Impact Analysis for Software changes in OpenLAB CDS A.01.04

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1. Document Purpose

This document provides an overview of the new functionality and software changes included in the product revision specified above.
This document may be used to assess the extent of the software changes and determine the appropriate delta qualification and acceptance test activities according to the application-specific requirements of the end-users in their respective work environment.

2. Overview of the Software Release

Revision A.01.04 is a minor release of the OpenLAB CDS software. This release covers both the ChemStation and EZChrom Editions of the product. It adds a few selected new features.

3. Scope of the Software Release

A.01.04 includes new and changed functionality improving the usability of the application in multiple areas. This revision of OpenLAB CDS introduces for example support for OpenLAB Data Store A.01.01, updates to Intelligent Reporting, and support of new instrument components.

3.1 ChemStation Edition

Major changes made in OpenLAB CDS ChemStation Edition revision C.01.04 support for OpenLAB Data Store, introduction of a Method and Sequence Queue and data analysis improvements.

3.2 EZChrom Edition

Major changes made in OpenLAB CDS EZChrom Edition revision A.04.04 include support for OpenLAB Data Store and data analysis improvements.

3.3 Master Installer

Major changes made in Master Installer include automatic upgrade installations, introduction of an OpenLAB CDS repair wizard and support of scripted installation.

3.4 OpenLAB Control Panel / OpenLAB Shared Services

Major changes in OpenLAB Control Panel / OpenLAB Shared Services include enhancements to the licensing user interface.

3.5 Documentation

An html-page allows users and administrator easier access OpenLAB documentation and manuals.

3.6 Intelligent Reporting

Major changes in Intelligent Reporting include user-entered report parameters, partially protected templates, double row tables, document maps and export of report as DOC and TXT.

3.7 Instrument Support

Major changes in the area of instrument support include new LC drivers revision A.02.05, Support for the 7650 Injector with 78xx GCs (G4567A), new menu item to extend run for 68xx GC, GC Tray user interface enhancements (RC.NET only), GC method audit trail and method resolution audit trail, method download options at instrument startup, and support for Waters Acquity.

3.8 OpenLAB Data Analysis A.01.01

Support for OpenLAB Data Analysis A.01.01 was introduced post-release of OpenLAB CDS A.01.04 (in November 2012).

With OpenLAB Data Analysis, Agilent introduces a new data analysis package. The first release is specially designed for data analysis in Chemical and Petrochemical laboratories and Hydrocarbon Processing Industry. OpenLAB Data Analysis features intuitive operation, easy sample review and fast reprocessing of large sets of chromatographic data.

OpenLAB Data Analysis is a new data analysis product for LC and GC data that can be used together with either OpenLAB CDS ChemStation Edition or OpenLAB CDS EZChrom Edition.

4. Functional Areas affected by the Software Release

This section describes all features and changes in the software release grouped by functional areas. For definition of classification codes please see Appendix A of this document.

4.1 ChemStation Edition

Feature	Description	Classification
Support for OpenLAB Data Store A.01.01		
OpenLAB CDS ChemStation Edition and OpenLAB Shared Services now support the use of OpenLAB Data Store is a central repository providing central Storage with security for small to medium sized labs and 21 CFR 11 compliant e-signatures, file versioning and audit trail. This includes the following features:	OpenLAB Data Store A.01.01 is a new product. No impact on existing functionality.	Minor

• User Authentication • Roles & Privileges • Generic Projects • User and Permission Management • Report History • Configurable Data Handling • Load data from Data Store • Save data to Data Store • Load/Save from/to Data Store - Master Methods and Sequence Templates • Load/Save from/to Data Store - Intelligent Reporting and other files: • Manual Data Store file upload / download		
Data Analysis Improvements		
<u>European Pharmacopeia:</u> Calculation of relative retention time, Resolution, Number of theoretical plates, S/N ratio, and Peak-to-valley ratio according to European Pharmacopeia and Japanese Pharmacopeia and reporting of these values using Intelligent Reporting.	New calculations according to European Pharmacopeia have been added.	Minor
<u>Area Summing:</u> Enhancement of existing "Area Summation" functionality allowing users to integrate over a cluster of peaks by setting an interval and define a baseline for the entire peak cluster. The RT of the area sum is time center point of time interval.	New timed integration events are available for enhancing area summing capabilities. The existing integration events have not been changed.	Minor
<u>Peak Performance:</u> Ability to	This feature extends the existing peak	Minor

