Instruction For Use

Vi-CELL BLU

Cell Viability Analyzer

PN C13232AJ
June 2023

Beckman Coulter, Inc.
250 S. Kraemer Blvd.
Brea, CA 92821 U.S.A.

BECKMAN COULTER

Vi-CELL BLU Cell Viability Analyzer
Instructions For Use
PN C13232AJ (June 2023)

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
- In Sweden, call us at +46 (0)8 564 859 14
- In the Netherlands, call us at +31 348 799 815
- In France, call us at 0825838306 6
- In the UK, call us at +44 845 600 1345
- In Ireland, call us at +353 (01) 4073082
- In Italy, call us at +39 0295392 456
- In other locales, contact your local Beckman Coulter Representative.

EC REP

Beckman Coulter Eurocenter S.A.
22, rue Juste-Olivier
Case Postale 1044
CH - 1260 Nyon 1, Switzerland
Tel: +41 (0) 22 365 36 11

May be covered by one or more pat. - see www.beckman.com/patents

Glossary of Symbols is available at beckman.com/techdocs (PN C24689).

Original Instructions

Revision History

This document applies to the latest software listed and higher versions. When a subsequent software version affects the information in this document, a new issue will be released to the Beckman Coulter Web site. For labeling updates, go to www.beckman.com/TechDocs and download the latest version of the manual or system help for your instrument.

Initial Issue, 03/19
Software version 1.0

Version AB, 06/19
Software version 1.1

Updates were made to the following sections:

Figure 2.3, Main menu, Table 2.1, Main menu buttons, Language Screen, Decluster Degree and File History.

Version AC, 10/19
Software version 1.2

Updates were made to the following sections:

Particle Size, RFID Module, Document Safety Symbols, Vi-CELL BLU Normal Mode, Vi-CELL BLU Fast Mode, Figure 2.2, Advanced Options screen, Install a Reagent Pack step 2 and step 8, Run Options Screen, Particle Size, Graphs Screen, Reviewing/Reanalyze Data step 5, Creating a New Cell Type step 8, Table 6.2, Cell Type Parameter Definitions, Table 6.6, User Types and Access Levels, Replace Reagent Pack step 2, step5, step 6 and step 7, Third-Party Software, Troubleshooting Table, APPENDIX B, Open Systems, APPENDIX B, File History and APPENDIX F, Vi-CELL BLU Software Installation.

Version AD, 01/21
Software version 1.3

Updates were made to the following sections:

General Warning and Cautions, Active Directory, Vi-CELL BLU Normal Mode, Vi-CELL BLU Fast Mode, Historical Perspective – The Hemacytometer, An Image Analysis Solution, Reagent Pack, Reagent Pack Storage Conditions and Stability, Worktable, Ventilation and Cleaning, Unpacking and Setup, First time Login, Home Screen, Figure 2.10, Figure 2.11, Figure 2.14, Main menu, Table 2.1, Main menu buttons, Settings Tab, Instrument Screen, Language Screen, Run Options Screen, Signatures Screen, Security Tab, User Administration, Add a User, Select Cell types, Edit a User, Set Security settings, Active Directory Configuration, Instrument Status, Instrument Time and Date Settings, Add Carousel Samples to the Sample Set, Add 96 Well Plate Samples to the Sample Set, Reviewing/Reanalyze Data, What is a Cell Type?, Creating a New Cell Type, Cell Type Optimization, Table 6.2, Figure 6.1, Completed Run Summary Reports, Run Results Reports, Quality Controls Reports, Cell Type Reports, Instrument Status, Audit Log, Sample Activity Log, System Error Log, Concentration Slope History Log, Storage Administration, Delete sample results, Import configuration, Add a Quality Control, Run a Concentration Control, Replace Reagent Pack, System Networking, Shutting Down the Instrument, Data Acquisition, Controls for Electronic Records, 21 CFR Part 11, File History, Generating Electronic Signatures, Software, Offline Analysis Installation steps 7, 10, 11 and 12, Tools/Supplies Needed, Vi-CELL BLU Software Installation and Vi-CELL BLU Software Installation Troubleshooting.

Changes that are a part of the most recent revision are indicated by a bar in the left margin. Sections that are entirely new are marked with  at the end of the title.

Version AE, 09/21
Software version 1.4
Updates were made to the following sections:

Safety Notice

- Electrical Safety
- EMC
- Safety Symbols
- RFID Module

CHAPTER 1, Introducing the Vi-CELL BLU

- Active Directory

CHAPTER 2, Installation and Verification

- Worktable
- Ventilation and Cleaning
- Unpacking and Setup
- Language Screen
- User Administration
- Edit a User
- Active Directory Configuration

CHAPTER 4, Run Samples

- Add Carousel Samples to the Sample Set
- Adding Samples to an Ongoing Run

CHAPTER 6, Software Administration

- Completed Run Summary Reports
- Run Results Reports
- Sample Activity Log
- Quality Controls Reports
- Cell Type Reports
- Instrument Status
- Scheduled Data Exports
- Completed Run Summary Reports
- Run Results Reports
- Sample Activity Log
- Quality Controls Reports
- Cell Type Reports
- Instrument Status
- Scheduled Data Exports

CHAPTER 7, Quality Control

- What Is the Control Feature?

Changes that are a part of the most recent revision are indicated by a bar in the left margin. Sections that are entirely new are marked with  at the end of the title.

CHAPTER 7, Quality Control

- What is the Control Feature?

CHAPTER 8, Maintenance Procedures

- Decontaminate with Bleach
- Focusing Wizard (Autofocus)
- System Networking was moved to Appendix G, Instrument Configuration Guidelines

CHAPTER 10, Troubleshooting

- Table 10.1, Troubleshooting Table - Instrument

APPENDIX E, Offline Analysis

- Software

APPENDIX F, Vi-CELL BLU Software Installation

- Upgrading from Version 1.2

APPENDIX G, Instrument Configuration Guidelines

APPENDIX H, Vi-CELL BLU Networking

APPENDIX I, Automation Mode

Version AF, 04/22

Software version 1.4

Updates were made to the following sections:

Safety

- RFID Module

Chapter 2, Installation and Verification

- Administration User

Chapter 6, Software Administration

- Database Backup
- Creating a New Cell Type
- Scheduled Data Exports
- Table 6.2, Cell Type Parameter Definitions
- Table 6.6, User Types and Access Levels

Chapter 8, Maintenance Procedures

- Set Focus

Appendix E, Offline Analysis

- Offline Analysis Installation
- Exporting Data to the Offline Software

Appendix F, Vi-CELL BLU Software Installation

- Vi-CELL BLU Software Upgrade Installation

Appendix I, Automation Mode

- Configuration Changes
- Figure I.3, Automation Enabled with A-Cup
- Figure I.4, Automation Disabled

Changes that are a part of the most recent revision are indicated by a bar in the left margin. Sections that are entirely new are marked with  at the end of the title.

Version AG, 10/22

Software version 1.4

Updates were made to the following sections:

Safety

- Safety Symbols

Version AH, 03/23

Software version 1.4

Updates were made to the following sections:

Safety

- RFID Module

Chapter 2

- Worktable
- Materials Shipped - Removal of 96 Well Plate
- Unpacking and Setup

Appendix E

- Offline Analysis Installation

Appendix F

- Upgrading from Version 1.2 or Higher

Version AJ, 06/23

Software version 1.4

Updates were made to the following sections:

Chapter 1, Introducing the Vi-CELL BLU

- Vi-CELL BLU Normal Mode
- Vi-CELL BLU Fast Mode
- Reagent Pack
- Figure 1.5, Vi-CELL BLU Reagent Pack

Chapter 8, Maintenance Procedures

- Replace Reagent Pack
- Prime the Instrument
- Flush the Instrument

Appendix I, Automation Mode

- Weekly Decontamination

Changes that are a part of the most recent revision are indicated by a bar in the left margin. Sections that are entirely new are marked with  at the end of the title.

Safety Notice

Read all product manuals and consult with Beckman Coulter-trained personnel before attempting to operate instrument. Do not attempt to perform any procedure before carefully reading all instructions. Always follow product labeling and manufacturer's recommendations. If in doubt as to how to proceed in any situation, Contact us.

Beckman Coulter, Inc. urges its customers to comply with all national health and safety standards such as the use of barrier protection. This may include, but is not limited to, protective eyewear, gloves, and suitable laboratory attire when operating or maintaining this or any other automated laboratory analyzer.

Alerts for Warning and Caution

Throughout this manual, you will see the appearance of these alerts for Warning and Caution conditions:

⚠ WARNING

WARNING indicates a potentially hazardous situation, which, if not avoided, could result in death or serious injury.

In this document the signal word WARNING is only used to indicate the possibility of personal injury. It is not used to indicate the possibility of erroneous data.

⚠ CAUTION

CAUTION indicates a potentially hazardous situation, which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices.

Safety Precautions

⚠ WARNING

Risk of operator injury if:

- **All doors covers and panels are not closed and secured in place prior to and during instrument operation.**
- **Instrument alarms and error messages are not acknowledged and acted upon.**
- **You mishandle broken parts.**
- **Doors, covers, and panels are not opened, closed, removed and/or replaced with care.**
- **Improper tools are used for troubleshooting.**

To avoid injury:

- **Keep doors, covers and panels closed and secured in place while the instrument is in use.**
- **Take full advantage of the safety features of the instrument.**
- **Acknowledge and act upon instrument alarms and error messages.**
- **Keep away from moving parts.**
- **Report any broken parts to your Beckman Coulter Representative.**
- **Open/remove and close/replace doors, covers and panels with care.**
- **Use the proper tools when troubleshooting.**

⚠ CAUTION

System integrity could be compromised and operational failures could occur if:

- **This equipment is used in a manner other than specified. Operate the instrument as instructed in the Product Manuals.**
- **You introduce software that is not authorized by Beckman Coulter into your computer. Only operate your system's computer with software authorized by Beckman Coulter.**
- **You install software that is not an original copyrighted version. Only use software that is an original copyrighted version to prevent virus contamination.**
- **You connect external devices such as thumb drives and external hard drives. Ensure that all external devices are free from viruses before connecting.**

⚠ CAUTION

If you purchased this product from anyone other than Beckman Coulter or an authorized Beckman Coulter distributor, and it is not presently under a Beckman Coulter service maintenance agreement, Beckman Coulter cannot guarantee that the product is fitted with the most current mandatory engineering revisions or

that you will receive the most current information bulletins concerning the product. If you purchased this product from a third party and would like further information concerning this topic, call your Beckman Coulter Representative.

⚠ CAUTION

Risk of instrument damage. This device is intended for indoor use only. To avoid device damage, do not install the instrument outdoors.

⚠ WARNING

Risk of personal injury. Safety protection can be impaired if used in a manner not specified by the manufacturer. To avoid personal injury, use the instrument according to the manufacturer's instructions only.

General Warning and Cautions

⚠ WARNING

Risk of infection. Dispose and handle all solid waste and Reagent Packs as biohazardous waste. Follow your local regulations.

Always use the appropriate Personal Protective Equipment (PPE) when working with biohazardous materials. If unsure, ask your Laboratory Safety Officer.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

⚠ WARNING

Risk of operator injury or biohazardous contamination if you have skin contact with the sample probe or reagent probe. The sample probe or reagent probe might contain residual biological material and must be handled with care. Clean up spills immediately.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

Always use the appropriate Personal Protective Equipment (PPE) when working with biohazardous materials.

⚠ WARNING

Risk of infection. Only let authorized personnel collect and work with biologic samples. Make sure to wear gloves.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste. Always use the appropriate Personal Protective Equipment (PPE) when working with biohazardous materials. If unsure, check with your Laboratory Safety Officer or Lab Supervisor.

⚠ WARNING

Risk of infection. Make sure that you wear gloves during replacement and maintenance procedures.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

⚠ CAUTION

Risk of operator injury. The reagent door and the sample station contain automated moving parts. Use caution around these areas to avoid injury.

⚠ CAUTION

Risk of instrument damage. If conditions cause static charge to exist in your lab, be sure to properly ground yourself before touching the instrument.

⚠ CAUTION

Risk of instrument damage if you use any non-Beckman Coulter control bead products. To prevent damage to the instrument when you use non-Beckman Coulter control bead products ensure the proper dilution and/or filtration to meet guidance in the following table.

Particle Size	Concentration
2µm ≤ d ≤ 6µm	≤ $1.5x10^7$ particles/mL
6µm ≤ d ≤ 11µm	≤ $2.0x10^6$ particles/mL
11µm ≤ d ≤ 22µm	≤ $1.0x10^6$ particles/mL

Electrical Safety

To prevent electrically related injuries and property damage, properly inspect all electrical equipment prior to use and immediately report any electrical deficiencies. Contact us for any servicing of equipment requiring the removal of covers or panels.

⚠ WARNING

Risk of electric shock. The external power supply module uses a three-wire power cord and plug to connect it to earth-ground. Make sure that the matching wall outlet receptacle is properly wired and earth-grounded. Never cut-off the plug's ground pin or use a three prong to two prong adapter.

⚠ CAUTION

Risk of equipment damage. This instrument uses an external, certified, power supply module. Do not substitute with another power supply module. If you experience problems, immediately unplug the power supply module from the wall outlet and call a Beckman Coulter representative for assistance.

⚠ CAUTION

Risk of instrument damage. The power-supply cord and plug of the analyzer must comply with national regulations. External devices connected to the analyzer must be in compliance with the standard UL 60950 for US and IEC 60950 for Europe. If the regulations are not complied with, the equipment may be damaged.

EMC

This device complies with the emissions and immunity requirements as specified in the EN/IEC 61326 series of Product Family Standards for a “basic electromagnetic environment.” Such equipment is supplied directly at low voltage from public mains network. This equipment is not intended for residential use.

⚠ CAUTION

This device generates, uses, and can radiate unintentional radio-frequency (RF) energy. If this device is not installed and operated correctly, this RF energy can cause interference with other equipment. It is the responsibility of the end user to be sure that a compatible electromagnetic environment for the device can be maintained so that the device operates as intended.

In addition, other equipment can radiate RF energy to which this device is sensitive. If one suspects interference between this device and other equipment, Beckman Coulter recommends the following actions to correct the interference:

1. **Evaluate the electromagnetic environment before installation and operation of this device.**
2. **Do not operate this device close to sources of strong electromagnetic radiation (for example: unshielded intentional RF sources), as these can interfere with proper operation. Examples of unshielded intentional radiators are handheld radio transmitters, cordless phones and cellular phones.**
3. **Do not place this device near medical electrical equipment that can be susceptible to malfunctions caused by close proximity to electromagnetic fields.**
4. **This device has been designed and tested to CISPR 11, Class A emission limits. In a domestic environment, this device may cause radio interference, in which case, you may need to take measures to mitigate the interference.**

Certification

Canadian Radio Interference-Causing Equipment Regulation, IECS-003, Class A:
Supporting test records reside with the manufacturer.

This Class A digital apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulations.

Cet appareil numérique de classe A répond à toutes les exigences de la réglementation canadienne sur les équipements provoquant des interférences.

FCC Part 15, Class "A" Limits
Supporting test records reside with the manufacturer. The device complies with Part 15 of the FCC Rules. Operation is subject to the following conditions:

1. The equipment may not cause harmful interference.
2. The equipment must accept any interference received, including interference that may cause undesired operation.

Changes or modifications to this equipment not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference

when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at their expense. The following techniques can be used to reduce interference problems:

1. Disconnect the equipment from its power source to verify that it is or is not the source of the interference.
2. If the equipment is connected to the same outlet as the device experiencing interference, connect the equipment to a different outlet.
3. Move the equipment away from the device receiving the interference.
4. Reposition the receiving antenna for the device receiving the interference.
5. Try combinations of the above.

NCC Requirements

Article 12

Low-power RF motors that have passed the type certification, the company, firm or user may not change the frequency rate, increase power or change the features and functions of the original design without permission.

Article 14

The use of low-power RF motors shall not affect flight safety and interfere with legitimate communications; if interference is found, it shall be immediately deactivated and improved until there is no interference before continuing to use.

Legal communication in the preceding paragraph refers to radio communications operating in accordance with the provisions of the Telecommunications Act.

Low-power RF motors must withstand interference from legitimate communications or radiological electrical equipment for industrial, scientific, and medical use.

Mexico

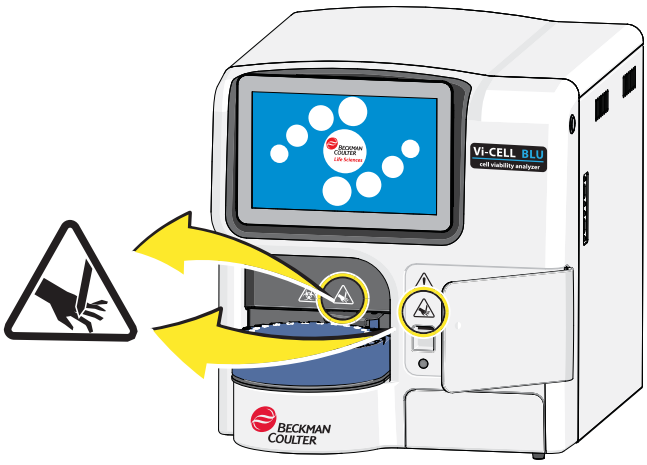
The operation of this equipment is subject to the following two conditions: (1) it is possible that this equipment or device may not cause harmful interference, and (2) this equipment or device must accept any interference, including interference that may cause undesired operation.

Moving Parts

⚠ WARNING

Risk of personal injury. To avoid injury due to moving parts, observe the following:

- **Never attempt to exchange labware, reagents, or tools while the instrument is operating.**
- **Never attempt to physically restrict any of the moving components of the instrument.**
- **Do not override instrument interlocks.**
- **Keep the instrument work area clear to prevent obstruction of the movement.**



Cleaning

⚠ WARNING

Risk of infection. Make sure that you wear gloves during replacement and maintenance procedures.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

Always use the appropriate Personal Protective Equipment (PPE) when working with biohazardous materials. If unsure, check with your Laboratory Safety Officer or Lab Supervisor.

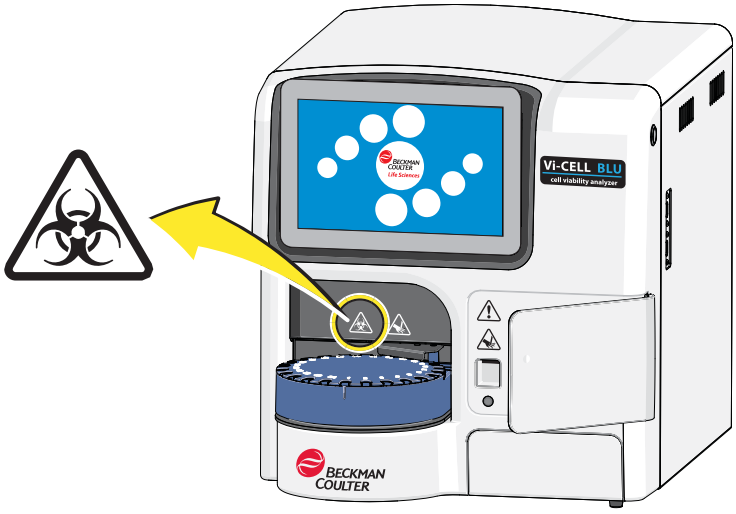
Observe the cleaning procedures outlined in this manual for the instrument. Prior to cleaning equipment that has been exposed to hazardous material:

- Contact the appropriate Chemical and Biological Safety personnel.

- Review the Chemical and Biological Safety information in this manual.

Hazardous Waste Precautions

Always observe local and state regulations regarding the handling and discarding of hazardous waste. Refer to the Safety Data Sheet for more information.



If a hazardous substance such as blood or biological sample is spilled, clean up the spill by using your laboratory decontamination procedure. Follow your laboratory procedure for disposal of hazardous materials.

Reagent Specific Precautions

⚠ WARNING

Observe the appropriate cautionary procedures when cleaning up spilled flammable reagents in or near a powered-up instrument.

Observe warnings on the packaging of Reagents (Vi-CELL BLU Reagent Pack) and other materials as well as Safety Data Sheets.

NOTE For Safety Data Sheets (SDS/MSDS) information, go to the Beckman Coulter website at **www.beckman.com/TechDocs**.

Other Precautions

Warnings

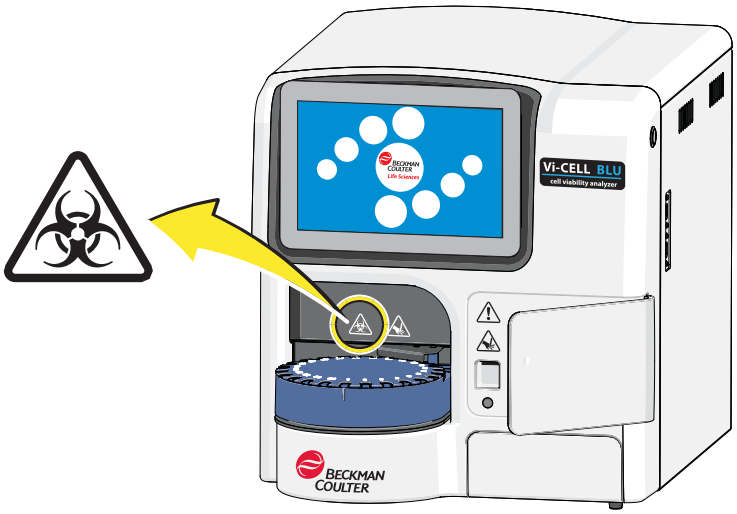
⚠ WARNING

If the equipment is used in a manner not specified by Beckman Coulter, Inc., the protection provided by the equipment may be impaired.

⚠ WARNING

Risk of biohazard contamination. Toxicity, safety, and proper handling procedures for diluents and reagents used should be adhered to at all times. To prevent biohazard contamination consult appropriate safety manuals, Safety Data Sheets and Material Safety Data Sheets for the items.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.



Maintenance

Perform only the maintenance described in this manual. Maintenance other than that specified in this manual should be performed only by service engineers.

IMPORTANT It is your responsibility to decontaminate components of the instrument before requesting service by a Beckman Coulter Representative or returning parts to Beckman Coulter for repair. Beckman Coulter will NOT accept any items which have not been decontaminated where it is appropriate to do so. If any parts are returned, they must be enclosed in a sealed plastic bag stating that the contents are safe to handle and are not contaminated.

Safety Symbols

Safety symbols alert you to potentially dangerous conditions. The symbol applies to specific procedures and appears as needed throughout this manual.

Symbol	Warning Condition	Action
	Caution	To signify a general warning.
	Pinch	To warn of a closing motion of mechanical parts of equipment.
	Biohazard symbol	The biohazard symbols indicate areas of the instrument and associated fluid handling equipment that can contain potentially infectious material from body fluids. Follow proper laboratory procedures for handling and disposing of materials from these areas.
	cNRTLus Certification Mark Canadian Standards Association Symbol	This symbol indicates recognition by the Canadian Standards Association (Nationally Recognized Test Laboratory or NRTL) that the instrument has met the relevant product safety standards.
	RCM Symbol	The “RCM” (Regulatory Compliance Mark) is depicted as a triangle with a partial circle and check. The mark is applied to products that comply with the EMC requirements of the Australian Communications Media Authority (ACMA) for use in Australia and New Zealand.

Symbol	Warning Condition	Action
	Recycling Symbol WEEE Wheeled Bin Symbol	The symbol of a crossed-out wheeled bin on the product is required in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union. The presence of this marking on the product indicates: **1.** that the device was put on the European Market after August 13, 2005 and **2.** that the device is not to be disposed via the municipal waste collection system of any member state of the European Union. For products under the requirement of WEEE directive, please contact your dealer or local Beckman Coulter office for the proper decontamination information and take-back program which will facilitate the proper collection, treatment, recovery, recycling, and safe disposal of device. For the Japan market: This system is considered an industrial waste, subject to special controls for infectious waste. Before disposal of the system, refer to the Waste Disposal and Public Cleaning Law for compliance procedures.
	RoHS Caution Symbol People's Republic of China Electronic Industry Standard SJ/T11364-2006	This label indicates that the electronic information product contains certain toxic or hazardous substances. The center number is the Environmentally Friendly Use Period (EFUP) date, and indicates the number of calendar years the product can be in operation. Upon the expiration of the EFUP, the product must be immediately recycled. The circling arrows indicate the product is recyclable. The date code on the label or product indicates the date of manufacture.
	European Conformity (CE Mark) Regulatory Mark	A "CE" mark indicates that a product has been assessed before being placed on the market, and has been found to meet European Union safety, health, and/or environmental protection requirements.

Symbol	Warning Condition	Action
	Consider all materials (specimens, controls, monoclonal antibodies, and so forth) as being potentially infectious. **NOTE** This symbol does not appear on the instrument. This symbol is used in instrument documentation.	Wear standard laboratory attire and follow safe laboratory procedures when handling any material in the laboratory.
UK CA	UK Conformity Assessed (UKCA Mark) Regulatory Mark	A "UKCA" mark indicates that a product has been assessed before being placed in UK market, and has been found to meet UK safety, health, and/or environmental protection requirements.

RFID Module

This instrument contains an internal radio frequency identification device (RFID) certified for the countries in which it will be marketed. Certification IDs are listed on the exterior label of the instrument.

Registration Information

Parameter	Value
FCC identification number	FCC ID: 2AOSQRFIDM2
Canadian ISED identification number	IC: 23864-RFIDM2
KCC certification number	R-CMM-bci-RFIDM2
Japan Radio Law (IFERW)	AC-18124
Mexico (IFETEL)	RCPBEC118-2040
Singapore (IMDA)	N4461-18
South Africa (ICASA)	TA-2018/3275
Thailand	NTC Supplier DoC# RT 0121
Hong Kong (OFCA)	HK0011902003
Taiwan (NCC)	CCAJ19LP1350T5
Russia (EAC)	EAEU N RU D-US.RA01.B.96116/21
Malaysia (SIRIM)	RALI/39D/0719/S(19-2567)
India (WPC)	ETA Certificate
Israel (MOC)	55-08268
Egypt	TAC.03072228350.WIR
Frequency	13.56 MHz ±7 kHz
RF output power	<200 mW

Contents

Illustrations

Tables

Introduction

Manual Description

This manual is intended to provide the user with information needed to operate and maintain the Vi-CELL BLU system safely and effectively.

Conventions

This manual applies the following conventions:

- Menu and dialog items that can be selected or clicked appear in **bold** type.
- Blue text indicates that you can click on the text to access related information.
- Instrument may be used when referring to the Vi-CELL BLU system.
- The terms “screen” and “window” are used interchangeably.
- *Italics font* indicates screen text displayed on the instrument, such as *Preparing Samples*.
- The term “select” is used to indicate either one or both of the following actions:
  - To tap or touch with your finger.
  - To click with a mouse.
- The software path to a specific function or screen appears with the greater than (>) symbol between the succeeding screen options, like this: File > Open Protocol.

NOTE A **Note** is used to call attention to notable information that should be followed during installation, use or maintenance of this equipment.

IMPORTANT An **IMPORTANT** is used for comments that add value to the step or procedure being performed. Following the advice in the **IMPORTANT** adds benefit to the performance of a piece of equipment or to a process.

CHAPTER 1

Introducing the Vi-CELL BLU

System Overview

This manual is intended to provide the user with information needed to operate and maintain the Vi-CELL BLU system safely and effectively.

The Vi-CELL BLU Cell Viability Analyzer is a video 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).

The main features of the system are:

- Fully automated sample preparation, analysis and post run cleaning
- Cell Viability reported in percentage, concentration and cell count
- Concentration range of 50,000 to 15,000,000 cells per mL
- Cell size range of 2 microns to 60 microns
- 24-position carousel auto-sampler
- 96 well plate auto-sampler
- User-friendly reagent system

Active Directory

IT administrators can use Active Directory to create user groups, to manage permissions and access network-connected Vi-CELL BLU instruments. This feature allows users in the designated groups to login to the Vi-CELL BLU system without a separate Vi-CELL BLU user login account.

