PA 800 Plus Pharmaceutical Analysis System

Software Validation Summary

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Introduction 1

This document outlines the new enhancements and fixes to the 32 Karat software, firmware and the PA 800 Plus software, lists the computer configuration and the software development environment, and provides a summary of the software validation report. A summary of how the software supports part 11 of the FDA regulation 21 CFR and a summaries of previous releases of the software and firmware are also included.

Software Overview

32 Karat software and PA 800 Plus software version 10.3 were released November 2018.

Intended Use

The 32 Karat software is intended to be used as a single-point controller for PA 800 Plus systems, and as a data acquisition and analysis system for capillary electrophoresis systems. The PA 800 Plus software interfaces with the 32 Karat software and simplifies routine operation of the PA 800 Plus system. The software history is included in an appendix. Refer to Software History.

Customer Base

The software is installed in commercial, academic and governmental research, analytical services, and quality control laboratories world wide.

General Description

The following general functions are provided:

- **Control:** Bi-directional communication with SCIEX hardware modules is accomplished through a GPIB communications adapter. Software features include automatic system configuration, automatic systems shutdown, configurable status and control, and system suitability.

- **Acquisition:** Data acquisition by the 32 Karat software from SCIEX hardware is accomplished digitally via the GPIB communication bus. There is no analog to digital or digital to analog conversion; the hardware communicates with the PC hosting the 32 Karat software using a GPIB protocol. Software features include real time system status and electropherogram display, audit trails for method and data files and acquisition of three-dimensional diode array data.

- **Analysis:** Features include reliable integration algorithms with graphical or manual optimization, peak identification with reference peaks, up to 10 level linear or nonlinear calibrations, statistical analysis of batch runs and system suitability calculations.

- **Reporting:** Features include a completely user-customizable report or pre-formatted report types, the ability to incorporate objects such as company logos in report templates, and results sign-off.

- **Compliance Features:** Features designed to assist the regulated laboratory in recording and providing documentation for compliance are included in the software. Refer to 21 CFR Part 11 Support.

Support

Installation

The PA 800 Plus and 32 Karat software is pre-installed on the controller that is provided with the system. The software can be installed on an appropriate personal computer as part of the installation of the PA 800 Plus system, but only limited support is available from SCIEX. Installation is performed by a trained Field Service Employee (FSE).

Customer Training

Up to four hours of in-lab training for up two operators is included with the purchase of the PA 800 Plus system. Training is performed by FSEs or product specialists.

Software Updates

From time to time, SCIEX updates the software or firmware to incorporate new features, support new devices, or to implement corrective actions. To the greatest reasonable extent, but at the sole discretion of SCIEX updated versions are compatible with data and method files, instrument and computer hardware used, or created by the immediately preceding version. Such new versions are available to both existing and potential customers. Contact your local sales representative for information.

Technical Support

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

Software License Key Options

A USB flash drive license key for data reprocessing is available. This license allows for data manipulation with the 32 Karat software but does not allow for system control.

Additional Information

The *32 Karat Software Help* is integrated with the software.

Additional literature is available. Refer to sciex.com.

Company Description

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

With over 40 years of proven innovation, SCIEX excels by listening to and understanding the ever-evolving needs of its customers to develop reliable, sensitive and intuitive solutions that continue to redefine what is achievable in routine and complex analysis.

For more information, refer to sciex.com.

Product Development Overview

The 32 Karat software was developed following the processes in the SCIEX Quality Management System. SCIEX maintains procedures to control the development phase activities and interfaces. SCIEX uses a problem reporting process to document, manage, and control all changes resulting from 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 retained 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 verify continuing compliance with system and software requirements, to provide 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

Customer reviews and audits of software development procedures, documentation, and source code for the purpose of complying with regulatory requirements related to software validation or verifying the quality management system are available by contacting the SCIEX Quality Manager.

