BioPhase 8800 System

Software Validation Summary

Contents

Contents

Introduction 1

This document describes the software validation for the software components of the BioPhase 8800 system and lists the computer configuration and the software development environment.

Software Overview

This section describes the most recent release of BioPhase 8800 system software components. For information about the changes in this release or information about previous releases, refer to the section: Software History.

The following BioPhase 8800 system software components were released April 2023:

- BioPhase 8800 Driver for Empower™, version 1.3. This the first release of the driver. Included with the driver is:

    - Method Editors for BioPhase System software, version 1.3. This is the first release of the software.

- BioPhase Front Panel, version 1.3.

Intended Use

The BioPhase software components give control of instrument functions, data acquisition, and data analysis for the BioPhase 8800 system. The system can be used in one of the following configurations:

- **BioPhase software**: The customer uses the touchscreen on the front panel to run sequences and save data to project folders on either a local computer or the network. After the data is saved, it can be analyzed with the BioPhase Analysis software. Refer to the section: General Description (BioPhase Software).

- **Waters Empower™software**: The customer uses the BioPhase 8800 driver for Empower™ to run sequences and save data. More functions are available from the Waters Empower™ software. Refer to the section: General Description (BioPhase 8800 Driver for Empower™).

General Description (BioPhase Software)

The following general functions are supplied:

- **Control:** The system is controlled from a touchscreen on the front panel of the system. The user can install and remove plates and cartridges, control the UV and LIF light sources, and start data acquisition.

- **Acquisition:** Data acquired by the BioPhase 8800 system is saved to a folder on the local computer or a folder location on a network domain selected by the customer. No acquired data is kept on the system.

- **Acquisition method development:** The BioPhase 8800 software is used to develop separation methods and analyze the acquired data. The software is installed on a computer that can either be local to the system or remote, communicating over the network. The software is also used to create sequences that are required for data acquisition.

- **Analysis:** The data analysis module lets the user set parameters to set a baseline and identify peaks. After the peaks are identified, the module calculates peak parameters. Performance parameters can be calculated for multiple data files.

- **Reports:** Features include a user-customizable report, and the ability to incorporate graphics, such as company logos, in report templates. The report also includes the sign off status.

- **Compliance features:** The software includes features to help the regulated laboratory record information and supply documentation for compliance.

- **Project management:** The Project Management application lets the user select projects that a BioPhase 8800 system can get access to. The Project Management application also lets users who have signature authority to have access to projects.

General Description (BioPhase 8800 Driver for Empower™)

The following general functions are supplied:

- **Control:** The system is controlled from a touchscreen on the front panel of the system. The user can install and remove plates and cartridges, and control the UV and LIF light sources. More instrument control functions are supplied in the Direct Control pane in the Waters Empower™ software.

- **Acquisition:** Data acquired by the BioPhase 8800 system is saved to the Empower database. No acquired data is kept on the system.

- **Acquisition method development:** The Method Editors for BioPhase System software is used to develop separation methods and sequences that are required for data acquisition. The Method Editors for BioPhase System software is accessed from the BioPhase 8800 driver for Empower™.

The following functions are supplied by the Waters Empower™ software. For instructions, refer to the Waters Empower™ software guides and help file.

- Analysis

- Reports

- Compliance features

- Project management

Support

Installation

Local or Network Configuration

The BioPhase 8800 software and Project Management software are pre-installed on the computers that are purchased from SCIEX. Customers who use their own computers are responsible for software installation. To download the software, go to sciex.com/software-support/software-downloads.

Only limited support is available from SCIEX for the user-installed software. If permitted by the customer, a SCIEX Field Service Employee (FSE) can support the customer with the software installation process.

Waters Empower™ Software Configuration

Customers can install and configure the BioPhase 8800 driver for Empower™ on the computer with the Waters Empower™ software.

Customer Training

Up to four hours of in-laboratory training for up two operators is included with the purchase of the BioPhase 8800 system. Training is done by FSEs or product specialists.

Software Updates

As necessary, SCIEX updates the software or firmware to add new features or corrective actions or support new devices. To the greatest reasonable extent, but at the sole discretion of SCIEX, updated versions are compatible with data and method files, system and computer hardware, and the previous software version. Such new versions are available to both existing and potential customers. Contact a local sales representative for information.

Technical Support

SCIEX and its representatives keep a staff of fully trained service and technical specialists throughout the world. These specialists can answer questions about the system or help to troubleshoot technical issues. For more information, visit the SCIEX website at sciex.com.

SCIEX supports the BioPhase 8800 driver for Empower™ but for some issues, users may be asked to contact Waters.

Software License

For the BioPhase software a software license from SCIEX is required.

For the BioPhase 8800 driver for Empower™ a software license from SCIEX is required. One or more licenses for the Waters Empower™ software is also required. To purchase a license, contact a Waters sales representative.

For SCIEX software license instructions and to download the software, go to sciex.com/software-support/software-downloads.

More Information

Software help is integrated with the BioPhase software, the BioPhase Analysis software, and the Method Editors for BioPhase System software.

More literature is available. Go to sciex.com.

