celsis®
Release Notes

Celsis® Software V5 Revision 01

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Revision	Effective Date	Reason for Revision
01	See Effective Date in Footer	Document Created

Dear Valued Customer,

Charles River strives to provide the highest level of support to our global customers by delivering industry-leading scientific and technological advances. As part of our ongoing effort to better serve our customers, we are pleased to inform you of updates to our Celsis® software.

Release Notes

The software for Celsis Advance II™ and Celsis Accel® instruments has been updated to **version 5**, and incorporate the following changes and new features, described in **Table 1**:

Table 1 – Changes and New Features in Celsis® Software V5

Change	Description
Data Storage	Postgres database (15.3) is utilized in version 5, so data will no longer be stored using flat files (e.g., .wkl, .rpt, etc.).
Supported Languages	Version 5 supports the following languages and translations: ▪ English ▪ French ▪ German ▪ Spanish ▪ Italian ▪ Portuguese (Brazilian)

User Interface	An updated user interface designed to improve user experience with customizable configurations. The new interface includes:
	▪ Login Page
	▪ Main Menu
	  ▪ Workload
	  ▪ Results
	  ▪ Reports
	  ▪ Import
	  ▪ Export
	▪ Tools/Administration
	  ▪ Settings
	  ▪ Audit Trail
	  ▪ Edit Password
	▪ Layout
	  ▪ Smart Feed
	  ▪ Status Pane
	  ▪ Navigation Bar
	▪ Information
	  ▪ About
	▪ Account

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	▪ Lock Software ▪ Exit ▪ Instrument Dashboard ▪ Navigation Bar ▪ Startup ▪ Controls ▪ Workload ▪ Shutdown ▪ Manual Control ▪ Maintenance ▪ Smart Feed ▪ Status Pane ▪ Active Display ▪ Active Status
Instrument Management	Version 5 currently supports the Celsis Accel® and Celsis Advance II™ instruments as well as a handheld barcode scanner capable of reading 2D barcodes. Individual instruments and barcode scanners are identified in the software by creating instrument and scanner records containing identification and configuration details which are managed in the new Instrument database.
Assay and Measurement Definitions	Version 5 uses a combination of Measurement Definitions, Assay Definitions, and Sample records to determine the protocols used to complete and interpret the results for each workload. The are set by default depending on the reagent technology used. A Measurement Definition contains one (1) Measurement Protocol and a set of user-configured variables for the selected protocol. These variables determine the timings, volumes, and speeds of the selected protocol as well as the length of time the photomultiplier tube (PMT) will take measurements. A Measurement Protocol defines the order of operations for instrument movements including how many and which injectors to use in the assay. Measurement Protocols are predefined and may not be edited by users. However, Measurement Protocols do contain variables such as the timings, volumes, and speeds which are configured when creating a Measurement Definition.

	An Assay Definition includes one (1) Measurement Definition and contains configuration details for setting the adjudication logic used in determining positive or negative results as well as the number of replicates to expect for each Sample defined in the workload.
Sample Database	The Sample Database is used to store, retrieve, and manage Sample records. A Sample is a digital record of the sample or material to be assayed and includes identification, classification, and calculation details such as the name, type, and calculation method to be used.
Smart Tracking	Selected during installation by enabling Smart Tracking, the system will automatically track the Reagents and accessories scanned into the Accessory Database. The system will also enforce Use by and Expiration dates and track the number of uses for each reagent. If Smart Tracking is disabled (during installation), also referred to as Legacy Mode, the user will be asked to enter volumetric data at any stage when reagents or accessories are dispensed. The Accessory Database is part of the optional Smart Tracking feature. When the feature is turned off, the Accessory Database is hidden and not accessible in the user interface. Accessory Types are reagents or other consumables used when performing Startup, Daily Control, Workload, or Shutdown procedures. The system includes preconfigured Accessory Types: ▪ Celsis LuminASE® ▪ Celsis LuminAMP® ▪ Celsis LuminEX® ▪ Celsis LuminATE® ▪ Washing Solution ▪ Rinsing Solution ▪ Reconstitution Buffer ▪ ATP Positive Control ▪ Reagent 1 (Monthly Maintenance and Cleaning) ▪ Reagent 2 (Monthly Maintenance and Cleaning) ▪ Reagent 3 (Monthly Maintenance and Cleaning)

User Management, Including Active Directory	The User Management feature allows administrators to manage user accounts and configure access to features and functionality in the Celsis software by configuring Users and Privilege Groups. ▪ A User record represents a profile of each user in the software including unique identifiers and a Privilege Groups assignment. Celsis offers a robust User Management feature. Within User Management administrators will configure User records for each user of the software. User records contain login account details, unique identifiers for the user, as well as an assigned Privilege Group to manage user access to application features and functionality. ▪ A Privilege Group record is a set of privileges controlling access to specific system features and functionality assigned to one (1) or more User records. When creating new User records, administrators must create Local account types one at a time. However, administrators may use the Import function to create multiple Windows account type records at a time by choosing to import users from a specific Windows Group or from multiple Groups using the Filter option.
Digital Signature	The Digital Signature feature allows users to digitally sign Workload reports. Administrators must configure Digital Signature Roles. Roles are configured by navigating to Settings in the main menu and then selecting Digital Signature Configuration from the drop-down. There are three (3) Digital Signature Role Levels: Level 1 (L1), Level 2 (L2), and Level 3 (L3). Each level represents a separate layer of review and a separate signature which may be added to a report. Not all levels must be used but no new or additional levels may be added; three (3) levels are the limit.