SCIEX will maintain possession of all documents and their reproductions and may require a non-disclosure agreement to be provided by those requiring 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.

Enhancements and Fixes 2

This section describes enchantments and fixes to the software and firmware in this release, the validated computer configuration, and the software development environment.

The changes to the software and firmware were validated and a summary of the results is included. Refer to Validation Summary.

Fixes and New Features in 32 Karat Software Version 10.3

The following changes were made:

- Support for the Windows 10 Enterprise LTSB 2016 (Windows 10 IoT) with Cybersecurity operating system was added.

- The software was rebranded.

- Unneeded files were removed from the installer, including the following:

  - Agilent 35900 E Add-on for elite

  - Pretreatment

  - GldCnvt32.exe

  - SS420 files

- An issue where relative migration time was reported as 0 has been fixed. The correct value is now reported.

- There is an internal limit to the number of records that can be stored in a data file. This limit can be reached if the data is repeatedly analyzed and saved. A warning has been added when the number of records exceeds the limit. (3798).

- A SCIEX software recovery DVD has been added to the system.

- The methods for capillary isoelectric focusing (cIEF) have been updated.

- New files required for the software qualification have been included in the installer.

Fixes and New Features in PA 800 Plus Software Version 10.3

The following changes were made:

*   Support for the Windows 10 IoT with Cybersecurity operating system was added.

*   The software was rebranded.

*   An issue where the **Autozero** button was always enabled in the Instrument Status and Direct Control window was fixed. The button is now only enabled when the system is connected.

Fixes and New Features in PA 800 Plus Firmware

There were no changes to the firmware.

Validated Controller Configuration

The software has been validated on a Lenovo M720s workstation with the following specifications:

*   8th Generation Intel Core i7-8700 3.2 GHz processor

*   16 GB RAM

*   22 inch wide-screen monitor with True Color and 1680 × 1050 resolution

*   Windows 10 Enterprise LTSB 2016 (Windows 10 IoT) with Cybersecurity

*   500 GB hard drive

*   DVD-RW drive

*   2 serial ports

*   2 Ethernet ports

*   8 USB ports

Note: SCIEX fully validates and supports the controllers supplied with the system. Only limited support is available for customer-supplied computers.

Development Environment

Configuration management system	Tortoise SVN 1.10.0, Build 28176
Source code language	C++ for 32 Karat software C# for PA 800 Plus software
Compilers	MSVC C++ 2003 for 32 Karat software Microsoft VS 2010 C# for PA 800 Plus software
Operating system	Windows 10 Professional (64-bit) and Windows XP
Prototype and simulator	Built-in

Validation Summary

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Validation Performed	Results
Verify installation of the PA 800 Plus software, the 32 Karat software, and the GU Value software and tools, including desktop icons and the end user license.	Pass
Verify that an instrument can be created, that a new method and sequence can be created, and that data can be acquired using the sequence and method. Verify that the correct methods and method templates are installed with the software. Verify the behavior of the software with the license keys. Verify that System Suitability is available for new instruments.	Pass
Verify that the PA 800 Plus system can acquire data from samples prepared using the Fast Glycan Labeling and Analysis Kit. Verify that the data can be analyzed with the GU Value software as described in the *Fast Glycan Labeling and Analysis Kit Application Guide*.	Pass
Verify that the System Administration wizard can be used to add users with different permissions. Verify that the users can create methods and sequences and acquire data based on their permissions.	Pass
Verify that the **AutoZero** button in the PA 800 Plus software is disabled when the PA 800 Plus system is initializing and enabled when the system is connected. Verify that the system can run a sequence and analyze a data file.	Pass
Verify functions in the Direct Control window, including loading samples, moving to the home position, stopping the system during sample injection, moving to a specified vial position, moving the sample trays up and down, viewing detector information, setting the temperature for the sample compartment, turning the lamp on and off, setting the pressure, and turning the system off and on. Verify that the UV detector filter settings cannot be modified in the Direct Control window.	Pass
Verify that the 32 Karat software clears the **For Capillary Fill** check box in the **Inject** dialog for the cIEF method when it is not necessary to fill the capillary. Verify that the software displays a message to the user when this occurs.	Pass
Verify that the following files or folders are not present on the controller: • 35900E driver • Pretreatment folder • GldCnvt32.exe • SS420 files	Pass
Verify that the relative migration time (RMT) calculation is correct.	Pass