Company Description

SCIEX helps make the world that we live in better by helping scientists and laboratory analysts find answers to the complex analytical challenges they face. Our global leadership and world-class service and support in the capillary electrophoresis, liquid chromatography, and mass spectrometry industry have made us a trusted partner to thousands of the scientists and laboratory analysts worldwide who are focused on basic research, drug discovery and development, food and environmental testing, forensics, and clinical research.

With over 50 years of proven innovation, SCIEX excels by listening to and understanding the ever-evolving needs of our customers to develop reliable, sensitive, and intuitive solutions that continue to redefine what is achievable in routine and complex analysis.

For more information, go to sciex.com.

Product Development Overview

The BioPhase software components were developed with the processes in the SCIEX Quality Management System. SCIEX uses procedures to control development phase activities. SCIEX uses a problem reporting process to document, manage, and control all changes caused by errors encountered during development.

Quality Management System

The software was designed, evaluated, validated, inspected, and tested to approved specified quality requirements of SCIEX in accordance with:

*   ISO 13485: 2016 Medical Devices – Quality management systems–Requirements for regulatory purposes

*   ISO 9001: 2015 Quality management systems–Requirements

It is further certified that:

*   The software was developed, verified, and controlled by qualified professionals.

- Source code is annotated and contains unique version control identification.

- All source code, development tools, and production documentation are archived for reasonable periods, with all necessary version control information kept, and with archive tapes secured in an off-site vault.

- Documentation for error reports and error report management are retained at the Brea, CA facility.

- Operational software has been monitored to make sure that it complies with system and software requirements, to supply proper tracking, review, disposition, and testing of system errors in post-release software, and to provide for prompt notification of affected customers.

Audits and Reviews

The SCIEX Quality Manager can supply customer reviews and audits of software development procedures, documentation, and source code to comply with regulatory requirements related to software validation or verifying the quality management system.

SCIEX keeps possession of all documents and their reproductions and might require a non-disclosure agreement to be supplied by those who require access to these documents.

Customer Feedback Reporting

All customer feedback for released software is handled according to the SCIEX customer complaint process and is used for improving subsequent versions of the software.

Development Environment

Table 1-1 BioPhase Analysis Software

Configuration management system	git version 2.20.1.windows.1
Source code language	C++
Compilers	MinGW for Windows clang++ for Mac
Operating system	Cross platform (Windows, Mac, Linux)
Prototype and simulator	No simulator

Table 1-2 BioPhase Software, BioPhase Project Management Software, BioPhase Log File Extractor Software, Front Panel, and BioPhase 8800 Driver for Empower™

Configuration management system	git version 2.20.1.windows.1

Table 1-2 BioPhase Software, BioPhase Project Management Software, BioPhase Log File Extractor Software, Front Panel, and BioPhase 8800 Driver for Empower™ (continued)

Source code language	C#
Compilers	Microsoft Visual Studio Enterprise 2019
Operating system	Windows 10 Enterprise (64-bit)
Prototype and simulator	Built-in

Table 1-3 BioPhase 8800 System Firmware

Configuration management system	git version 2.20.1.windows.1
Source code language	C++
Compilers	Keil ARM Compiler-5
Operating system	Keil CMSIS-RTOS2 for Cortex-M
Prototype and simulator	HW (no simulator)

Validation Summary 2

Validation Summary for Version 1.0

Table 2-1 BioPhase Front Panel Validation

Validation Performed	Results
Make sure that the BioPhase front panel software and tools, including the desktop icon and the end user license, are installed.	Pass
Make sure that the BioPhase front panel is accessible.	Pass
Make sure that the BioPhase system can be unlocked from the BioPhase front panel software.	Pass
Make sure that the **Ejected** button in the top ribbon changes to **Loaded** when touched. Make sure that the icon to the left changes from **Ejected** to **Loaded** when the cartridge is loaded.	Pass
Make sure that the **UV** and **LIF** light sources are off. Make sure that the **UV** and **LIF** buttons change status when touched.	Pass
Make sure that the front panel Home Page shows two sections: Acquisition and Management.	Pass
Make sure that the front panel Acquisition section shows three tiles: **Direct Control**, **Run Sequence**, and **Capillary View**.	Pass
Make sure that the front panel top left pane shows the green system icon.	Pass
Make sure that the system status shows **Idle** in the bottom pane.	Pass
Make sure that the system status shows default values for **Sample Temperature**, **Cartridge Temperature**, **Pressure, Voltage**, **Current**, and **Detector** type.	Pass
Make sure that the Run Sequence window shows the project sequences in the project column. Make sure that the window shows the sequence method, sample, and reagent after any sequence and that the **Run Sequence** button is disabled.	Pass
Make sure that the Capillary View window shows the electropherogram for the Detector, Current, and Mixed tabs.	Pass
Make sure that the Log window shows the Events and System tabs. Make sure that the Events tab shows **Export Event Logs** button to save the event log and the **Initialize System** button to start the system. Make sure that the System tab shows the system log history.	Pass