calculate peak performance characteristics for a given peak from the Data Analysis view.	performance calculations to unidentified peaks.	
Other new Features and Enhancements		
Method and Sequence Queue: Single Sample Queuing: Single Sample can now be added to the Easy Sequence Queue. • Enhanced options for single run data file naming Run Method / Run Sequences are submitted to the queue.	With this feature, single runs are handled via the queue which allows for e.g. scheduling several runs or pausing the queue.	Minor.
Distributed System (AIC) - Privilege for session take over: Only users with the privilege "Take over ChemStation Remote session" have the ability to take over an instrument session.	This privilege did not exist in the previous revision, every user could take over the session. During the upgrade, the new privilege "Take over ChemStation Remote session" is automatically granted to the Roles "ChemStation Administrator" and "ChemStation Lab Manager". Only users belonging to one of these roles will have the privilege by default.	Major
Harmonization of tokens for report and data file names.	This feature affects the Sample Information dialog. The previous options for Prefix/Counter or Manual file naming are now available via new options in a combined redesigned field. With this feature it is also possible to create reports with unique name.	Minor
Method Audit Trail for instrument changes.	This affects all methods where Method Audit Trail is switched on. Additional entries are written for each change of instrument parameters. Any report containing the method parameters will therefore also be longer and might take longer time to be generated.	Major
Please refer to the Software Release Bulletin for OpenLAB		Minor

CDS ChemStation Edition for a list all fixes and enhancements in OpenLAB CDS ChemStation Edition revision C.01.04. The Software Release Bulletin can be found on the OpenLAB CDS installation media on *\Disk2\Support\History\C.xx.xx\ C.01.04\M83xxAA-SRB.*		

4.2 EZChrom Edition

Feature	Description	Classification
New Product Introduction - Support for OpenLAB Data Store A.01.01 OpenLAB CDS EZChrom Edition and OpenLAB Shared Services now support the use of OpenLAB Data Store is a central repository providing central Storage with security for small to medium sized labs and 21 CFR 11 compliant e-signatures, file versioning and audit trail. EZChrom/ Data Store integration is tightly integrated on the file level	EZChrom platform was extended to add support for Data Store. Existing support for file based system or ECM based system was not affected.	Minor
ASCII Sequences: ASCII sequences now support the coding of injection volumes in the sequence to use the volume from the method.	The ASCII format was extended to allow sequence developers to instruct data system to use injection volume from method (for supported drivers). This is additional functionality and existing format is not modified.	Minor
European Pharmacopeia Signal/Noise Calculations: The built in signal to noise custom parameter has been updated to	New calculations according to European Pharmacopeia have been added.	Minor

reflect new European Pharmacopeia calculation requirements regarding baseline drift corrected noise calculation.		
Please refer to the Software Release Bulletin for OpenLAB CDS EZChrom Edition for a list all fixes and enhancements in OpenLAB CDS EZChrom Edition revision A.04.04. The Software Release Bulletin can be found on the OpenLAB CDS installation media on \Disk4\Support\SSB\M82xxAA-SRB.		Minor

4.3 Master Installer

Feature	Description	Classification
Master Installer now supports installation on top of an existing OpenLAB CDS ChemStation Edition C.01.01, C.01.02, C.01.03 or EZChrom Edition A.004.02, A.04.03 system resulting in an automatic upgrade.		Minor
An OpenLAB CDS repair wizard allows repairing corrupted or missing installation files.		Minor
Support of scripted installation of OpenLAB CDS clients and AICs. An XML file may be exported at the end of installer parameter definition which can then be used to install an identical configuration on other machines.		Minor

4.4 OpenLAB Control Panel / OpenLAB Shared Services

Feature	Description	Classification
Enhancements to the Licensing User Interface: New options in the administration licensing section allowing an administrator to link to the SubscribeNet web site, Save the MAC Address to a text file, copy the MAC Address to the clipboard and remove installed licenses.		Minor

4.5 Documentation

Feature	Description	Classification
An html-page allows users and administrator easier access OpenLAB documentation and manuals.	This feature provides the user with easy access to the user documentation.	Minor

4.6 Intelligent Reporting

Feature	Description	Classification
User-entered report parameters: Allow a Report Template creator to create/edit report parameters as part of report properties. Allow user to enter values report parameters during report rendering which can be displayed in the report and used in the expression edition (for e.g. calculations, sorting, and filtering)		Minor
Partially protected templates: Allow the template author to		Minor

lock/unlock a report item or groups of report items in a template. A new user privilege allows access to lock/unlock function. A user without the privilege will not be able to modify the locked report item(s) – except moving them		
Double row table: Allow to design tables with two headers and two detail rows. Tables can include summary calculations for both detail rows		Minor
Document map: Automatically create a TOC of long reports (e.g. sequence summary)		Minor
Export report as DOC and TXT: Allow users Word (.doc) and Text (.txt) export of reports both automatically and interactively (from Review View and Report Template Editor).	This feature is available in ChemStation Edition, only.	Minor
Improved handling of page sizes		Minor
New feature to document template design in the form of a “design report”		Minor
Enhancements to the signal plot (e.g. turn grid off, nicer signal colors, pen width for signals)		Minor
Fraction results reporting (markers in signal plot and results table)		Minor
Custom expressions for limit lines in a chart		Minor
“No rows” tag for tables		Minor
Change column width for matrix static columns		Minor

UI design changes		Minor
Improvements in method reporting (better filtering)		Minor
Solving memory issues		Minor