Validation Performed	Results
Verify that the following items in the software display the SCIEX logo: • PA 800 Plus software opening screen • the desktop icon • the splash screen • the About box • the Instrument Wizard dialog box • the Method page in the Sequence wizard	Pass
Verify that the PA 800 Plus system uses the same version of 32 Karat software as the CESI 8000 Plus and the P/ACE™ MDQ Plus systems.	Pass
Verify that the PA 800 Plus system works correctly with the Lenovo M720s controller, including running a sequence. Refer to Validated Controller Configuration.	Pass
Verify that the 32 Karat software displays a warning advising the user that additional analysis may risk the stability of the data file when file already contains a large number of analysis results.	Pass
Verify that the system automatically turns on the lamp or laser before starting data acquisition.	Pass
Verify that the software qualification feature (used by SCIEX Field Service Employees) in the 32 Karat software works correctly.	Pass
Verify the performance of the IgG Purity and Heterogeneity Assay kit.	Pass
Verify the performance of the cIEF Peptide Marker kit.	Pass
Verify the performance of the Carbohydrate Labeling and Analysis kit.	Pass

21 CFR Part 11 Support   B

This section describes the 32 Karat software features that support compliance with 21 CFR Part 11.

"N/A" indicates that the requirement does not apply to the 32 Karat software.

Subpart B - Electronic Records

Table B-1 Section §11.10, Controls for closed systems

Text of Regulation	32 Karat Software Feature
(a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.	System validation testing is performed to confirm that the product meets documented user needs.
(b) The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency. Persons should contact the agency if there are any questions regarding the ability of the agency to perform such review and copying of the electronic records.	Standard and custom report templates are supported and can be viewed and printed. Export of data to ASCII and AIA format is supported.
(c) Protection of records to enable their accurate and ready retrieval throughout the records retention period.	Printer drivers for PDF output are installed with the software.
(d) Limiting system access to authorized individuals.	A system administration feature allows user, project, and instrument access control. Logon by domain user or group credentials is supported. Rules for password complexity, aging, and lockout after unsuccessful logon attempts are inherited from the domain. Logon using individual local data system accounts is supported.

Table B-1 Section §11.10, Controls for closed systems (continued)

Text of Regulation	32 Karat Software Feature
(e) Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.	Reports and audit trails inherit a time stamp from the domain or operating system. Once enabled, audit trails cannot be disabled or altered. Audit trails are integral to data, method, and sequence files. The ability to enable audit trails is restricted by permissions that are granted to users by a designated system administrator. The ability to perform actions that result in audit trail update are restricted by permissions that are granted to users by a designated system administrator.
(f) Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.	A designated system administrator can set up to five levels of electronic signature roles, role titles, and signature reasons. Sequence files can be created to control the order of sample acquisition. Analysis parameters are set with methods and can only be edited by users granted permission by a designated system administrator. Data analysis can be performed automatically at the end of data acquisition or manually. Manual analysis can only be performed by users with the permission to do so.