	There are three (3) Digital Signature Role Names: Analyst, Reviewer, and Quality Control. The Role Name is linked with the Role Level; Analyst is linked with the L1 level, Reviewer with the L2 level, and Quality Control with the L3 level. While administrators may not change this linkage, they may change the Role Names themselves. Finally, each Digital Signature Role (Name and Level) must be assigned at least one (1) Signature Meaning but may assign multiple meanings. When users walk through the process of digitally signing reports, the system will prompt them to select a Signature Meaning.
Lock Management	When a record is opened in one user session, the system "locks" the record from being opened by another user until the original user closes the record. This is to prevent users from unintentionally overwriting another user's changes. However, in some instances it may be necessary to release this system lock on the record manually; for example, if the original user's computer crashes or a user locks their session with the record still open. In these instances, administrators and other users assigned the "Manage Locks" privilege may access the lock management feature.

Global Settings	In Global Settings, users with the appropriate privileges can modify the various settings including:
	
	▪ General
	  ▪ This portion of the Global Settings applies to where exported files are saved, the file format and name of the exported files, and options on how changes to signatures and Global Settings are documented.
	▪ Security
	  ▪ Password Timeout – Days
	  ▪ Password History
	  ▪ Login Timeout – Minutes
	  ▪ Password Attempts

	▪ Password Warning – Days ▪ Server Backup Details ▪ Backups Enabled ▪ Next Backup ▪ Prefix ▪ Backup Destination ▪ Backup Now ▪ Report ▪ Report Logo ▪ Lab Name
Procedures	Before beginning a Workload, users must perform a Startup procedure to load the reagent technology and open a new session then perform a Daily Controls procedure to qualify the instrument and reagent technology for the upcoming Workloads. Once the Startup and Daily Controls procedures are complete, users may perform Workloads. To change Measurement Definitions, users will need to reperform Startup and Daily Controls. To close the current session for the day, users will complete a Shutdown procedure. ▪ The Startup procedure runs wash and rinse solutions through the instrument's injector system, then primes the injectors with the appropriate reagent(s) in preparation for any upcoming Workloads. ▪ The Daily Controls procedure serves to qualify the instrument in preparation for any upcoming Workloads; control samples are loaded into the instrument and tested with the results stored for reference. ▪ The Workload procedure is where the actual testing of samples occurs. The Reagent Technology loaded during Startup and validated during Daily Controls is used to run assays set up by users with the associated privileges. ▪ The Shutdown procedure is like the Startup procedure but in reverse: reagent bottles are removed from the instrument, then rinse and

	wash solutions are run through the instrument's injector system.
Workloads and Results	After a workload completes, the tab of results from the workload remains open in the Work Area providing users a chance to review or print the results immediately. After closing the tab, workload results are accessed through the Workload Explorer. To search or filter Workload results, first open the Workload Explorer by selecting Results from the main menu, in the Workload section. C collection of filters allows users to search for Workloads by date range, Workload name, and keywords. Users may also view all Workloads or filter between user Workloads, imported Workloads, and Workload templates.
Audit Trail	The Audit Trail supports traceability by recording specific user and system actions. The Audit Trail allows user to search, or filter based on Date/Time, Full Name, Instrument Serial Number, Audit Details and Search Criteria/Keywords. Users may print a report for a set of Audit Trail records. The report will include all columns and rows of results displayed in the table of the Audit Trail dialog and will exclude any hidden columns.
Import Legacy Workload Files	Version 5 supports importing legacy workload files. By selecting Import from the Main Menu under Workload, this will open the import dialog and the user can select the folder containing the legacy workload files or select Choose Workload folder to open a Windows file explorer window.
Database Backup and Restore	There are two (2) options for creating and scheduling database backups: Backup Now and Automated Backup. Backup Now allows users to create a single backup file at any time. Automated Backup is configured by setting values for specific Global Settings options. To perform a Database Restore, the user will need to start from the Login screen. In the top right, click Settings and select Connect/Restore Database. In the window that opens, select Browse. Select the folder containing the backup file in the file explorer

	and click Open. Then click Restore to restore the Database.

Impact

Installing Celsis® Software V5 does not impact the performance of the Celsis Advance II™ and Celsis Accel® system, hardware system calibration, validation, or calibration. Updates are downward compatible not upward, meaning the latest version 5 can read old data (using the 'Import Legacy Workload Files' feature) while newly formatted data cannot be read on old versions (e.g., v 4.0.6 or earlier).

Software Validation

- Project name: Celsis® 5.0
- Project Number: MSCHA-Celsis-5.0

There are many factors that contribute to our overall decision-making process regarding software updates, including rapid advancements in technology and the constantly evolving standards of care and maintenance. We continually strive to incorporate advancements to better serve our customers and provide solutions that ultimately put consumer and patient safety first. If you should have any questions, please contact the Charles River Technical Services team at Celsis-Support@crl.com.

Sincerely,

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