BioPhase 8800 System

Software Validation Summary

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Introduction 1

This document gives a description of the software validation for the software for the BioPhase 8800 system and supplies a list of requirements for the computer configuration and the software development environment.

Software Overview

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

The following software components were released June 2024:

- BioPhase software 1.4
- BioPhase Analysis software 1.4
- BioPhase Front Panel 1.4
- BioPhase firmware 1.4
- Project Management software 1.4
- BioPhase Log File Extractor 1.4

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 a local computer or the network. After the data is saved, it can be analyzed with the BioPhase Analysis software. Refer to the section: BioPhase Software General Description.

- **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: BioPhase 8800 Driver for Empower™ General Description.

BioPhase Software General Description

The following general functions are supplied:

- Control: The system is controlled from a touchscreen on the front panel. The user can install and remove plates and cartridges, control the ultraviolet (UV) and laser-induced fluorescence (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 software is used to create separation methods and analyze the acquired data. The software is installed on a computer that can be local to the system or remote. Remote communication occurs 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: The software has features that let users create customized reports and include graphics, such as company logos, in report templates. The report also includes the sign-off status.

- Compliance: The software includes features to supply documentation for compliance.

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

BioPhase 8800 Driver for Empower™ General Description

The following general functions are supplied:

- Control: The system is controlled from a touchscreen on the front panel. The user can install and remove plates and cartridges, and control the UV and LIF light sources. More system 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 Waters Empower™ database. No acquired data is kept on the system.

- Acquisition method development: The Method Editors for BioPhase System software is used to create separation methods and sequences that are required for data acquisition. The user gets access to the Method Editors for BioPhase System software 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

- Project management

Support

Installation

Local or Network Configuration

The BioPhase software and Project Management software are installed at the factory 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-downloads.

Only limited support is available from SCIEX for software installed by the user. 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

A maximum of 4 hours of in-laboratory training for a maximum of 2 operators is included with the purchase of the BioPhase 8800 system. Training is done by FSEs or product specialists.

Software Updates

As required, 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 active 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, go to sciex.com.

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

Software License

For the BioPhase software and the BioPhase 8800 driver for Empower™, software licenses from SCIEX are required. For SCIEX software license instructions and to download the software, go to sciex.com/software-downloads.

If the BioPhase 8800 driver for Empower™ will be used, then one or more licenses for the Waters Empower™ software is also required. Contact a SCIEX sales representative for information about which license is required from Waters.

More Information

Software help is included with the BioPhase software, BioPhase Analysis software, and 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 create 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 created 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 found 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 required version control information kept, and with archive tapes secured in an off-site vault.

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

- Operational software has been monitored to make sure that it complies with system and software requirements, and that it supplies the correct tracking, review, disposition, testing, and customer notification of system errors in post-release software.

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 verification of the quality management system.

SCIEX keeps all documents and their reproductions. A non-disclosure agreement might be required from be supplied by those who require these documents.

Customer Feedback Reporting

All customer feedback for released software goes through the SCIEX customer complaint process and is used to make subsequent versions of the software better.

Development Environment

Table 1-1 BioPhase Analysis Software

Configuration management system	Git 2.43.0.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, Project Management Software, BioPhase Log File Extractor Software, Front Panel, and BioPhase 8800 Driver for Empower™

Configuration management system	Git 2.43.0.windows.1.
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 2.43.0.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)

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Validation Summary for Version 1.0

Table 2-1 Front Panel Validation

Validation Done	Results
Make sure that the front panel software is installed.	Pass
Make sure that the front panel is accessible.	Pass
Make sure that the BioPhase 8800 system can be unlocked from the front panel.	Pass
When **Ejected** is touched, make sure that the text changes to **Loaded**. When a cartridge is loaded, make sure that the icon to the left changes from **Ejected** to **Loaded**.	Pass
Make sure that the **UV** and **LIF** light sources are off. When **UV** and **LIF** are touched, make sure that the status changes.	Pass
Make sure that the Home Page on the front panel shows two sections: Acquisition and Management.	Pass
Make sure that the Acquisition section on the front panel shows three tiles: **Direct Control**, **Run Sequence**, and **Capillary View**.	Pass
Make sure that the top left pane on the front panel top shows the green system icon.	Pass
Make sure that the system status in the bottom pane shows `Idle`.	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. Make sure that the window shows the three columns: **Method**, **Sample**, and **Reagent**. Make sure that the **Run Sequence** button is not available.	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 two tabs: Events and System. Make sure that the Events tab shows the **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 history log.	Pass

