaView™ Software Activation** dialog, follow the prompts to install a license, and then click **OK**.



After the license installation is complete, a **License installed successfully** message appears.



Licensing Issues

- To confirm that you have a current license installed, click **Settings** and view the **BioPharmaView Settings** dialog, **About BioPharmaView™ Software and Software License Activation** page.
- The message “This software is not licensed” can appear for several reasons:
 - A current license is not installed. Follow the steps to install a current BioPharmaView Software license.
 - The computer network connection is disabled. The licensing components used by AB SCIEX software require the computer’s network adapter to be enabled, although a physical connection to the network is not required.

Some laptop computers automatically disable the network connection when the power cable is removed from the computer. To determine whether this is the cause of the message, click **Start > Connect To > Show all connections**. In the **Network Connections** window, verify that the **Status** field for all connections is **Enabled**. If any of the connections are disabled, right-click, and then click **Enable**. Quit the BioPharmaView software, and then open the software.

Known Issues and Limitations

- **Attempting installation from a .zip file causes problems during installation**
If using a .zip file that contains the BioPharmaView software installer, Extract All 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.
- **Installation might fail on a machine without connectivity to the Internet**
During installation of the BioPharmaView software, the system might determine that Microsoft .NET Framework 4.0 is not installed. If this occurs, the system needs to be connected to the Internet to download additional components for the Microsoft .NET Framework 4.0 installation process. If the system fails to install the Microsoft .NET

Framework 4.0, the BioPharmaView 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 4.0, and then reinstall the BioPharmaView software.

- **The BioPharmaView software cannot be launched on systems unable to display 32-bit graphics**

If the following error message appears: “The image format is unsupported.” go to **Control Panel > Display Settings > Color Quality** and select **Highest (32 bit)**.

- **The BioPharmaView software is not backward compatible with previous Beta releases**

Newer versions of the BioPharmaView software are not backward compatible with previous Beta versions of the software. Existing projects must be recreated and reprocessed in newer versions of the software.

- **A new member of the Users group for Windows XP might not be able to open BioPharmaView software projects previously created by Admin or other users**

After a member of the Admin group creates a new user that is only a member of the Users group, a new user is able to create new projects and process data within projects they create. However, the new user might not be able to open projects in the BioPharmaView software that were created by other users. In this case the following error message appears: “The project could not be opened. Access to the path ‘C:\AB SCIE\BioPharmaView\Data\Projects\(\Project name)\AssayInformation’ is denied.”

Whether this error occurs depends on the operating system security policy on the computer. If it is a requirement for various operating system users to open projects created by other users, make sure the users of the BioPharmaView software are members of the same group in the operating system, with the ability to read and write each other’s files. For additional support on creating users, groups, and security policies for your organization, contact your local IT manager.

- **When characterizing standards, the BioPharmaView software can save only the last processing result for each workflow in a project**

When characterizing standards, only the last processing result for each workflow can be saved and opened. Previously saved results will be overwritten by more recent results and cannot be saved or opened.

- **Processing a large file or large batches multiple times can use up available RAM**

If large data files or batches are processed multiple times under certain conditions, all available RAM might be used up. If this occurs, close and then open the BioPharmaView software.

- **Generating a Peptide Mapping Batch Report might fail after processing large batch files**

After processing of a large batch (for example, 50 data files), generation of the Peptide Mapping Batch Report might fail. If this occurs, close and then open the BioPharmaView software and then create the batch report.

- **User cannot cancel processing from the UI when performing "Intact Protein > Generate Protein Forms" or "Peptide Mapping > Digest" tasks**

When generating a large number of protein forms or peptides, the BioPharmaView software might stop responding. If this occurs, cancel processing by clicking **Windows Task Manager > Processes > End Process**.

- **Error message can occur if assay settings or modifications are out of sync with characterization results**

The error message “The assay information has been modified and no longer matches the characterization result. You must reprocess and update the assay information before saving the result” can appear. Resolve the issue by updating the assay information. This might need to be done in the workflow that is not currently active (for example, if you are working in Peptide Mapping workflow, the Intact Protein workflow assay information might need to be updated).

- **Report generation might fail when generating a report to C:\ or C:\Program Files (Win 7)**

When saving a report to either the **C:** or **C:\Program Files** folder (in Win 7), an error message appears and the report is not created.

- **Editing a report template for the first time displays error message**

When editing a report template for the first time, the following error message might appear: “Are you sure you want to install this customization?” To resolve the issue, close any open report templates and any open copies of Microsoft Word. Navigate to the **C:\Program Files (x86)\AB SCIEX\ReporterOfficeAddins\ TemplateContentControlManager** folder, double click on the **TemplateContentControlManager.vsto** file, and then install the component.