Sequence of Analysis Events

IMPORTANT The Vi-CELL BLU performs Nightly Cleaning every 24 hour period at 2:00AM. If the unit is turned off during its scheduled cleaning, it will perform cleaning upon the next turn on.

Vi-CELL BLU Normal Mode

IMPORTANT Vi-CELL BLU **Normal Mode** requires measured initial sample volume of 200 µL +/- 20 µL for best results.

The time to complete one cycle in the Vi-CELL BLU **Normal Mode** is approximately 130 seconds. The time to complete is subject to change based upon number of images taken and analysis time.

- The carousel or sample plate rotates and places the sample under the sample probe.
- The sample probe lowers into the sample.
- The syringe primes the valve with buffer.
- The syringe resuspends all cells by aspirating and dispensing the sample in the tube or well.
- The syringe aspirates the full volume of the sample.
- The syringe dispenses all but 0.15 mL of the sample to waste.
- The syringe draws in the trypan blue.
- The sample and trypan blue are mixed by being dispensed into the tube and drawn back into the syringe as specified in the Cell Type parameter.
- The mixed sample is then aspirated and dispensed through the flow cell for image collection.
- The remaining sample is dispensed to waste.
- The flow cell is rinsed and back flushed with cleaning agent.
- The sample tube or well is rinsed with cleaning agent.
- The flow cell and sample tube or well are rinsed with conditioning solution.
- The flow cell and sample tube or well are rinsed with buffer.
- The syringe is dried with 1 cycle of air flush.
- The sample probe raises from the sample tube or well.
- The carousel rotates and ejects the sample tube or the 96 well plate moves to place next designated sample under the sample probe.

Vi-CELL BLU Fast Mode

NOTE Administration users can disable or enable Fast Mode for Normal users.

The time to complete one cycle in the Vi-CELL BLU **Fast Mode** is approximately 90 seconds. The time to complete is subject to change based upon number of images taken and analysis time.

The Vi-CELL BLU Fast Mode provides quicker results by omitting two steps: dosing of the sample volume before the addition of trypan blue, and conditioning solution rinsing.

IMPORTANT Vi-CELL BLU **Fast Mode** requires an accurately measured initial sample volume of 170 µL. Due to different fluid handling sequences, using 200 µL of sample in Normal mode and 170 µL of sample in Fast mode result in the same dilution and cell counts.

NOTE In Fast Mode there may be increased variability due to pipetting or carry over. Conduct studies to understand when Fast mode is applicable to use with specific samples.

- The carousel or sample plate rotates and places the sample under the sample probe.
- The sample probe lowers into the sample.
- The syringe primes the valve with buffer.
- The syringe draws in the trypan blue and adds it into the sample tube or well.
- The sample and trypan blue are mixed by being drawn back into the syringe and dispensed back into the tube or well as specified in the Cell Type parameter.
- The mixed sample is now aspirated and dispensed through the flow cell for image collection.
- The remaining sample is dispensed to waste.
- The flow cell is rinsed and backflushed with cleaning agent.
- The sample tube or well is rinsed with cleaning agent.
- The flow cell and sample tube or well are rinsed with buffer.
- The syringe is dried with 1 cycle of air flush.
- The sample probe raises from the sample tube or well.
- The carousel rotates and ejects the sample tube or the 96 well plate moves to place next designated sample under the sample probe.

Measuring Viability and Cellular Parameters

Why Measure Viability?

The measurement of overall health of cell cultures requires accurate measurements of both cell concentration and percentage of viable or live cells. This data is essential to the decision making process for basic tissue culture cell growth and maintaining optimum culture conditions in bioreactors.

Historical Perspective – The Hemacytometer

Cell viability (The Trypan Blue Dye Exclusion Method) determinations traditionally have been performed using a light microscope and hemacytometer. Unfortunately, this technique has numerous major shortcomings. The hemacytometer has significant repeatability errors, different technicians analyzing the same sample obtain different results. In addition, the manual method is tedious and time consuming for today's busy laboratory environment.

How Viability is Determined

The Trypan Blue Dye Exclusion Method

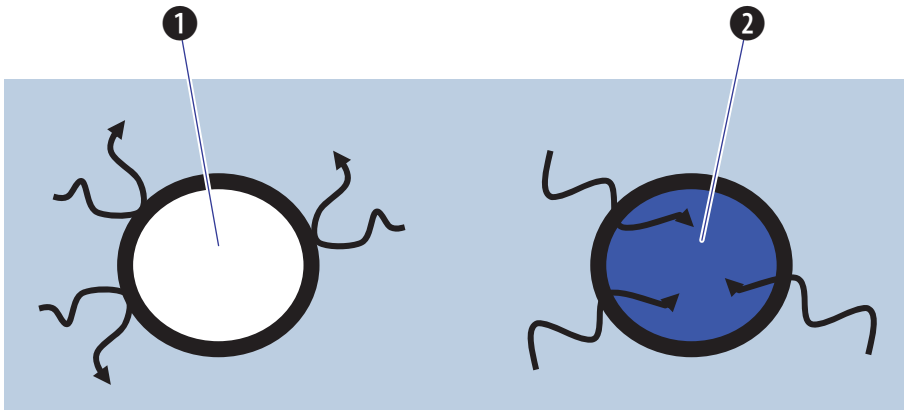
The widely accepted method for cell viability determination is the trypan blue dye exclusion method. When cells die, their membranes become permeable allowing the uptake of the trypan blue dye. As a result, the dead or non-viable cells become darker than the viable cells. This contrast is what is measured in order to determine viability.

An Image Analysis Solution

The Beckman Coulter Vi-CELL BLU automates the Trypan Blue Dye Exclusion Method. Utilizing video capture technology and sample handling, the Vi-CELL BLU takes the cell sample and delivers it to a flow cell and camera for imaging. The Vi-CELL BLU will capture from 1 to 100 images for its determination of cellular viability. The image capture setting is configurable.

The software determines which cells have absorbed trypan blue dye and those which have not. Cells absorbing the trypan blue dye appear darker hence have lower gray scale values. Cells with higher gray scale values are considered viable.

Figure 1.1 Trypan Blue Dye Exclusion Method

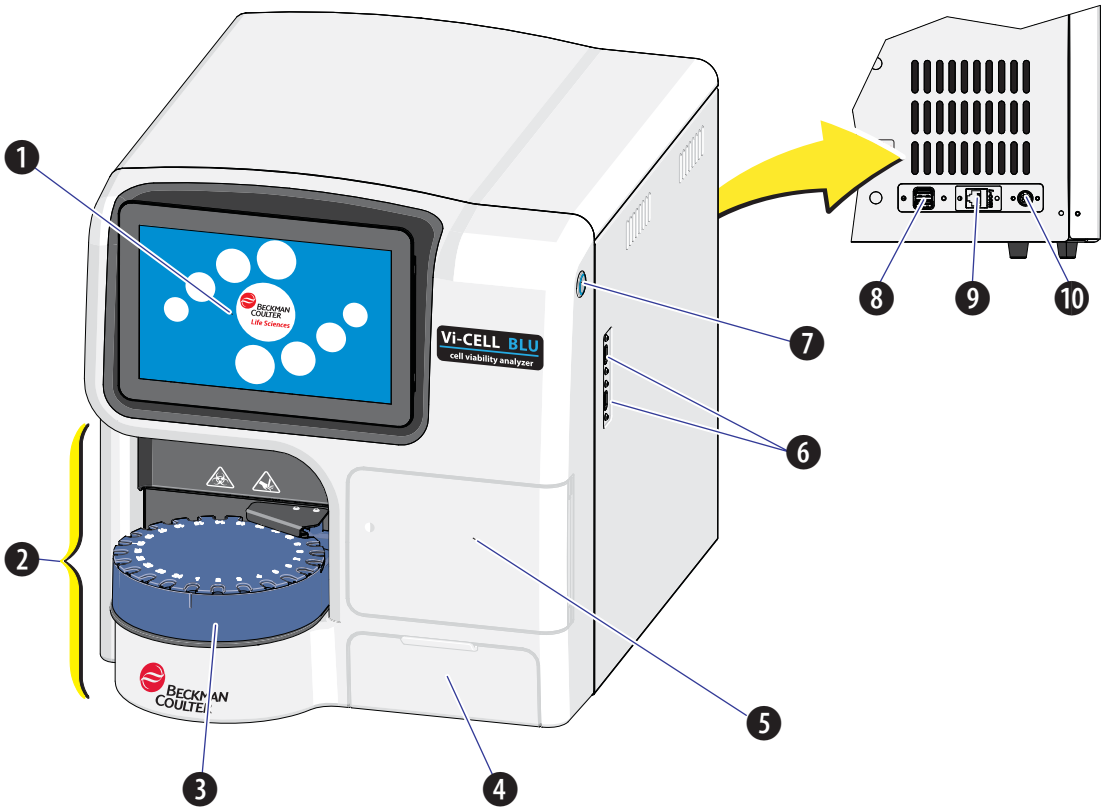


1. Live cells exclude dye
2. Dye permeable dead cells

System Components

The following images describe the main components of the Vi-CELL BLU Cell Viability Analyzer.

Figure 1.2 Vi-CELL BLU with carousel

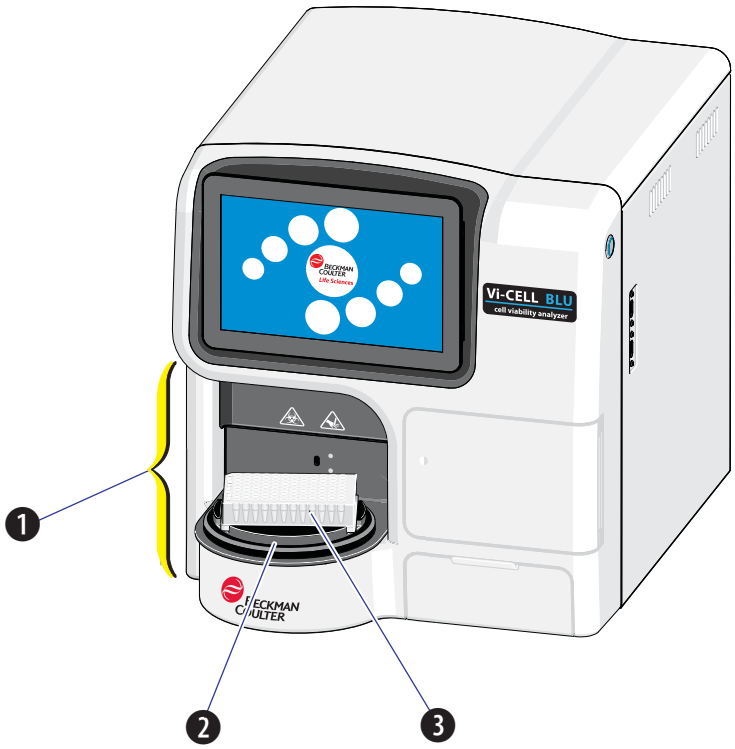


1. Touchscreen

   NOTE The touchscreen has an independent power button on the bottom-right corner of the screen.

2. Sample Station
3. Carousel
4. Waste Tube Tray Door
5. Reagent Door
6. USB 3.0 Ports
7. Power Button
8. USB 2.0 Port (rear)
9. Ethernet Port
10. Power Connector

Figure 1.3 Vi-CELL BLU with 96 well plate



1. Sample Station
2. Plate Holder
3. 96 Well Plate

Software

Beckman Coulter provides the Vi-CELL BLU software.

Reagent Pack

The Vi-CELL BLU Reagent Pack (PN C06019, Figure 1.5) is located behind the reagent door. Refer to Figure 1.2 and/or Figure 1.4.

Contents: 50mL trypan blue, 210mL conditioning solution, 210mL buffer solution, 210mL cleaning agent, safety sticker, and a waste bottle

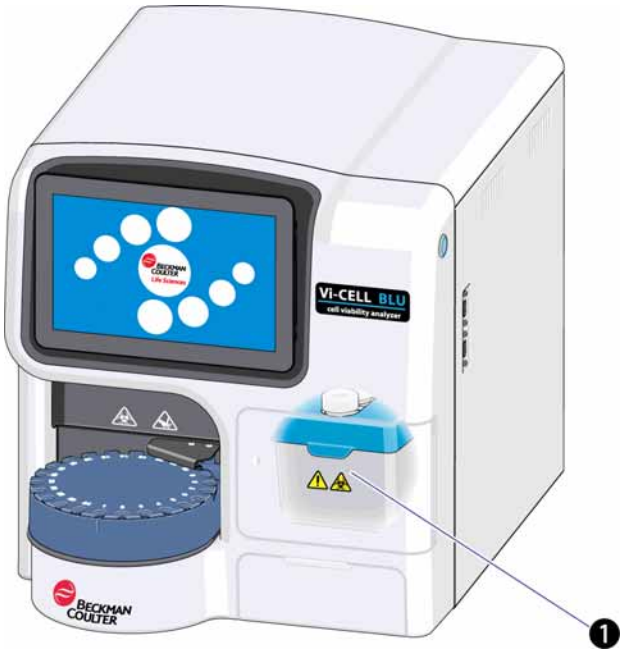
⚠ WARNING

Risk of biohazardous exposure if you have skin contact with the Reagent Pack waste liquid. The Reagent Pack waste bottle has a vent and the waste bottle must be upright whenever you are handling a used Reagent Pack in order to prevent waste liquid from leaking out of the waste bottle. Clean up spills immediately. Dispose of the Reagent Pack and the solid waste in accordance with your local regulations and acceptable laboratory procedures.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

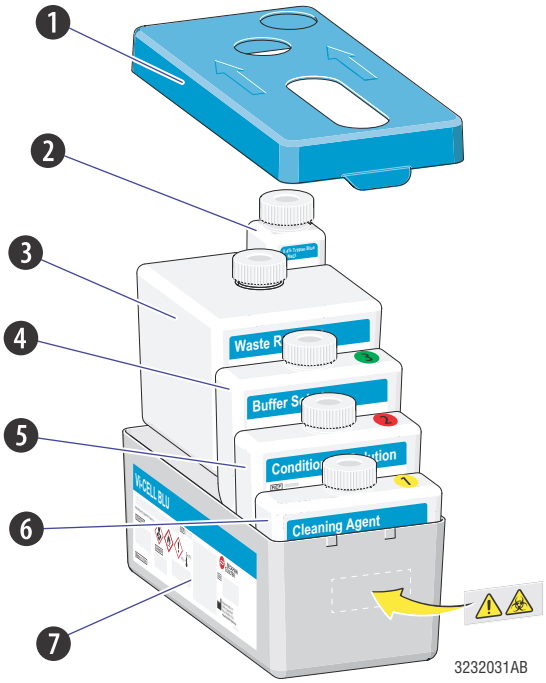
Always use the appropriate Personal Protective Equipment (PPE) when working with biohazardous materials.

Figure 1.4 Vi-CELL BLU Reagent Pack



1. Reagent Pack

Figure 1.5 Vi-CELL BLU Reagent Pack



1. Reagent Pack Lid
2. Trypan Blue Bottle
3. Waste Bottle
4. Buffer Solution Bottle
5. Conditioning Solution Bottle
6. Cleaning Agent Bottle
7. Reagent Pack Tray

Reagent Pack Reactive Ingredients

Isopropyl Alcohol 70-80%

Trypan Blue 0.1-1%

Diazolidinyl Urea 0.1-1%

Subtilisin 0.1-1%

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-33-one [EC# 247-500-7] and 2-mothyl-4-isothiazolin-3-one [EC# 220-239-6)(3:1) <0.05%

Reagent Pack Warnings and Precautions

Health Hazard: May cause allergy or asthma symptoms or breathing difficulties if inhaled and may cause cancer.

Flammable Material: Contains highly flammable liquid and vapour. Keep away from heat, hot surfaces, and sparks. No smoking.

 Harmful: May cause an allergic skin reaction, causes serious eye irritation, may cause drowsiness or dizziness.

- Highly flammable liquid and vapour
- May cause an allergic skin reaction
- Causes serious eye irritation
- May cause allergy or asthma symptoms or breathing difficulties if inhaled
- May cause drowsiness or dizziness
- May cause cancer
- Obtain special instructions before use
- Keep away from heat, hot surfaces, and sparks. No smoking
- Avoid breathing vapours
- Wear protective gloves, protective clothing, and eye/face protection
- If exposed or concerned: Get medical advice/attention

 Safety Data Sheet is available at beckman.com/techdocs.

Reagent Pack Storage Conditions and Stability

The Vi-CELL BLU Reagent Pack is stable to the expiration date on the tray label when stored at 15-25°C. In-use Vi-CELL BLU Reagent Pack is stable for 90 days or up to the expiration date, whichever is sooner.

Refer to Vi-CELL BLU Reagent pack SDS and/or decontamination procedure in the event of damage to reagent pack protective packaging.

NOTE If the Cleaning Agent has been partially or completely frozen, allow the product to warm to room temperature. Mix product by gentle inversion prior to placement on the instrument. Install the reagent, and prime if necessary, as directed in your instrument product manuals and/or online help.

Table 1.1 Vi-CELL BLU Reagents Shipping and Storage Conditions

Product	PN	Ship	Store
Vi-CELL BLU Reagent Pack	C06019	No temperature control	15-25°C (room temperature)
Vi-CELL BLU 50% Viability Ctrl	C09145	No temperature control	2-8°C (refrigerate upon arrival)
0.5M Vi-CELL Ctrl	C09147	2-30°C	2-8°C (refrigerate upon arrival)
2M Vi-CELL Ctrl	C09148	2-30°C	2-8°C (refrigerate upon arrival)
4M Vi-CELL Ctrl	C09149	2-30°C	2-8°C (refrigerate upon arrival)
10M Vi-CELL Ctrl	C09150	2-30°C	2-8°C (refrigerate upon arrival)

Safety Data Sheets (SDS/MSDS)

To obtain an SDS for Beckman Coulter reagents used on the system:

1. On the internet, go to http://www.beckman.com:
   a. Select Safety Data Sheets (SDS/MSDS) from the Support menu.
   b. Follow the instructions on the screen.
   c. Contact us if you have difficulty locating the information.
2. If you do not have internet access, contact us.

CHAPTER 2

Installation and Verification

Special Requirements – Pre-installation Checks

Environment

The instrument should be placed on a surface that is not subject to:

1. Excessive airborne dust
2. Strong vibrations
3. Extremes of temperature and humidity

Power Requirements

⚠ WARNING

Risk of electric shock and/or instrument damage. Ensure that the power outlet is properly grounded. Improper grounding can cause electric shock and damage the system. Verify that the output voltage of the power outlet conforms to the system requirements. To prevent personal injury, Beckman Coulter recommends using a power outlet designed to protect against electrical shock.

⚠ CAUTION

Possible instrument damage could occur if you use an extension cord or a power strip to connect the instrument. Always plug the instrument into a dedicated outlet with an isolated ground.

- Power: 200 watts max.
- AC Input: 100-240V AC, 2.5A, 50-60 Hz

Temperature and Humidity Requirements

⚠ CAUTION

Risk of instrument damage and/or erroneous results. To ensure reliability, the system must be operated in the specified environment, within the required temperature and humidity ranges. If the ambient temperature or humidity level falls outside the ranges mentioned below, use appropriate air conditioning.

- Temperature: 13 to 37°C (55 to 99°F)
  Temperature Variation of: ±3°C over 8 hours.
- Humidity: 10 to 90%

Acoustic Noise Level

Peak sound pressure level <65 dBA with an average ≤ 50dBA.

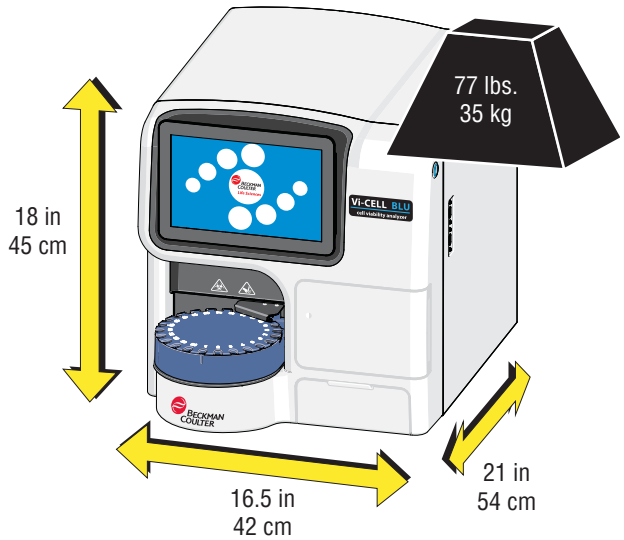
Worktable

⚠ CAUTION

Risk of instrument damage. Place the instrument on a level surface. Failing to do so places the system in danger of toppling and can result in damage. Take all necessary precautions throughout the process of storing or transporting the instrument.

- The tabletop must be smooth and level.
- Minimum tabletop load bearing capacity 35 kg (77.16 lb).

Figure 2.1 Vi-CELL BLU size and weight



- The tabletop must not vibrate or shake.
- Position the instrument so that the power cable can be disconnected from the back of the instrument. See Operating and Servicing clearances below.

  Operating clearances

  — 10 cm (4 in.) clearance right side
  — 5 cm (2 in.) clearance left side
  — 5 cm (2 in.) clearance back of instrument
  — 1 cm (0.5 in.) clearance top of instrument

  Servicing clearances

  — 20 cm (7.9 in.) clearance right side
  — 20 cm (7.9 in.) clearance left side
  — 20 cm (7.9 in.) clearance back of instrument
  — 70 cm (27.2 in.) clearance top of instrument

Ventilation and Cleaning

IMPORTANT If necessary, use ventilation equipment. Airflow must not be allowed to blow directly on the instrument, it will affect the reliability of the data.

- Ensure that the working environment is well ventilated for proper heat dissipation.
- Maintain a clearance of at least 5 cm from the back of the instrument for heat dissipation.
- Keep the environment as dust free as possible.
- Avoid direct exposure to sunlight.
- Avoid placing near heat sources or exposing to drafts.
- Avoid corrosives or flammable gases.

Materials Shipped

NOTE The Instrument and Start Up Kit are shipped separately.

Instrument container

- Vi-CELL BLU Instrument
- Vi-CELL BLU Quick Start Guide
- Vi-CELL BLU Safety Notices

Start Up Kit

- Power Supply Adapter, 100-240 VAC, 200 W, 12V/15A
- Assy, 24 position Ejection Carousel, Vi-CELL BLU
- Power Cord, 18VBI SVT blk

- Microfuge Tube, no cap, 350 count
- 96-Well Plates, 5 count
- Vinyl Film, 10 count
- Waste Tube Tray
- 8mm Hex Allen Wrench, Std L
- Snap-in Hole Plug, Blk Nyl, 0.750-in. dia

Unpacking and Setup

⚠ CAUTION

If the system fails to start properly, check first to see whether the power cable and connection cables are properly connected. Never shut off the power or disconnect a data cable while the system is performing a task. Doing so can result in data loss or damage to the system.

⚠ WARNING

Risk of personal injury when removing the strap from the shipping box. Hold the strap on the upper corner of the crate and cut the strap near the lower corner of the crate to prevent strap snap back that could cause injury.

⚠ WARNING

Risk of personal injury if only one person lifts the instrument. The instrument has no lifting handles, and it weighs more than one person should lift. Therefore, to prevent injury, at least two people following necessary safety precautions should lift the instrument together. Use caution when lowering the instrument to avoid pinching fingers.

⚠ CAUTION

Risk of instrument damage. Place the instrument on a level surface. Failing to do so places the system in danger of toppling and can result in damage. Take all necessary precautions throughout the process of storing or transporting the instrument.

1. Raise the instrument box from the wooden shipping pallet to access the instrument.
2. Remove the accessories from the Start Up Kit and check the Materials Shipped list above to ensure all the Start Up Kit items are included and there is no damage. Notify Beckman Coulter if damage is observed or parts are missing.
   - Worldwide, find us via our website at *www.beckman.com/support/technical.*
   - In the USA and Canada, call us at 1-800-369-0333.

- Outside of the USA and Canada, contact your local Beckman Coulter Representative.

⚠ WARNING

Risk of personal injury. Use caution when lowering the instrument to avoid pinching fingers.

3. Place the instrument on a bench with an appropriate amount of space and tabletop load bearing capacity (refer to Worktable).

Instrument dimensions

- 42 cm (16.5 in.) W
- 55 cm (21.7 in.) D
- 45 cm (18 in.) H

Operating clearances

- 10 cm (4 in.) clearance right side
- 5 cm (2 in.) clearance left side
- 5 cm (7.9 in.) clearance back of instrument
- 1 cm (0.5 in.) clearance top of instrument

Servicing clearances

- 20 cm (7.9 in.) clearance right side
- 20 cm (7.9 in.) clearance left side
- 20 cm (7.9 in.) clearance back of instrument
- 70 cm (27.6 in.) clearance top of instrument

Instrument weight

- Total instrument weight: 74-77 lbs.

4. Remove the shipping restraints.

   NOTE Make sure to keep and store the shipping restraint.

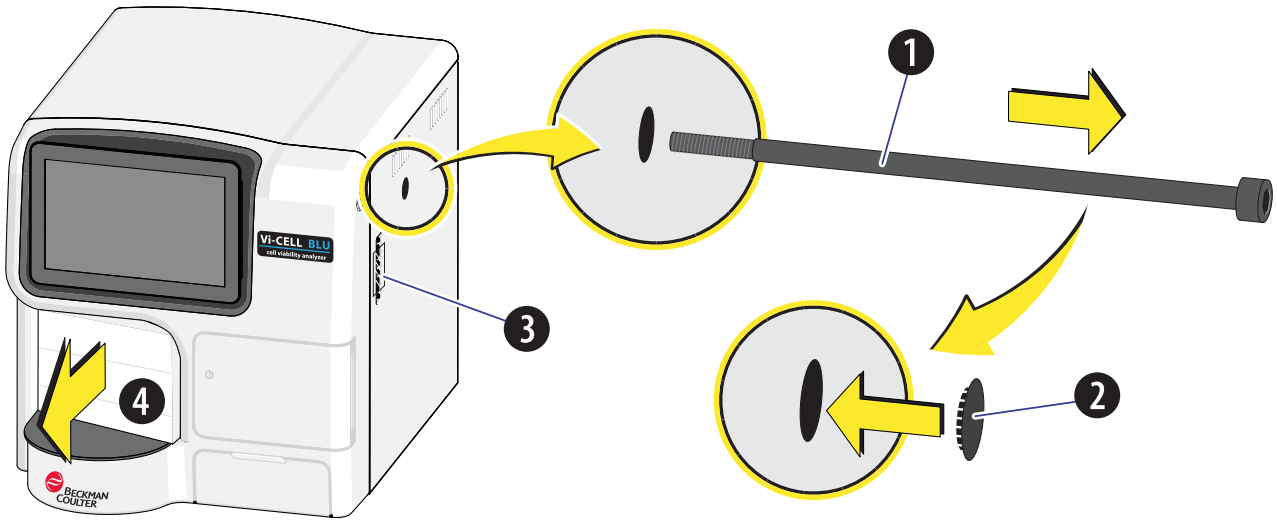
   a. Remove the large Allen bolt (1) on the right side of the instrument with the 8mm Allen key from the start up kit and then cover the hole with the plug (2) from the kit.

   b. Remove the piece of shipping tape (3) on the right side of the instrument.

      NOTE If the shipping tape requires significant force to remove and/or stretches and breaks during removal rather than coming off cleanly, contact us prior to using the instrument.