Validation Summary

Table 2-2 BioPhase Software Validation

Validation Done	Results
Make sure that the BioPhase software and tools, which includes 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
When **Edit** is clicked on the Method Summary tab, make sure that the Method Settings tab opens.	Pass
When a project folder is selected on the Project/Methods pane, make sure that the **PRINT** button is available. When **PRINT** is clicked, make sure that the SCIEX Method report is created.	Pass
When the home icon on the ribbon is clicked, make sure that the Home page is shown.	Pass
When a sequence is selected on the Available Sequences pane, make sure that the **PRINT** button is available. When **PRINT** is clicked, make sure that the SCIEX Sequence report is created.	Pass
Make sure that the **Data Analysis** tile opens the BioPhase Analysis software. **Note:** If the BioPhase Analysis software is not installed on the local system, then the **Data Analysis** tile is not available.	Pass

Table 2-3 BioPhase Analysis Software Validation

Validation Done	Results
Make sure that the BioPhase Analysis software can be 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
Make sure that the Data pane shows two tabs: Single and Overlay.	Pass

Table 2-3 BioPhase Analysis Software Validation (continued)

Validation Done	Results
When an analysis file is opened, make sure that the Analysis Parameters pane contains the saved integration parameters.	Pass
When **Analyze** is clicked, make sure that the peaks are automatically integrated on the electropherogram with the loaded integration parameters.	Pass
Make sure that the Analysis Parameter tab shows three tabs: Integration, Library, and Post Analysis.	Pass
Make sure that the top table on the Integration tab has three columns: **Event**, **Start**, and **Value**. Make sure that the **Event** column contains a list, and that the fields for **Start** and **Value** columns can be edited.	Pass
Make sure that the bottom table on the Integration tab has two columns: **Type** and **Value**. Make sure that all of the fields, lists, and buttons are available and, when applicable, can be edited.	Pass
Make sure that the **Clear** and **View** buttons in the Manual Events section on the Integration tab are available. When **Clear** is clicked, make sure that the manual integration events from the graph are removed. When **View** is clicked, make sure that a dialog that shows the manual integration events on the graph.	Pass
Make sure that all of the buttons, fields, check boxes, and lists on the Integration tab are available and, when applicable, can be edited.	Pass

Table 2-4 Project Management Software Validation

Validation Done	Results
Make sure that the Project Management software and tools can be 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. When **Browse** is clicked, make sure that the Select Folder dialog opens.	Pass
Make sure that a new user can be added to the project from the Properties tab with the ⊞ icon.	Pass
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 a local drive.	Pass
Make sure that the user can browse to a server in File Explorer.	Pass

Table 2-4 Project Management Software Validation (continued)

Validation Done	Results
Make sure that sequences from a server can be copied to the project.	Pass

Validation Summary for Version 1.1

Table 2-5 Front Panel Validation

Validation Done	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 Management section shows three tiles: **Log**, **Configuration**, and **Calibration**.	Pass
When the optics door is opened, make sure that the front panel shows an error message.	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**. When **Ejected** is touched, make sure that the **Transport Home** function is available.	Pass
For users with administrator access, make sure that the Configuration tile is available. Make sure that the Configuration window shows two tabs: General and Network. Make sure that the General tab shows the **Change Password** and **Idle Timeout** features. Make sure that the Network tab shows information for the domain isolator and BioPhase 8800 system.	Pass
Make sure that the Calibration window shows the LIF intensity calibration parameters, setup, and results. When **Start Calibration** is touched, make sure that the Run Sequence window opens. After the LIF calibration procedure is completed, make sure that the **Save Calibration** button is available. When **Reset to Default** is touched, make sure that the LIF calibration value is set to the default.	Pass

Table 2-6 BioPhase Software Validation

Validation Done	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

Table 2-6 BioPhase Software Validation (continued)

Validation Done	Results
When **New Method** is clicked, make sure that the Method Settings tab opens. Make sure that the New Method workspace shows three tabs: Method Summary, Method Settings, and Method Program. When the **Open Method** tile is clicked, make sure that the Open a Method dialog opens.	Pass
When the method information is edited and no errors have occurred, make sure that the **SAVE** and **SAVE AS** buttons are available.	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
When **New Sequence** is clicked, make sure that the Sample Plate Setup tab opens. Make sure that the New Sequence workspace shows three tabs: Sequence Summary, Sample Plate Setup, and Plates Layout. When **Open Sequence** is clicked, make sure that the Open a Sequence dialog opens.	Pass
When the sequence information is edited, make sure that the **SAVE** and **SAVE AS** buttons are available and no errors have occurred.	Pass
Make sure that the Configuration workspace shows two tiles: **New Reagent Set** and **Open Reagent Set**. Make sure that the workspace shows three buttons: **NEW**, **SAVE**, and **CLOSE**. When the information in the **Inlet Reagents from Reagent Set** and **Outlet Reagents from Reagent Set** tables is edited and no errors have occurred, make sure that the **SAVE** button is available.	Pass
When **Open a Reagent Set** is clicked, make sure that the Open a Reagent Set dialog opens.	Pass