- **Editing a report template after installing MasterView software displays error message**

After installing MasterView software on a 64-bit workstation where the BioPharmaView software is currently installed, an error might occur when editing a BioPharmaView report template. To resolve the issue, close any open report templates and any open copies of Microsoft Word. Navigate to the **C:\Program Files (x86)\AB SCIEX\ReporterOfficeAddins\ TemplateContentControlManager** folder, double click on the **TemplateContentControlManager.vsto** file, and then install the component.

- **Opening a report template on a system with Office 2010 Professional installed might fail and display an error message**

When attempting to open a BioPharmaView report template for the first time on a system with Office 2010 Professional installed, the following Microsoft Office Document Customization error message might appear: **Exception from HRESULT: 0x8004063E**. 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 website using the following URL: <http://www.microsoft.com/en-us/download/details.aspx?id=43664>, and then double-click the **vstor_redist.exe** file and follow the installation prompts.

- **Only the first sample listed in a .wiff file is selected for processing**

The BioPharmaView software can select only the first sample listed in a .wiff file for sample processing. Additional samples are ignored.

- **Cannot use Save As with a project containing only imported peptides**

If a project is new or updated with only imported peptides in the Peptides table, but with no proteins, the project cannot be saved. If this occurs, click Digest to digest the protein on the Assay Information Peptide Mapping tab, and then delete software-generated peptides to leave only the user-defined peptides.

- **When importing a protein or peptide with a modification, the software might replace the imported modification by an existing modification**

When importing peptides or proteins, the software searches the list of modifications, attempting to find the imported modification by name or by symbol. If the imported modification name matches the symbol of an existing modification, the imported modification is replaced by the existing modification.

- **Import can fail if user has modified the column order**

Column header values being imported must be in the same order as the default column order in the Peptides or Characterized Proteins table. If the user has modified the column order in the BioPharmaView software and then attempts to import peptides or characterized proteins, the import fails. To resolve the issue, return the Peptides or Characterized Proteins table columns to their default order, and then import.

Where to Get Help

Customer Training and Documentation

- *BioPharmaView™ Software QuickStart Installation*: Links and steps required to install the BioPharmaView software
- *BioPharmaView™ Software Tutorial Video*: Brief introduction and demonstration of the features and functions available in the BioPharmaView software
- *BioPharmaView™ Software User Guide*: Procedures, descriptions, and reference information to assist with use of the BioPharmaView software
- *BioPharmaView™ Software Online Help*: Step-by-step instructions to perform the various procedures available in the BioPharmaView software

Contact Us

- Email: support@absciex.com
- Web: www.absciex.com

This document is provided to customers who have purchased AB SCIEX equipment to use in the operation of such AB SCIEX equipment. This document is copyright protected and any reproduction of this document or any part of this document is strictly prohibited, except as AB SCIEX may authorize in writing.

Software that may be described in this document is furnished under a license agreement. It is against the law to copy, modify, or distribute the software on any medium, except as specifically allowed in the license agreement. Furthermore, the license agreement may prohibit the software from being disassembled, reverse engineered, or decompiled for any purpose. Warranties are as stated therein.

Portions of this document may make reference to other manufacturers and/or their products, which may contain parts whose names are registered as trademarks and/or function as trademarks of their respective owners. Any such use is intended only to designate those manufacturers' products as supplied by AB SCIEX for incorporation into its equipment and does not imply any right and/or license to use or permit others to use such manufacturers' and/or their product names as trademarks.

AB SCIEX warranties are limited to those express warranties provided at the time of sale or license of its products, and are AB SCIEX's sole and exclusive representations, warranties, and obligations. AB SCIEX makes no other warranty of any kind whatsoever, expressed or implied, including without limitation, warranties of merchantability or fitness for a particular purpose, whether arising from a statute or otherwise in law or from a course of dealing or usage of trade, all of which are expressly disclaimed, and assumes no responsibility or contingent liability, including indirect or consequential damages, for any use by the purchaser, or for any adverse circumstances arising therefrom.

The trademarks mentioned herein are the property of AB Sciex Pte. Ltd. or their respective owners.

For research use only. Not for use in diagnostic procedures.

AB SCIEX™ is being used under license.

© 2014 AB Sciex Pte. Ltd.

Printed in Canada.



AB Sciex Pte. Ltd.
Blk 33, #04-06
Marsiling Ind Estate Road 3
Woodlands Central Indus. Estate
SINGAPORE 739256

