C41933AJ
December 2023

Vi-CELL BLU Software Validation Guide

Description

Identification

Vi-CELL BLU software, Version 1.4.4.1, released December 2023. The version of the subject product being executed is displayed on the Instrument screen.

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Boulevard
Brea, California, USA 92821

Software Description

Vi-CELL BLU software controls and analyzes images and reports final results consistent with the typical user requirements.

General Description

The Vi-CELL BLU Cell Viability Analyzer is an imaging system for analyzing yeast, insect and mammalian cells in culture media or in suspension. It automates the widely accepted trypan blue dye exclusion protocol and is designed to analyze a wide variety of cell types. The software includes features to monitor bioreactors and other cell culture processes and is designed to facilitate compliance with the US Food and Drug Administration's (FDA) regulations on electronic records and electronic signatures (21 CFR Part 11).

It is not intended for use in a clinical setting.

Compliance Features

Features designed to assist the laboratory in recording and providing documentation for compliance include the following:

- User Logon - access of the system by authorized personnel only
- Authentication and authorization with Active Directory

- System Audit Trail
- Date and Time, Operator, Lot and other information is stored with the data
- Electronic Records cannot be edited
- Electronic Signature Feature
- Viewing of electronic signatures
- Addition of electronic signatures by authorized personnel
- Inactivity screen lock after specified time (set up by an administrator)
- Password Renewal after specified time (set up by an administrator)

Product History

Development/Release History

Version 1.0, March 2019

Version 1.1, July 2019
Updates were made to the following sections,
IMPORTANT, Data Integrity and Security improvements, Multi language user interface, Other improvements and Fixes from previous version 1.0.

Version 1.2, November 2019
Updates were made to the following sections,
Cell Analysis, Reports, Offline analysis and Customer Workflow.

Version 1.3, January 2021
Updates were made to the following sections,
Compliance Features, .NET Components:, Software Version 1.3 Updates, Data handling and storage, Customer workflow, Data Integrity and Security improvements, Fixes from previous version 1.2, Software Product Development Environment and Quality Management System.

Version 1.4, July 2021
Updates were made to the following sections,
Compliance Features, Software Version 1.4 Updates, Data Handling and Storage, Customer Workflow, Fixes from Previous Version 1.3 and Notices.

Version 1.4, June 2022
Updates were made to the following section; Identification, Compliance Features, and Software Version 1.4 Updates.

Version 1.4, March 2023
Updates were made to the following section; Identification, System Requirements, and Software Upgrade Process.

Version 1.4, December 2023
Updates were made to the following section; Identification and Software Version 1.4 Updates.

NOTE Changes that are part of the most recent revision are indicated in text by a bar in the margin of the amended page.

Technical Description

System Requirements

Hardware

The Offline Analysis package is compatible with the following platform configurations:

Processor:	Intel i7 6th generation processor (or better)
Memory:	16 GB RAM (or greater)
Disk storage:	Minimum 1 GB for the install image;
	Minimum 100 GB for data analysis requirements, additional storage space required for larger data sets
	Currently, all installation targets for application and data are limited to the "C" drive; thus, the data storage requirement applies to that drive.
Display resolution:	Minimum 1280 x 800 resolution

Software

The offline analysis package may be run on the following configurations:

Operating System:	Windows 10 Professional or better, build 1809 and later, 64-bit versions. Build 1809 corresponds to the 2019 LTSC release build version. 32-bit OS versions are not supported.
.NET Components:	.NET 4.8.0 or later; this .NET version is compatible with the listed OS versions. The installer for the .NET 4.8.0 package is included in the Offline Analysis installation package. The Offline Analysis package installer ensures that the .NET components are installed and saves the component installer with the installed tools.
7-zip:	The Offline Analysis installation provides 7-zip version 1806, 64-bit, for installation if required; the Offline Analysis package installer provides the option during installation to install the 7-zip utility, or save it with the installed tools.

For more information on the Offline Analysis package, refer to the Vi-CELL BLU Instructions for Use Manual.

Beckman Coulter, Inc. Support Accessories

The Vi-CELL BLU supports the following Beckman Coulter, Inc. accessories:

- 24 position carousel
- 96 well plate

Software Version 1.4 Updates

Changes since the last official released version 1.3 are as follows:

Data Handling and Storage

- Added the ability to schedule exports of sample data.
- Added the ability to schedule exports of the audit and error logs.

Customer Workflow

- Added support for wireless keyboard and mouse.
- Added support for Automation Mode. Automation mode adds the ability to connect the Vi-CELL BLU to an external sample delivery robot or fluid delivery robot to supply samples, control sample processing, and control the collection of sample results with minimal human intervention.
- Added the ability to adjust the cell concentration to improve concentration matching.
- Enhanced support for specific automation instruments.
- Extended the allowable range for password expiration to 365 days and added the “password expiration off” capability.

Fixes from Previous Version 1.3

All English regions are defaulting to US English region.

Software Upgrade Process

- The software is customer upgradeable and supports direct upgrades from version 1.2.43 and later versions. The installer package checks the database version and updates to the most recent validated version, if required.