Table 2-2 BioPhase Software Validation

Validation Performed	Results
Make sure that the BioPhase software and tools, including the desktop icon and the end user license, are installed.	Pass
Make sure that the BioPhase software is accessible. Make sure that the Home page shows the correct version number for the software	Pass
Make sure that the Home page shows three sections: Acquisition, Processing, and Management.	Pass
Make sure that the Acquisition section shows two tiles: **Method Editor** and **Sequence Editor**.	Pass
Make sure that the Processing section shows one tile: **Data Analysis**.	Pass
Make sure that when the **Edit** is clicked in the Method Summary tab, the Method Settings tab opens.	Pass
Make sure that the **PRINT** button is enabled when a project folder is selected from the Project/methods pane. Make sure that the SCIEX Method Report is created when the **PRINT** button is clicked.	Pass
Make sure that the Home page is shown when the home icon is clicked on the ribbon.	Pass
Make sure that the **PRINT** button is enabled when a sequence is selected on the Available Sequences pane. Make sure that the SCIEX Sequence report is generated when the **PRINT** button is clicked.	Pass
Make sure that the **Data Analysis** tile opens the BioPhase Analysis software. For validation information about the BioPhase Analysis software, refer to the table: Table 2-3. **Note:** The **Data Analysis** tile is disabled if the BioPhase Analysis software is not installed on the local system.	Pass

Table 2-3 BioPhase Analysis Software Validation

Validation Performed	Results
Make sure that the BioPhase Analysis software and tools, including the desktop icon and the end user license, are installed.	Pass
Make sure that the BioPhase Analysis software is accessible.	Pass
Make sure that the top menu shows the **File Toolbar** icons and the right pane shows the **Project Toolbar** icons	Pass

Table 2-3 BioPhase Analysis Software Validation (continued)

Validation Performed	Results
Make sure that the Data pane shows the Single and Overlay tabs for the graph.	Pass
Make sure that the Analysis Parameters pane contains the saved peak integration parameters when an existing analysis file is opened.	Pass
Make sure that the peaks are automatically integrated on the electropherogram with the loaded peak integration parameters after the **Analyze** button is clicked.	Pass
Make sure that the Analysis Parameter tab shows three tabs: Integration, Library, and Post Analysis.	Pass
Make sure that the upper table on the Integration tab has three colums: **Event**, **Start**, and **Value**. Make sure that the **Event** column contains a list, and that the fields for **Start** and **Value** columns are editable.	Pass
Make sure that the lower table on the Integration tab has two columns: **Type** and **Value**. Make sure that all of the fields, lists, and buttons are enabled and editable for both of the columns.	Pass
Make sure that the **Clear** and **View** buttons in the Manual Events section on the Integration tab are enabled. Make sure that the manual integration events from the graph are removed after the **Clear** button is clicked. Make sure that a dialog that shows all of the manual integration events on the graph and related parameters opens when the **View** button is clicked.	Pass
Make sure that all of the buttons, fields, check boxes, and lists on the Integration tab are enabled and editable.	Pass

Table 2-4 BioPhase Project Management Software Validation

Validation Performed	Results
Make sure that the BioPhase Project Management software and tools, including the desktop icon and the end user license, are installed.	Pass
Make sure that the domain is accessible from the Project Management software.	Pass
Make sure that a new project can be added with the ⊞ icon and that the Add New Project dialog shows the **Project Name** and **Files Location** fields. Make sure that the Select Folder dialog opens when the **Browse** button is clicked.	Pass
Make sure that a new user can be added to the project from the Properties tab with the ⊞ icon.	Pass

Table 2-4 BioPhase Project Management Software Validation (continued)

Validation Performed	Results
Make sure that a user and a project can be deleted with the 🗑 icon.	Pass
Make sure that a new project can be mapped to the local drive.	Pass
Make sure that the File Explorer can be accessed to navigate to the server.	Pass
Make sure that sequences from the server can be copied to the project.	Pass

Validation Summary for Version 1.1

Table 2-5 BioPhase Front Panel Validation

Validation Performed	Results
Make sure that the Front Panel Log on window shows the following message: `Tap the screen to login and unlock the instrument.`	Pass
Make sure that the front panel Management section shows three tiles: **Log**, **Configuration**, and **Calibration**.	Pass
Make sure that the BioPhase 8800 system front panel shows an error message when the optics door is opened.	Pass
Make sure that the Direct Control window shows the following functions: **Set Temperature**, **Direct Settings**, **Rinse**, **Inject**, **Separate**, **Eject Sample**, **Eject Reagent**, **Transport Home**, **Wavelength Settings**, and **Cartridge Info**. Make sure that the **Transport Home** function is enabled when the **Ejected** button on the ribbon is touched.	Pass
Make sure that the Configuration tile is enabled for the users with administrator access. Make sure that Configuration window shows the General and Network tabs. Make sure that the General tab shows the **Change Password** and **Idle Timeout** feature. Make sure that the Network tab shows the Domain Isolator and BioPhase information.	Pass
Make sure that the Calibration window shows the LIF intensity calibration parameters, setup, and results. Make sure that the Run Sequence window opens after **Start Calibration** is touched. Make sure that the **Save Calibration** button is enabled after the LIF calibration procedure is completed. Make sure that the LIF calibration value is set to default after **Reset to Default** is touched.	Pass