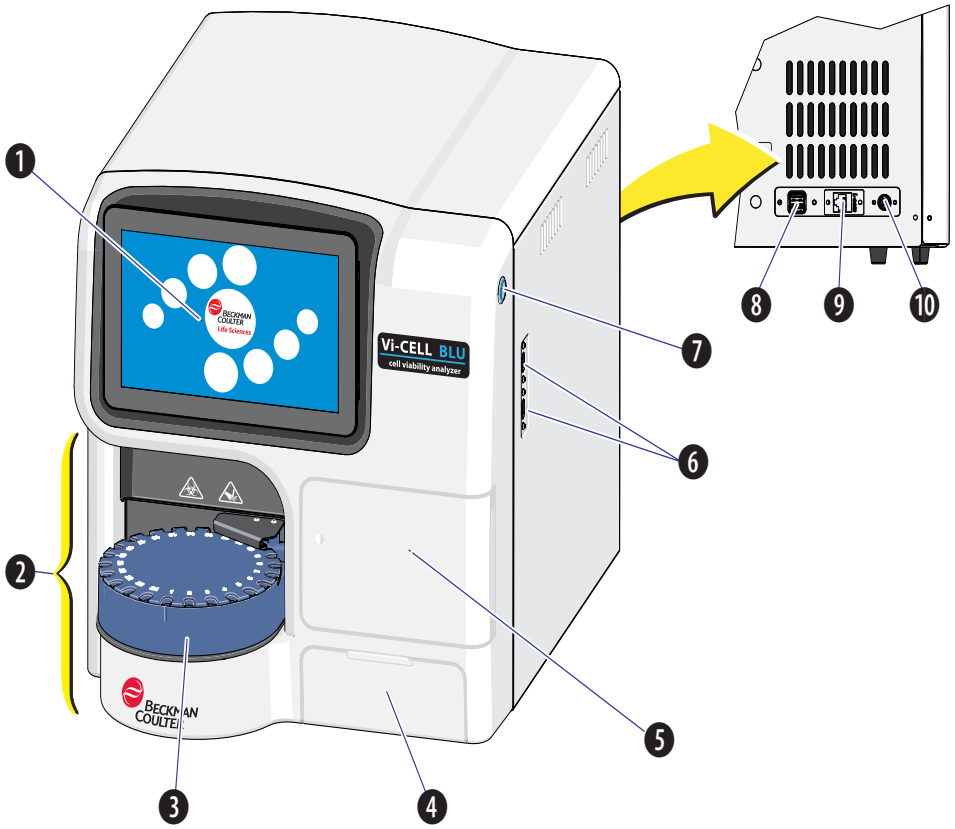
   c. Remove the foam insert (4) from the carousel location.

Figure 2.2 Vi-CELL BLU shipping restraints



5. Vi-CELL BLU system components.

Figure 2.3 Vi-CELL BLU components



1. Touchscreen
2. Sample Station
3. Carousel
4. Waste Tube Tray Door
5. Reagent Door
6. USB Ports
7. Power Button
8. USB Port (rear)
9. Ethernet Port
10. Power Connector

⚠ CAUTION

Risk of injury from electrical shock. Follow the order of the instructions below for connecting the instrument to prevent electrical shock.

6. Connect the instrument to the power supply module.

The power supply Module supports 100-240 VAC; 50-60 Hz.

7. Use the appropriate cable to plug the power supply module into an electrical outlet.

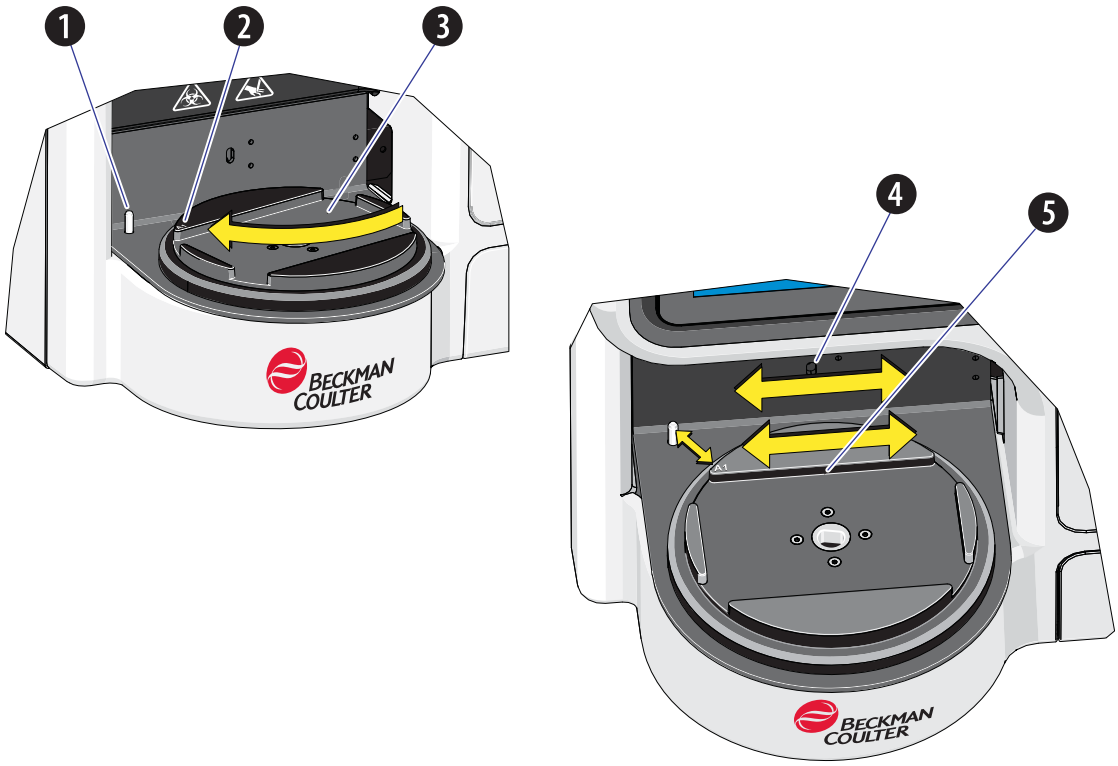
8. Press the power button and follow the instructions for First time Login.

9. Install the Carousel.

a. Orient the turntable so that,

- The A1 indicator (2) is near the silver pin (1),
- The Reference surface (5) is parallel to the back wall (4).

Figure 2.4 Install Vi-CELL BLU carousel

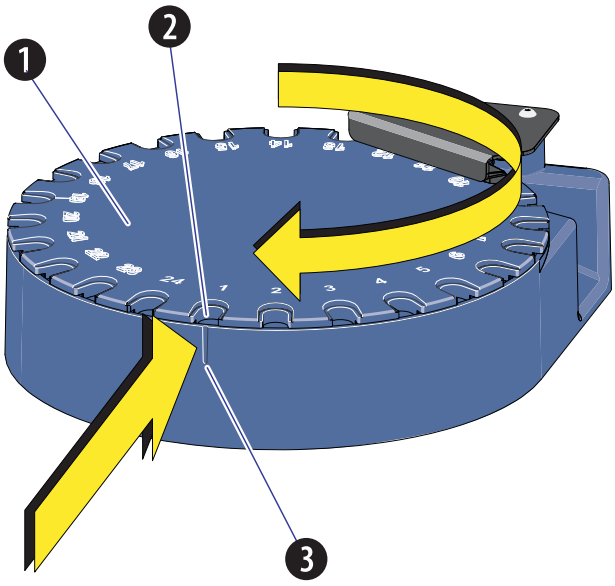


1. Silver pin
2. A1 indicator
3. Turntable
4. Back wall
5. Reference surface

b. Ensure that the turntable is fully extended. If the turntable is not fully extended, the carousel will not fit.

c. Align the carousel so that position 1 is centered on the indicator mark.

Figure 2.5 Align Vi-CELL BLU carousel

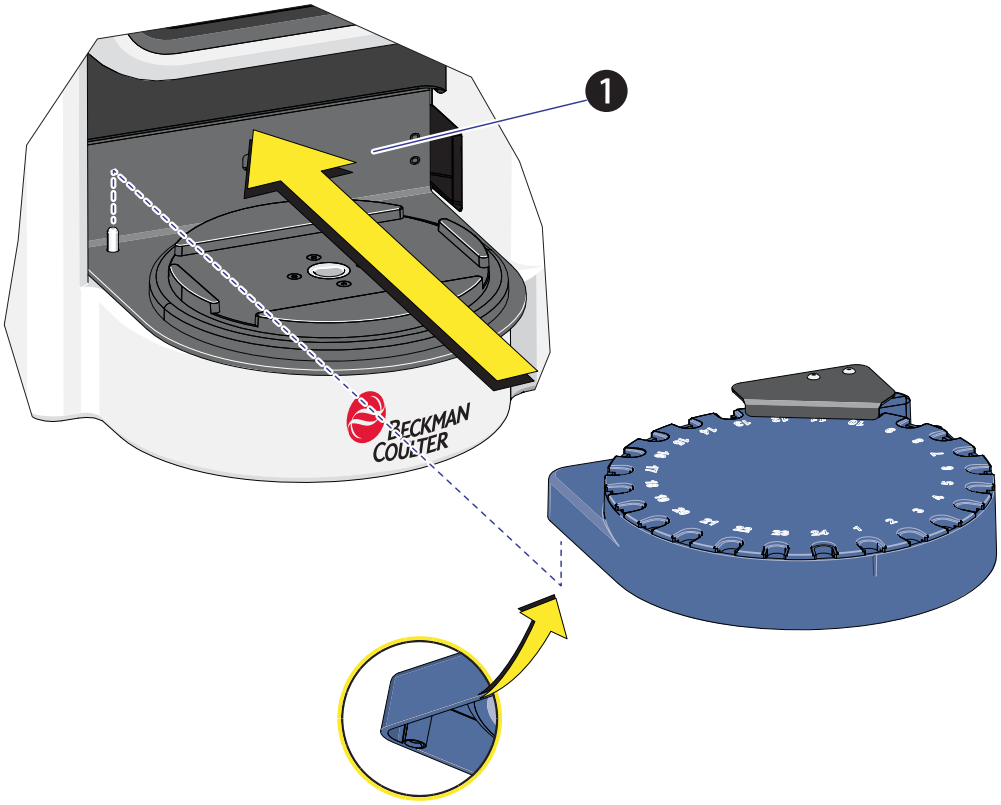


1. Carousel
2. Position 1
3. Indicator mark

d. To install the carousel on the instrument:

- Do not rotate carousel
- Keep carousel level
- Horizontally insert the carousel until contacting the black surface
- Lower the carousel straight down

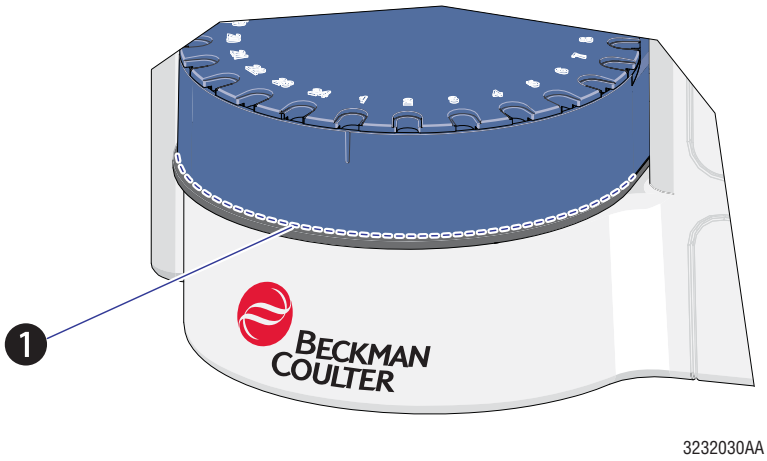
Figure 2.6 Insert Vi-CELL BLU carousel



1. Black surface

e. Once carousel is installed, check that the gap between the carousel and the turntable (1) is not greater than 1 mm.

Figure 2.7 Vi-CELL BLU carousel gap

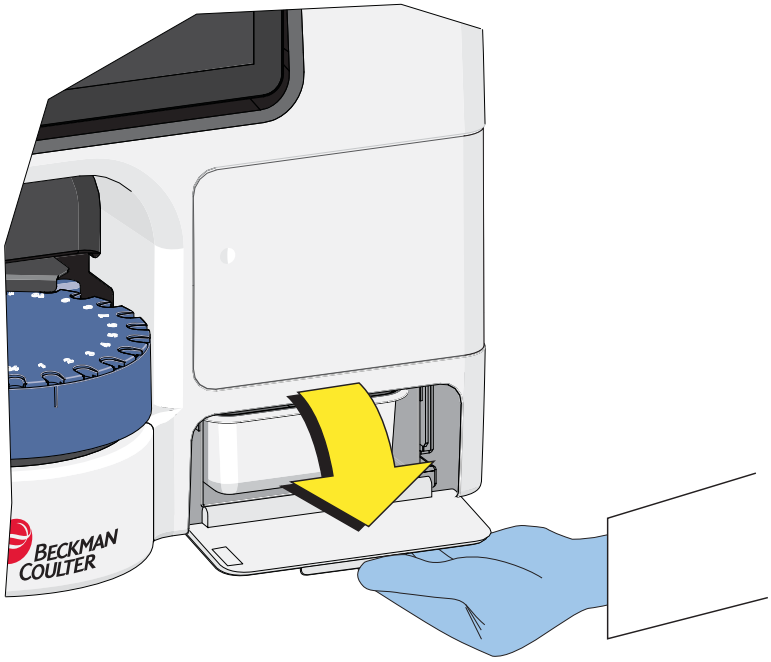


1. Gap not more than 1 mm.

f. Install the waste tube tray.

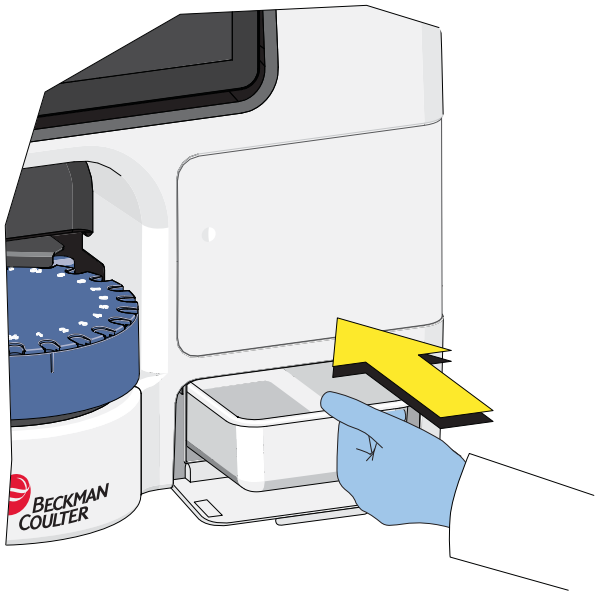
1) Open the waste tube tray door.

Figure 2.8 Open waste tube tray door



2) Insert the waste tube tray.

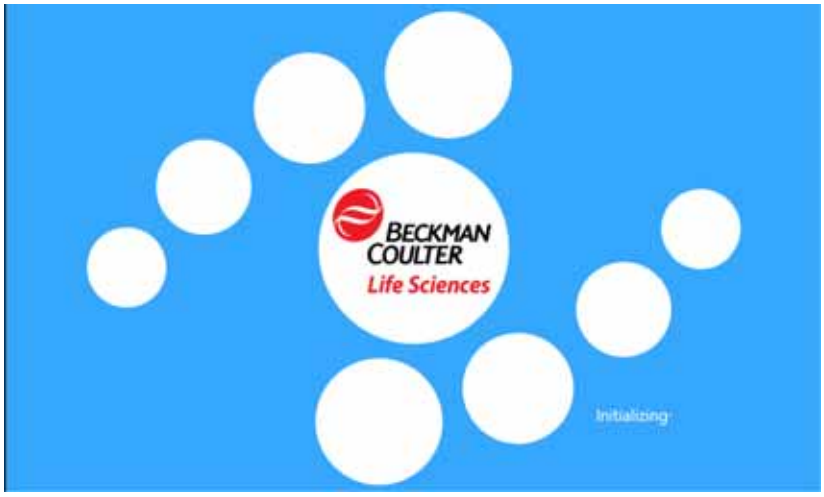
Figure 2.9 Insert waste tube tray



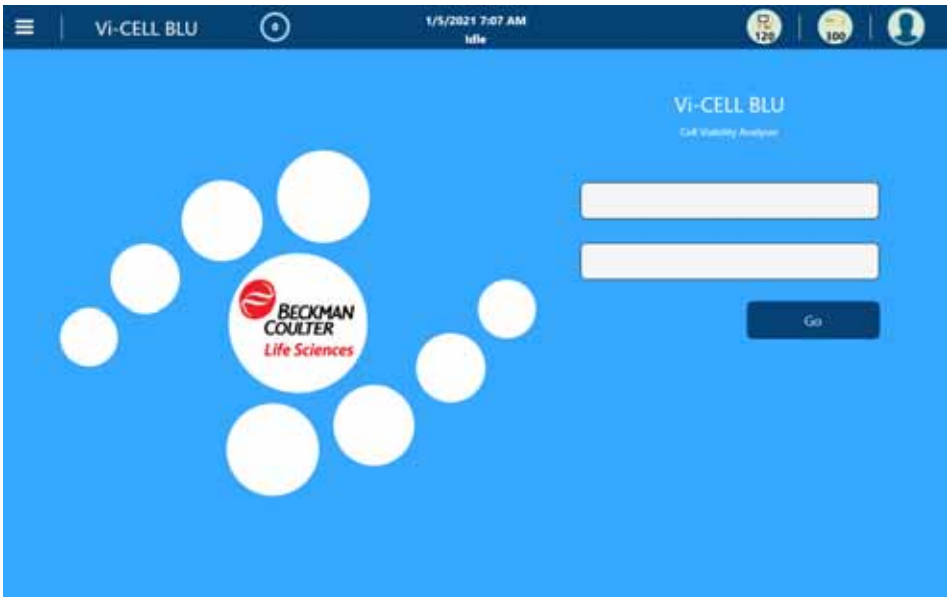
3) Close the waste tube tray door.

First time Login

1 After powering on the instrument the Initializing screen is displayed.



2 After Initialization, the login screen is displayed.



3 Enter the default login credentials:

- Username - factory_admin
- Password - Vi-CELL#0

NOTE After the first successful login, the user will be prompted to change the default password. After changing the password, record the new password.

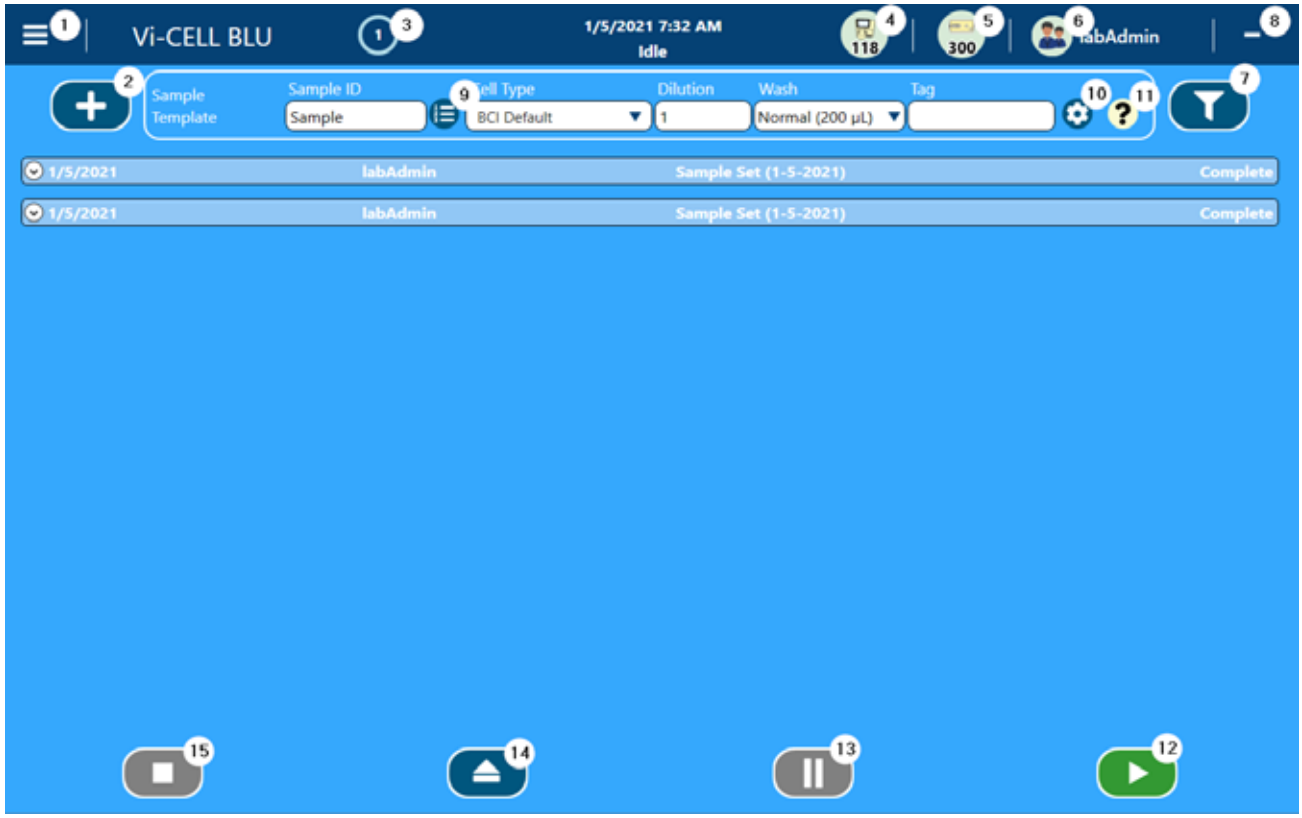
4 Select Go to launch the software.

See User Administration for adding additional users.

Home Screen

After login, the home screen is displayed.

Figure 2.10 Home screen



1. Main menu, see Figure 2.14, Main menu
2. Add a Sample Set, see Run Samples
3. Active notifications
4. Instrument status
5. Reagent status
6. Current user
7. Filter Sample Sets, see Figure 2.11, Filter Sample Sets and Figure 2.12, Filter Samples
8. Minimize the software (only available to admin users when security is enabled)
9. Sequential Sample Naming see 6, Enter a Sample ID .
10. Advance options, see Figure 2.13, Set up Advanced Options
11. Help, Enhanced Sample Workflow
12. Run Sample Sets
13. Pause
14. Eject
15. Stop

NOTE **(3)** shows the active notification on the instrument. The notification will change color in response to the severity of the notifications present. Select this button to display the list of notifications. Yellow and Red notifications indicate issues with the instrument which must be addressed prior to continued use (some examples may be expired/empty reagents, hardware/mechanical faults).

Red notifications also cause the screen to pulse pink as a reminder of the need to acknowledge the notification.

NOTE Select Advanced Options **(10)** in the Home screen (refer to Figure 2.10) to modify the run options settings for an individual sample. Note that if security is On, only operators with the appropriate permission level can modify the run options settings. Refer to Figure 2.13.

Figure 2.11 Filter Sample Sets

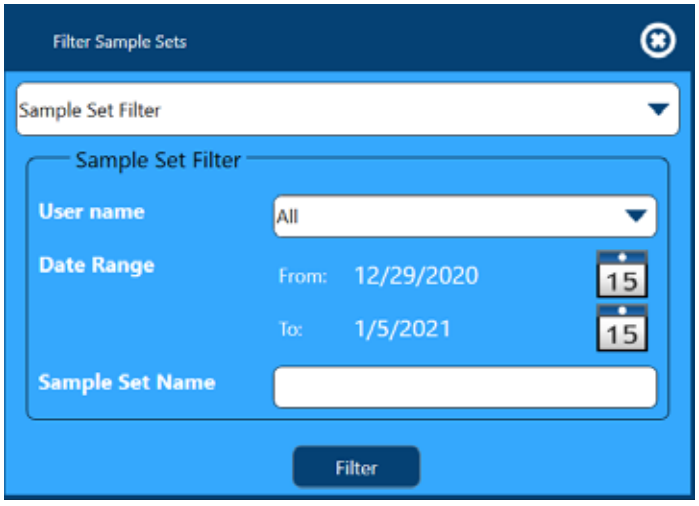


Figure 2.12 Filter Samples

Figure 2.13 Set up Advanced Options

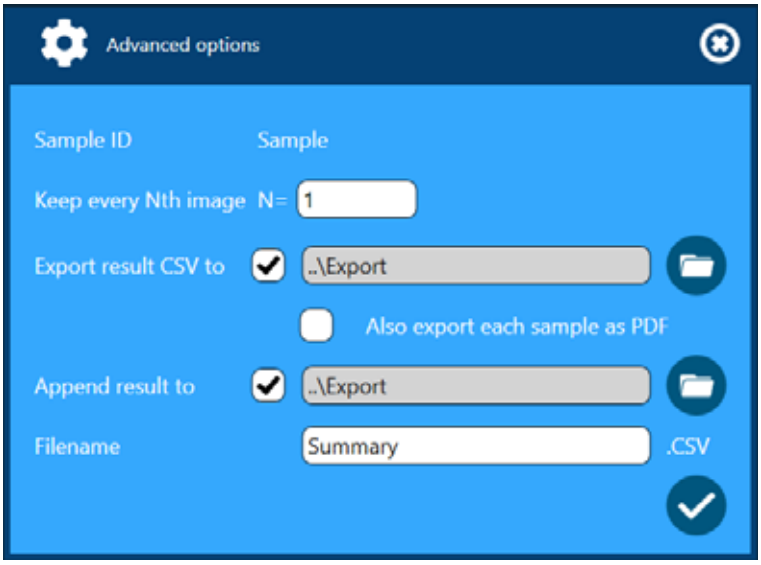


Figure 2.14 Main menu

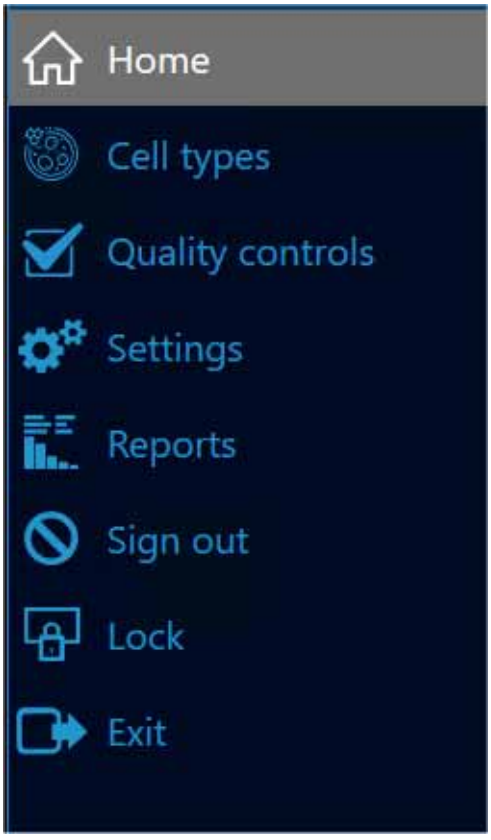


Table 2.1 Main menu buttons

Home	Sample Set creation screen to program and run samples.
Cell types	View, copy, edit, save or delete Cell types.
Quality controls	View, export and sign a Quality Control or add a Quality Control.
Settings	Setup the system settings, see Settings Tab.
Reports	Create, print or export results reports and view or export audit, sample error and calibration log files.
Sign out	Sign out the current user without exiting the software.
Lock	Lock the software user interface.
Exit	Exit the software.

Install a Reagent Pack

⚠ WARNING

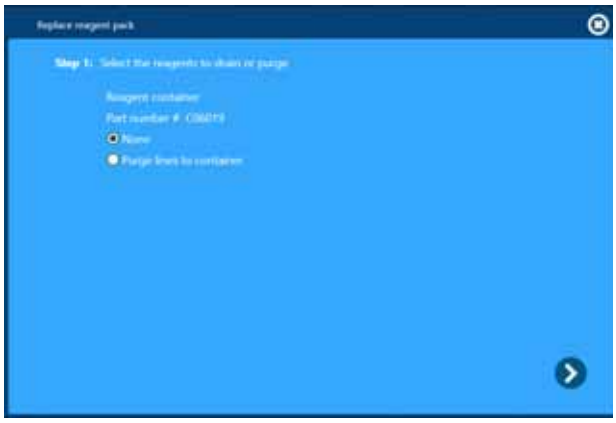
Risk of biohazardous exposure if you have skin contact with the Reagent Pack waste liquid. The Reagent Pack waste bottle cap has a vent and the Reagent Pack must be upright whenever you are handling a used Reagent Pack in order to prevent waste liquid from leaking out of the Reagent Pack waste bottle. Clean up spills immediately. Dispose of the Reagent Pack and the solid waste in accordance with your local regulations and acceptable laboratory procedures.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

Always use the appropriate Personal Protective Equipment (PPE) when working with biohazardous materials.