Table 2-7 BioPhase Analysis Software Validation

Validation Done	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 available and can be edited.	Pass
Make sure that the Post Analysis tab shows two tables. Make sure that the **Module** column in the top table shows Fast Glycan Analysis and System Suitability. When **Settings** for a Fast Glycan Analysis is clicked, make sure that the Fast Glycan Analysis dialog opens. When **Settings** for a System Suitability analysis is clicked, make sure that the System Suitability Setup dialog opens.	Pass

Table 2-8 Project Management Software Validation

Validation Done	Results
When the [i] icon is clicked, make sure that the Project Management software version and other information is shown.	Pass

Table 2-9 BioPhase Log File Extractor Software Validation

Validation Done	Results
Make sure that the BioPhase Log File Extractor software and tools can be installed.	Pass
When **Browse** is clicked, make sure that the available instrument IDs are shown on the left pane. Make sure that the Browse For Folder dialog opens.	Pass
In Browse For Folder dialog, make sure that the **Make New Folder**, **OK**, and **Cancel** buttons are available.	Pass
Make sure that the **Start Date** and **End Date** fields are available. When the destination folder is selected, make sure that the **Ok** button on the BioPhase Log File Extractor Home page is available. When **Close** is clicked, make sure that the software closes.	Pass

Validation Summary for Version 1.2

Table 2-10 Front Panel Validation

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

Table 2-11 BioPhase Software Validation

Validation Done	Results
Make sure that the Reagent Editor workspace shows two tiles: **New Reagent Set** and **Open Reagent Set**. Make sure that the workspace shows three buttons: **NEW**, **SAVE**, and **CLOSE**. When the information in the **Inlet Reagents from Reagent Set** and **Outlet Reagents from Reagent Set** tables is edited and no errors have occurred, make sure that the **SAVE** button is available.	Pass

Table 2-11 BioPhase Software Validation (continued)

Validation Done	Results
Make sure that the location of the project and reagent folders can be configured from the Configuration workspace.	Pass

Table 2-12 Project Management Software Validation

Validation Done	Results
When **Upload Data** is clicked, make sure that the Project Management software uploads the archived data to the server.	Pass

Table 2-13 BioPhase Log File Extractor Software Validation

Validation Done	Results
When **Refresh** is clicked, make sure that the **Instrument List** is refreshed.	Pass
When the [i] icon is clicked, make sure that the BioPhase Log File Extractor software version and other information is shown.	Pass

Validation Summary for Version 1.3

Table 2-14 Front Panel Validation

Validation Done	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.	Pass
Make sure that error handling by the front panel during a sample run or direct control actions is correct. Make sure that the error is added to the error log and the system can be initialized again from the front panel.	Pass
Make sure that functions for use by a SCIEX field service employee (FSE) can be done. Tests include a separation test, pressure leak test, and coolant log test.	Pass

Table 2-15 BioPhase 8800 Driver for Empower™ Validation

Validation Done	Results
Make sure that the BioPhase 8800 driver for Empower™ can be installed and uninstalled, and that the license can be activated.	Pass
Make sure that the BioPhase 8800 driver for Empower™ can do direct control actions such as change the temperature, do a rinse, and turn the detector light source on and off.	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 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 operate with the Waters Empower™ software to start, stop, and start a stopped run. Make sure that 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 that occurs during a sample run or direct control actions. Make sure that the error is added to the error log on the front panel and the system can be initialized from the front panel.	Pass
Make sure that the BioPhase 8800 driver for Empower™ can control a maximum of 2 BioPhase 8800 systems with one LAC/E module.	Pass
Make sure that an Instrument Method report can be printed.	Pass
After a run, 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.	Pass
Make sure that functions for use by a SCIEX field service employee (FSE) can be done. Tests include a separation test, pressure leak test, and coolant log test.	Pass
When the BioPhase 8800 system is connected to a network with high latency, make sure that the system can do direct control actions, run a sample set method, and stay online after a period of inactivity.	Pass

Table 2-16 Method Editors for BioPhase System Software Validation

Validation Done	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 is shown for each window and dialog in the Method Editors for BioPhase System software.	Pass