Table 2-6 BioPhase Software Validation

Validation Performed	Results
Make sure that the Management section shows one tile: **Configuration**.	Pass
Make sure that the Method Editor workspace shows two tiles: **New Method** and **Open Method**. Make sure that the workspace shows five buttons: **NEW**, **SAVE**, **SAVE AS PRINT**, and **CLOSE**.	Pass
Make sure that the Method Setting tab opens when the **New Method** tile is clicked. Make sure that the New Method workspace shows three tabs: Method Summary, Method Settings, and Method Program. Make sure that the Open a Method dialog opens when the **Open Method** tile is clicked.	Pass
Make sure that the **SAVE** and **SAVE AS** buttons are enabled when the method information is edited, and no errors are present.	Pass
Make sure that the Sequence Editor workspace shows two tiles: **New Sequence** and **Open Sequence**. Make sure that the workspace shows five buttons: **NEW**, **SAVE**, **SAVE AS PRINT**, and **CLOSE**.	Pass
Make sure that the Sample Plate Setup tab opens when the **New Sequence** tile is clicked. Make sure that the New Sequence workspace shows three tabs: Sequence Summary, Sample Plate Setup, and Plates Layout. Make sure that the Open a Sequence dialog opens when the **Open Sequence** tile is clicked.	Pass
Make sure that the **SAVE** and **SAVE AS** buttons are enabled when the sequence information is edited and no errors are present.	Pass
Make sure that the Configuration workspace shows the **New Reagent Set** and **Open Reagent Set** tiles. Make sure that the workspace shows three buttons: **NEW**, **SAVE**, and **CLOSE**. Make sure that the **SAVE** button is enabled when Projects/Reagent Sets are selected, or the **Inlet Reagents from Reagent Set** and **Outlet Reagents from Reagent Set** information is edited, and no errors are present.	Pass
Make sure that the Open a Reagent Set dialog opens when the **Open a Reagent Set** tile is clicked.	Pass

Table 2-7 BioPhase Analysis Software Validation

Validation Performed	Results
Make sure that the Library tab shows two tables: Marker Table and Peak Table. Make sure that all of the buttons, fields, check boxes, and lists on the Library tab are enabled and editable.	Pass

Table 2-7 BioPhase Analysis Software Validation (continued)

Validation Performed	Results
Make sure that the Post Analysis tab shows two tables. Make sure that the **Module** column in the upper table shows Fast Glycan Analysis and System Suitability. Make sure that the Fast Glycan Analysis dialog opens when the **Settings** button for Fast Glycan Analysis is clicked. Make sure that the System Suitability Setup dialog opens when the **Settings** button for System Suitability is clicked.	Pass

Table 2-8 BioPhase Project Management Software Validation

Validation Performed	Results
Make sure that the BioPhase Project Management software version and other information is shown after the [i] icon is clicked.	Pass

Table 2-9 BioPhase Log File Extractor Validation

Validation Performed	Results
Make sure that the BioPhase Log File Extractor software and tools, including the desktop icon and the end user license, are installed.	Pass
Make sure that the available instrument IDs are shown on the left pane. Make sure that the Browse For Folder dialog opens after the **Browse** button is clicked.	Pass
Make sure that the **Make New Folder**, **OK** and **Cancel** buttons are enabled in Browse For Folder dialog.	Pass
Make sure that the **Start Date** and **End Date** fields are accessible. Make sure that the **Ok** button on BioPhase Log File Extractor Home Page is enabled after the destination folder is selected. Make sure that the BioPhase Log File Extractor software is closed after the **Close** button is clicked.	Pass

Validation Summary for Version 1.2

Table 2-10 BioPhase Front Panel Validation

Validation Performed	Results
Make sure that the Log window shows the Events and System tabs. Make sure that the Events tab shows the **Initialize System** button to start the system. Make sure that the System tab shows the system log history and that the log is sorted with the most recent events at the top.	Pass

Table 2-11 BioPhase Software Validation

Validation Performed	Results
Make sure that the Reagent Editor workspace shows the **New Reagent Set** and **Open Reagent Set** tiles. Make sure that the workspace shows three buttons: **NEW**, **SAVE**, and **CLOSE**. Make sure that the **SAVE** button is enabled when Projects/Reagent Sets are selected, or the **Inlet Reagents from Reagent Set** and **Outlet Reagents from Reagent Set** information is edited, and no errors are present.	Pass
Make sure that the location of the project and reagent folders can be configured from the Configuration workspace.	Pass

Table 2-12 BioPhase Project Management Software Validation

Validation Performed	Results
Make sure that the BioPhase Project Management software manually uploads the archived data to the main server after the **Upload Data** button is clicked.	Pass

Table 2-13 BioPhase Log File Extractor Validation

Validation Performed	Results
Make sure that the **Instrument List** is refreshed after the **Refresh** button is clicked.	Pass
Make sure that the BioPhase Log File Extractor software information is shown after the 🛈 icon is clicked.	Pass

Validation Summary for Version 1.3

Table 2-14 BioPhase Front Panel Validation

Validation Performed	Results
Make sure that the IP address of the BioPhase 8800 system can be updated on the front panel.	Pass
Make sure that the BioPhase 8800 system can be configured for third-party control. Make sure that the correct items are available on the front panel when the system is under third-party control.	Pass
Make sure that the front panel handles errors during a sample run or during direct control actions. Make sure that the error is added to the error log and the system can be reinitialized from the front panel.	Pass