Database Backup

- Within the Vi-CELL BLU application, an administrative-level customer account may specify the password for a read-only user allowed to perform backups of the database using standard off-

the-shelf database tools. The name for the backup user is provided in the Vi-CELL BLU Instructions for Use.

Software Version 1.3 Updates

Changes since the last official released version 1.2 are as follows:

Data handling and storage

Moved storage for sample data and critical configuration files to an SQL-based database for persistent data storage.

Customer workflow

- Users can create new sample sets to add to queue while the queue is active.
- Sample data sets are always displayed on Home screen in reverse chronological order and are accessed directly from the home screen.
- Filter capability to search or organize display of data
- Sample queues are now organized as sample sets for execution and review.
- User may only modify or delete samples in a queue that belong to them.
- User can type in a dilution factor from 1-9999.
- User can optionally configure sample names to use auto-incrementing numbers. The number can be set ahead-of or following the sample name.
- The sampling position is no longer appended to the end of the sample name.
- Displayed fields for Total and Viable concentrations can be configured to display a user selectable number of decimal digits, 2, 3 or 4.
- In the Run review table, the fields to display can be selected/deselected.
- Run review table field columns can be resized.
- Data in the run review table is configured to wrap characters.
- Ability to conduct/access some tasks and functions while samples are being acquired.
- Improved touchscreen layout and button responses.
- Screen layout in alignment with general software conventions.
- Reduced system menu complexity and options.

Data Integrity and Security improvements

- The instrument now includes the ability for an admin user to configure security to use 'Active Directory' for login authentication.
- Ability to map groups from the Active Directory server to user Roles.
- FAST Mode can be restricted for normal users.
- Ability to minimize to desktop restricted by user role.

Fixes from previous version 1.2

In the cell types menu, the data file selected for reanalysis can now be reanalyzed repeatedly without reopening the data file.

Software Version 1.2 Updates

Version 1.2 began shipping with new Vi-CELL BLU's beginning with serial number C1919619L14 in November 2019.

NOTE Results generated on the original application version 1.0 cannot be viewed on later versions of Vi-CELL BLU software (version 1.1 or greater). Therefore, **we are requiring all Vi-CELL BLU systems migrate to version 1.2**. The instructions for upgrading Vi-CELL BLU Software can be found in the Instructions for Use (IFU), under Appendix F Vi-CELL BLU Software Installation. The IFU is available for downloading or viewing on our website, *www.beckman.com*. Contact your regional Tech Support Hotline for support with this procedure and to obtain the version 1.2 software listed below.

- C10358 Instrument Application Software
- C40752 Offline Analysis Software

Contact us for more information.

Cell Analysis

Additional measurement parameters added to per-cell image overlay display

Reports

- Ability to enable automatic generation of PDF sample report as each sample is completed
- Search results increased to a maximum of 5000 samples
- Audit log entry format adjusted for readability and clarity
- Logs are displayed with newest entries listed first

Offline analysis

Offline tool may be installed to drives other than C:

Customer Workflow

- User is reminded to loosen the Trypan Blue cap during the reagent installation sequence
- User is warned if the current reagent pack or discard tray capacity is insufficient for the queue defined
- Removed "Drain reagent pack to waste" option from the "Replace reagent pack" workflow
- Workflow to save cell type changes updated to be more intuitive

Fixes from previous version 1.1

- Cells near bottom of image cannot be selected to see measurement details
- Sample comment tooltip background color changed to indicate that it is not an edit field
- Audit, error and sample log files overwritten by software update
- Fix to prevent user from being "stuck" during at-login password change
- Reagent pack capacity display on header correctly refreshed after decontamination and nightly cleaning cycles
- Y axis in QC graphs shows incorrect dataset
- Sample discard tray remaining capacity not decremented after decontamination, dust-subtract or autofocus sequences
- Quality control viability assay range expanded from 45-55% to 1-100%
- Fixed issue where scrolling the queue creation list would alter / erase sample identifiers
- Summary CSV file duplicated existing entries as new data was added during queue execution

Software Version 1.1 Updates

IMPORTANT Data results generated on the original application version 1.0 software cannot be viewed on the offline version of Vi-CELL BLU 1.1 offline application.