Validation Summary for Version 1.4

Table 2-17 Front Panel Validation

Validation Done	Results
Make sure that the front panel software is installed.	Pass
Make sure that a user with the correct credentials can log on to the front panel. For a user who does not have the correct credentials, make sure that the front panel shows the correct error messages.	Pass
Make sure that a user can install a capillary cartridge, see cartridge details, and set the cartridge temperature. When applicable, make sure that the system shows the correct error messages.	Pass
Make sure that the IP address of the BioPhase 8800 system can be updated on the front panel.	Pass
Make sure that all of the actions on the Direct Control window are correct.	Pass
Make sure that a sequence can be run from the front panel and the acquired data is saved to a network location. Make sure that the system can recover from an error that occurs during data acquisition.	Pass
When the cartridge coolant level is close to empty or empty, make sure that the level of coolant is correctly reported in the Status pane.	Pass

Table 2-17 Front Panel Validation (continued)

Validation Done	Results
Make sure that the Calibration window shows the LIF intensity calibration parameters, setup, and results. When **Start Normalization** is touched, make sure that the Run Sequence window opens. After the LIF normalization procedure is completed, make sure that the **Save Normalization** button is available. When **Reset to Default** is touched, make sure that the LIF normalization value is set to the default.	Pass

Table 2-18 BioPhase Software Validation

Validation Done	Results
Make sure that the BioPhase software, which includes the desktop icon and the end-user license, can be installed.	Pass
Make sure that reagent set templates can be created and modified in the Reagent Editor workspace.	Pass
Make sure that methods can be created and modified in the Method Editor workspace.	Pass
Make sure that sequences can be created, modified, and imported in the Sequence Editor workspace. Make sure that a sequence report can be created.	Pass
Make sure that the correct help topic is shown for each window and dialog in the software.	Pass

Table 2-19 BioPhase Analysis Software Validation

Validation Done	Results
Make sure that the initial settings for the BioPhase Analysis software are correct. Make sure that data files can be opened.	Pass
Make sure that the functions on the **File**, **Workspace**, **View**, and **Help** menus operate correctly.	Pass
Make sure that the buttons on the File toolbar operate correctly. Functions include opening, saving, and closing files.	Pass
Make sure that the functions in the Files pane operate correctly. Functions include overlay control, selection of files for analysis and overlay, and order of the files.	Pass
Make sure that the buttons on the Project toolbar operate correctly. Functions include data analysis, opening, and saving analysis parameter files.	Pass

Table 2-19 BioPhase Analysis Software Validation (continued)

Validation Done	Results
Make sure that the buttons on the Display toolbar operate correctly. Functions include the selection of annotations and drop lines on the electropherogram.	Pass
Make sure that the buttons on the Axis toolbar operate correctly. Functions include scaling options for the electropherogram and x-axis.	Pass
Make sure that the functions on the Single and Overlay tabs in the Data pane operate correctly. Functions include zoom, manual integration, and the display of other types of data.	Pass
Make sure that the Data pane functions for the Results Table operate correctly. Functions include the selection of table columns, column width, and analysis of multiple electropherograms.	Pass
Make sure that the BioPhase Analysis software can analyze data files that were acquired by a PA 800 Plus system with the 32 Karat software.	Pass
Make sure that the functions on the Integration tab operate correctly. Functions include peak integration and data analysis.	Pass
Make sure that the functions on the Library tab operate correctly. Functions include peak and marker identification.	Pass
Make sure that the functions on the Post Analysis tab operate correctly.	Pass
Make sure that the Fast Glycan analysis functions operate correctly.	Pass
Make sure that the system suitability functions operate correctly.	Pass

Table 2-20 Project Management Software Validation

Validation Done	Results
Make sure that the Project Management software can be installed.	Pass
Make sure that the Project Management software can edit and save user authentication information. Make sure that the Project Management software can create, edit, and delete projects, and upload data to a server after a run.	Pass

Table 2-21 BioPhase Log File Extractor Software Validation

Validation Done	Results
Make sure that the BioPhase Log File Extractor software can extract log files from the system.	Pass

Table 2-22 BioPhase 8800 Driver for Empower™ Validation

Validation Done	Results
When the door to the optical compartment is opened, make sure that the UV lamp and LIF laser turn off and the Waters Empower™ software shows the correct status.	Pass
Make sure that the Post Run report shows the correct number of injections, and the start and end times for the run.	Pass
Make sure that the status ribbon in the Waters Empower™ software refreshes and updates the values for voltage, pressure, and other items after each action.	Pass
Make sure that the front panel and the Waters Empower™ software show the correct coolant level. When the coolant level is close to empty, make sure that sequences and sample sets cannot be run.	Pass

Validated Computer Configuration

Table 2-23 Validated Computer Configuration

Item	Details
Operating system	Microsoft Windows 10 Enterprise LTSC 2019
Other software	OS Windows Media .NET Framework 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

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BioPhase Software 1.0

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

- BioPhase software
- BioPhase Front Panel software
- Project Management software

BioPhase Software 1.1

BioPhase software 1.1 was released in February 2022.