Table B-1 Section §11.10, Controls for closed systems (continued)

Text of Regulation	32 Karat Software Feature
(g) Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.	Individual user permissions can be set for different degrees of access to instruments, projects, and electronic signature authority. Individual user permissions can be set to allow editing of method or sequence files. Network or operating system permissions can be set to prevent deletion of files. User permissions can be set by a designated system administrator to allow electronic signature of a record. All permissions designated by the system administrator can be summarized in a report generated by the 32 Karat software. The original data acquired by the 32 Karat software is never modified. Analysis results are appended to the data file and any previous analysis results are never discarded. and audit trails are automatically maintained. The 32 Karat software verifies connection to a properly configured instrument when it is connected. The system serial number can be viewed in the instrument configuration dialog.
(h) Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.	Data validation with format messages is used for critical input fields. If a data file name is not specified, the software automatically populates the data file name field with a name consisting of the date and time of acquisition. The user may optionally enter a sample ID that is independent of the data file name.
(i) Determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.	The 32 Karat software is developed and maintained by trained and qualified software engineers as required by the SCIEX Quality Management system. Use of electronic signature features is the responsibility of the customer.
(j) The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.	Electronic signature policies are the responsibility of the customer.

Table B-1 Section §11.10, Controls for closed systems (continued)

Text of Regulation	32 Karat Software Feature
(k) Use of appropriate controls over systems documentation including:	
(1) Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.	The 32 Karat software documentation for system operation and maintenance is developed and maintained following the SCIEX documentation control process. Current released revisions of 32 Karat software documentation are available in electronic format (PDF) on the SCIEX website. Refer to sciex.com.
(2) Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.	Revision and change control of SCIEX documents is defined in SCIEX quality procedures. The SCIEX document control procedure defines the sequence by which documents are developed, reviewed, modified, and released. The SCIEX document control procedure requires a history of all document changes for each revision. SCIEX products are developed following the SCIEX product development process. This process defines all deliverable documents for a new product or a revision of an existing product.

Table B-2 Section §11.30, Controls for open systems

Text of Regulation	32 Karat Software Feature
Persons who use open systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, as appropriate, the confidentiality of electronic records from the point of their creation to the point of their receipt. Such procedures and controls shall include those identified in §11.10, as appropriate, and additional measures such as document encryption and use of appropriate digital signature standards to ensure, as necessary under the circumstances, record authenticity, integrity, and confidentiality.	N/A

Table B-3 Section §11.50, Signature manifestations

Text of Regulation	32 Karat Software Feature
(a) Signed electronic records shall contain information associated with the signing that clearly indicates all of the following:	
(1) The printed name of the signer;	Domain credentials are used.
(2) The date and time when the signature was executed; and	The system time from the domain or operating system is used.
(3) The meaning (such as review, approval, responsibility, or authorship) associated with the signature.	The electronic signature feature includes five pre-defined meanings that can be edited. The pre-defined meanings are "I am the author", "Ready for review", "Reviewed", "Ready for approval", and "Approved". Additional meanings can be defined by a designated system administrator.
(b) The items identified in paragraphs (a)(1), (a)(2), and (a)(3) of this section shall be subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout).	Refer to Table B-1.

Table B-4 Section§11.70, Signature/record linking

Text of Regulation	32 Karat Software Feature
Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.	Electronic signatures are linked to records and cannot be deleted, copied, or otherwise transferred to falsify an electronic record.

Subpart C-Electronic Signatures

Table B-5 Section §11.100, General requirements

Text of Regulation	32 Karat Software Feature
(a) Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.	The electronic signature uses domain credentials.
(b) Before an organization establishes, assigns, certifies, or otherwise sanctions an individual's electronic signature, or any element of such electronic signature, the organization shall verify the identity of the individual.	The electronic signature uses domain credentials.
(c) Persons using electronic signatures shall, prior to or at the time of such use, certify to the agency that the electronic signatures in their system, used on or after August 20, 1997, are intended to be the legally binding equivalent of traditional handwritten signatures.	N/A
(1) The certification shall be submitted in paper form and signed with a traditional handwritten signature, to the Office of Regional Operations (HFC-100), 5600 Fishers Lane, Rockville, MD 20857.	N/A
(2) Persons using electronic signatures shall, upon agency request, provide additional certification or testimony that a specific electronic signature is the legally binding equivalent of the signer's handwritten signature	N/A

Table B-6 Section §11.200, Electronic signature components and controls

Text of the Regulation	32 Karat Software Feature
a) Electronic signatures that are not based upon biometrics shall:	
(1) Employ at least two distinct identification components such as an identification code and password.	The electronic signature feature uses domain credentials.