Table 2-14 BioPhase Front Panel Validation (continued)

Validation Performed	Results
Make sure that functions for use by a SCIEX FSE, including a separation test, a pressure leak test, and a coolant log test, can be done.	Pass

Table 2-15 BioPhase 8800 Driver for Empower™ Validation

Validation Performed	Results
Make sure that the BioPhase 8800 driver for Empower™ can be installed, uninstalled, and the license activated.	Pass
Make sure that the BioPhase 8800 driver for Empower™ can do direct control actions such as changing the temperature, rinsing, turning the detector light source on and off, and other functions.	Pass
Make sure that the Waters Empower™ software can import and open instrument methods created by the BioPhase software.	Pass
Make sure that a method set can be created from an existing instrument method.	Pass
Make sure that a sample set method can be created, edited and saved with the Waters Empower™ software.	Pass
Make sure that the BioPhase 8800 driver for Empower™ can work with the Waters Empower™ software to start, stop, and restart a run. Also make sure a run can be completed and the Waters Empower™ software shows real time progress during the run. After the run, make sure that absorbance, current, and voltage data can be seen.	Pass
Make sure that the BioPhase 8800 driver for Empower™ can recover from an error during a sample run or during direct control actions. Make sure that the error is added to the error log on the front panel and the system can be reinitialized from the front panel.	Pass
Make sure that the BioPhase 8800 driver for Empower™ can control up to two BioPhase 8800 systems with one LAC/E box.	Pass
Make sure that an instrument method report can be printed.	Pass
Make sure that the Waters Empower™ software can create a report with details such as serial number, system group information, method set, sample set, and brief and full summaries after running a sample.	Pass
Make sure that functions for use by a SCIEX FSE, including a separation test, a pressure leak test, and a coolant log test, can be done.	Pass

Table 2-15 BioPhase 8800 Driver for Empower™ Validation (continued)

Validation Performed	Results
When the BioPhase 8800 system is connected to a high latency network, make sure that the system can do direct control actions, run a sample set method, and remain on-line after a period of inactivity.	Pass

Table 2-16 Method Editors for BioPhase System Software Validation

Validation Performed	Results
Make sure that the Method Editors for BioPhase System software can create, edit, and save a reagent set.	Pass
Make sure that Method Editors for BioPhase System software can open, create, edit, and save instrument methods.	Pass
Make sure that a sample set method can be created, edited, and saved.	Pass
Make sure that a sample set method report can be printed.	Pass
Make sure that the correct help topic appears for each window and dialog in the Method Editors for BioPhase System software.	Pass

Validated Computer Configuration

Table 2-17 Validated Computer Configuration

Item	Details
Operating system	Microsoft Windows 10
Additional software	OS Windows Media .NET Framework version 4.7.2 or later
CPU	Heatsink 5820 Tower
Random access memory (RAM)	32 GB 2 × 16 GB DDR4 3200 MHz RDIMM ECC memory
Solid state drive	M.2 1 TB PCIe NVMe Class 40
Ethernet adapters	Ethernet port for network connectivity

Software History   A

BioPhase Software Version 1.0

The initial versions of the following software components for the BioPhase 8800 system were released August 2021:

• BioPhase software

• BioPhase Front Panel software

• BioPhase Project Management software

BioPhase Software Version 1.1

BioPhase software version 1.1 was released in February 2022.

New Features in Version 1.1

• The BioPhase Log File Extractor, a utility that lets the user to export the log from a BioPhase 8800 system, is included in the Project Management software installer. (BRKSW-2103)

• Users can now use the ℹ️ at the bottom of the home page to see the software version in the Project Management software. (BRKSW-1993)

Additions to the Front Panel

• A function to calibrate the LIF detector has been added. (BRKSW-0929)

• Sequences can be sorted by name or date. (BRKSW-0955)

• A function to zoom in on the data during a run has been added to the Capillary Overlay View window. (BRKSW-1290)

• If a method contains an injection, then when the sequence is running, the **Method** column shows the number of the sample plate column where the injection occurs. If the sequence contains replicate runs, then the number of replicates is also shown. (BRKSW-1495)

• The cartridge information section has been redesigned. (BRKSW-1513)

• The date and time has been added to the entries on the Events tab in the log. (BRKSW-1801)

• If the network connection is lost, then a message is shown on the log on screen and recorded in the log. (BRKSW-1837)

• Functions have been added to configure the network connection for the system. These functions are only available to users with administrative privileges. (BRKSW-1183)

- An option has been added to lock the front panel if the system has been idle for a specified time. This option can be configured by a user with administrator privileges. (BRKSW-1915)

- A numeric keypad is now available for entering numeric values. (BRKSW-1947)

- An option has been added to let the system run an error recovery method if a run is stopped by a user. (BRKSW-2088)

Additions to the BioPhase Software

- Three reports are available in the sequence editor: Summary Report, Detailed Report, and Plate Layout Report. The reports can be printed or saved as a PDF file. (BRKSW-1837)

- Existing sequences and methods can be edited and saved with the same name. An audit trail, with the reason for the change, is saved with the file. (BRKSW-1870)

- In the Configuration workspace, the functions for adding reagents have been modified and a tooltip with viscosity values is available for the most used reagents. (BRKSW-1880)