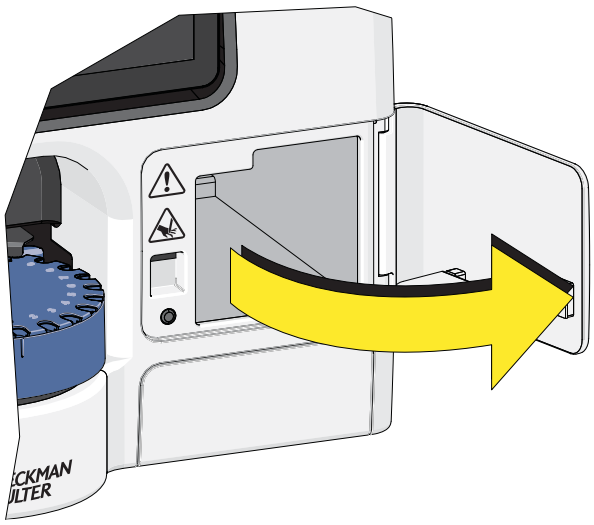
1 Select 285 or and **Replace Reagent Pack.**

2 Select **None** and select .

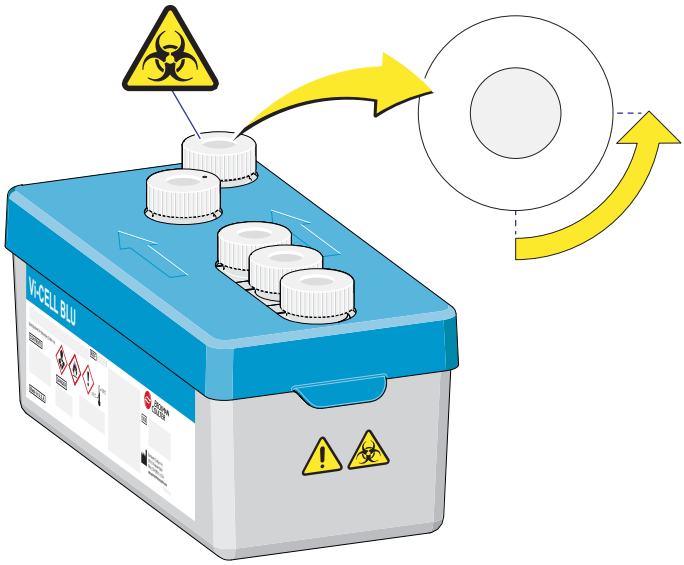


NOTE Select **None** if you do not wish to purge the fluids. Use **None** to install a new reagent pack. Select **Purge lines to container** to empty the system fluidics to waste. Use **Purge lines to container** for storage or service.

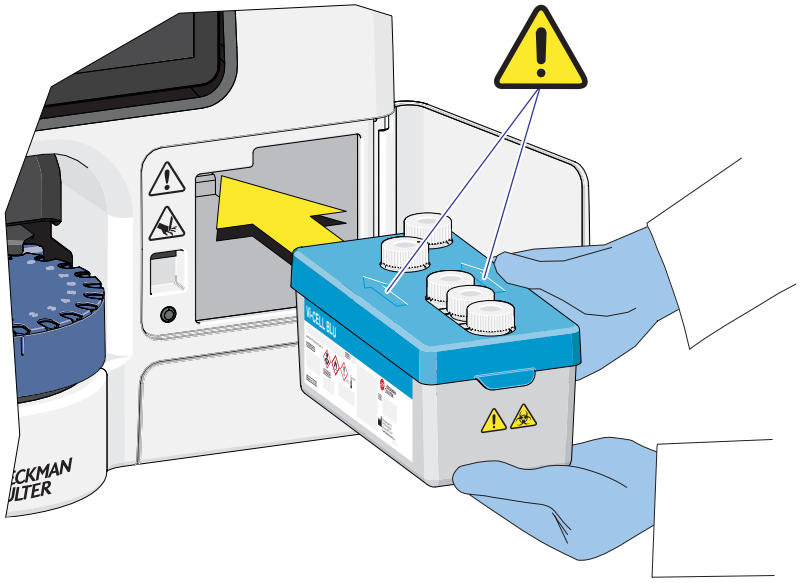
3 The reagent door opens.



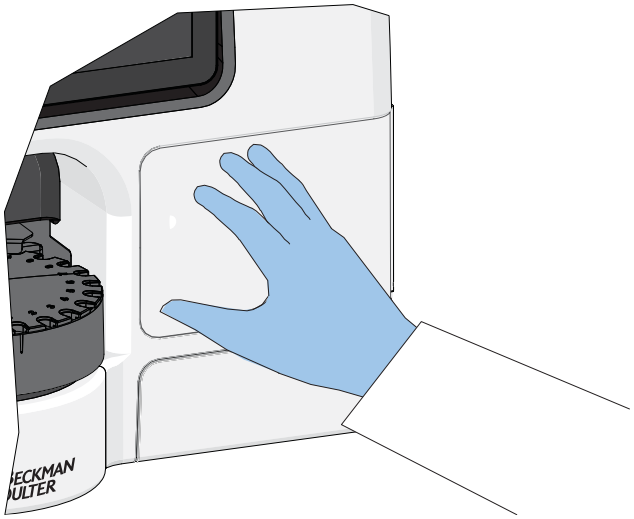
4 Before inserting the Reagent Pack, loosen the trypan blue lid in the reagent pack ¼ turn. Failure to do so may cause the bottle to form a high vacuum which could impact counting accuracy and an increased concentration results error, most frequently occurring the first three samples of each day.

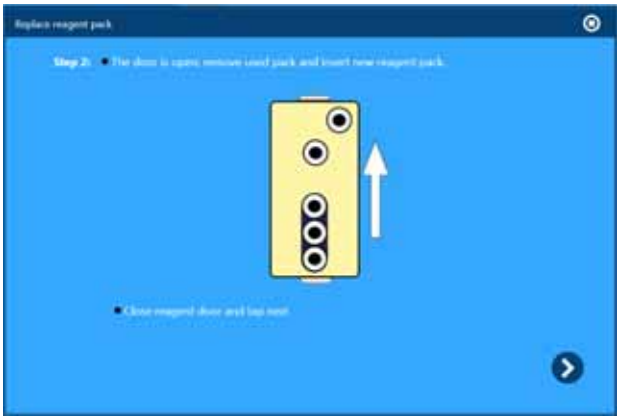


5 Place the included biohazard label on the end of the reagent tray (or on the waste bottle if the waste bottle will be disposed of separately) and insert a Reagent Pack.



6 Close the reagent door and select .





7 Confirm Reagent information and select .

8 Select  , empty the waste tube tray and select  .

Settings Tab

Select  and 

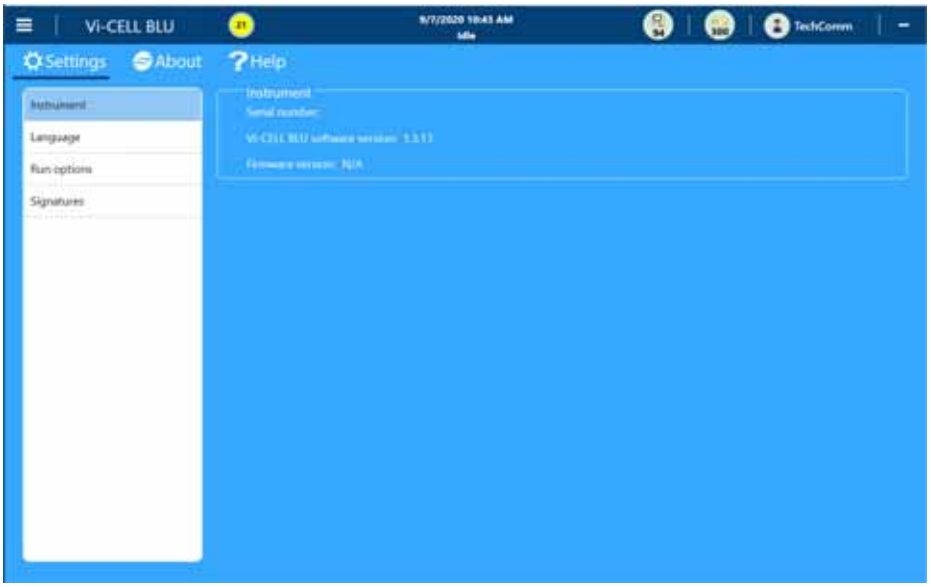
to access the System Settings.

There are four System Settings screens Instrument Screen, Language Screen, Run Options Screen and Signatures Screen.

Instrument Screen

Standard User

- Instrument screen displays the:
  - Serial Number
  - Software Versions
  - Firmware Version



Administration User

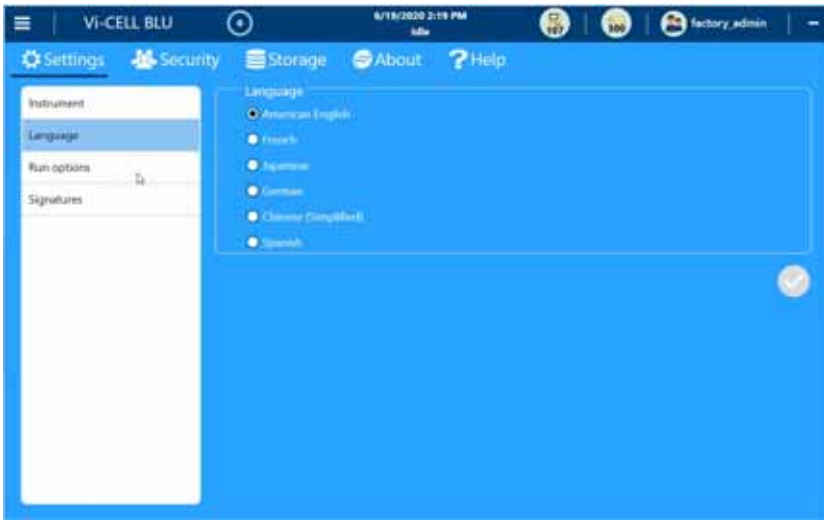
- Instrument screen displays the:
  - Serial Number
  - Software Versions
  - Firmware Version

NOTE Only Administration Users can make changes to the SMTP Configuration settings. The SMTP configuration is used to set up email address to notify users of a password change.

Language Screen

Select your language and select . The software prompts to ensure you want to save the changes even if no changes have been made.

When making this change, ensure that your IT Administrator has appropriately configured the country, region and regional format settings for the operating system.

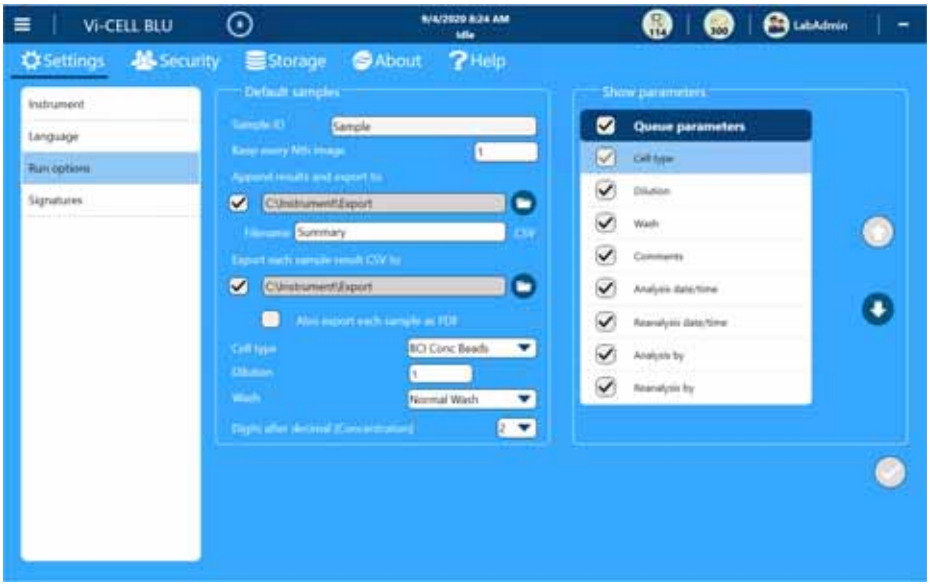


Run Options Screen

- Set up the Default samples

  NOTE The number of digits displayed in the numerical concentration value is selectable between 2-4 digits.

- Choose the Show Parameters settings you wish to have displayed on the Detail Review screen.



NOTE The Save every Nth image option indicates the images that are saved for reanalysis purposes. Set to 99 to save the minimum number of images.

NOTE Saving less than the original number of images can cause changes in the results values during reanalysis. If planning to perform cell type optimization it is important to save the entire image set to use for reanalysis.

Use  to arrange the order of the parameters.

Select  to exit. The software prompts to ensure you want to save the changes even if no changes have been made.

Signatures Screen

- Set Signatures settings

NOTE  plus the 3 letter abbreviation indicates the signature type that has been attached.

Select  to exit. The software prompts to ensure you want to save the changes even if no changes have been made.

Security Tab

NOTE The Security Tab can only be accessed by Administration Users.

Select ☰ > Settings > Security to access the Security Settings.

1. Add User, see Add a User
2. Edit, see Edit a User
3. Edit Security Settings, see Set Security settings

User Administration

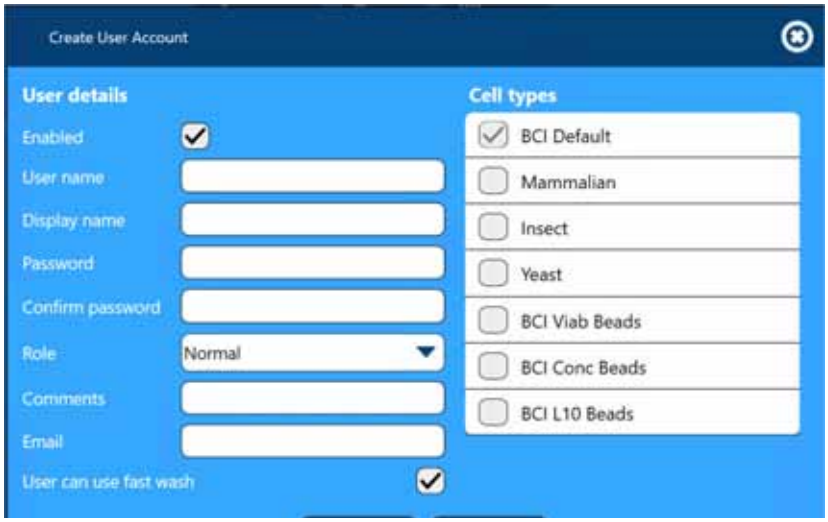
Add a User

NOTE You must be logged in as an administrator to add a user.

---

1 Select ☰ > Settings > Security.

2 Select Add User.



NOTE In Active Directory mode you cannot add users from within Vi-CELL BLU software.

- Enter User name

  User names are also used for result data folder creation, and therefore cannot contain characters prohibited for use in folder names. The prohibited list of characters is presented below:

  — the “space” character
  — the single-quote character (‘)
  — the double-quote character (“)
  — the backslash character (/)
  — the forward slash character, either single or multiple (\ or \\ )
  — either square bracket character ([or])
  — either curly-brace character ({ or })
  — the semi-colon character (;)
  — the colon character (:)
  — the vertical bar character (|)
  — the equal sign (=)
  — the comma character (,)
  — the plus sign (+)
  — the asterisk character (*)
  — the question mark character (?)
  — the ‘less than’ symbol character (<)

— the ‘greater than’ symbol character (>)

NOTE To better support 21 CFR Part 11 the user name should be the users full display name. Data and audit log entries are tagged with the user name as entered.

- Enter Display name

NOTE The Display name field is optional and is not written to any log files.

- Enter Password
- Confirm Password

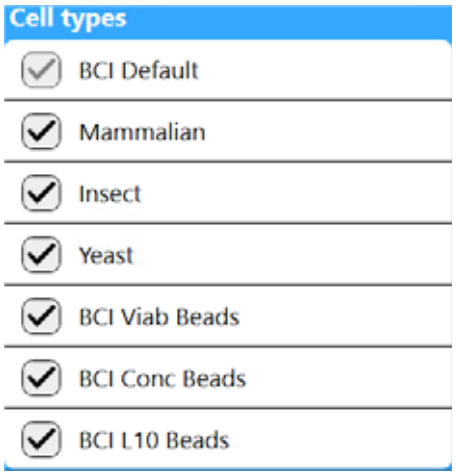
NOTE This is a temporary password that must be changed the first time the new user logs in. The password requirements include:

1. Minimum length of 10 characters
2. Maximum length of 16 characters
3. At least 1 lowercase character
4. At least 1 uppercase character
5. At least 1 number
6. At least 1 special character (all characters are allowed)

- Select Role
- Enter Comment (optional)
- Enter Email address (optional)

NOTE Email address is used to notify a user when their password has been changed

- Select whether User can use **Fast Mode**
- Select Cell types



NOTE Only the Cell types that are selected for each user will be displayed in the User Screen when the users attempt to create a Sample Set. The BCI Default will always be available to run.

- Select Create to create and save User.

NOTE The Admin is prompted for the username and password when adding or making changes to users to ensure the admin is the person operating the machine.

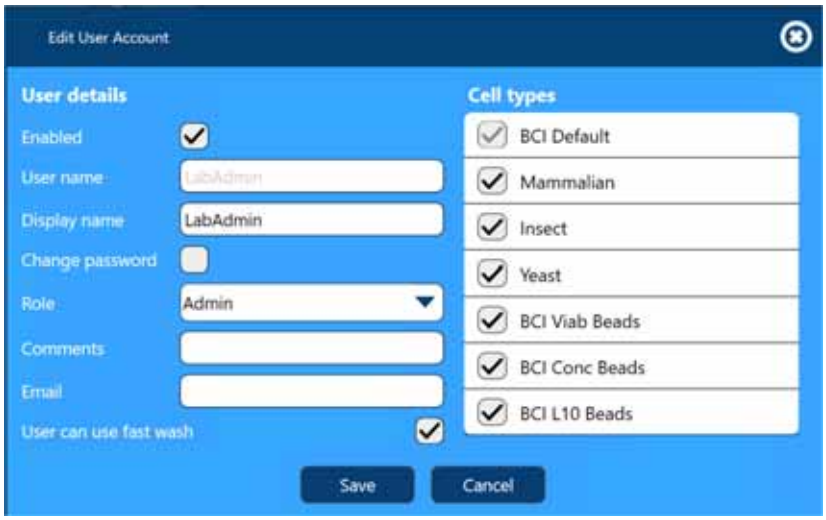
Edit a User

NOTE You must be logged in as an administrator to edit a user.

NOTE In Active Directory mode, only those user configuration fields controlling instrument operation or designating a user as enabled/disabled are editable for Active Directory users from within the Vi-CELL BLU software. See Active Directory Configuration.

1 Select > Settings > Security.

2 Select Edit.



You can choose to:

- Change Display name
- Change Password
- Change Role
- Change Comment
- Change Email address
- Change whether User can use fast mode
- Change Cell Types

- Select Save to save changes to User Account.

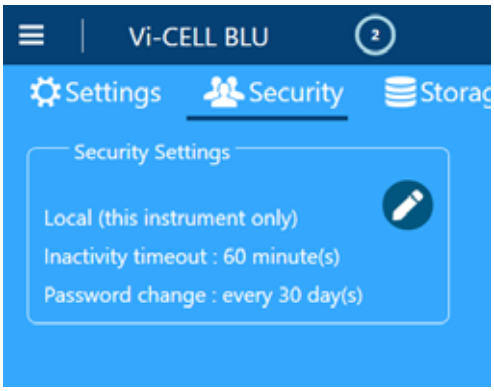
NOTE Name, password and role are not editable in Active Directory mode.

Set Security settings

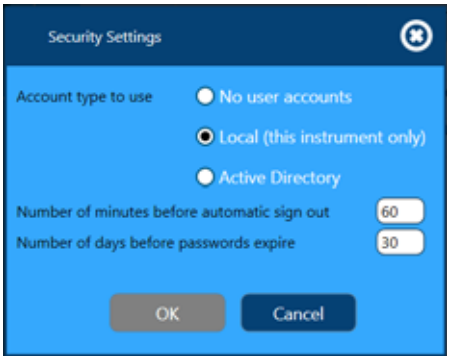
NOTE You must be logged in as an administrator to access Security Settings.

Select ☰ > Settings > Security.

NOTE The instrument is set to have security on by default.



Select .



- No user accounts
- Local (this instrument only)
- Set the Number of minutes before automatic sign out.

  Range: minimum 1 minute, maximum 60 minutes.

  NOTE Inactivity timeout is set to prevent unofficial access to the system, as when the system is left unattended directly after starting the Sample Set.

— Set the Number of days before passwords expire.

Range: minimum 1 day, maximum 60 days.

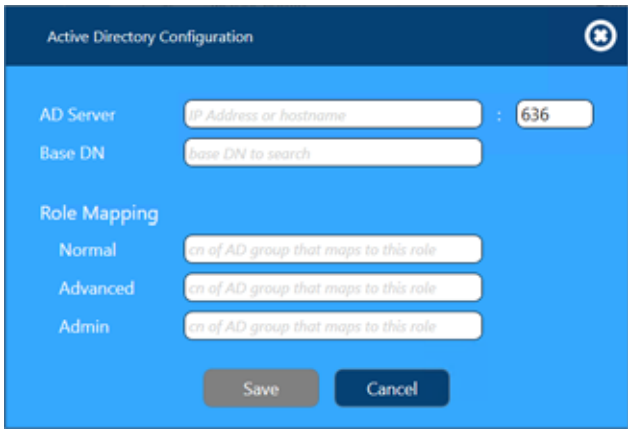
— Active Directory (see Active Directory Configuration)

— Select OK.

— Enter your administrator password and select Go.

— Select OK.

Active Directory Configuration



- AD Server
  - — Full hostname

    Administrator enters the full hostname of the Active Directory server.
- Base DN
  - — base DN to search

    Specifies the root for searches in the Active Directory.
- Role Mapping
  - — Normal
    - cn of AD group that maps to this role

      The cn (or Common-Name) is a single-value attribute that is the object's relative distinguished name. The cn is the name of the group in Active Directory Domain Services that would map to the Normal role in Vi-CELL BLU.
  - — Advanced
    - cn of AD group that maps to this role

      The cn (or Common-Name) is a single-value attribute that is the object's relative distinguished name. The cn is the name of the group in Active Directory Domain Services that would map to the Advanced role in Vi-CELL BLU.

— Admin

- cn of AD group that maps to this role

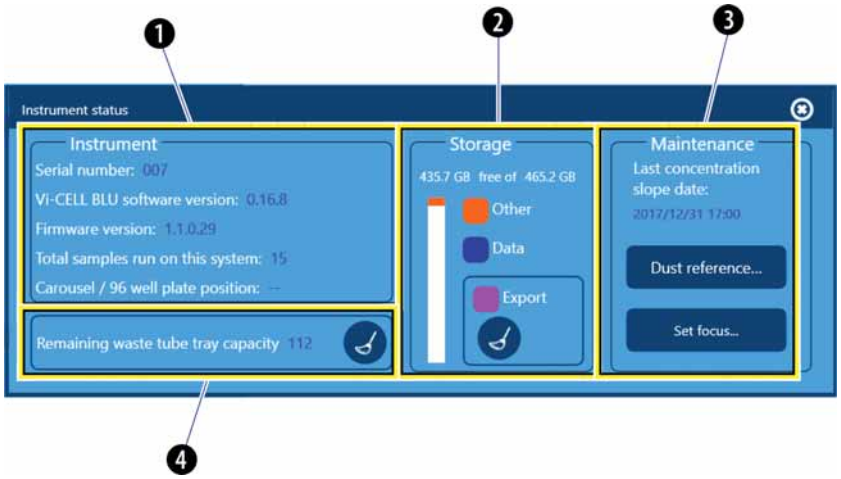
  The cn (or Common-Name) is a single-value attribute that is the object's relative distinguished name. The cn is the name of the group in Active Directory Domain Services that would map to the Admin role in Vi-CELL BLU.

NOTE Role names are case sensitive.

- Select Save
- Enter the name and password of an Active Directory user whose account is a member of the group mapped to the Vi-CELL Admin role and select Go.
- Select OK.

Instrument Status

1 Select  to display the Instrument Status.



1. **Instrument.** Displays the instrument information including serial number, software version, firmware version, total number of samples run on the system, and the Carousel/96 well plate position.
2. **Storage.** Displays the remaining storage space and breaks down the use of space by Data (internal data used for future reference which cannot be deleted here), Other (system data), and Export (reports exported and configuration data). Select  to delete all of the export data. Note that these files are visible on the network interface.
3. **Maintenance.** Displays the last date for concentration slope. The dust reference and set focus functions can be run from this window.
4. **Remaining waste tube tray capacity.** Displays the remaining capacity for the waste tube tray. Note that the maximum capacity is 120 tubes. Remaining waste tube tray capacity is the number of tubes the waste tray will hold. A message will appear if the count reaches zero. Select  to reset the count.

   NOTE If the count reaches zero, the instrument will stop running and you must reset the count to start running samples again.

Instrument Time and Date Settings

IMPORTANT When signing out of the active user account to change to another instrument OS user account, a hard-wired keyboard will be required by the OS. The touch panel keyboard is not available in the initial login lock screen. Returning to the normal instrument state should be accomplished by restarting the instrument through the start menu option or use of the power button.

To setup the date and time, use the Microsoft Windows tools.

To access the Microsoft Windows tools, you must be logged into the operating system with administrator privileges. Log into the application software as an administrator and exit the software from the main menu. If security is disabled, exit the application from the main menu.

From the Windows Start menu, select the user icon and sign out.

Using a USB keyboard press Ctrl, Alt, Del to get to the sign in screen and sign into Windows using the following credentials:

Username: ViCellAdmin

Password: Vi-CELL#0

NOTE The password provided is the initial password. The user will be prompted to change the password upon the first login.

Access date and time settings through the **Start Menu > Settings > Time & Language** to customize the date and time.

Instrument Performance Verification

Daily Verification

A control should be run daily to ensure proper instrument performance. The Beckman Coulter Vi-CELL Concentration Controls have been developed for this purpose. Concentration Controls are 2M (PN C09148), 4M (PN C09149) or 10M (PN C09150) Control Beads. Refer to your reagent IFUs. We recommend running the level(s) of control that are representative of your sample. More levels can be run in accordance with your Standard Operating Procedures. Follow sample preparation as indicated in the control assay sheet.

If the concentration control does not meet the results listed in the Vi-CELL BLU Concentration Control assay sheet:

- Ensure that BCI ConcBeads is selected in the Vi-CELL BLU software when running concentration control.
- Verify that the concentration control did not freeze at any time. Freezing may result in bead aggregation and decreased counts. See the Vi-CELL Concentration Control assay sheet for the recommended storage temperatures.
- Ensure that the concentration control is handled properly, as proper mixing and centrifugation are crucial to recovery results. Mix and centrifuge the concentration control per the Vi-CELL Concentration Control assay sheet instructions. Make sure no droplets are stuck in the cap or on wall of the tube. Do not leave the tube uncovered for extended period of time as this affects the concentration.
- If there is debris inside the flow cell, perform the decontamination procedure in CHAPTER 8, Maintenance Procedures to ensure that the internal components are clean, as debris can affect results. If the debris does not clear after two decontamination attempts, contact us.
- Try a new vial of concentration control. If after two attempts the concentration control does not meet the results specified in the Vi-CELL Concentration Control assay sheet, contact us.
- Ensure the concentration control is stored at the recommended storage temperature at all times before usage.