Table B-6 Section §11.200, Electronic signature components and controls (continued)

Text of the Regulation	32 Karat Software Feature
(i) When an individual executes a series of signings during a single, continuous period of controlled system access, the first signing shall be executed using all electronic signature components; subsequent signings shall be executed using at least one electronic signature component that is only executable by, and designed to be used only by, the individual.	The 32 Karat software allows signing of multiple records at the same time using all electronic signature components. All signing of records requires use of all electronic signature components.
(ii) When an individual executes one or more signings not performed during a single, continuous period of controlled system access, each signing shall be executed using all of the electronic signature components.	All signing of records requires use of all electronic signature components.
(2) Be used only by their genuine owners; and (3) Be administered and executed to ensure that attempted use of an individual's electronic signature by anyone other than its genuine owner requires collaboration of two or more individuals.	N/A
(b) Electronic signatures based upon biometrics shall be designed to ensure that they cannot be used by anyone other than their genuine owners.	N/A

Table B-7 Section §11.300, Controls for identification codes/passwords

Text of the Regulation	32 Karat Software Feature
Persons who use electronic signatures based upon use of identification codes in combination with passwords shall employ controls to ensure their security and integrity. Such controls shall include:	
(a) Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.	N/A
(b) Ensuring that identification code and password issuances are periodically checked, recalled, or revised (e.g., to cover such events as password aging).	The rules for password aging are inherited from domain credentials. Identification codes are not applicable.

Table B-7 Section §11.300, Controls for identification codes/passwords (continued)

Text of the Regulation	32 Karat Software Feature
(c) Following loss management procedures to electronically deauthorize lost, stolen, missing, or otherwise potentially compromised tokens, cards, and other devices that bear or generate identification code or password information, and to issue temporary or permanent replacements using suitable, rigorous controls.	N/A
(d) Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.	The 32 Karat software supports notification of the system administrator after a number of failed logon attempts. Identification codes are not applicable.
(e) Initial and periodic testing of devices, such as tokens or cards, that bear or generate identification code or password information to ensure that they function properly and have not been altered in an unauthorized manner.	N/A

Software History C

32 Karat Software Version 9.0

Version 9.0 was released in December 2008.

The following changes were made:

- The software supports only PA 800 *Enhanced* systems.

- The PA 800 Plus software has been added. Refer to PA 800 Plus Software Version 1.0.

- Method, sequence, data, and template files from previous versions can be opened in this version of the software. After an older file is opened with version 9.0, it cannot be opened again with a version before 9.0. New files created in version 9.0 cannot be opened in previous versions.

- The design takes advantage of Windows XP environment and uses the Window XP look and feel. This includes Windows XP styling for tool bars, dialogs, and icons, and a navigation pane to access software functions.

- The user interface layout allows greater graphical consistency. This release includes:

  - New default color scheme

  - More consistent menu behavior

  - An improved user interface for graphical integration

- The on-screen help for certain functions has been reformatted and expanded. Several functions have additional messages in the data window or in the status bar, and dialogs with instructions have been added to some functions.

- The export feature now includes a customized graphical depiction of the electropherogram in a scalable graphics format (.wmf).

- New electropherogram annotations have been added: Group #, Area, Area Percent, Start Time, End Time, ESTD Concentration, ISTD Concentration, and NORM Concentration.

- A new system administration report utility showing project settings, users and permission, instrument configurations, and enterprise-wide settings has been added.

- A new sequence table report that can print sequence table information in a more condensed fashion has been added. This includes a format that limits the width of report to one page. The user can also select columns, change column widths, and print columns separately or as a group.