- Users can click **About** in the launcher in the upper left corner of the Home page to see the software version. (BRKSW-1936)

- In the sequence editor, a data file name is supplied by default. (BRKSW-2061)

- In the Program pane on the Method Program tab in the sequence editor, the tiles now show the inlet and outlet reagents. Previously only the inlet reagent was shown. (BRKSW-2069)

- In the method editor, an option to inject from the reagent plate has been added to the **Inject** action. For methods that include the injection of a water plug, this option lets water to be injected from the reagent plate instead of the sample plate, leaving room for more samples on the sample plate. (BRKSW-2000)

- Error messages that are shown when a sequence or method is not available because the connection to the network was lost have been made more clear. (BRKSW-2070)

- The user can access the Reagent Set Configuration tab from the method editor. (BRKSW-1714)

- If a method has two inject actions that both inject from the sample plate, then the software prevents another method from being assigned to any of the wells in the sequence that are already assigned for the second injection. Two injections occur if the second injection is a water plug or in other situations. Those wells are red in the Sample Plate Layout pane in the Sample Plate Setup tab in the sequence editor. (BRKSW-2095, BRKSW-2152)

- In the sequence shown in the Sample Plate Summary, any row containing a separation method can be collapsed to show only the method or expanded to show the individual well assignments. (BRKSW-1857)

Additions to the BioPhase Analysis Software

- The **Group Peaks** option has been added to the **Event** list on the Post Analysis tab in the Analysis Parameters pane. This function creates a new peak in the Results Table where the

area is the sum of the peak areas of the individual peaks. The individual peaks stay in the Results Table. (BRKSW-1301)

- The columns in the lower table in the Post Analysis tab in the Analysis Parameters pane have changed. The columns are now **Event**, **Cal MT (L)**, **Cal MT (R)**, and **Value**.

- An option has been added to do a system suitability test on a set of files without reintegrating the data. (BRKSW-1991)

- Point to point calibration has been added to the **Fit Type** list on the Library tab in the Analysis Parameters pane. A point to point calibration is a linear interpolation between two calibration points. If more than two points are selected, then a straight line is drawn between the first two points, then the second and the third point, and so on. If more than two points are selected, then the final calibration curve consists of a series of line segments. (BRKSW-2111)

Fixed Issues in 1.1

- (Front panel) If a method fails during a run, then the status is correct while the error recovery method is running. (BRKSW-1742)

- (Front panel) If a sequence fails, then the exclamation mark is shown at the action in the method where the error occurred. (BRKSW-1792)

- During data acquisition, only one data file is saved. Previously, sometimes two copies of the same data file were saved. (BRKSW-1892)

- (Front panel) The run count in the **Recorded Number of Runs** field increases by one for each run in a cIEF separation. (BRKSW-1896)

- (Front panel) If **Initialize System** is touched while the light source is warming up, then the time remaining for the light source to warm up is now correct. (BRKSW-1924)

- (BioPhase Analysis software) The software can now be accessed while the Help file is open. (BRKSW-1945)

- (BioPhase software) The position of the conditioning method does not change after the sequence is saved and opened again. (BRKSW-1977)

- (BioPhase software) An issue where data file names that included the project name might result in data not being saved because the file name being too long is fixed. (BRKSW-1981)

- (BioPhase Analysis software) If the graphs are tiled on the Overlay tab, then the file names do not overwrite each other. (BRKSW-1546)

- (BioPhase Analysis software) If the **Optimizer** is selected on the Integration tab, then no message that parameters were modified is shown after the data is analyzed . (BRKSW-1551)

- (BioPhase software) During creation of a method, actions can be added at any position in the method. (BRKSW-1978)

- (BioPhase software) The project lists on the Sequence Summary and Sample Plate Set Up tabs no longer show different information. (BRKSW-1934)

- (BioPhase software) An issue where a method name was incorrectly shown in red with a line through it after an error that resulted from a bad network connection has been fixed. (BRKSW-1927)

- (BioPhase software) An issue where if the reagents in a reagent configuration file are changed, then a method created before the change might not have the correct reagents has been fixed. (BRKSW-1369)

- (BioPhase software) An error where the **Project** field (in the Method Summary pane on the Method Summary tab) sometimes showed the wrong project has been fixed. (BRKSW-1859)

- (BioPhase software) When **Search** is clicked in the Open a Method dialog the software no longer stops responding or closes. (BRKSW-1865)

- (Front panel) After a sequence is cancelled, a message indicating that the error recovery method will be run is now shown only if an error recovery method is present in the sequence. (BRKSW-1751)

- (Front panel) In the header that is shown during the run, long sequence names are now truncated and three dots are shown at the end. (BRKSW-1686)

- (BioPhase software) When the user hovers over the **Fill Down Run Type** cell, the correct tooltip is now shown. (BRKSW-1803)

- If the same sequence is run multiple times, then the data files have the date and time in the file name. (BRKSW-1912)

- (BioPhase Analysis software) When the report template has a logo and text in the header, specifying a value for the **Width** that is between 1 and 100 prevents the logo from overwriting the text. (BRKSW-1304)

BioPhase Software Version 1.2

BioPhase software version 1.2 was released in May 2022.