CHAPTER 3
Startup

Startup

The instrument is not required to be powered down every night. In the event that the instrument has been powered down, use the following startup instructions when the instrument is powered on again.

NOTE If nightly clean is skipped because the instrument was powered off before the cleaning, the instrument will attempt a nightly clean during the initialization sequence the next time the instrument is powered on.

⚠ WARNING

Ensure all doors are closed and secured in place prior to and during instrument operation.

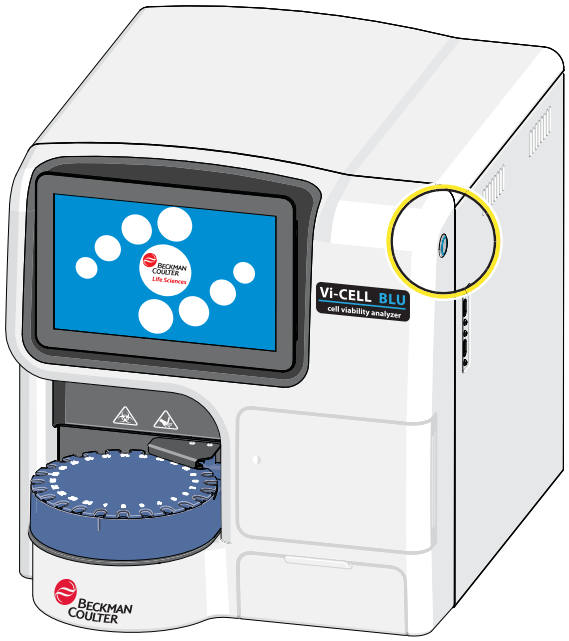
⚠ WARNING

Risk of personal injury. Rings or jewelry can contact exposed electronic components, causing personal injury from burns. Remove rings and other metallic jewelry before performing maintenance or service on the electronic components of the instrument.

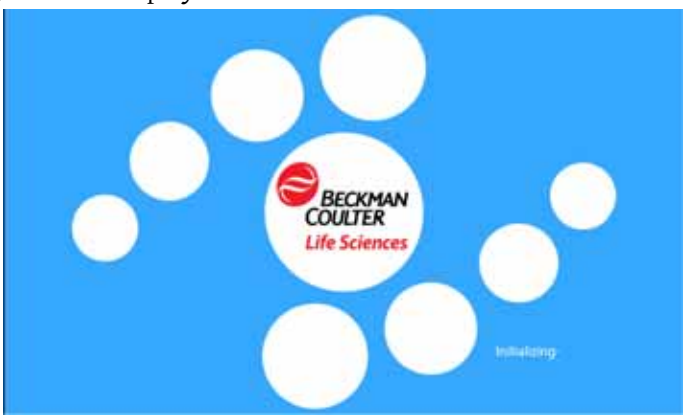
When the Vi-CELL BLU program is run for the first time, the Security Configuration and Preferences should be verified. See Settings Tab in CHAPTER 2, Installation and Verification for instructions on setting Security Configuration and Preferences.

IMPORTANT When you power on the instrument it goes through initialization and homes the carousel position. Ensure the carousel does not have any sample tubes and a 96 well plate is not installed.

1 Press the power button on the right side of the instrument.



The Initializing screen is displayed.



NOTE If Security is not enabled, you do not need to login, the Home screen is displayed. Skip to step 3.

2 Enter your login credentials.

3 Select  to view instrument status.

Select  to close the Instrument status screen.

4 Select  to view reagent status.

Select  to close the Reagent status screen.

Or

Note the number of tests remaining on the reagent status button ().

If you need to add reagents, see CHAPTER 8, Replace Reagent Pack.

Setting Up Preferences

See Settings Tab in CHAPTER 2, Installation and Verification for instructions on setting your preferences.

CHAPTER 4

Run Samples

Add Carousel Samples to the Sample Set

⚠ WARNING

Risk of biohazard contamination. Toxicity, safety, and proper handling procedures for controls and reagents used should be adhered to at all times. To prevent biohazard contamination, consult appropriate Safety Data Sheets for the items.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

⚠ WARNING

Risk of personal injury. To avoid injury due to moving parts, observe the following:

- **Never attempt to exchange microcentrifuge tubes while the instrument is operating.**
- **Never attempt to physically restrict any of the moving components of the instrument.**
- **Keep the instrument work area clear to prevent obstruction of the movement.**

⚠ WARNING

Risk of instrument damage or biohazardous contamination due to a misaligned carousel or plate. Misaligned sample carousels or plates can cause the sample container ejection mechanism to jam and spill sample. Ensure the carousel or plate is aligned correctly in the sample station prior to running the sample. Clean up spills immediately.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

Always use the appropriate Personal Protective Equipment (PPE) when working with biohazardous materials.

⚠ CAUTION

Risk of instrument damage if you use any non-Beckman Coulter control bead products. To prevent damage to the instrument, ensure the proper dilution and/or filtration to meet guidance in the following table.

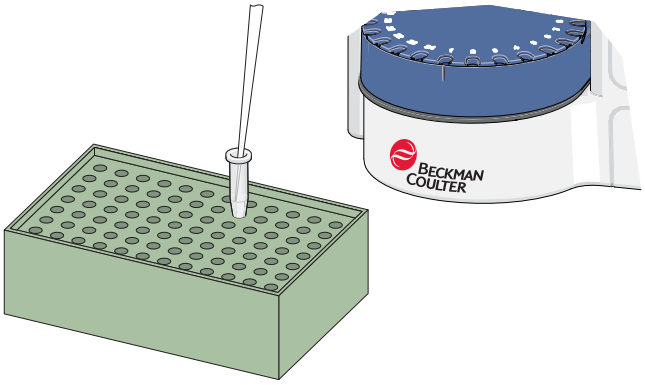
Particle Size	Concentration
2µm ≤ d ≤ 6µm	≤ $1.5x10^7$ particles/mL
6µm ≤ d ≤ 11µm	≤ $2.0x10^6$ particles/mL
11µm ≤ d ≤ 22µm	≤$1.0x10^6$ particles/mL

1 Install the carousel and ensure it is secure.

⚠ CAUTION

Risk of instrument damage if labware other than the supplied Beckman Coulter tubes and plates are used. Only use the tubes and plates supplied by Beckman Coulter.

2 If necessary, remove any caps if present and place 200uL +/- 20uL of sample into conical microcentrifuge tubes for **Normal Mode** or exactly 170uL for **Fast Mode**.



NOTE For optimum accuracy, use the specified volume. This is critical when using **Fast Mode**.

3 Select > Home to display the carousel Sample Set.

NOTE Select to display the Filter Sample Sets.

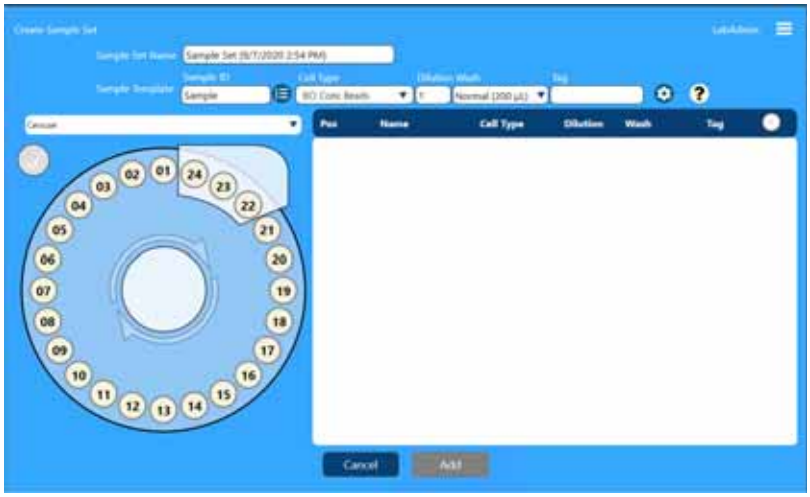
4 Check the Reagent Status 285 to ensure the reagent pack has enough cycles remaining to complete the Sample Set. If there are not enough cycles in the reagent pack, replace the reagent pack. Refer to Replace Reagent Pack in CHAPTER 8, Maintenance Procedures.

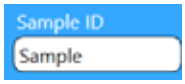
NOTE Check the available drive space to ensure that you have enough space to save your samples. Maximum drive storage is 465.2 GB. If the drive space is full, deleting samples is the only supported method to clean up the hard drive. Refer to Delete sample results in CHAPTER 6, Software Administration.

NOTE Select to delete all sample requests in the carousel. The following message appears: *Are you sure you want to remove all currently defined items?* Select **Yes**.

Or, select an individual highlighted well to delete the single well.

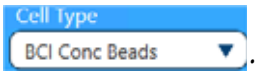
5 Select  to create a Sample Set.



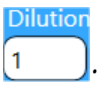
6 Enter a Sample ID 

.

- Select  to set up Sequential Sample Naming. Use this button to specify if the sequencing is positioned at the beginning or the end of the sample name. (i.e. 001SampleName vs. SampleName001).

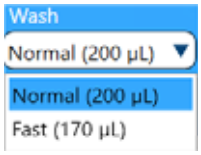
7 Select a Cell Type from the drop down list 

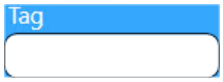
.

8 Enter a Dilution factor 

.

The dilution factor can be set as a whole number between 1 to 9999.

9 Select the wash mode from the drop down list 

10 Optionally, enter a Tag for the Sample Set 

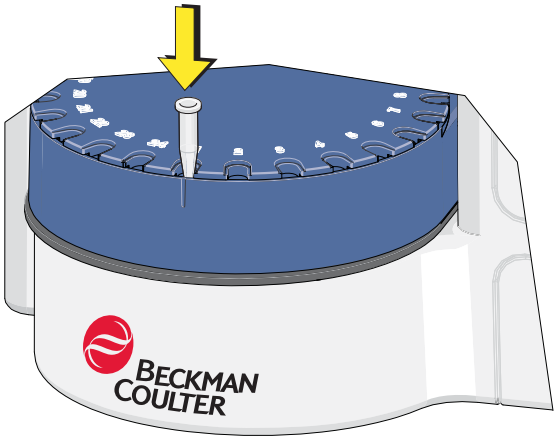
. A Tag is the same as a comment and can be used to describe the sample.

11 Select 

to create the Sample Set.

IMPORTANT Do not rotate the first loaded sample position past the sample probe as it will eject the sample tube to the waste tube tray.

12 Manually rotate the carousel to load the sample tubes onto the carousel as per the Sample Set.



13 Select  to Run the samples in the carousel.

The carousel rotates, looking for tubes and processes the samples.

NOTE The procedure above may be used to add multiple defined sample sets to a run prior to starting the run. Each defined sample set may contain different analysis parameters or sample naming properties.

NOTE If you have set up Active Directory Configuration or if the security mode is set to local users the samples will be associated with the currently logged in user.

NOTE If you add sample tubes to empty locations after processing begins and you do not define the parameters, they are processed with the parameters associated with the sample in the Sample Template field.

NOTE If you begin processing a Sample Set and the instrument encounters empty locations where it expects to see valid samples, the empty location will be skipped without the Sample Set being stopped. The instrument will indicate skipped samples in the Sample Set list.

14 The completed Sample Set screen is displayed.

On this screen you can:

- Select  to display the Detailed Review screen.
  See also CHAPTER 5, Data Analysis.
- Save a single sample run as CSV file  .
- Save all sample runs in the Sample Set as CSV file  .
- Select  to display the Signature screen.

Adding Samples to an Ongoing Run

Additional samples may be added to an ongoing sample processing run. If the original user has logged out of the system after starting the run processing, the additional sample sets may be added by any user allowed to log into the instrument.

The additional run sample sets may be added either as undefined samples as described above in step 13 or through the addition of a defined sample set.

Undefined samples may be placed on the carousel in empty locations following the sample currently being processed. Samples may be added in this manner without defining the analysis parameters, cell type, or other analysis characteristics for those samples. The analysis and sample parameters used will be those defined as the default values for the run.

⚠ CAUTION

When adding undefined samples, take care not to attempt to place samples in tube positions inside the carousel sample carrier indentation to avoid personal injury or possible machine jam.

Additional defined sample sets may be added during an ongoing run. These additional defined sample sets may use analysis parameters different from those used by the previously defined sample sets in the run or from the default analysis parameters defined for undefined samples.

The steps to add additional defined sample sets to an ongoing run will be identical to those presented in steps 4-9 above. When adding samples during a run the system will go to the **Paused** state, as necessary, to allow sufficient time for the sample set to be created and the samples placed onto the carousel.

When adding samples during a run the system will not allow samples to be defined in positions which are already in use or are in locations on the carousel within the curved sample carrier indentation. These sample positions are shown as grayed-out locations and inaccessible. Once the sample set is defined and the samples are added, click the **Add** button to append the new sample set

to the ongoing run processing. If the system has gone to the fully paused state before the sample set is added, it will automatically resume processing.

Add 96 Well Plate Samples to the Sample Set

⚠ WARNING

Risk of biohazard contamination. Toxicity, safety, and proper handling procedures for controls and reagents used should be adhered to at all times. To prevent biohazard contamination consult appropriate Safety Data Sheets for the items.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

⚠ WARNING

Risk of personal injury. To avoid injury due to moving parts, observe the following:

- **Never attempt to exchange labware, reagents, or tools while the instrument is operating.**
- **Never attempt to physically restrict any of the moving components of the instrument.**
- **Keep the instrument work area clear to prevent obstruction of the movement.**

⚠ WARNING

Risk of pinch-point injury when using 96 well plates. Keep your hands away from moving parts.

The instrument contains probes and moving parts.

- **The probes are sharp and the probe motor is strong enough to cause the probe to puncture your skin.**
- **The probe may contain biohazardous materials, including controls and blood samples.**
- **The probe is in motion during many types of instrument cycles such as startup and shutdown, not just during sample analysis.**

⚠ CAUTION

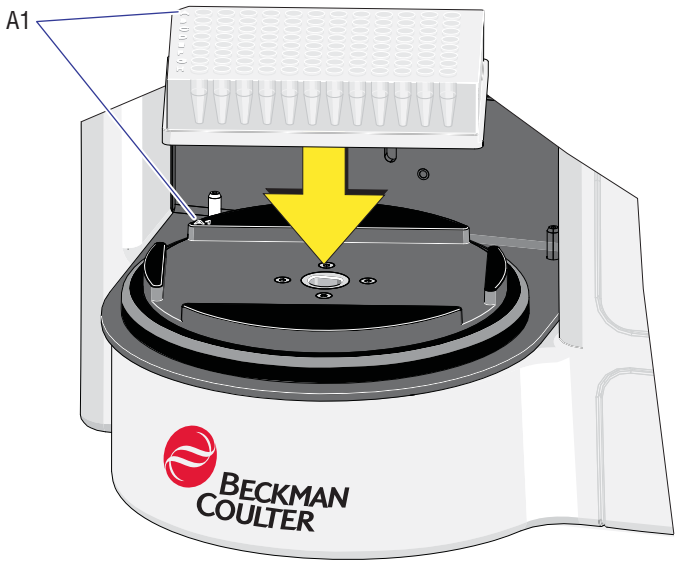
Risk of instrument damage if labware other than the supplied Beckman Coulter tubes and plates are used. Only use the tubes and plates supplied by Beckman Coulter.

IMPORTANT Do not remove the 96 well plate from the instrument while the instrument is busy processing a Sample Set. If a plate must be removed, the Sample Set must be paused prior to removing the plate from the sample deck.

1 Place samples into the desired wells of a 96 well microplate, 200uL +/- 20uL for **Normal Mode** or exactly 170uL for **Fast Mode**.

2 Pull the carousel all the way out, towards you and lift the carousel to remove the carousel.

3 Install the 96 well microplate on the plate holder and ensure it is secure.



4 On the Create Sample Set screen, select 

to switch to the 96 well Sample Set creation screen.

NOTE It is recommended that the Sequential Sample ID numbering is activated when running plates to ensure that the sample results are uniquely labeled.

5 Select  on the top, left corner of the on-screen plate image to select or deselect the whole plate.

Alternatively, you can select the column header (for example: Select ) or row header (for example: Select ) from the on-screen plate image to select or deselect a whole column or row.

You can also select a sample in the Sample Set and enter the Sample ID, Cell Type, Dilution factor and Wash speed for each well position to modify samples to the plate Sample Set.

Select  to delete the whole plate. The following message appears: Are you sure you want to remove all currently defined items? Select Yes.

NOTE Select  to change the order that the samples are run on the plate.  indicates that samples run vertically. For example, samples run in well A1 first, followed by well B1, C1, etc...  indicates samples run horizontally. For example, samples run in well A1 first, followed by A2, A3, etc...

Check the Reagent Status  to ensure the reagent pack has enough cycles remaining to complete the Sample Set. If there are not enough cycles in the reagent pack, replace the reagent pack. Refer to Replace Reagent Pack in CHAPTER 8, Maintenance Procedures.

NOTE Selecting options for each sample allows you to adjust the following:

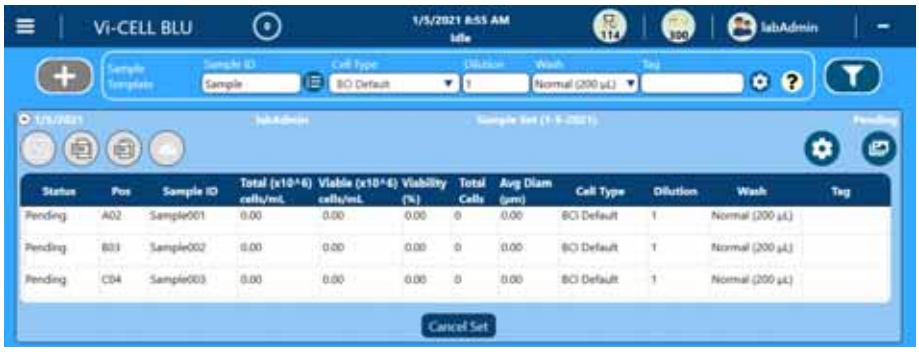
- The frequency of images stored
- The option to export results and the location of the export
- The option to append results and the location of the append
- The name of that file

6 Select  to run the 96 well Sample Set.

7 Select 

to create the Sample Set.

8 The completed Sample Set screen is displayed.



On this screen you can:

- Select  to display the Detailed Review screen.
  See also CHAPTER 5, Data Analysis.
- Save a single sample run as CSV file  .
- Save all sample runs in the Sample Set as CSV file  .
- Select  to display the Signature screen.

CHAPTER 5

Data Analysis

Reviewing/Reanalyze Data

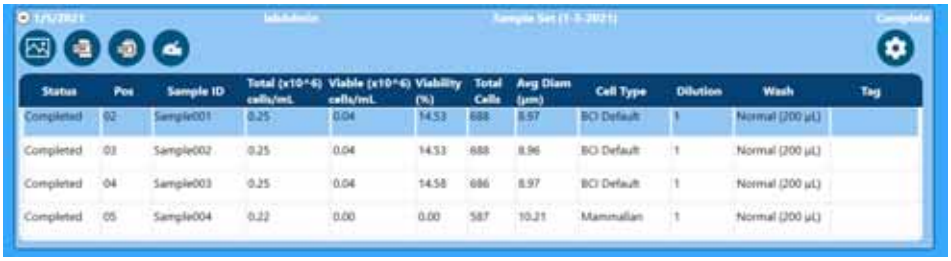
1 Select  and 

to display the completed Sample Sets.

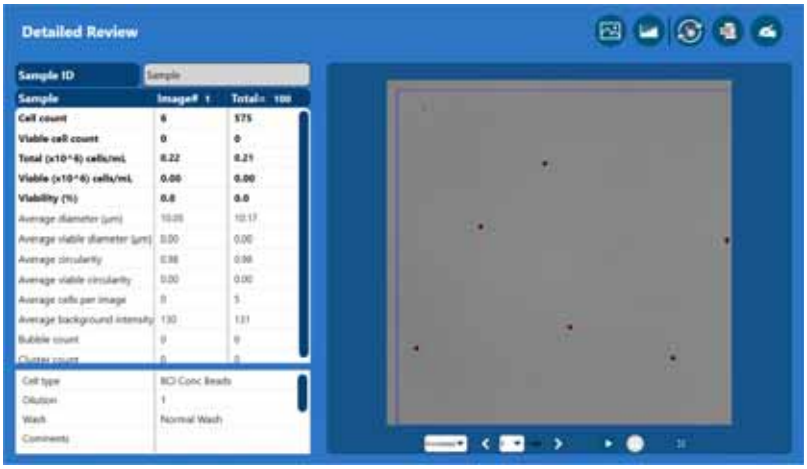
2 Select a completed Sample Set to review.

Use  to filter results. See Figure 2.11, Filter Sample Sets and Figure 2.12, Filter Samples.

3 Select a sample to review and select  .



4 The selected sample is displayed.



On this screen you can:

- Select  to display images.

  Use  and  to cycle through the images one at a time.

  Use  to replay all the images.

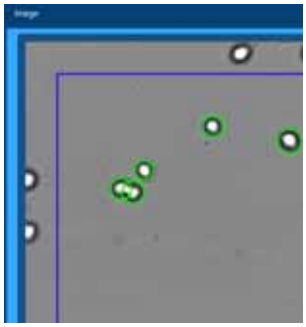
- Select  to display graphs.
- Select  to display the Reanalysis screen and reanalyze the data with a different Cell Type.
- Save a single sample run as CSV file  .
- Select  to display the Signature screen.

5 If desired, change the camera image options by pressing and holding on the image or by right clicking on the image with a mouse.

NOTE Selecting a cell/particle in the image located on the right side of the screen displays the average diameter, circularity, and viability for that cell/particle.

- Full width image

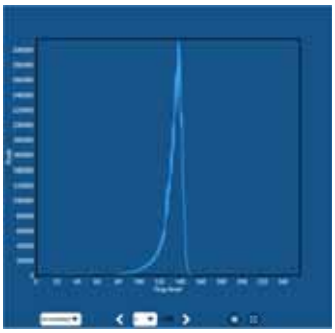
- Image actual size.



- Color code for annotated images:
  - Green - viable cell
  - Red - non-viable cell

- Blue - Identified as a particle within the image, but not defined as a cell as per the current Cell Type definition
- Yellow - a bubble
- A Red box - large cluster of cells that could not be counted

- Grey level histogram.

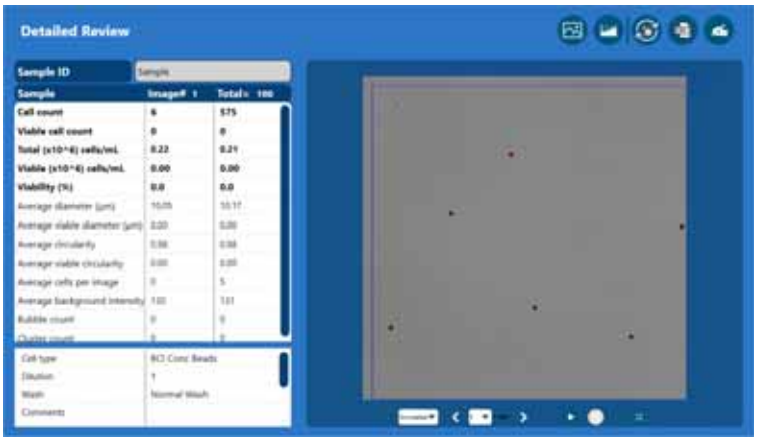


NOTE Select « at the bottom of the grey level histogram to switch from the histogram view back to the cell/particle image.

- For each image option the drop-down selections are:
  - Raw image
  - Annotated image
  - Binary image

Signoff Results

1 On the review screen, you can select to signoff results.



2 Enter your User Name and Password and select the appropriate signature type.

3 Your approval credentials are shown on the Review screen.

CHAPTER 6

Software Administration

Cell Type Administration

What is a Cell Type?

Cell Types are files that store the optical settings required to correctly identify cells of a particular type within an image and to quantify identified cells as viable or non-viable. Cells will vary in their optical characteristics and understanding how to establish the correct settings is important. The primary role of the Cell Type is to identify what in an image is a cell and whether it is viable.

For many Cell Types, the default cell type values are suitable. In the event any of the parameters must be changed for a given sample, a new Cell Type may be created or an existing can be used as the starting point for a new cell type. Existing Cell Types can only be modified if they were created by a user. Factory-provided Cell Types cannot be altered. This section provides the instructions for creating new Cell Types for use with the software. The Vi-CELL BLU software has 7 Cell Types predefined, which are intended to be used as starting points for additional customer-defined Cell Types.

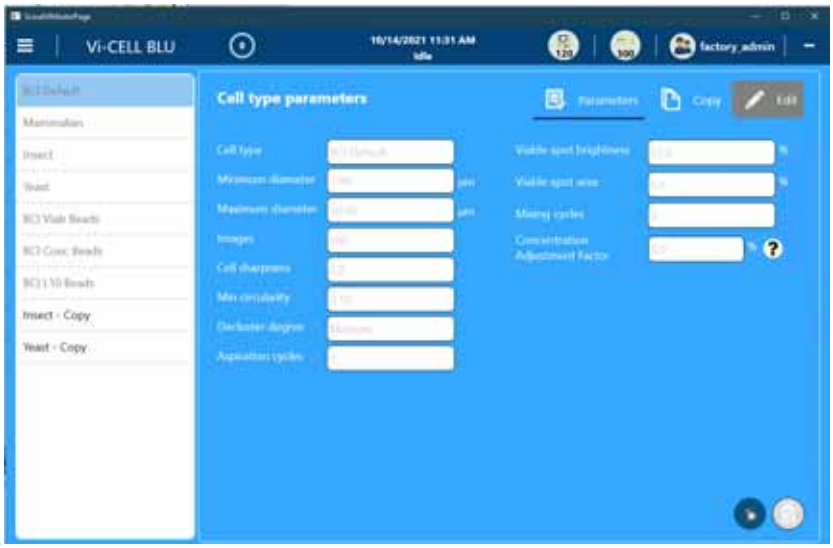
Enter the appropriate information for the particular Cell Type. Use the default settings as a starting point if necessary. Use the minimum diameter parameter for excluding cellular debris or unwanted cells. Use fewer mixing cycles to adjust for cell lines that tend to shear under the stress of mixing, use more mixing cycles to allow more time for uptake of the trypan blue dye.

Creating a New Cell Type

1 Select > Cell types to view the Cell Type parameters screen.

2 To create a new cell type, select one of the default Cell types and select 

.



3 Enter a new name for the Cell type.

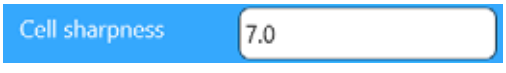
4 Enter the **Minimum** (1.00 µm) and **Maximum** (60.00 µm) range of expected diameters for the cell line.

Any cells that fall outside of this range are ignored. They will appear within the camera image and will be annotated as “identified objects”, but will not be included in any of the numerical run results. The minimum diameter can be used to exclude debris and/or unwanted cells. The size range should be used only to specify the expected range of cell sizes within the sample and should not be used to identify sub ranges.

5 Enter the number of **Images** (10 to 100). 

NOTE The number of images entered here is the number of images captured during the initial analysis.

A larger number will give a statistically better result. Concentration also affects the number of images required for an accurate answer. High-concentration samples require fewer images than lower-concentration samples for the same overall accuracy.

6 Enter the **Cell Sharpness** (0-100). 

Cell Sharpness is the clarity of an image and specifies the minimum sharpness of a cell. A higher value will require a more sharply-defined cell to be accepted. Enter a range from 0 to 100. 100 represents the sharpest possible, 0 represents the least sharp possible. This value also affects the transition from cell boundary (dark) to light (background).

7 Enter the **Min circularity** (0-1.0).

(Least Circular=0, Perfectly Circular=1). This parameter can be used to reject debris that exceeds the minimum cell diameter and are too irregularly shaped to be treated as a real cell. All objects with original circularity less than this value will be ignored in the analysis. Raise this value to bypass debris more easily.