New Features in Version 1.1

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

- Users can use the [i] button at the bottom of the Home page to see the version of the Project Management software. (BRKSW-1993)

Front Panel

- A function to calibrate the LIF detector was added. (BRKSW-0929)

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

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

- If a method contains an injection, then when the sequence is in progress, 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 changed. (BRKSW-1513)

- The date and time were 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)

Software History

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

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

- A numeric keypad is now available to supply numeric values. (BRKSW-1947)

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

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)

- 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 to add reagents have been changed and a tooltip with viscosity values is available for reagents that are used frequently. (BRKSW-1880)

- In the launcher in the top left corner of the Home page, users can click **About** 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 show the inlet and outlet reagents. Before, only the inlet reagent was shown. (BRKSW-2069)

- In the method editor, an option to inject from the reagent plate was added to the **Inject** action. For methods that include the injection of a water plug, this option lets water be injected from the reagent plate so that more samples can be included on the sample plate. (BRKSW-2000)

- When a sequence or method is not available because the connection to the network was lost, the error messages were made more clear. (BRKSW-2070)

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

- If a method has two inject actions that both occur from the sample plate, then another method cannot be assigned to any of the wells in the sequence that are 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 on the Sample Plate Setup tab in the sequence editor. (BRKSW-2095, BRKSW-2152)

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

BioPhase Analysis Software

- On the Post Analysis tab in the Analysis Parameters pane, the **Group Peaks** option was added to the **Event** list. 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 bottom table on the Post Analysis tab in the Analysis Parameters pane changed. The columns are **Event**, **Cal MT (L)**, **Cal MT (R)**, and **Value**.

- An option was added to do a system suitability analysis on a set of files without integrating the data again. (BRKSW-1991)

- Point-to-point calibration was 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 another between the second and third points, and so on. If more than two points are selected, then the final calibration curve is a series of line segments. (BRKSW-2111)

Corrected Issues in Version 1.1

Front Panel

- If a method fails during a run, then the status is not correct while the error recovery method is running. (BRKSW-1742)

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

- Sometimes two copies of the same data file were saved. (BRKSW-1892)

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

- If **Initialize System** is touched while the light source is warming, then the time remaining for the light source to warm fully is not correct. (BRKSW-1924)

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

- In the header that is shown during the run, long sequence names are truncated. (BRKSW-1686)

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

BioPhase Software

- If the reagents in a reagent configuration file are changed, then a method created before the change might not have the correct reagents. (BRKSW-1369)

- When the user hovers over the **Fill Down Run Type** cell, the tooltip is not correct. (BRKSW-1803)

- In the Method Summary pane on the Method Summary tab, the **Project** field, sometimes shows the incorrect project. (BRKSW-1859)

- In the Open a Method dialog, when **Search** is clicked, the software does not respond or it closes. (BRKSW-1865)

- After an error caused by a bad network connection occurs, the method name is shown in red with a line through it. (BRKSW-1927)

- The project lists on the Sequence Summary and Sample Plate Set Up tabs shows different information. (BRKSW-1934)

- The user cannot get access to the software while the Help file is open. (BRKSW-1945)

- The position of the conditioning method changes after the sequence is saved and opened again. (BRKSW-1977)

- In the method editor, on the Method Program tab, if there are more than nine actions in Actions pane, then more actions cannot be added. (BRKSW-1978)

- Data file names that include the project name might be too long to let the data be saved. (BRKSW-1981)

BioPhase Analysis Software

- When the report template has a logo and text in the header, if the value for **Width** is not between 1 and 100, then the logo will overwrite text in the report or cause other issues with the report. (BRKSW-1304)

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

- If **Optimizer** is selected on the Integration tab, then a message that parameters were changed is shown after the data is analyzed. (BRKSW-1551)

- The user can get access to the software while the Help file is open. (BRKSW-1945)

BioPhase Software 1.2

BioPhase software 1.2 was released in May 2022.