New Features in Version 1.2

Front Panel

- For the Separate parameters, `Capillary cartridge is not installed` is shown when the cartridge is not engaged. (BRKSW-2214)

- The user can now delete the log errors from the front panel Log. (BRKSW-2183)

BioPhase Software

- Formatting issues including row alignment and missing borders from are now fixed. (BRKSW-1996)

- The BioPhase software logs all of the actions and changes made in the application. (BRKSW-2105)

- The user can configure and see the locations for projects and reagents in the Configuration workspace. Also, the functions related to reagent sets have moved from the Configuration workspace to the Acquisition workspace. (BRKSW-2133)

- The Method Summary tab now shows the values for each selected action. (BRKSW-2151)

- The Method Summary and Sequence General Information panes now show three more fields: **Modified On**, **Modified By**, and **Reason for Change**. (BRKSW-2279)

BioPhase Analysis Software

- The BioPhase Analysis software logs all of the activity in the software. (BRKSW-2105)

- The **Fast Glycan Analysis** option has been added to the Post Analysis tab in the Analysis Parameters result table pane. (BRKSW-2271)

Project Management Software

- If the network connection between the instrument and domain isolator is lost during the run, then the user can manually upload data from the Project Management software to the server. (BRKSW-2037)

Fixed Issues in 1.2

- (BioPhase Analysis software) If the graphs are tiled on the Overlay tab and the selected data files in the Files pane change, then the report for the Overlay tab does not show the correct graphs. (BRKSW-1909)

- (BioPhase Analysis software) For data files with LIF detection that were exported from the 32 Karat software in ASCII format, the label on the Y-axis of the electropherogram is incorrect. The label is "AU" instead of "RFU". (BRKSW-1954)

- (BioPhase Analysis software) Any changes made to the Glycan Analysis parameters were not saved when the **OK** button was clicked. (BRKSW-2134)

- (BioPhase software) In the Method Settings pane, **Capillary Type** list was cut off. (BRKSW-2150)

- (BioPhase Analysis software) The user was not able to print the report for the selected and all data on a single view with peak results. (BRKSW-2161)

- (BioPhase software) In the Sequence Editor, the user was not able to open the Sequence Validation tab and adjust the width in the **Sample Plate Setup** manually. (BRKSW-2164)

- (BioPhase software) When a sequence or method is edited or created, the path on the **Path Configuration** tab did not change until the method or sequence was saved. (BRKSW-2176)

- (Front panel) In the front panel Configuration tab, the touch screen keyboard was not shown when the user touched the text box. (BRKSW-2178)

- (Front panel) If the user stops the sequence during a run and then clicks **Yes** to run the error recovery method, a message that the run did not complete is shown, even though the run was stopped by the user. (BRKSW-2207)

- (Front panel) If the network connection was lost during data acquisition, then the data files might not be copied to the server or the local computer. (BRKSW-2208)

- (Front panel) In the front panel Separate tab, `Capillary cartridge is not installed` message was shown even when the cartridge was engaged. (BRKSW-2214)

- (Front panel) For a sequence that did not have an error recovery method assigned, if the user stopped the sequence during a run, the reagent trays might not go to the home position. If the trays were not in the home position, then the cartridge might be damaged and need to be replaced. (BRKSW-2218)

- (Front Panel) Front panel **Events** and **Systems** log showed the newest events on the top and older events on the bottom. (BRKSW-2231)

- (Front panel) The log files from the front panel were deleted when the system was initialized. (BRKSW-2235)

- (BioPhase software) If a reagent name was very long, then the **Color** column in the reagent table is narrow and hard to read. (BRKSW-2241)

- (BioPhase software) In the sequence editor, the message shown during the opening of a sequence that was corrupted stated that the file was not accessible. If the user clicks **New** after dismissing the error message, then the software might close. (BRKSW-2246)

- (BioPhase Analysis software and Front panel) The user was able to edit an existing method and sequence without adding a **Reason for Change**. However, the user was unable to run a sequence from the front panel. (BRKSW-2248)

- (Front panel) If the system was idle longer than the **Timeout Duration**, then the lock screen did not display the name of the logged in user. Therefore, it was impossible to know who can unlock the system. (BRKSW-2249)

- (Front panel) If the front panel was locked during the LIF calibration, then the user was not able to save or see any new calibration factors. (BRKSW-2250)

- (Front panel) If a method was edited and saved with the same name, then the user was not able to see the changes to the method. (BRKSW-2255)

- (BioPhase Analysis software) If the value in the **Width** field in the Report Setup dialog was out of range and **File** > **Print Preview** was selected, then the print preview was blank. The Results Table was also blank after the Print Preview dialog was closed. (BRKSW-2256)

- (BioPhase Analysis software) Report Setup instructions for the user were missing. (BRKSW-2257)

- (Project Management software) Duplicate copies of the same data files were saved during the acquisition. (BRKSW-2265)

- (BioPhase software) If the **Error Recovery Method** check box was selected for a method with assigned samples, then a method was not selected in the sequence. (BRKSW-2269)

- (BioPhase software) The incorrect help topic was shown for the **Method Editor**. (BRKSW-2275)