8 Enter the **Decluster degree.**

The default setting is medium. This function increases the ability of the software to detect cells that are clumped together. Set the de-cluster degree according to how well the cells within clumps are defined (if not de-clustered properly). Generally, a higher value will identify more cells within a cluster, but a higher value may also split a single non-circular cell into more than one cell. If the cells in a sample are circular, a higher value can be safely used. High will perform the most aggressive declustering; Low will perform the least aggressive declustering. If individual cells are being split into 1 or more cells by the de-clustering, set this value to Medium or Low. If excessive clusters are present in the sample, consider rerunning the sample with increased aspiration and/or mixing cycles. An excessively large cluster will be identified by the software with a red box and will not be counted.

9 Enter the **Aspiration Cycles** (1-10).

In order to ensure that all of the cells are equally dispersed some of the sample is aspirated and then returned to the cup. Enter a range from 1 to 10. Three cycles are normally sufficient but if the cells are difficult to keep in suspension and have a tendency to attach themselves to the walls of the cup then additional aspirate cycles may be beneficial.

NOTE Cells must be in single cell suspension prior to placement on the system.

10 Enter the **Viable spot brightness** (0-95).

This is the brightness of the center spot of the cell. This is a percentage of the grayscale range. Cell centers must be higher (lighter) than this percent to be counted as viable. Enter a range from 0 to 95%. 55% is a typical value.

NOTE The cell spot brightness and area determine whether or not a cell is viable.

11 Enter the **Viable spot area** (0-95).

The Viable spot area is a percentage of the total area of the Cell. The bright center spot must be larger than this, as a percent of the total area, to be considered viable. Enter a range from 0 to 95%. A value of 5 to 10% is typical. Any extremes in this value will either make the cells all viable or non-viable. If the area of the center spot is greater than this percentage of the total area contained within the outer edge of the cell then the cell is considered to be viable.

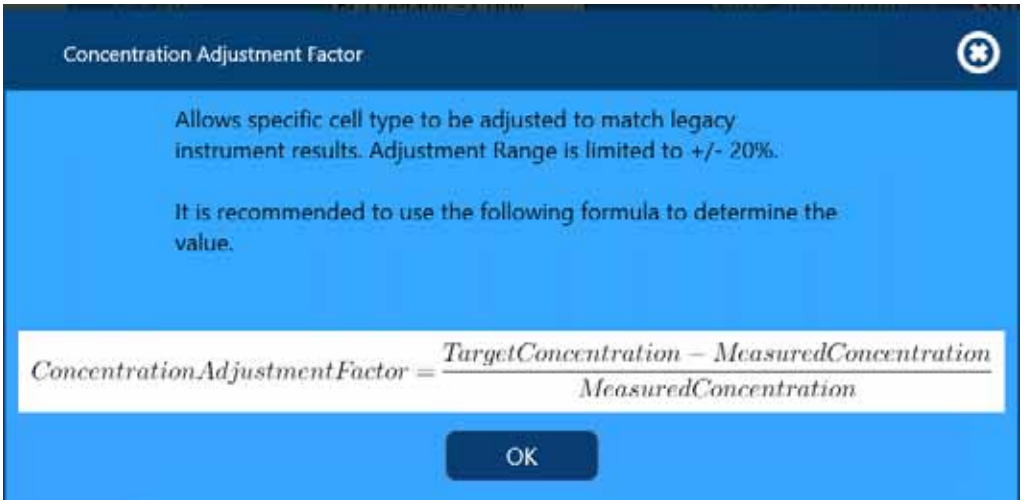
12 Enter the **Mixing cycles** (1-10).

The trypan blue and sample are mixed by sending the mixture back and forth between the sample cup and syringe. This parameter determines the number of times that the mixture is returned to the cup. Enter a range between 1 and 10. Normally three times is sufficient but if the sample resists mixing with trypan blue then a higher value may be necessary to achieve good mixing and even background intensities.

This feature is especially useful for Cell Types which may shear due to excessive mixing. Decreasing the number of mixing cycles will alleviate this situation.

13 Enter the Concentration Adjustment Factor as a percentage (e.g., 5.0% or -5.0%, range is limited to +/-20%).

The Concentration Adjustment Factor is used to adjust the concentration to match the results of other instruments. The Concentration Adjustment Factor is the percentage of a sample's determined concentration value applied to produce the final concentration value. This value is only applied to samples processed using the specified Cell Type. The **question mark** button displays the formula for calculating the Concentration Adjustment Factor.



NOTE Target concentration is the concentration value that the Vi-CELL BLU should correlate with and Measured concentration is the concentration measured on the Vi-CELL BLU. It is recommended to use a data set from replicate samples of varying concentration to achieve a representative adjustment factor.

14 Select  to save the new or edited Cell Type.

NOTE The system prompts the user to enter the password upon adding and/or editing the Cell Type.

Cell Type Optimization

For many Cell Types, the default Cell Type values provided in the software are suitable. For some cell lines, parameters will need to be changed to optimize the analysis of the cells. Table 6.1, Figure 6.1, Table 6.3, and Table 6.4 below helps to guide you through the Cell Type optimization process.

NOTE Saving less than the original number of images can cause changes in the results values during reanalysis. If planning to perform cell type optimization it is important to save the entire image set to use for reanalysis.

Table 6.1 Cell Type Guidelines

	Cell Type Parameters	Typical Range	Full Range	Increase Value	Decrease Value	When/Why You Would Want to Change This	Warnings
Defines whether there is a cell present or not	**Minimum Diameter**	5 to 12 µm	1 to 60 µm	Fewer cells identified	More cells identified	Software is excluding small cells (circled blue) Debris included in analysis	Too low, may be including debris Too high, cells excluded
	Maximum Diameter	15 to 50 µm	1 to 60 µm	More cells identified	Less cells identified	Software is excluding large cells (circled blue) Clumps of cells are included	Too low, may be excluding cells Clumps of cells included
	Cell Sharpness	5 to 25	0 to 100	Less cells identified	More cells identified	Software is excluding "fuzzy" cells Unwanted debris is being picked up	Set too high may cause dead cell to be excluded and alter the percent viability.
	Minimum Circularity	0 to 0.60	0 to 1.00	More irregular shaped dead cells will be excluded	Less irregular shaped dead cells will be excluded	Unwanted irregular shaped debris are being picked up	Too low, may be capturing unwanted debris Too high, may start excluding cells
	Decluster Degree	None, Low, Medium or High	N/A	More cells identified	Less cells identified	Cells in clusters are being missed Single cells are being identified as 2 or more cells	Too low, may be missing cells in clusters Too high, may over decluster by annotating single cells as 2 or more cells
Defines whether identified cells are viable or not	Viable Cell Spot Brightness	40 to 60%	0 to 95%	More cells identified as dead	More cells identified as viable	Viable cells are identified as dead Dead cells are identified as viable	Too low, may start identifying dead cells as live Too high, may start identifying live cells as dead
	Viable Cell Spot Area	3 to 12%	0 to 95%	More cells identified as dead	More cells identified as viable	Viable cells are identified as dead Dead cells are identified as viable	Too low, may start identifying dead cells as live Too high, may start identifying live cells as dead

Table 6.2 Cell Type Parameter Definitions

Cell Type Parameter	Role in identifying viable cells
Cell Sharpness	Cell sharpness is a measure of cell edges ranging from 0-100. Decreasing the value allows for fuzzier objects to be identified as cells. Increasing the sharpness will eliminate fuzzier cells from the cell count.
Viable Cell Spot Brightness	Viable Cell Spot Brightness measures the brightness of the center of the cells to determine whether the cell is viable or non-viable (green or red annotation). At high values, only cells with bright white centers are counted as viable (viability will decrease). At low values cells with grey centers will be counted as viable (viability will increase). It is important to check annotation to determine if Viable Cell Spot Brightness is set correctly.
Viable Cell Spot Area	Viable Cell Spot Area is a percentage of the white area of a cell used to determine if the cell is viable or non-viable. At high values, only cells with bright white centers are counted as viable (viability will decrease). It is normally not necessary to adjust this parameter.
Minimum Circularity	This parameter is used to eliminate debris. Assume "1" is a perfect circle.
Decluster Degree	The declustering degree defines intensity of declustering clumps of cells. Selecting None will not decluster any clumps of cells - good for samples with cells that contain no cell clumps. Select Low for samples with clumps of 2-3 cells. Select Medium for samples with some clumps of with more than 3 cells. Select High for yeast cells. **NOTE** Any cluster marked with a red box will not be subjected to declustering. A red box indicates a large cluster that is automatically excluded. This is NOT a failed decluster attempt.
Concentration Adjustment Factor	The Concentration Adjustment Factor is used to adjust the concentration to match the results of other instruments. The Concentration Adjustment Factor is the percentage of a sample's determined concentration value applied to produce the final concentration value. This value is only applied to samples processed using the specified Cell Type. The range of allowed values +/ - 20 percent in 0.1% increments.

Figure 6.1 Cell Type Workflow

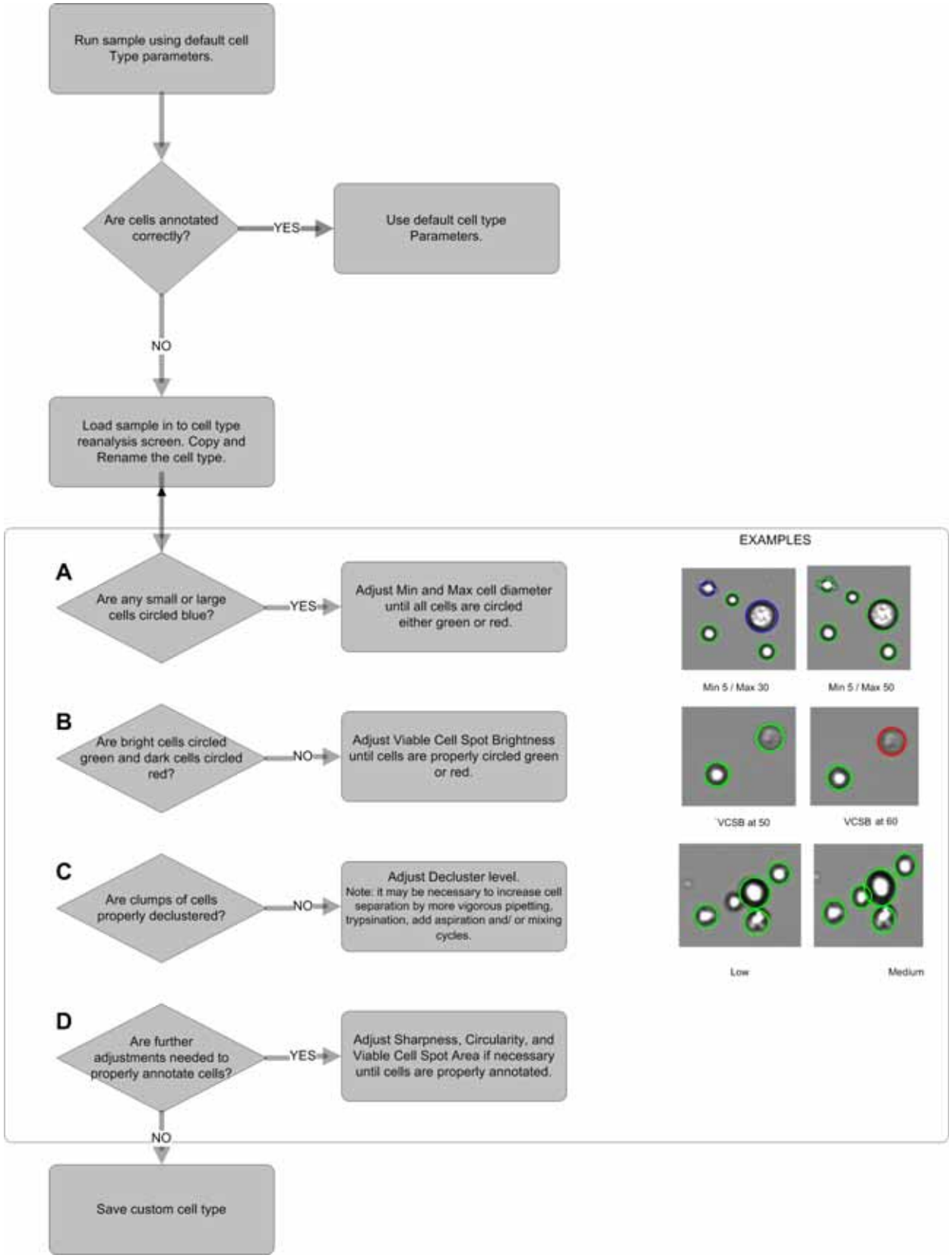


Table 6.3 Decluster

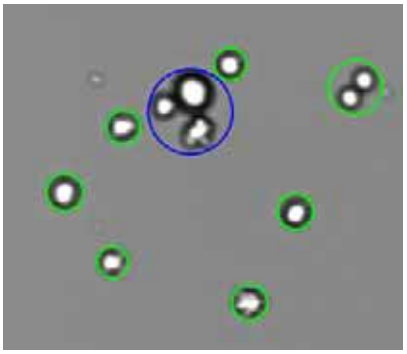
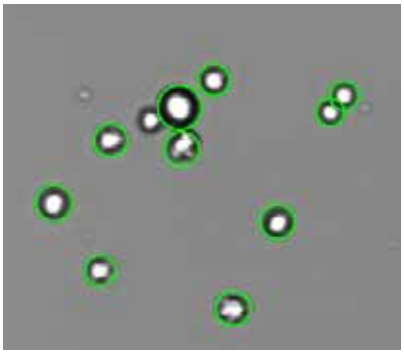
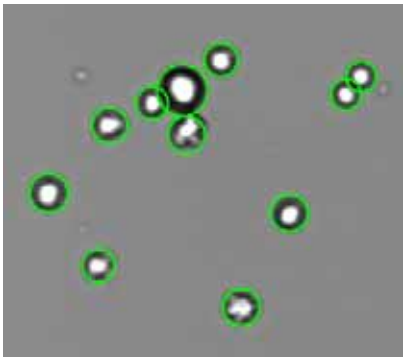
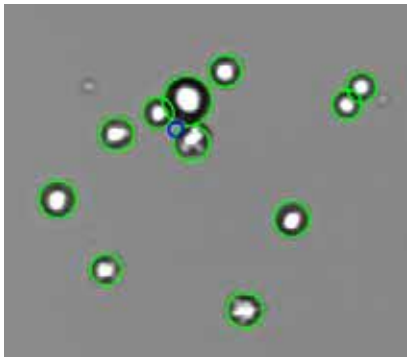
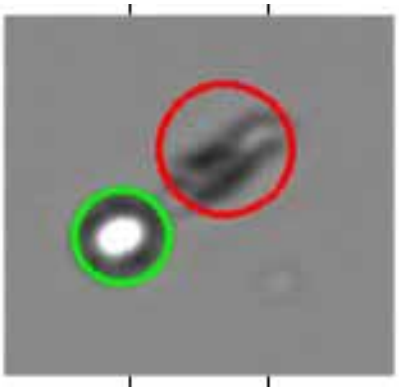
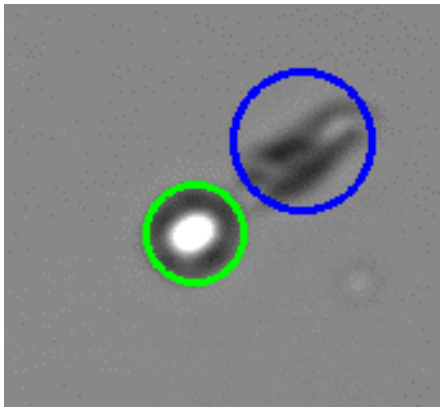
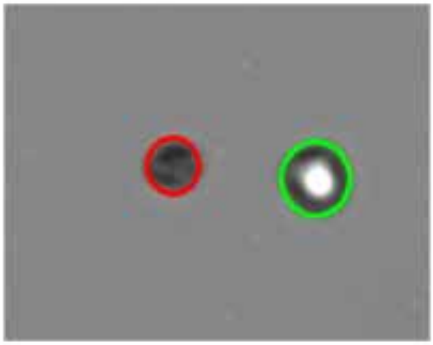
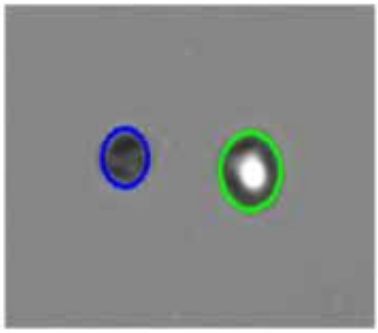
No Decluster	**Low Decluster**
	
Medium Decluster	**High Decluster**
	

Table 6.4 Cell Sharpness

Cell Sharpness 7 (Default)	Cell Sharpness 30
	
Cell Sharpness 7 (Default)	**Cell Sharpness 30**
	

NOTE Table 6.4 shows an example of cell sharpness set to 7 (default), on the left. Cell sharpness is set to 30, on the right, and is used to eliminate debris. However, at 30, some dead cells are also eliminated.

Reports Administration

Report Results

Completed Run Summary Reports

1 Select ☰ > Reports > Results to view the **Report Results** screen.

The **Completed run summary report** screen is displayed by default.

You can choose to create other reports. Use the links below to create other reports.

- Run Results Reports.

- Quality Controls Reports
- Cell Type Reports
- Instrument Status

2 On the **Completed run summary report** screen:

- Select the **User name**.
- Select the **From** and **To** dates.
- Select your **Print Options**.
- Enter a **Print title**.
- Enter any additional **Comments**.

3 Select PDF to generate the PDF report.

4 Select  to save the report as a PDF file.

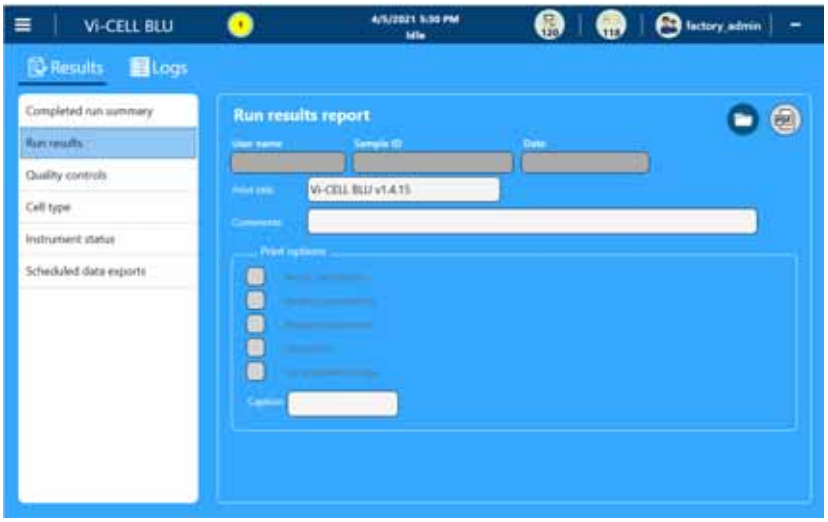
Run Results Reports

1 Select  > 

> 

to view the **Report Results** screen.

2 Select **Run Results**.



3 Select  to choose a data file to create a report.

- Select a **User name**.
- Select the **From** and **To** dates.
- Select  .

- Select a listing in the **Sample Set**.
- Select a Sample from the **Sample ID** list.

- Select  .

4 On the **Run Results** screen,

- Enter a **Print title**.
- Enter any additional **Comments**.
- Select your **Print Options** and enter a **Caption** if required.

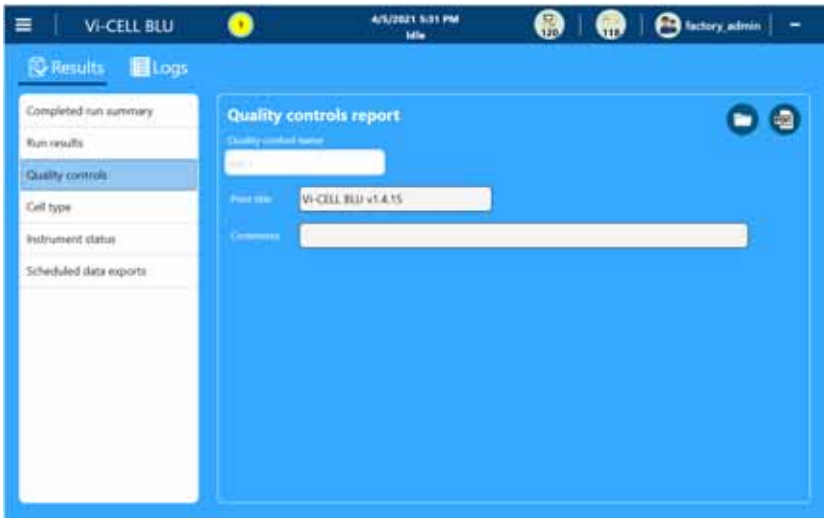
5 Select  to generate the PDF report.

6 Select  to save the report as a PDF file.

Quality Controls Reports

1 Select > Reports > Results to view the **Report Results** screen.

2 Select **Quality controls**.



3 Select to choose a Quality control file for the report.

- Select a Quality control file.
- Select .

4 On the **Quality controls** screen:

- Enter a **Print title**.

- Enter any additional **Comments**.

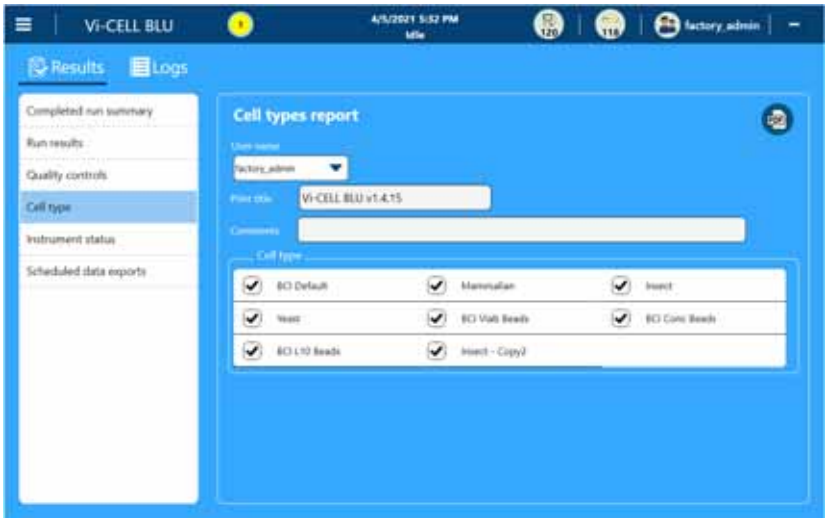
5 Select  and then  to save the report as a PDF file.

NOTE Acceptable limit bars are present based on assay value and tolerance. However, they do not appear until the second data point is available.

Cell Type Reports

1 Select  >  >  to view the **Report Results** screen.

2 Select **Cell type**.



3 On the **Cell type** screen:

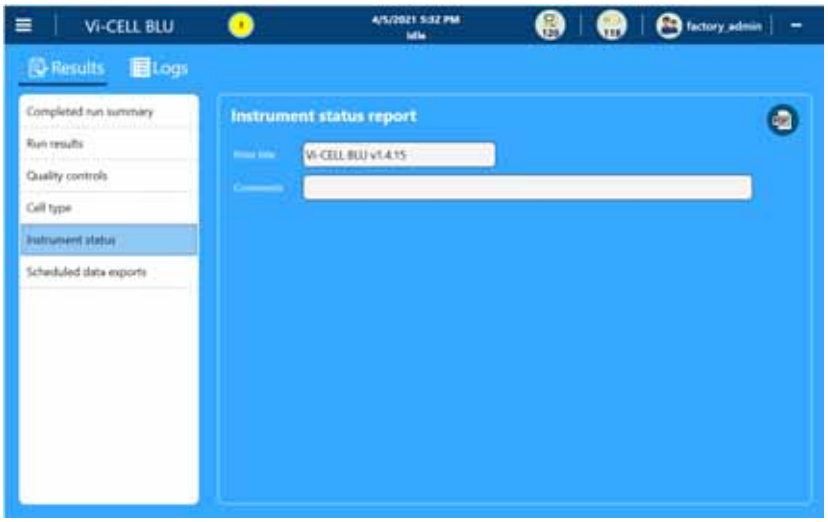
- Select a **User name**.
- Select your **Cell type** options.
- Enter a **Print title**.
- Enter any additional **Comments**.

4 Select  to save the report as a PDF file.

Instrument Status

1 Select  >  >  to view the **Report Results** screen.

2 Select **Instrument status**.



3 On the **Instrument status report** screen:

- Enter a **Print title**.
- Enter any additional **Comments**.

4 Select  to generate the PDF report.

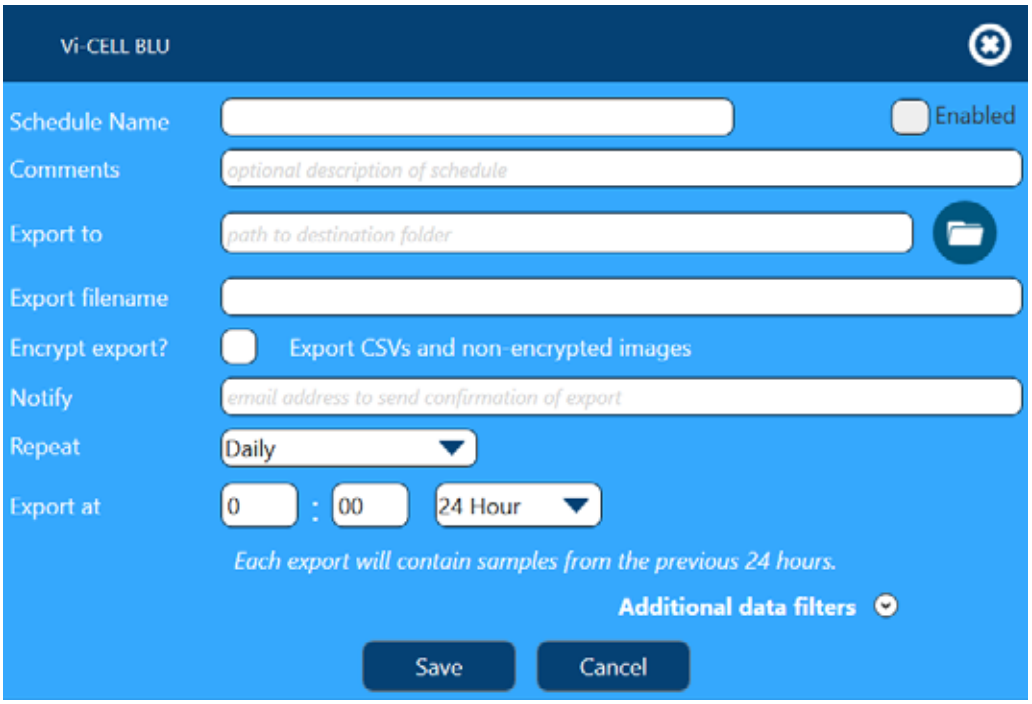
5 Select  to save the report as a PDF file.

Scheduled Data Exports

1. Select the “New” icon.

2. Enable the export.

3. Enter a **Schedule Name** and **Comments** to distinguish each scheduled report.



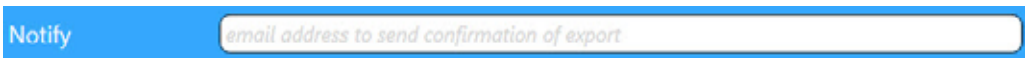
NOTE Valid file paths for Scheduled File/Log Exports are as follows:

- C:\Instrument\Export
- File path for an external USB drive
- File path for the location on a mapped network drive

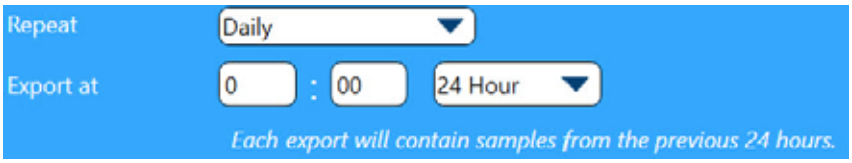
4. Select whether the export is for Offline Analysis or a collection of CSV files and un-encrypted images contained in a single zip file.