New Features in Version 1.2

Front Panel

- The user can delete the errors from the log. (BRKSW-2183)

- The **Events** and **System** logs show the newest events on the top and older events on the bottom. (BRKSW-2231)

BioPhase Software

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

- The BioPhase software records 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 shows the values for each selected action. (BRKSW-2151)

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

BioPhase Analysis Software

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

- More instructions have been added to the Report Setup dialog. (BRKSW-2257)

- The **Fast Glycan Analysis** option has been added to the Post Analysis tab in the Analysis Parameters 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)

Corrected Issues in Version 1.2

Front Panel

- On the Configuration tab, the touchscreen keyboard is not shown when the user touches the text box. (BRKSW-2178)

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

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

- In the Separate section, `Capillary cartridge is not installed` is shown even when the cartridge is engaged. (BRKSW-2214)

- For a sequence that does not have an error recovery method, if the user stops the sequence during a run, the reagent trays might not go to the home position. If the trays are not

in the home position, then the cartridge might be damaged and need to be replaced. (BRKSW-2218)

- The log files from the front panel are deleted when the system is initialized. (BRKSW-2235)

- The user can edit a method and sequence and not add a **Reason for Change**. However, the user cannot run a sequence from the front panel. (BRKSW-2248)

- If the system is idle longer than the **Timeout Duration**, then the lock screen does not show the name of the user who is logged on and it is impossible to know who can unlock the system. (BRKSW-2249)

- If the front panel is locked during the LIF calibration, then the user cannot save or see any new calibration factors. (BRKSW-2250)

- If a method is edited and saved with the same name, then the user cannot see the changes. (BRKSW-2255)

- On the Wavelength Settings tab, the **Done** button is available before the **Filter Wavelength** is changed. (BRKSW-2277)

- On the Configuration tab, the **Idle Timeout** function does not operate after the **Timeout Duration** is saved. (BRKSW-2306)

- If more than 12 columns of sample are added to a sequence, then the reagent and sample plate layouts do not show any reagents. (BRKSW-2318)

- On the Method Settings tab, if the value for the **PMT Gain** is **5** while running a sequence, then an error is shown on the front panel. (BRKSW-2351)

BioPhase Software

- If a reagent name is very long, then the **Color** column in the reagent table is narrow and not easy to read. (BRKSW-2241)

- In the sequence editor, if the user tries to open a sequence that is corrupted, then a message that there is no access to the file is shown. If the user dismisses the message and then clicks **New**, then the software might close. (BRKSW-2246)

- In the Method Settings pane, the **Capillary Type** list is truncated. (BRKSW-2150)

- In the sequence editor, the user cannot open the Sequence Validation tab and adjust the width in the **Sample Plate Setup**. (BRKSW-2164)

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

- For a row in the sequence where there are assigned wells, the **Error Recovery Method** check box can only be selected if the row is expanded. (BRKSW-2269)

- The help topic shown for the method editor is not correct. (BRKSW-2275)

- On the Method Settings tab, if the value for the **PMT Gain** is **5** while running a sequence, then an error is shown on the front panel. (BRKSW-2351)

- If **Save As** is clicked, then changes made to a sequence or method are not saved. (BRKSW-2356)

BioPhase Analysis Software

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

- For data files with LIF detection that are exported from the 32 Karat software in ASCII format, the label on the Y-axis of the electropherogram is not correct. The label is *AU* instead of *RFU*. (BRKSW-1954)

- In the Glycan Analysis dialog, changes made to the parameters are not saved when **OK** is clicked. (BRKSW-2134)

- The user cannot print the report for the selected and all data on a single view with peak results. (BRKSW-2161)

- The user cannot start a run with a sequence that has an empty **Reason for Change**, but the sequence editor lets the sequence be saved without a **Reason for Change**. The software has the same issue with a method that has an empty **Reason for Change**. (BRKSW-2248)

- If the **Width** value in the Report Setup dialog is out of range and **File** > **Print Preview** is selected, then the print preview is empty. The Results Table is empty after the Print Preview dialog is closed. (BRKSW-2256)

- The **Filter (Area)** and **Filter (Area%)** functions on the Post Analysis tab do not operate. (BRKSW-2281)

Project Management Software

- Sometimes duplicate data files are saved during acquisition. (BRKSW-2265)

BioPhase Software 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™. Access is only available from the Waters Empower™ software.

Front Panel

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

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

BioPhase Software 1.4

Version 1.4 was released in July 2024.