4.7 Instrument Support

Feature	Description	Classification
Updated LC Drivers revision A.02.05		
Improved status dashboard for enhanced control and interaction 1290 Quat Pump (G4204A) 1220 Infinity LC with DAD (G4294B) Flexible Cube (G4227A)(Standalone Driver) Universal Interface Box II (G1390B)	The new functionality does not affect any other instrument type.	Minor
Updated Agilent GC Drivers		
Support for the 7650 Injector with 78xx GCs (G4567A) New menu item to extend run for 68xx GC GC Tray user interface enhanced (RC.NET only) Method Audit Trail and Method Resolution Audit Trail	The new functionality does not affect any other instrument type. For instrument types supported in previous revisions, the new driver includes defect fixes as described in the SRB.	Minor
Method Download Options at Instrument startup		
Upon instrument startup, users are given a choice: a) download the ChemStation method to the instrument, b) upload the instrument method to ChemStation or c) create a new method from instrument method. A differences viewer highlights the differences between the	This feature is available in ChemStation Edition, only. The new feature provides advanced options for handling differences between instrument method and last loaded method in ChemStation.	Major

ChemStation method and the instrument method.		
Support for Waters Acquity		
Support for Waters Acquity drivers was introduced post-release of OpenLAB CDS A.01.04 (in October 2012). The Waters Acquity driver allows the control of the following Waters Acquity and Acquity H-Class modules in OpenLAB CDS ChemStation Edition C.01.04 and C.01.05 and EZChrom Edition A.04.04 and A.04.05: • ACQUITY Sample manager • ACQUITY Binary solvent manager • ACQUITY Column manager (CM) • ACQUITY H-Class Sample manager FTN • ACQUITY H-Class Quaternary solvent manager • ACQUITY H-Class Column manager (CM-A) • ACQUITY H-Class Column manager AUX • ACQUITY and ACQUITY H-Class Sample organizer • ACQUITY and ACQUITY H-Class TUV detector • ACQUITY and ACQUITY H-Class PDA detector • ACQUITY and ACQUITY H-Class PDA eLambda detector • ACQUITY and ACQUITY H-Class Fluorescence detector	The new functionality does not affect any other instrument type.	Minor

• ACQUITY and ACQUITY H-Class ELSD detector		

4.8 OpenLAB Data Analysis A.01.01

Feature	Description	Classification
With OpenLAB Data Analysis, Agilent introduces a new data analysis package. The first release is specially designed for data analysis in Chemical and Petrochemical laboratories and Hydrocarbon Processing Industry. OpenLAB Data Analysis features intuitive operation, easy sample review and fast reprocessing of large sets of chromatographic data. OpenLAB Data Analysis is a new data analysis product for LC and GC data that can be used together with either OpenLAB CDS ChemStation Edition or OpenLAB CDS EZChrom Edition.	OpenLAB Data Analysis is a separate application installed via Master Installer. Direct interaction with ChemStation (i.e. automatic processing with OpenLAB Data Analysis during data acquisition) is only possible via a macro in the run-time checklist of the method. During processing, OpenLAB Data Analysis does not alter any ChemStation raw data or methods, but only writes new results into the .acaml file. The content of the .acaml files is displayed in the ChemStation in the Review View only. Therefore if ChemStation data was processed in OpenLAB Data Analysis, there is no impact on the results displayed in ChemStation. Only in the Review View, there will be no results available until the data is reprocessed in ChemStation again.	Minor
	OpenLAB Data Analysis is supported on Windows 7 SP1 (32bit and 64bit) only. It requires RC.NET Framework 4.5. It is supported on stand-alone workstations without central data storage only. The software does not provide features for compliance with regulations like GLP or 21 CFR Part 11. There are no qualification services available.	Major

5. Recommended re-qualification Activities

The Agilent Product Development Lifecycle for Software includes an intensive test of any new developments as well as regression testing of already existing functionality. Due to our process driven development and testing the impact of implementing these changes on existing software installation is considered to be of low risk.

Agilent recommends the following re-validation activities after installation of the release specified in this document:

	YES	NO
Verify the Software Installation using the Agilent Software IQ	X	
Use change control with customer's revalidation plan	X	
Review the new or changed functionality of the release and revalidate the affected workflows based on the intended use of the software.	X	
Execute complete system revalidation		X

Appendix A: Classification Codes of Software Changes

The following classification codes for software changes are used in this document:

Classification	***Definition***
Major	Software changes with an appreciable effect on the operational characteristics and reliability of the product and its fitness for the intended purpose, relative to the previous version. Major software changes typically warrant full re-qualification of the system or the execution of detailed acceptance tests at least in the affected areas. Examples for major software changes in chromatography data systems are modified or new algorithms, calculation changes, storage format changes for central system functions such as integration or quantification of chromatographic signals.
Minor	Changes with no appreciable negative effect on the operational characteristics and reliability of the product and its fitness for the intended purpose relative to the previous version. Minor software changes typically result in one or multiple modified system files. The installation of an update or service release containing minor software changes typically requires the execution of the updated qualification protocols specified and provided by the supplier.