- Support for multi-level bracketed calibrations has been added.

- The ability to stop an individual run without stopping the sequence has been added.

- Peak or system-wide custom parameters can now be specified on a run-by-run basis. These parameters are not used in any intrinsic calculations, but are available as graph annotations, for export, in custom parameters, and in advanced reports.

- To improve the speed of connection to large domains, you can now enter a name to quickly select a user.

- For a PDA detector, a reference channel for subtraction from selected multi-electropherogram data can be specified.

- System administrators can now define reasons for audit trails while setting up audit trails. Support for customized reasons has also been added.

- The PA 800 *Enhanced* system can perform longer capillary rinses at up to 100 psi. Click **For Capillary Fill** on the 32 Karat software Inject screen to access this feature.

- This release identifies injections as sample events when performing an injection instead of a rinse, thereby simplifying reports and sample incrementing the sequence.

- Suggestions for resolving errors have been added to error messages.

PA 800 Plus Software Version 1.0

Version 1.0 was released in December 2008.

The PA 800 Plus software interfaces with the 32 Karat software and simplifies routine operation of the PA 800 *Enhanced* system.

32 Karat Software Version 9.1

Version 9.1 was released in April 2009.

The system requires firmware version 9.1.

The following changes were made:

- Support for the PA 800 Plus Pharmaceutical Analysis System was added.

- The PA 800 Plus software was updated. Refer to PA 800 Plus Software Version 1.1.

- The 32 Karat software help was updated, broken links were fixed, and content was added.

- Error messages were updated to present more information.

- The LIF Calibration wizard was made more reliable.

- Training videos and shortcuts were added.

PA 800 Plus Software Version 1.1

Version 1.1 was released in April 2009.

The following changes were made:

- The PA 800 Plus software help was updated with more content.

- Additional colors for traces were added to the Run Task graph.

- A video viewer was added and training videos were included.

- Cosmetic changes have been made.

- Fixes to low-probability software errors were made.

32 Karat Software Version 10.1

Version 10.1 was released in January 2013.

The system requires firmware version 10.2 or later.

The following changes were made:

- The PA 800 Plus software has been updated. Refer to PA 800 Plus Software Version 10.1.

- Support for the Windows 7 32-bit operating system has been added.

- The PA 800 Plus icon and wizard images have been updated.

- The software desktop icon has been changed.

- An abnormal termination issue caused by mismatching Caesar option instrument configuration has been fixed.

- The firmware internal settings have been made available through the user interface and are password protected.

- A warning dialog has been added so that if an instrument is configured with more than one detector, a warning dialog appears when a data file from that instrument is opened.

- PeakAreaPercent.dll has been added. This DLL allows the user to specify the peaks and other parameters for the area percent calculation. The command line format is:

  `P{N}{n1,n2…} {Tt1} {REG} {%}`

  where:

  `P{N}{n1,n2…}` is the list of the peaks to be used for the calculation. Use named peaks (`PN`) or detected peaks (`P`). Peaks to be excluded are listed as individual peaks (`n1,n2...`) or a range of peaks (`n1-nx`). If there are no excluded peaks, then all peaks are included.

  `{Tt1}` is the trace channel number to be used for the base area calculation. If a trace channel is not specified, then each trace channel uses its own base area.

  `{REG}` specifies the area is to be used in the peak area calculation: corrected area (`none`) or regular area (`REG`).

  `{%}` reports the results as a percentage (for example 25.6 instead of 0.256). If this field is not specified, then the result is a decimal value.

- PeakSignalToNoise.dll has been added. This DLL allows the user to specify the range and interval to be used for the calculation of signal-to-noise. The command line format is:

```
ASTM -a {start time} {stop time} {time interval}
RSM -r {start time} {stop time} {time interval}
6 Sigma -a {start time} {stop time} {time interval}
```

where:

{start time} is the specified time interval start time, in minutes

is the specified time interval stop time, in minutes

{time interval} is the noise scanning time interval, in seconds

- Support for the PA 800 Plus and Generic System instrument types has been added.