New Features in Version 1.4

Front Panel

- Made the following functions better:

  - Reporting of the cartridge coolant level. (BRKSW-2220, BRKSW-2446)

  - Behavior of the system when the cartridge coolant is low. (BRKSW-2384, BRKSW-2385, BRKSW-2447)

- Added a function so that if the run is stopped, for any separation that was complete before the run was stopped, the data is saved. (BRKSW-2598)

- Data transfer from the BioPhase 8800 system to the domain isolator is done differently. [BRKSW-2722]

- Made the transfer of a sequence from the computer with the BioPhase software to the domain isolator faster. (BRKSW-3055)

BioPhase Software

- Added a function to save an audit trail to a method file. (BRKSW-1562)

- Added a function to the Sequence Editor so that the user can change undo the last change to a sequence file. (BRKSW-2237)

- Added a field to the General Information panes in the Method Editor and Sequence Editor that shows the revision of the method or sequence. (BRKSW-2540)

- Added a function to export a sequence to be used as a template, and made the import function better. (BRKSW-3096)

- Added a function to save an audit trail to a sequence file. (BRKSW-2345)

- Added keyboard commands to the Method Program tab in the Method Editor. (BRKSW-2421)

- Added a function to the Detector Type section on the Method Summary tab in the Method Editor so that a custom wavelength can be saved to a method. Added the options for 214 nm and 260 nm to the **Wavelength** list. (BRKSW-3124)

BioPhase Analysis Software

- Added a function to the Post Analysis tab in the Analysis Parameters pane so that **Cal MT** can be used to exclude peaks from analysis. (BRKSW-1454)

- Added a function to the Post Analysis tab in the Analysis Parameters pane so that peaks can be filtered by corrected area and corrected area %. (BRKSW-1717)

- Added a function so that the user can change the order of the graphs on the Overlay tab by dragging the file name in the list of files. (BRKSW-2311)

- Added a function to the Information Setup dialog so that the Results Table in the report shows the same columns as the Results Table in the software user interface. (BRKSW-2354)

- Made tiling in the Data pane better. (BRKSW-2565)

- Added a function to label the Y-axis in the Cal MT Curve dialog. (BRKSW-3089)

- Added functions to the Fast Glycan dialog to let the user use the default parameters for the analysis without selecting a `glycan` file. (BRKSW-3369)

- Added a function to let the user cancel the action to open multiple data files. (BRKSW-3381)

- Added a check mark to the Manual Events section to show that manual integration events are applied to the data. (BRKSW-3407)

- On the Single tab in the Data pane, when the graph is zoomed, an option to include the graph at the original resolution in the report was added. (BRKSW-3381)

Project Management Software

- Added a function to change sign-off privileges for a user and a function to change the location of a project. (BRKSW-3070)

- Added a function to configure how users are authenticated. (BRKSW-3088)

BioPhase 8800 Driver for Empower™

- Made the following features better:

  - Reporting of the cartridge coolant level. (BRKSW-2220)

  - Behavior of the system when the coolant is low. (BRKSW-3447, BRKSW-3449)

- When the optics access door is accidentally opened, added a message and updated the status of the light or laser. (BRKSW-2519)

- Added **Run Start Time**, **Run End Time**, and **Date Acquired** fields to the Waters Empower™ software Post Run Report. (BRKSW-3186)

- Made the number of runs in the Waters Empower™ software Post Run Report more accurate. The field is updated after each sample injection. Before, the field showed the number of runs at the start or the sample set method and was not updated. (BRKSW-3320)

Corrected Issues in Version 1.4

Front Panel

- If the domain isolator is turned off or not available on the network, then users cannot unlock the front panel or log on to the system. (BRKSW-2171)

- If a sequence fails during a separate action, then the exclamation mark (!) is not added next to the action where the failure occurred. (BRKSW-2268)

- If an error occurs during a run, then the front panel continues to show the incorrect error message even after the error recovery process is completed. (BRKSW-2322)

- A new user is sometimes added to the wrong project when the projects have different paths. [BRKSW-2755]

- If the domain isolator is turned off during data acquisition, the data files are not saved. (BRKSW-3149)

- The **Recorded Number of Runs** field in the Cartridge Info window does not change after each run. (BRKSW-3346)

- Removed the message about the maximum number of runs. (BRKSW-3506)

- If the domain isolator times out during data acquisition, then the data files stay on the BioPhase 8800 system and are not transferred to the domain isolator. (BRKSW-3594)

- If the BioPhase 8800 system is disconnected from the domain isolator for more than an hour, then the data files stay on the BioPhase 8800 system and only a field service employee (FSE) can get access to them. (BRKSW-3603)

BioPhase Software

- If more than eight files are selected, then only eight files can be tiled on the Overlay tab. (BRKSW-2327)

- The **File** > **Print** command only prints one file at a time. (BRKSW-2330)

- On the Method Settings tab, when a new reagent project is added, the reagent project list does not change. (BRKSW-2335)

- In the graph in the Data pane, if the X-axis is changed to **Cal MT**, then the **Autoscale Y** and **Autoscale XY** commands do not operate. (BRKSW-2355)