- (Front panel) The **Done** button in the Wavelength Settings tab was enabled before the **Filter Wavelength** was updated. (BRKSW-2277)

- (BioPhase Analysis software) The **Filter (Area)** and **Filter (Area%)** functions in the Post Analysis tab did not work. (BRKSW-2281)

- (Front panel) The **Idle Timeout** function in the Configuration tab did not work after the **Timeout Duration** was saved. (BRKSW-2306)

- (Front panel) When more than 12 columns of sample were added in a sequence, then the reagent and sample plate did not show any reagents. (BRKSW-2318)

- (BioPhase software and Front panel) In the Method Settings tab, if the value for the **PMT Gain** was set as 5, then the system showed an error on the front panel while running a sequence. (BRKSW-2351)

- (BioPhase software) Any changes made to an existing sequence or method were not saved when **Save As** was clicked. (BRKSW-2356)

BioPhase Software Version 1.3

Version 1.3 was released in April 2023.

New Features in Version 1.3

The initial versions of the following software components for the BioPhase 8800 system were released:

- BioPhase 8800 driver for Empower™ (BRKSW-2454, BRKSW-2576)

- Method Editors for BioPhase System software (BRKSW-2546)

Note: The Method Editors for BioPhase System software is included with the BioPhase 8800 driver for Empower™ and can only be accessed from the Waters Empower™ software.

Additions to the Front Panel

- Support for the BioPhase 8800 driver for Empower™ was added. (BRKSW-2524, BRKSW-2455)

Note: No changes were made to the firmware, the BioPhase software, the BioPhase Analysis software, or the Project Management software for the 1.3 release.

Firmware History   B

Note: If a version is not listed, then the firmware was not released to customers.

BioPhase Firmware Version 1.0

BioPhase firmware version 1.0 was released in August 2021.

BioPhase Firmware Version 1.1

BioPhase firmware version 1.1 was released in February 2022.

Changes in this version include:

- Made the plate and cartridge engagement functions better to prevent a "cartridge not found" error. (BRKSW-2094)

- Made the UV scan algorithm for finding capillary centers better. (BRKSW-2163 and BRKSW-2169)

- Added support for the dehumidifier. (BRKSW-1295)

BioPhase Firmware Version 1.2

BioPhase firmware version 1.2 was released in May 2022.

Changes in this version include:

- Added internal functions to improve how the pressure is attained. (BRKSW-1935)

- Added a command to support a new alignment mechanism for the sample and reagent trays. (BRKSW-2085)

- Increased the sample cooler motor holding current for the tray holder. (BRKSW-2329)

- Made the capillary position more accurate relative to the 280 nm UV filter. (BRKSW-2367)

- Increased the voltage range for the photomultiplier for LIF detection. (BRKSW-2374)

BioPhase Firmware Version 1.2.4

BioPhase firmware version 1.2.4 was released in July 2022.

Changes in this version include:

- Fixed issues with the movement of the Z-lifter when a plate is not found in the plate compartment. (BRKSW-2197)

- Changed capillary detection by the UV and LIF detectors. (BRKSW-2367)

- Changed the motion of the filter wheel. (BRKSW-2359)

- Increased the range for gain for the LIF detector. (BRKSW-2374)

- Added a function to make sure that the plate compartment door closes properly and to prevent the sample and reagent plates from moving when the door is open. (BRKSW-2427)

- Made the temperature more consistent and corrected temperature oscillations for the cartridge compartment. (BRKSW-2520)

BioPhase Firmware Version 1.2.5

BioPhase firmware version 1.2.5 was released in August 2022.

Changes in this version include:

- Fixed an error with the tray lifting mechanism that occurred at the calibration step during manufacturing. (BRKSW-2588)

BioPhase Firmware Version 1.2.6

BioPhase firmware version 1.2.6 was released in January 2023.

Changes in this version include:

- Fixed an issue where the system might require a power cycle if the user touches **Engage** on the front panel when a cartridge is not installed. (BRKSW-2632)

- Changed the filter wheel homing procedure. (BRKSW-2710)

- Changed capillary detection by the UV and LIF detectors. (BRKSW-2949)

Contact Us

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

- SCIEX Now Learning Hub

Purchase Supplies and Reagents

Reorder SCIEX supplies and reagents online at store.sciex.com. To set up an order, use the account number, found on the quote, order confirmation, or shipping documents. Currently, customers in the United States, Canada, United Kingdom, Belgium, Netherlands, France, Germany, and Switzerland have access to the online store, but access will be extended to other countries in the future. For customers in other countries, contact a local SCIEX representative.

SCIEX 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 SCIEX website at sciex.com or contact us in one of the following ways:

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

CyberSecurity

For the latest guidance on cybersecurity for SCIEX products, visit sciex.com/productsecurity.

Documentation

This version of the document supercedes all previous versions of this document.

To see this document electronically, Adobe Acrobat Reader is required. To download the latest version, go to https://get.adobe.com/reader.

Contact Us

To find software product documentation, refer to the release notes or software installation guide that comes with the software.

To find hardware product documentation, refer to the documentation that comes with the system or component.

The latest versions of the documentation are available on the SCIEX website, at sciex.com/customer-documents.

Note: To request a free, printed version of this document, contact sciex.com/contact-us.