Data Integrity and Security improvements

- Application whitelisting enabled in operating system
- Audit log entry added for failed firmware update attempt
- If an Admin resets another user's password, that user will be asked to change their password on their next login
- The factory_admin account will now honor the same password expiration rules as the other accounts
- The minimum password length is now 10 characters which will be enforced when password is reset or a new user is created

Multi language user interface

Supports the following languages:

- English (default)
- Chinese (simplified)
- French
- German
- Japanese
- Spanish

Other improvements

- Ability to create and reuse sample work queue definitions between instruments
- **Fit to Width** is the default selection for the expanded image view

Fixes from previous version 1.0

- Fault when attempting to store a reanalyzed result generated from existing data
- Missing cumulative result row in per-sample CSV export file
- Graph selection not maintained when changing between tabs in Review screen
- Inconsistent right-click options when viewing gray-level histogram vs. other image choices
- **Home** button disappears from header bar after selecting **Help** or **About** from Menu
- **Software fault** displayed after entering invalid username/password 5 times
- A disabled Administrator-level user is able to unlock the screen
- Cannot select **Graphs** tab from Run Results screen's **Queue** tab
- New Quality Control saves with an expiration date one day earlier than the expiration date
- Changing the default path and filename is ignored for summary CSV file generation
- Quality Controls: Range check for **Viability** assay value displays incorrect allowed range
- Application hang after saving *Complete run summary* PDF file from **Reports** > **Results** screen
- Summary CSV file rolls over at start of each queue of samples
- Application does not always restart after importing a configuration
- Wrong units are shown for Viability range check in Quality Control creation screen

Algorithms and Product Documentation

Descriptions of the Software Algorithms used in Vi-CELL BLU Software can also be found in the following documentation:

- **Vi-CELL BLU Instructions for Use.** It is available on *www.beckman.com.*

Development Environment

Project Identification

Vi-CELL BLU Software

Software Product Development Environment

Source Language: C, C++, C#

Compilers, Assemblers: Microsoft Visual Studio 2019, Freescale Kinetis Design Studio 3.0

Operating System: Windows 10

Graphical User Interface: Windows 10

Quality Management System

The Vi-CELL BLU Software (Version 1.4) was designed, evaluated, validated, inspected and tested to approved specified Quality requirements of Beckman Coulter, Inc., in accordance with the following:

- ISO 9001:2015 Certified Quality Management System registration number FM 663565 issued by the British Standards Institute (BSI).
- The software was developed, verified, and controlled by qualified professionals.
- The source code 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 under defined backup and retention procedures.
- Documentation for error reports and error report management are retained at Beckman Coulter, Inc.

Product Development Life Cycle

Product and software development for Beckman Coulter follows the process elements of ISO 9001:2015 through Beckman Coulters Design Control Procedures.

Product Testing Evaluation

Testing of Vi-CELL BLU software is accomplished as follows:

- Software development engineers perform initial testing of the software at the module and system levels.

- Further system testing is performed by internal and external evaluators of the software from various departments. A test plan is used to assign areas of responsibility and features to be tested.
- At all stages of the process, errors are reported and dispositioned using a Problem Report process.

Support Policies

Limited Warranty

For more information on the Limited Warranty, refer to the Beckman Coulter, Inc. Customer End User License Agreement in the Vi-CELL BLU Instructions for Use manual.

Customer Training

In-lab software training is included with instruments installed by a Beckman Coulter, Inc. Field Service Technician.

Online training is available via the Beckman Coulter Learning Center. Create a user profile and access training at www.beckman.com/training.

Technical Support

Software support via telephone is provided through Beckman Coulter's field offices worldwide, for customers under Vi-CELL BLU service agreements.

The Vi-CELL BLU supports remote connectivity for service and support via BeckmanConnect. BeckmanConnect is a software program which allows file transfer and remote desktop control after operator approval. Signing up for BeckmanConnect allows Beckman Coulter Service to provide elevated support, potentially increasing uptime of your Vi-CELL BLU. For more information, refer to the Vi-CELL BLU Instructions for Use.

Updates

From time to time, Beckman Coulter, Inc. updates the subject product to incorporate new features, support new devices or to implement corrective actions. To the greatest reasonable extent, but at the sole discretion of Beckman Coulter, Inc., updated versions are compatible with data and method files used and/or created by the immediately preceding version. Such new versions are available to both existing and potential customers.

Contact us for current Vi-CELL BLU software update information.

Customer Feedback Reporting

Customer feedback can be provided directly to a Beckman Call Center, Client Services, Field Service, see Contact Us.

Supplier Information

Company Description

Beckman Coulter, Inc. designs, manufactures, markets and services a broad range of laboratory systems, reagents and related products, that address the needs of diagnostic laboratories as well as bioanalytical laboratories in the life science market, including those in universities, research institutes, pharmaceutical companies and biotechnology companies.

Product Specific Experience

Beckman Coulter, Inc. has been a manufacturer of analytical instrumentation since being founded in 1936. Beckman Coulter, Inc. has been developing and manufacturing cell viability analyzers since 1999 with the first Vi-CELL Single and Autosamplers.

Notices

The information presented here, although believed to be correct at the time of approval, is not warranted for accuracy nor completeness. Some of the information presented here is subject to change without notice. For additional detail or current status or corrections except as explicitly noted herein Quality System or Process, direct questions to Lifesciencesquality@beckman.com.

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14/Dec/2023
Date

Contact Us

If you have any questions, contact our Customer Support Center.

- Worldwide, find us via our website at www.beckman.com/support/technical.
- In the USA and Canada, call us at 1-800-369-0333.
- In Austria, call us at 0810 300484
- In Germany, call us at 02151 333999
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- In other locales, contact your local Beckman Coulter Representative.

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