5. Enter an email address that will receive notification that the export has run.

NOTE This requires SMTP to be configured.



6. Configure the repeated frequency for this scheduled export.



NOTE When a scheduled export is run, all data is retrieved from the database using the given filter criteria. If data is deleted from the instrument before a scheduled export run, that data will not be included in the exported data file.

NOTE If an export run fails, it will be attempted again every 24 hours until the export is successful.

7. Select additional filter options for the data to export. The exported data can be limited by applying additional filters such as sample set and individual sample information.

NOTE •Scheduled exports are a lower priority task in the system and run slower when the system is processing samples.

NOTE Only one scheduled export (logs or data) will run at a time. If more than one export is ready at the same scheduled time, the first export in the list is selected.

NOTE The system checks for scheduled exports (logs and data) about every minute. It does not check while another export is running or if a user is deleting sample records.

Report Logs

Audit Log

1 Select > Reports > Logs to view the **Report Logs** screen.

2 Select **Audit log.**

NOTE Refer to Audit Trail Events for a list of audit log entries and the related descriptions.

3 Select a file and CSV to save the log as a CSV file.

Audit Trail Events

Refer to Audit Trail Events Table 6.5 for a list of audit trail events and the related descriptions.

Table 6.5 Audit Trail Events

Audit Trail Event	Description
evt_login	User login
evt_logout	User log out
evt_logoutforced	Log out User after Time Out
evt_unlockedbyuser	Unlocked by User
evt_loginfailure	Login Failed
evt_accountlockout	Account locked out
evt_useradd	Add User

Table 6.5 Audit Trail Events *(Continued)*

Audit Trail Event	Description
evt_userremove	User removed
evt_userenable	User enabled
evt_userdisable	User disabled
evt_passwordchange	Change password
evt_passwordreset	Reset password
evt_userpermissionschange	Changed user level
evt_securityenable	Security On
evt_securitydisable	Security Off
evt_celltypecreate	New cell type
evt_celltypemodify	Cell type modified
evt_celltypedelete	Cell type deleted
evt_analysiscreate	Answer type file created
evt_analysismodify	Answer type modified
evt_analysisdelete	Answer type deleted
evt_qcontrolcreate	Quality Control created
evt_qcontroldelete	Quality Control deleted
evt_fluidicsflush	Flush
evt_fluidicsprime	Prime
evt_fluidicsdrain	Drain
evt_fluidicsdecontaminate	Decontaminate
evt_fluidicsnightlyclean	Nightly clean
evt_reagentload	Reagent Pack installed
evt_reagentunload	Reagent Pack removed
evt_reagentinvalid	Reagent pack could not be read/verified
evt_reagentunusable	Reagent pack empty or expired
evt_firmwareupdate	Firmware updated
evt_auditlogarchive	Audit log archived
evt_errorlogarchive	Error log archived
evt_samplelogarchive	Sample log archived
evt_datavalidationfailure	Inconsistency found in data or configuration file
evt_signaturedefinitionadd	Signature meaning added
evt_signaturedefinitionremove	Signature meaning removed
evt_concentrationinterceptset	Concentration intercept set
evt_concentrationinterceptnotset	Concentration intercept setting not found or could not be stored
evt_concentrationslopeset	Concentration slope offset set

Table 6.5 Audit Trail Events *(Continued)*

Audit Trail Event	Description
evt_concentrationslopenotset	Concentration slope setting not found or could not be stored
evt_sizeinterceptset	Sizing intercept set
evt_sizeinterceptnotset	Sizing intercept not found or could not be stored
evt_sizeslopeset	Sizing slope set
evt_sizeslopenotset	Sizing slope not found or could not be stored
evt_notAuthorized	User not authorized to perform operation
evt_instrumentconfignotfound	A configuration file could not be found/read
evt_instrumentconfigimported	Instrument configuration imported
evt_instrumentconfigexported	Instrument configuration exported
evt_focusaccepted	Focus accepted
evt_clearedexportdata	"ExportData" folder contents cleared
evt_clearedcalibrationfactors	Concentration/Sizing slope and intercept history cleared
evt_dustsubtractionaccepted	New "dust subtraction" image stored for use
evt_deletesamplerecord	Sample result removed (analyses and images)
evt_deleteworkqueuerecord	Queue record removed
evt_manualfocusoperation	Camera focus position manually adjusted
evt_datasignatureapplied	Data signed
evt_deleteresultrecord	Sample analysis record removed
evt_sampleprocessingerror	Failure while processing a user sample
evt_offlinemode	Software is running in offline analysis mode
evt_sampleresultcreated	Sample analysis record created
evt_Instrumentdataexported	Result data exported from instrument
evt_setuserpasswordexpiration	Password duration setting changed
evt_setuserinactivitytimeout	Inactivity timeout setting changed
evt_serialnumberupdated	Serial number updated
evt_serialnumberupdatefailed	Serial number update failed
evt_serialnumbernotset	Serial number not set
evt_serialnumberinconsistent	Serial number is inconsistent
evt_setuser	Set User Configuration
evt_updatefailed	Firmware Update Failed
evt_fluidicsautomationnightlyclean	ACup Nightly Clean
evt_automation	Automation State
evt_acupusingstandardconcentrationintercept	ACup Using Standard Concentration Slope

Sample Activity Log

1 Select > Reports > Logs to view the **Report Logs** screen.

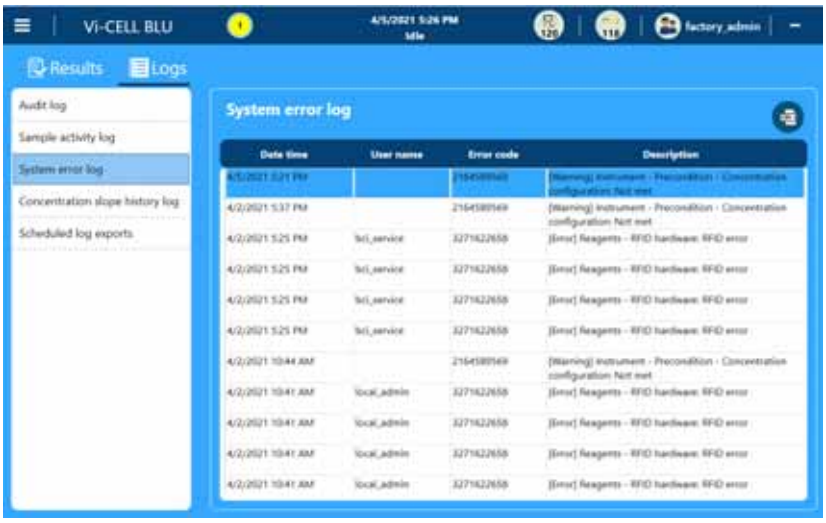
2 Select **Sample activity log.**

3 Select a file and CSV to save the log as a CSV file.

System Error Log

1 Select ☰ > Reports > Logs to view the **Report Logs** screen

2 Select **System error log**.

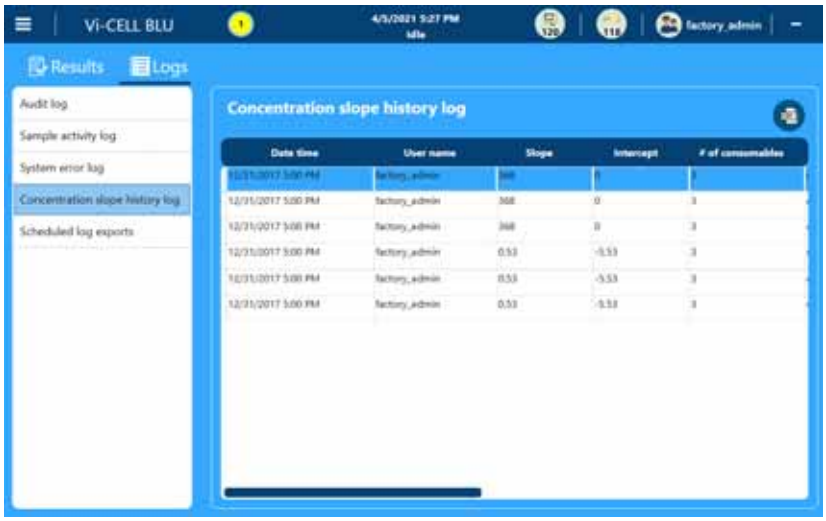


3 Select a file and 💾 to save the log as a CSV file.

Concentration Slope History Log

1 Select ☰ > Reports > Logs to view the **Report Logs** screen.

2 Select **Concentration Slope History Log.**



3 Select a file and CSV to save the log as a CSV file.

Scheduled Log Exports

1. Select the “New” icon.

2. Enter a **Schedule Name** and **Comments** to distinguish each scheduled report.

3. Select the logs to export.

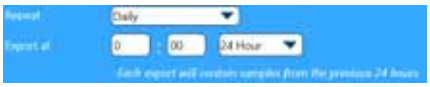
NOTE Valid file paths for Scheduled File/Log Exports are as follows:

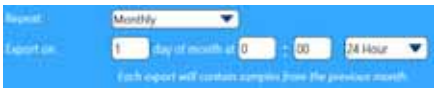
- C:\Instrument\Export
- File path for an external USB drive
- File path for the location on a mapped network drive

4. Enter an email address that will receive notification that the export is run.

NOTE This requires SMTP to be configured.

5. Configure the repeated frequency for this scheduled export.





NOTE •Scheduled exports are a lower priority task in the system and run slower when the system is processing samples.

NOTE •Only one scheduled export (logs or data) will run at a time. If more than one export is ready at the same scheduled time, the first export in the list is selected.

NOTE •The system checks for scheduled exports (logs and data) about every minute. It does not check while another export is running or if a user is deleting sample records.

Storage Administration

1 Select > Settings > Storage to display the Storage Administration screen.

2 To display a range of samples:

- Select a **User name.**
- Select the **From** and **To** dates.

- Select .

Storage Administration Functions

Export sample results

Export sample results to archive data. Sample results should be exported regularly to avoid errors due to a full hard drive. PDF and CSV files can be exported by the system.

NOTE If no external device is detected, the samples export to C:\Instrument\Export by default. If an external device is detected, the samples export to the root of the external device.

The files export as a zip file with the instrument and timestamp in the file name.

1. Select a value for N=.
2. Select .

NOTE Large data sets may take significant time to export. The instrument cannot be used during export. The software prompts an "exporting data" message, displays a progress bar and locks the user out of the instrument until the process is complete.

Delete exported results

All of the exported result files are deleted.

NOTE Large data sets may take significant time to delete. The instrument cannot be used while deletions are being processed.

NOTE The export folder may contain items being exported for reanalysis, or instrument configuration information being exported for use on other instruments. The deletion operation removes all contents of the export folder, thus care should be exercised to avoid deletion of other data which may not yet have been collected for its intended use.

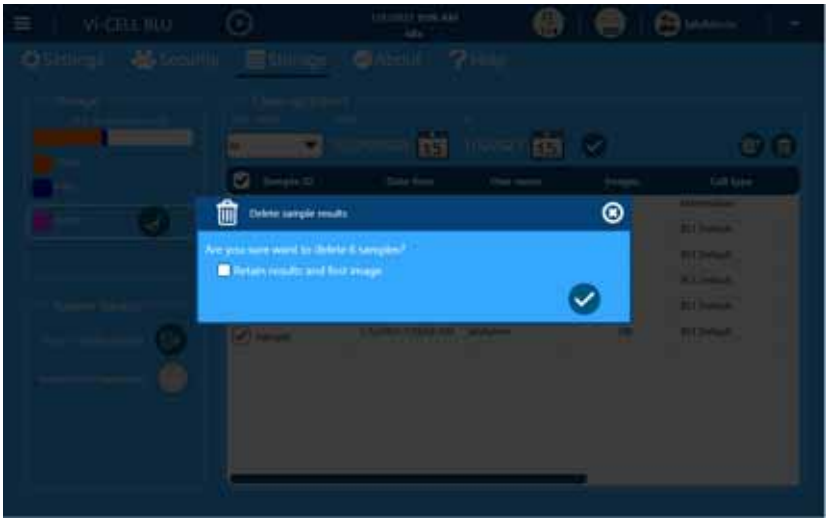
Delete sample results

1. Check available drive storage space as shown below.

2. Choose the Clean Up search function by selecting the User name, and the date range to delete samples as shown below.

NOTE The Clean Up search function is limited to 1000 samples only.

3. Select  next to the Clean Up criteria and the Delete Sample Results window will appear.



4. Select the checkbox shown above to remove unwanted images but retain the sample record and associated object data with the first image only.

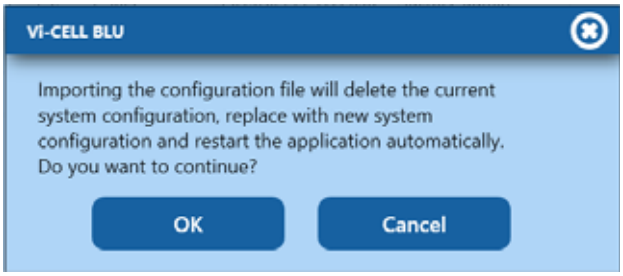
5. Select  if you want to complete the deletion.

Export configuration 

The export configuration feature creates a copy of the instrument's current configuration including the user list, cell type lists, quality controls and signatures. The exported configuration file may be used to reproduce a configuration across multiple instruments in a laboratory or as a periodic backup against instrument failure.

1. Save As dialog opens to choose a location to save the configuration file.
2. Select **Save**.

Import configuration



1. Select **OK** or **Cancel**.

NOTE In order to import a configuration all instrument sample data will be cleared.

⚠ CAUTION

Risk of overwriting the instrument configuration files. Importing a configuration file from an offline version of the software will overwrite the following instrument configuration parameters:

- **Cell Type**
- **Quality Control**
- **Reagent Configuration**
- **Signatures**
- **User List**

System Backup

A comprehensive data management process should include periodic system backups. This will provide a recovery point to allow restoration of system state or data content from known intervals.

System-level backup can be performed using the instrument OS backup tools or any Enterprise tools employed by the customer IT department that are compatible with the instrument OS. Request assistance from an IT representative if necessary.

Backup tools typically must be run under an administrative OS user account. Users performing the system-level backup should be familiar with the OS and the backup tools and exercise care to avoid destructive processes. Prior to performing a system-level backup, ensure that the Vi-CELL BLU application software is shutdown, and the PostgreSQL database engine service is stopped.

Database Backup

NOTE This feature requires version 1.4.2 or newer.

Periodic maintenance should include backing up the integrated instrument database to preserve custom cell-types, user configuration, and other customer modifications. The database provides a special non-privileged user role named DbBackupUser to perform these backups. This specific user is allowed to read database contents but is not allowed to alter the contents of the database configuration or any data.

The password for the DbBackupUser is set through the Vi-CELL BLU application settings menu on the **Instrument** sub-item. Only Vi-CELL BLU application administrative users may set the password. Refer to Figure 6.2 and Figure 6.3.

NOTE When in **Security-Off Mode**, any user can set this password.

Figure 6.2 Database Backup Screen 1

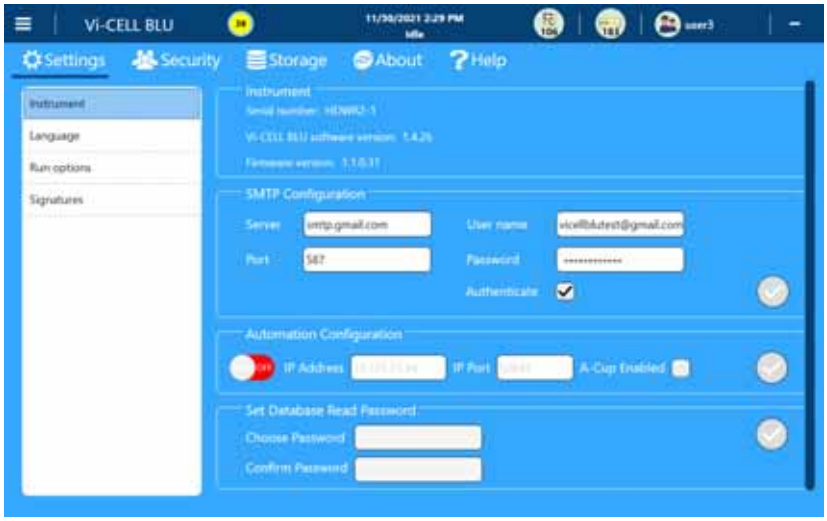
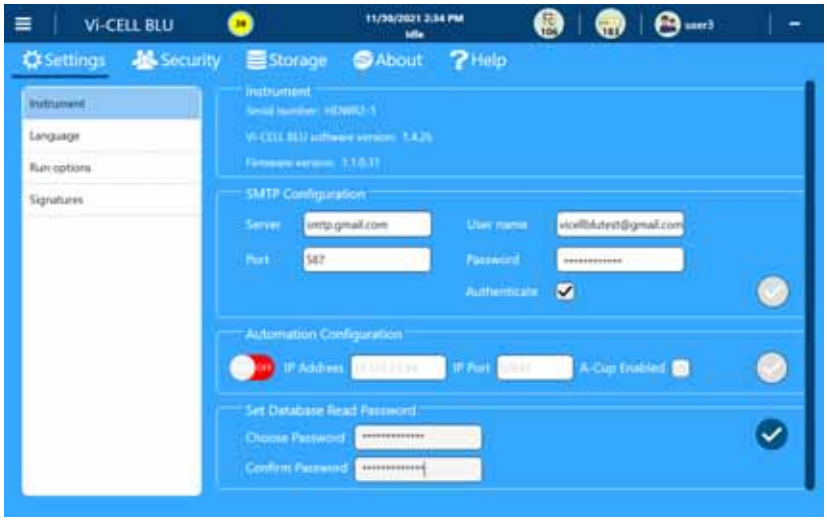


Figure 6.3 Database Backup Screen 2



The Vi-CELL BLU instrument application does not provide or perform the backup operations. The customer may use any standard database utility compatible with the PostgreSQL database. Since the Vi-CELL BLU application holds data and configuration tables open during operation, it is recommended that backups be performed with the application shutdown.

While not required, it is also recommended that backups be performed under an administrative OS user login. The PostgreSQL server engine should not be shutdown, as it is used to access the data tables during the backup.

User Types and Access Levels

The types of user roles on the instrument are: Normal, Advanced and Admin. When instrument security is disabled, feature availability is as described in the **Security OFF** column and individual user roles are not used.

Refer to Table 6.6 for a list of software features and sub features that are enabled (✓), disabled/read-only (✗), and hidden () for each user type.

Table 6.6 User Types and Access Levels

Features	Sub features	Normal user	Advanced user	Admin user	Security (Off)
Main Menu					
Home	Sample Set creation screen	✓	✓	✓	✓
	Run Results screen	✓	✓	✓	✓
	Export options	✓	✓	✓	✓
	Cell type selection	✓ *1	✓	✓	✓
Review	Reanalyze	✗	✓	✓	✓
	Search all users results	✗	✓	✓	✓
	Signature	✓	✓	✓	✗
Cell types	Access Cell Types menu		✓	✓	✓
	Create (Copy) /Edit/Delete		✓	✓	✓
Quality controls	Add QC	✗	✓	✓	✓
	Export results		✓	✓	✓
	View results	✓	✓	✓	✓
	Sign	✓	✓	✓	N/A

Table 6.6 User Types and Access Levels

Features	Sub features	Normal user	Advanced user	Admin user	Security (Off)
Settings	Language	✓	✓	✓	✓
	Instrument	✓	✓	✓	✓
	Security	✗	✗	✓	✗ *2
	Signature settings	✗	✗	✓	✗
	Run options	✓	✓	✓	✓
Reports	Completed Run Summary	✓	✓	✓	✓
	Run Results	✓	✓	✓	✓
	Quality controls	✓	✓	✓	✓
	Instrument status	✓ *3	✓	✓	✓
Admin:users	Add/Edit/Delete	👁	👁	✓	👁
	Change password	✗	✗	✓	👁
Admin:Storage	View storage info	👁	👁	✓	✓
	Clear export folder contents	👁	👁	✓	✓
	System backup	👁	👁	✓	✓
Reagents	View reagent status	✓	✓	✓	✓
	Prime, Flush, Decontaminate, Replace	✓	✓	✓	✓
Help		✓	✓	✓	✓
About		✓	✓	✓	✓
Sign in/ Sign out		✓	✓	✓	👁
Exit software		✗	✗	✓	✓
Title bar (Top Blue bar)					
Instrument status icon		✓	✓	✓	✓
Message hub icon		✓	✓	✓	✓
Minimize option		✗	✗	✓	✓

Table 6.6 User Types and Access Levels

Features	Sub features	Normal user	Advanced user	Admin user	Security (Off)
My profile		✓	✓	✓	

*1 Only assigned cell types for normal user

*2 In this mode, the user is able to turn security back on

*3 Instrument status report for a normal user does not contain a list of users

CHAPTER 7

Quality Control

What Is the Control Feature?

The control feature monitors Vi-CELL BLU performance. The accuracy of concentration measurements (Total Cells/mL) can be checked using Vi-CELL BLU controls obtained from Beckman Coulter.

- 0.5M Vi-CELL Concentration Ctrl (Optional)
- 2M Vi-CELL Concentration Ctrl
- 4M Vi-CELL Concentration Ctrl
- 10M Vi-CELL Concentration Ctrl
- CC Size Standard L10
- Vi-CELL BLU 50% Viability Ctrl

The instrument contains special software that makes it very easy to run the control sample and to store and review the results obtained.

A collection of results from the same control sample are grouped together and can be saved, exported and printed as a single entity called a control. The Vi-CELL BLU is supplied with a Concentration Control Cell Type for use with Beckman Coulter Vi-CELL BLU single use concentration controls.

⚠ CAUTION

Risk of instrument damage if you use any non-Beckman Coulter control bead products. To prevent damage to the instrument if you use non-Beckman Coulter control bead products, you must filter the beads through a 30 micron filter.

Add a Quality Control

1 Select > Quality controls > to add a Quality Control.

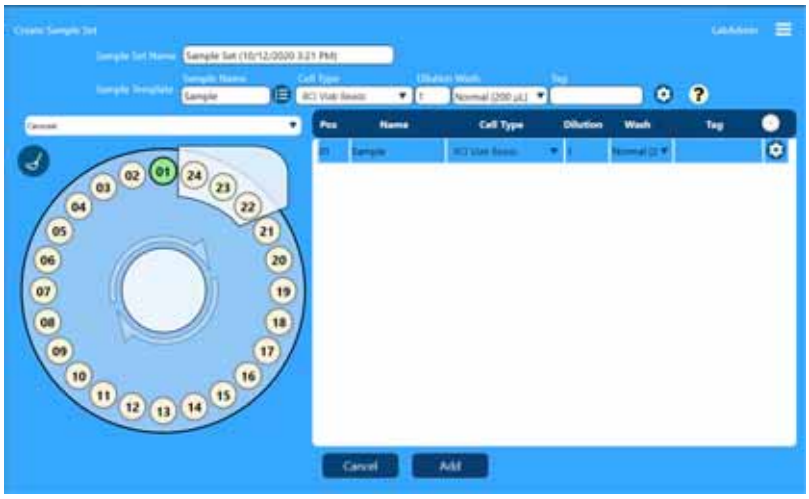
2 Enter the information for the new Quality Control.

- Enter the **Name**.
- Select the **Cell type**.
- Select the **Assay parameter**.
- Enter the **Lot number**.
- Enter the **Assay value**.
- Enter the **Acceptance limits**
- Select the **Expiration** date.
- Enter a **Comment** if required.
- Select .

NOTE The cell type to be used for the beads is noted on the appropriate bead IFUs.

Run a Quality Control

1 On the Home screen, select  and assign the Quality Control to a carousel position.



2 Select  and  to run the Control.

3 After the control run is completed, you can choose to view the **Summary**, **Image** and **Graphs** or select  to save a sample result as CSV file or  to save the entire Sample Set.

NOTE In the quality controls screen when a QC is selected, you can select the historical button in order to see the results for only that QC over time, with the error bars being applied to the graph.

Weekly Decontamination

Decontaminate the instrument with bleach on a weekly basis. It is also recommended to run a decontaminate cycle if the background in the images becomes darker over time. Running the decontaminate with bleach cycle removes staining from the flow cell.

Decontaminate with Bleach

1 Select  and **Decontaminate.**

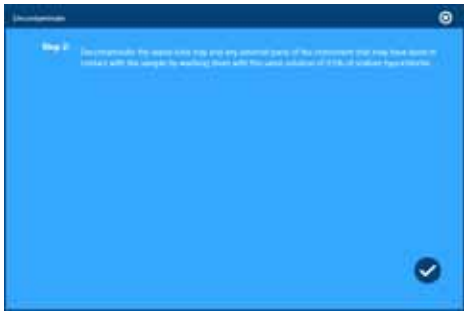
⚠ WARNING

Risk of chemical injury from bleach. To avoid contact with the bleach, use barrier protection, including protective eyewear, gloves, and suitable laboratory attire. Refer to the Safety Data Sheet for details about chemical exposure before using the chemical.

2 Prepare a bleach solution according to the instructions on the screen and select .

NOTE In cases of significant staining, undiluted household bleach can be used. Ensure you use pure bleach with no commercial additives.

3 Decontaminate the rest of the instrument per the instructions displayed and tap .



NOTE Decontamination takes approximately 10 minutes to perform.

4 Run three or four sample tubes of deionized water to ensure the bleach is flushed from the system.

NOTE If run as "controls", the results will appear in the quality controls report and associated logs.

Replace Reagent Pack

⚠ WARNING

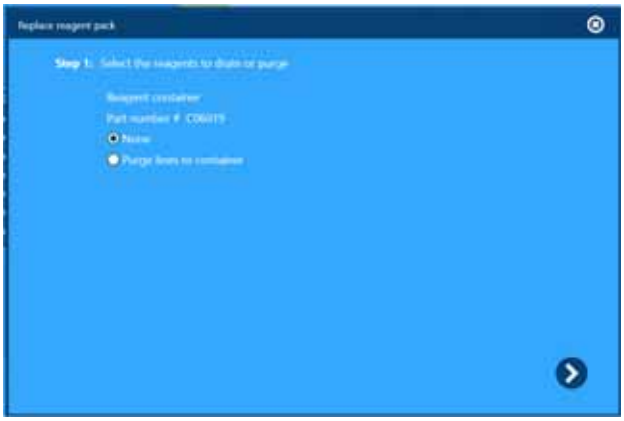
Risk of biohazardous exposure if you have skin contact with the Reagent Pack waste liquid. The Reagent Pack waste bottle cap has a vent and the waste bottle must be upright whenever you are handling a used Reagent Pack in order to prevent waste liquid from leaking out of the waste bottle. Clean up spills immediately. Dispose of the Reagent Pack and the solid waste in accordance with your local regulations and acceptable laboratory procedures.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

Always use the appropriate Personal Protective Equipment (PPE) when working with biohazardous materials.

1 Select  and **Replace Reagent Pack**.

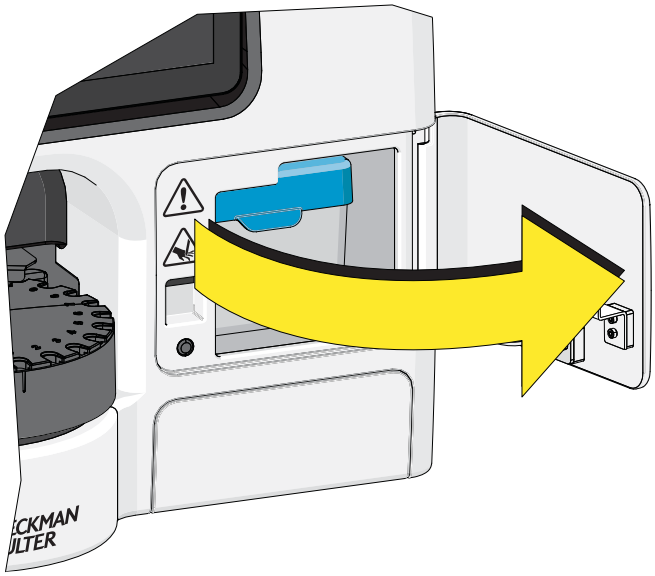
2 Select whether to Purge and select .