- If a method has two separate actions, then the incorrect number of reagent rows are added to the plate layouts. (BRKSW-2434)

- When the optimizer is available, then the results in the **Value** cell on the Integration tab are whole numbers. (BRKSW-2461)

- BioPhase software 1.2 can overwrite data files in some situations. (BRKSW-2601)

- If a sequence is stopped before the run completes, then no data is saved. (BRKSW-3271)

- If a sequence that has not changed is open in the sequence editor and two more sequences are opened, then a warning that the first sequence has been changed is shown. (BRKSW-3588)

- When a corrupted method or sequence file is opened, the error message that is shown does not tell the user that the file is corrupted. (BRKSW-3590)

- If a sequence that has been changed is open in the sequence editor and another sequence is opened, then a prompt to save the changes to the first sequence is not shown. (BRKSW-3595)

BioPhase Analysis Software

- For data analyzed with the Fast Glycan analysis, all peaks in the graph are shown in red. The colors for peaks that are identified with glycan analysis should be changed to another color. (BRKSW-1440)

- In the graph in the Data pane, when the user changes the X-axis from **MT** to **Cal MT**, or vice versa, the scaling on the Y-axis changes. This is more obvious when annotations are shown because the annotations are truncated. (BRKSW-1494)

- If a peak tail is deleted after a peak is split, the incorrect area is deleted. (BRKSW-1571)

- The number of decimal places shown in the system suitability report is not the same as the number configured in the Report Setup dialog. The report uses the number configured in the Information Setup dialog. (BRKSW-1835)

- When the user applies or revokes a signature, the comment field in the Signature dialog accepts more characters than can be saved. (BRKSW-1849)

- If the graph image is saved or copied, then the annotations might be truncated. (BRKSW-1905)

- If there are too many lines in the report header, then the Results Table is truncated when it is in landscape format. (BRKSW-1908)

- If data file names include a comma when a report is saved from the Overlay tab, then the comma might cause an issue when the file is opened in another program. If the file is opened in Microsoft Excel, then the comma is incorrectly interpreted as a delimiter, and the file name is shown in two columns. The other data is moved by one column. (BRKSW-2179)

- For LIF data, when the traces on the Overlay tab are tiled, the text for the units on the Y-axis is truncated. (BRKSW-2341)

- In a report, the full path to the data file is not shown. (BRKSW-3135)

Software History

- If a page range is set in the Print dialog, then the full report is printed. (BRKSW-1923)

- When the glycan analysis parameters are saved to a read-only folder, then no error message is shown. (BRKSW-3511)

Project Management Software

- When a project is deleted in the Project Management software, a message that the project will be deleted from the server is shown. (BRKSW-2012)

- The instrument serial number is not shown in the instrument list. (BRKSW-2175)

Firmware History

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

BioPhase Firmware 1.0

BioPhase firmware 1.0 was released in August 2021.

BioPhase Firmware 1.1

BioPhase firmware 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 used to find capillary centers better. (BRKSW-2163, BRKSW-2169)

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

BioPhase Firmware 1.2

BioPhase firmware 1.2 was released in May 2022.

Changes in this version include:

- Added internal functions to increase performance of the pressure system. (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 in relation to the 280 nm UV filter. (BRKSW-2367)

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

BioPhase Firmware 1.2.4

BioPhase firmware 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 correctly and to make sure that the sample and reagent plates do not move when the door is open. (BRKSW-2427)

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

BioPhase Firmware 1.2.5

BioPhase firmware 1.2.5 was released in August 2022.

Changes in this version include:

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

BioPhase Firmware 1.2.6

BioPhase firmware 1.2.6 was released in January 2023.

Changes in this version include:

- Corrected 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)

BioPhase Firmware 1.4.2

BioPhase firmware 1.4 was released in May 2024.

Changes in this version include:

- Added support for tray sensors to detect trays better. (BRKSW-3034)

- Made the inject with pressure function better. (BRKSW-2612)

- Corrected an issue where the light source was not correctly recorded in the capillary calibration log. (BRKSW-2562)

- Added more detail about how the cartridge coolant level is reported. (BRKSW-2220)

- Changed the behavior of the system when the coolant is low. (BRKSW-2385)

- Made the capillary temperature control better. (BRKSW-2308)

- Added a function to turn off the sample compartment cooler when the system has been idle for 24 hours. (BRKSW-3038)

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 have a global staff of fully-trained service and technical specialists. They can supply answers to questions about the system or any technical issues that might occur. For more information, go to the SCIEX website at sciex.com or use one of the following links to contact us.

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

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

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.

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