- Low-pressure failure issues with the PA 800 Plus system have been resolved.

- The PA 800 Plus system now beeps every 5 seconds if the sample cover is opened when a method is running or the system is under direct control.

- The PA 800 Plus system now opens a warning dialog when the photodiode array detector board is not installed. The user can continue operating the system without issues.

PA 800 Plus Software Version 10.1

Version 10.1 was released in January 2013.

Note: Beginning with this release, the PA 800 Plus software version number has been changed to be the same as the 32 Karat software.

The following changes were made:

- The instrument serial number has been integrated in the instrument configuration in the software.

- A field to allow the location for the run sequence output file to be selected has been added to the Sample/Vial page.

- The PA 800 Plus software will generate a configuration error message when trying to connect to a non-PA 800 Plus system.

- A **Show Desktop** button has been added to allow viewing of the desktop.

- A feature for a scheduled run has been added to allow a method or sequence run to be started at a later time.

- A vial position indicator has been added to the Instrument Status page.

32 Karat Software Version 10.2

Version 10.2 was released in December 2014.

The system requires firmware version 10.2 or later.

The following changes were made:

- Support for the P/ACE™ MDQ Plus Capillary Electrophoresis System was added.

- The software brand was changed to SCIEX.

- The copyright was changed to AB Sciex Pte. Ltd.

32 Karat Software Version 10.2.32

Version 10.2.32 was released in March 2018.

The following changes were made:

- Support for the Microsoft Windows 7 64-bit operating system with SP1 was added.

- Data processing features for the C100HT Biologics Analyzer system were added.

- Support for off-line processing for the Windows 7 (64-bit) operating system was added.

Firmware History D

Firmware Version 10.1

Version 10.1 was released in August 2012.

The following changes were made:

- The analog output from the LIF detector has been scaled by a factor of 8 to prevent clipping at higher RFU values.

- The firmware was modified to provide the following information to the console software:

    - The system serial number

    - The firmware checksum, used to make sure that the proper version of firmware is installed on the system.

    - EEPROM settings and debugging parameters

- The firmware has been modified for RoHS hardware compliance.

- When using LIF detection, a delay between when the system is turned and when the laser is turned on has been added. Only after the lasers have been turned on, is the PMT gain set. The delay helps reduce the occurrence of the "PMT background too high" condition.

Firmware Version 10.1.45

Version 10.1.45 was released in February 2014.

The following changes were made:

- A CEMS identifier was added to the 32 Karat software banner.

- An EEPROM setting was added to control on and off for pressure line blow out at method start.

- An EEPROM calibration setting was added to allow for adjusting current offset for the calculation of returned current.

- A timeout was added to loop "wait()" loop when motors are running.

- Logic was added to synchronize the various boards at sample injection.

Firmware Version 10.2.2

Version 10.2.2 was released in October 2014.

The following changes were made:

* The logic for opening relay 2 was changed so that the relay only opens automatically if it was previously closed automatically.

Firmware Version 10.2.3

Version 10.2.3 was released in March 2015.

A feature to allow the amplitude of the LIF detector analog output to be configured by a SCIEX Field Service Employee was added.

Firmware Version 10.2.3R

Version 10.2.3R was released in March 2015.

The firmware was updated to operate with new RoHS-compliant system boards. No enhancements or other modifications were made.

Firmware Version 10.2.5R

Version 10.2.5R was released in September 2016.

Note: Firmware version 10.2.4R was not released.

An issue where the baseline had random dips while collecting data with a UV detector with simultaneous pressure was fixed. This issue was a side effect of changing a component on a system board for RoHS compliance. The control parameters for the component have changed so that data collection functions as it did before changing the component. This revision has no other impact on system performance.

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