NOTE

- Select **None** if you do not wish to purge anything.
- Select **Purge lines to container** to empty the system fluidics to waste. Use **Purge lines to container** for storage or service.

3 The reagent door opens.



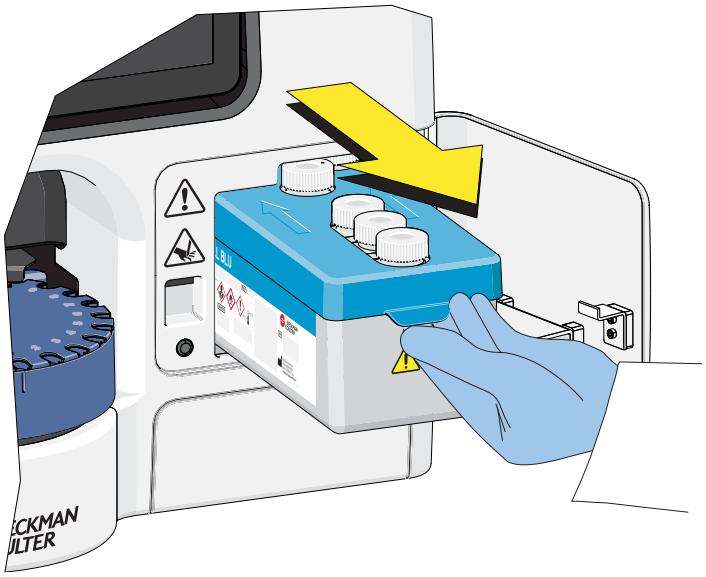
⚠ WARNING

Risk of biohazardous contamination if you have skin contact with the Reagent Pack and the solid waste container and its contents. The Reagent Pack and the solid waste container and its contents could contain residual biological material and must be handled with care. Clean up spills immediately. Dispose of the Reagent Pack and the solid waste in accordance with your local regulations and acceptable laboratory procedures.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

Always use the appropriate Personal Protective Equipment (PPE) when working with biohazardous materials.

4 Remove the Reagent Pack.

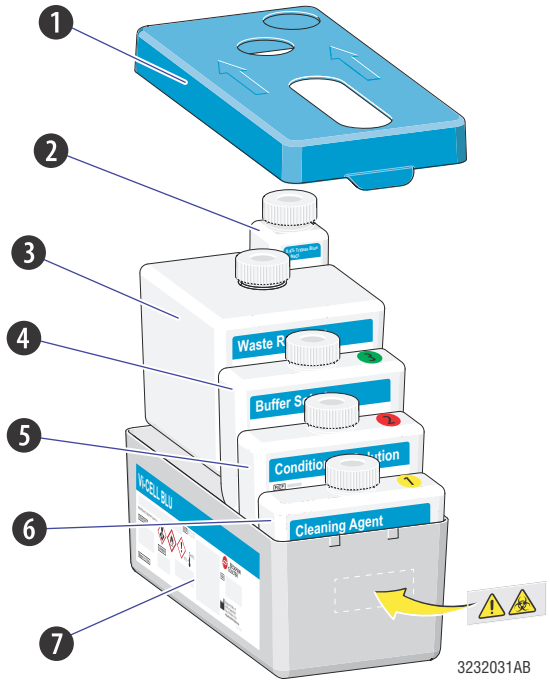


5 Tighten the trypan blue lid on the old Reagent Pack before disposing.

6 If disposing, recycle the Reagent Pack.

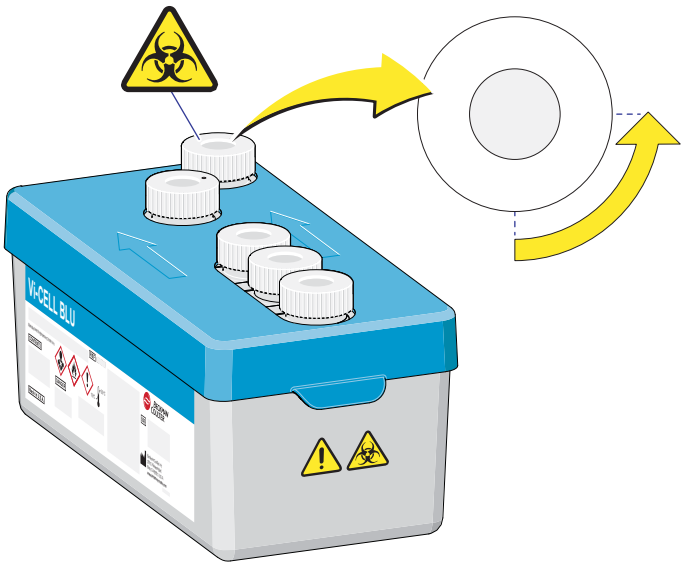
The Reagent Pack lid, tray, and bottles are recyclable. Dispose of the Reagent Pack and the solid waste in accordance with your local regulations and acceptable laboratory procedures. In the US, Check this website: *www.call2recycle.org* for local recycle regulations and centers.

IMPORTANT If disposing of the waste bottle separately, apply the biohazard sticker to the waste bottle. If disposing of the whole Reagent Pack, apply the biohazard sticker to the Reagent Pack container.

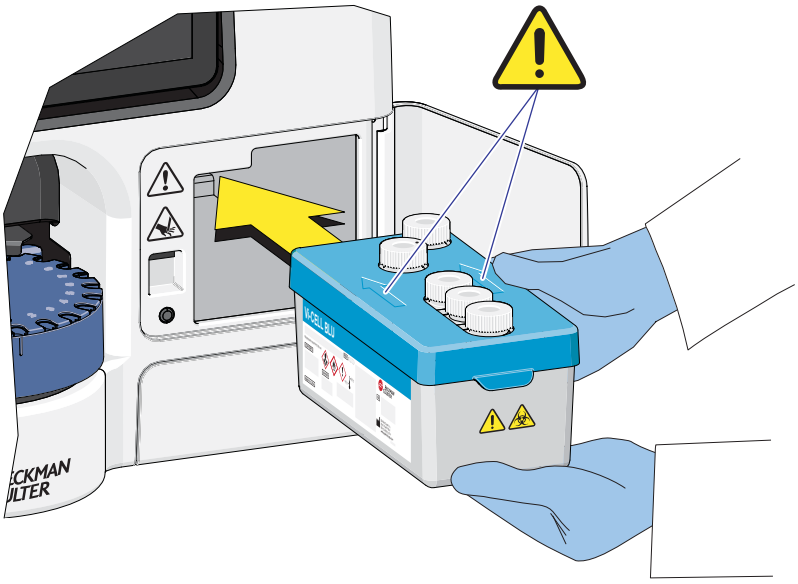


1. Reagent Pack Lid
2. Trypan Blue Bottle
3. Waste Bottle
4. Buffer Solution Bottle
5. Conditioning Solution Bottle
6. Cleaning Agent Bottle
7. Reagent Pack Tray

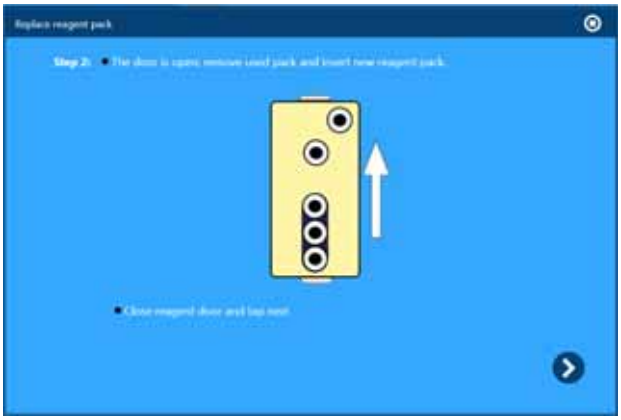
7 Before inserting a different Reagent Pack, loosen the trypan blue lid in the reagent pack ¼ turn. Failure to do so may cause the bottle to form a high vacuum which could impact counting accuracy and an increased concentration results error, most frequently occurring during the first three samples of each day.



8 Place the included biohazard label on the end of the reagent tray and insert the Reagent Pack.



9 Close the reagent door and select .



10 Confirm Reagent information and select .

Empty Waste Tube Tray

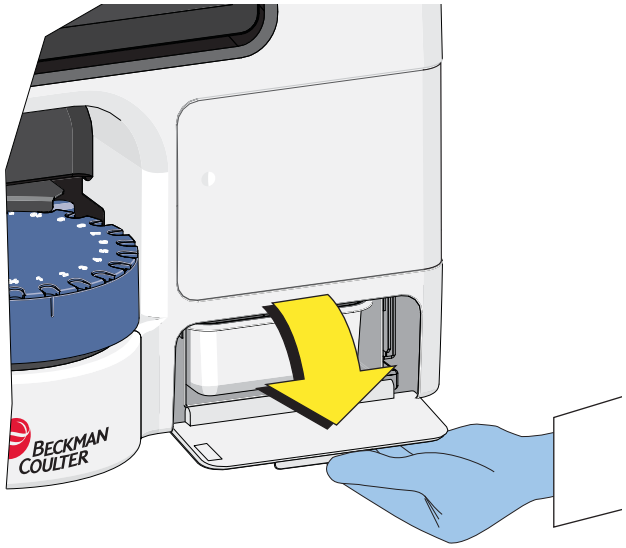
⚠ WARNING

Risk of biohazardous contamination if you have skin contact with the waste tube tray or its contents. The waste tube tray and its contents could contain residual biological material and must be handled with care. Clean up spills immediately. Dispose of the contents of the waste tube tray in accordance with your local regulations and acceptable laboratory procedures.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

---

1 Open the waste tube tray door. Follow the disposal instructions in step 6 below.



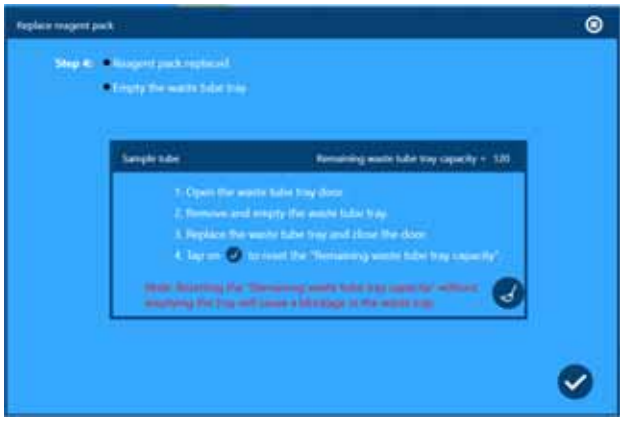
2 Remove the waste tube tray.

3 Empty the waste tube tray. Follow the disposal instructions in step 6 below.

4 Insert the waste tube tray.

5 Close the waste tube tray door.

6 Select  and  .



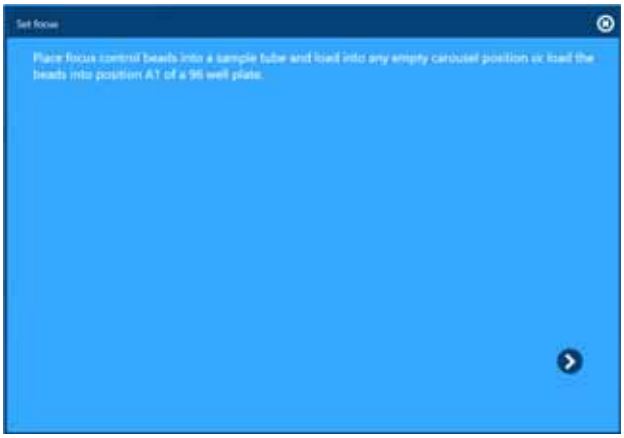
Focusing Wizard (Autofocus)

A focusing wizard is provided that automatically adjusts the focus. Focus should be run if the instrument is moved or the ambient temperature changes by 5°C or more. Focus should also be run if the images look more defocused than usual or if a size control fails specification. Focus control beads can be purchased from Beckman Coulter.

Set Focus

1 Select  and 
.

2 Dispense 200 µL, or approximately 8-10 drops of focus controls, into a tube and place into the empty position in the carousel (or A1 position in the 96 well plate) and select  .



3 Wait while the Focus Control sample is being processed. The instrument should not be moved during the focusing process.

4 After the focus position is identified, visually check that the graph shows a complete bell curve. Reject the focus and redo the process if that is not the case. Choose to accept or to reject the new reference image. Select to exit the screen.

NOTE If the focus position is rejected, the focus motor moves back to its previous position and a message appears indicating the duration to move back to the previous position.

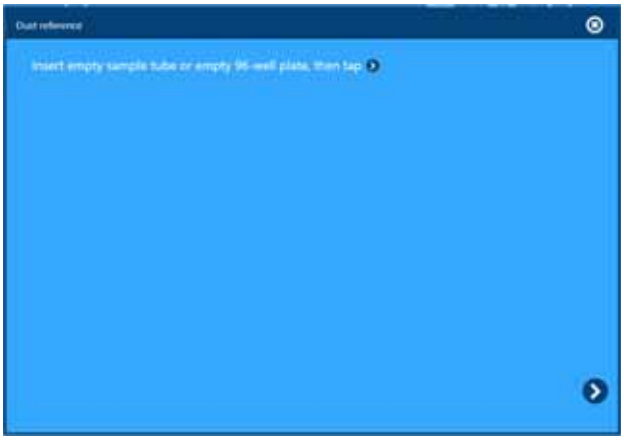
5 Select at the bottom of the screen to exit Set Focus.

Dust Reference Wizard

Run the Dust Reference Wizard in the instance there is an object/smudge on every image that does not move with subsequent runs.

1 Select and Dust reference....

2 Insert an empty sample tube or empty 96 well plate, then select .



3 Dust reference processing in progress.

NOTE Check that the white pixels accurately represent particles to remove from sample cell counts.

4 Choose to accept or reject the new reference image or to reject the new reference image.

Prime the Instrument

The instrument is automatically primed when a reagent pack is loaded. Prime can be performed in the following instances:

- Before running samples as a quality control measure
- If bubbles are seen in the images

1 Select and **Prime**.

2 When priming is complete, select to exit the screen.

Flush the Instrument

The flush feature attempts to clear the flow cell by rinsing the cell in both directions. Flush the instrument in the following instances:

- To reduce carryover
- If bubbles are observed
- If you suspect contamination
- To remove a suspected clog
- If the previous samples were particularly adherent

1 Select and **Flush**.

NOTE This will take one use away from the reagent pack.

2 When flushing is complete, select to exit the screen.

Annual Preventative Maintenance

Beckman Coulter recommends annual PM of the system by a trained Beckman Coulter Field Service Engineer.

This maintenance will replace high use parts, confirm system performance, and clean or check all critical components.

CHAPTER 9

Shutdown

The instrument is not required to be powered down every night.

Shutting Down the Instrument

1 If necessary, empty all solid waste from the waste tube tray. Refer to Empty Waste Tube Tray in CHAPTER 8, Maintenance Procedures.

2 Remove any sample tubes or plates from the instrument and store according to your laboratory procedures.

3 Exit the software.

4 Push the power button on the right side of the instrument or select the Windows start menu then select **Shut down**.

NOTE If you need to unplug the instrument, always ensure the instrument is powered off before unplugging the instrument. Unplugging the instrument without following the proper shutdown process may result in corrupted files and require a service visit.

NOTE If nightly clean is skipped because the instrument was powered off before the cleaning, the instrument will attempt a nightly clean during the initialization sequence the next time the instrument is powered on.

Extended Shutdown

If the instrument will be shut down for an extended period of time (1 week or more), ensure you remove the Reagent Pack from the instrument. Refer to Replace Reagent Pack in CHAPTER 8, Maintenance Procedures. **Ensure the Purge lines to container** option is selected on the Replace reagent pack wizard screen. Once the Reagent Pack is removed, shut down the instrument. Refer to Shutting Down the Instrument.

CHAPTER 10

Troubleshooting

Troubleshooting Table

Table 10.1 through Table 10.6 lists problems that the operator could encounter while running the Vi-CELL BLU instrument, the probable causes of each problem, and the corrective actions. These problems are split into individual tables for each system affected. These problems are listed alphabetically in the Index, under the primary entry "troubleshooting."

IMPORTANT There are four different severities catalogued by the system:

- Notification. This means no special attention is required.
- Warning. This means the system is operational, but requires special attention.
- Error. This means the system is inoperative, but recoverable.
- Fatal. This means the system is inoperative and the error is not recoverable.

NOTE When the active notification button is selected, the displayed error messages will be either yellow or red, depending on the severity. Refer to CHAPTER 2, Home screen for the location of the active notification button.

NOTE A particular failure mode can potentially display any level of severity depending on whether or not the system was able to self-correct the problem.

Table 10.1 Troubleshooting Table - Instrument

Problem	Probable Cause	Corrective Action
Subsystem: Configuration		
Failed validation	• Hard disk corruption • Software error	1. Restart the system. 2. If the problem persists, contact us.
Subsystem: Storage		
File not found	• Disk degradation • Software error • Configuration lost because of software update	1. Restart the system. 2. Refocus the optics. See Focusing Wizard (Autofocus) in CHAPTER 8, Maintenance Procedures. 3. If the problem persists, contact us.
Backup restore failed	• Disk degradation • Software error • Configuration lost because of software update	1. Restart the system. 2. Refocus the optics. See Focusing Wizard (Autofocus) in CHAPTER 8, Maintenance Procedures. 3. If the problem persists, contact us.

Table 10.1 Troubleshooting Table - Instrument

Problem	Probable Cause	Corrective Action
Read error	• Disk degradation • Software error • Configuration lost because of software update	**1.** Restart the system. **2.** Refocus the optics. See Focusing Wizard (Autofocus) in CHAPTER 8, Maintenance Procedures. **3.** If the problem persists, contact us.
Write error	• Disk degradation • Software error • Configuration lost because of software update	**1.** Restart the system. **2.** Refocus the optics. See Focusing Wizard (Autofocus) in CHAPTER 8, Maintenance Procedures. **3.** If the problem persists, contact us.
Storage Near Capacity	System storage is near capacity	Perform sample deletion for samples which have been exported and archived. See Storage Administration in CHAPTER 6, Software Administration.
Subsystem: Integrity		
Software Fault	Software error	Contact us.
Not permitted at this time.	Unable to execute instruction at this time	See notices in the notification button. Refer to Figure 2.10.
Subsystem: Precondition		
Not Met	A required configuration step has not yet been performed.	Perform the necessary steps to satisfy the unmet precondition.

Table 10.2 Troubleshooting Table - Controller Board (Main Board)

Problem	Probable Cause	Corrective Action
Subsystem: General		
Connection Error	Unable to connect to main board.	**1.** Power cycle the system by turning off power, unplugging the Analyzer from the outlet and plugging it back in. **2.** Turn on the Analyzer. **3.** If the problem persists, contact us.
Firmware Update Error	• Corrupt firmware update file • Main board failure	Contact us.
Firmware Bootup Error	• Corrupted firmware image on the main board. • Main board failure	Contact us.
Invalid Firmware Version	• Incorrect firmware version	Contact us.
Firmware interface error	• Communication error with the main board • Damaged cabling • Communication chip malfunction	Contact us.

Table 10.2 Troubleshooting Table - Controller Board (Main Board)

Problem	Probable Cause	Corrective Action
Firmware state machine error	Problem with the firmware on the main board.	Contact us.
Hardware health	Problem reported with measured power levels on main board	Contact us.
Subsystem: Communication		
Host Communication Error	• Main board failure • Problem with firmware • Problem with communication chips	Contact us.

Table 10.3 Troubleshooting Table - Reagents

Problem	Probable Cause	Corrective Action
Subsystem: RFID Hardware		
Hardware Error	• Component failure • Loose or faulty wiring between the main board and the RFID board. • Main board failure	**1.** Restart the system. **2.** Replace the reagent pack. See Replace Reagent Pack in CHAPTER 8, Maintenance Procedures. **3.** If the problem persists, contact us.
RFID error	• Failed to read RFID tags • Bad tag • Bad reader	Refer to Corrupt Reagent Pack RFID Tag Troubleshooting.
Subsystem: Reagent Bay Hardware		
Subsystem: Reagent Pack		
Invalid	Corrupted or unprogrammed consumable identification tag	**1.** Replace the reagent pack. See Replace Reagent Pack in CHAPTER 8, Maintenance Procedures. **2.** If the problem persists, contact us.
Expired	• The reagent pack is past its expiration date. • The 90-day in-service life of the reagent pack is expired.	Replace the reagent pack. See Replace Reagent Pack in CHAPTER 8, Maintenance Procedures.
Empty	• The reagent pack is empty	Replace the reagent pack. See Replace Reagent Pack in CHAPTER 8, Maintenance Procedures.
No Pack Found	• Reagent pack not installed • Failure of the recognition component of the reagent pack	**1.** Install the reagent pack. See Replace Reagent Pack in CHAPTER 8, Maintenance Procedures. **2.** Restart the system. **3.** If the problem persists, contact us.

Table 10.3 Troubleshooting Table - Reagents

Problem	Probable Cause	Corrective Action
Write Failure	• Failing RFID module • Failed/corrupt consumable	**1.** Replace the reagent pack. See Replace Reagent Pack in CHAPTER 8, Maintenance Procedures. **2.** Restart the system. **3.** If the problem persists, contact us.
Load failed	• Failing RFID module • Failed/corrupt consumable	**1.** Replace the reagent pack. See Replace Reagent Pack in CHAPTER 8, Maintenance Procedures. **2.** Restart the system. **3.** If the problem persists, contact us.

Table 10.4 Troubleshooting Table - Motion

Problem	Probable Cause	Corrective Action
Subsystem: Sample Deck		
Not Registered	• Stage/Controller replaced • Software update failed to retain previous settings • Corrupt settings	Contact us.
Initialization failure	• Motor hardware failure • Software error	**1.** Restart the system. **2.** If the problem persists, contact us.
Positioning failure	The system did not reach the requested position due to one of the following: • Encoder failure • Motor failure • Main board failure • Motion obstructed	**1.** Power cycle the system by turning off power, unplugging the Analyzer from the outlet and plugging it back in. **2.** Turn on the Analyzer. **3.** If the problem persists, contact us.
Eject failure	The system did not reach the requested position due to one of the following: • Encoder failure • Motor failure • Main board failure • Motion obstructed	**1.** Ensure that there are no sample tubes lodged in the discharge chute. **2.** Empty the spent tube tray. Refer to Empty Waste Tube Tray in CHAPTER 8, Maintenance Procedures. **3.** Power cycle the system by turning off power, unplugging the Analyzer from the outlet and plugging it back in. **4.** Turn on the Analyzer. **5.** If the problem persists, contact us.

Table 10.4 Troubleshooting Table - Motion

Problem	Probable Cause	Corrective Action
Homing failure	The system did not reach the requested position due to one of the following: • Encoder failure • Motor failure • Main board failure • Motion obstructed	1. Power cycle the system by turning off power, unplugging the Analyzer from the outlet and plugging it back in. 2. Turn on the Analyzer. 3. If the problem persists, contact us.
Tube detected	Sample tube detected in the carousel during registration or initialization.	Remove any sample tubes from the carousel and retry the operation.
Subsystem: Motor		
Initialization failure	The motor failed to complete the initialization sequence due to one of the following: • Home sensor failure • Encoder failure • Motor failure • Main board failure • Motion obstructed	1. Power cycle the system by turning off power, unplugging the Analyzer from the outlet and plugging it back in. 2. Turn on the Analyzer. 3. If the problem persists, contact us.
Timeout	• Motor failed to execute operation in the allowed time — Motor may be stalled or broken — Main board may have a failing component	1. Power cycle the system by turning off power, unplugging the Analyzer from the outlet and plugging it back in. 2. Turn on the Analyzer. 3. If the problem persists, contact us.
Homing Failure	• The system may not have found homing flag within the allowed time — Sensor failure — Encoder failure	1. Power cycle the system by turning off power, unplugging the Analyzer from the outlet and plugging it back in. 2. Turn on the Analyzer. 3. If the problem persists, contact us.
Positioning Failure	• The system did not reach the requested position. — Encoder failure — Motor failure — Main board failure — Motion obstructed	1. Power cycle the system by turning off power, unplugging the Analyzer from the outlet and plugging it back in. 2. Turn on the Analyzer. 3. If the problem persists, contact us.
Holding current failure	• Failed to engage or release the motor holding current • Main board failure	1. Power cycle the system by turning off power, unplugging the Analyzer from the outlet and plugging it back in. 2. Turn on the Analyzer. 3. If the problem persists, contact us.

Table 10.4 Troubleshooting Table - Motion

Problem	Probable Cause	Corrective Action
Motor driver error	• Software error • Firmware error	**1.** Power cycle the system by turning off power, unplugging the Analyzer from the outlet and plugging it back in. **2.** Turn on the Analyzer. **3.** If the problem persists, contact us.
Logic error	• Failed to set the motor parameter • Software error • Firmware error	**1.** Power cycle the system by turning off power, unplugging the Analyzer from the outlet and plugging it back in. **2.** Turn on the Analyzer. **3.** If the problem persists, contact us.

Table 10.5 Troubleshooting Table - Fluidics

Problem	Probable Cause	Corrective Action
Subsystem: Syringe Pump		
Initialization error	• Failed to initialize the syringe pump/valve controller • Controller disconnected • Controller failed • Software error	**1.** Power cycle the system by turning off power, unplugging the Analyzer from the outlet and plugging it back in. **2.** Turn on the Analyzer. **3.** If the problem persists, contact us.
Hardware error	• Hardware error with the syringe pump • Syringe pump malfunction	**1.** Power cycle the system by turning off power, unplugging the Analyzer from the outlet and plugging it back in. **2.** Turn on the Analyzer. **3.** If the problem persists, contact us.
Over pressure error	• Obstruction in the fluidics path • Wear in the syringe mechanism	**1.** Ensure that the sample concentrations are below the system limit. **2.** If the problem persists, contact us.

Table 10.6 Troubleshooting Table - Imaging

Problem	Probable Cause	Corrective Action
Subsystem: General		
Timeout	• Software error • Other software on the system is consuming resources	**1.** Ensure that no third-party software has been installed on the system. **2.** If the problem persists, contact us.
Logic error	• Failed to retrieve data from the camera • Camera driver corrupt	**1.** Power cycle the system by turning off power, unplugging the Analyzer from the outlet and plugging it back in. **2.** Turn on the Analyzer. **3.** If the problem persists, contact us.

Table 10.6 Troubleshooting Table - Imaging

Problem	Probable Cause	Corrective Action
Image Quality	• Image brightness out of range • LED failing • Image path is contaminated • Opaque sample media • Camera failure	1. Select **Decontaminate** on the Reagent status screen to decontaminate the flow cell. 2. If the problem persists, contact us.
Background intensity adjustment failure	• Unable to reach optimal image brightness level • Image brightness out of range • LED failing • Image path is contaminated • Opaque sample media • Inconsistent mix of reagents • Camera failure • Bubble during background adjustment • Insufficient sample volume	1. Rerun the sample if it is a rare occurrence. 2. Run decontamination. Refer to Decontaminate with Bleach in CHAPTER 8, Maintenance Procedures. 3. Contact us.
Subsystem: Camera		
Hardware Error	• Camera is disconnected • Camera failure	1. Power cycle the system by turning off power, unplugging the Analyzer from the outlet and plugging it back in. 2. Turn on the Analyzer. 3. If the problem persists, contact us.
Timeout	• The camera failed to trigger • Faulty camera connections • Camera failure	1. Power cycle the system by turning off power, unplugging the Analyzer from the outlet and plugging it back in. 2. Turn on the Analyzer. 3. If the problem persists, contact us.
Connection error	• Camera disconnected • Camera failure • Wiring fault • Camera driver fault	1. Power cycle the system by turning off power, unplugging the Analyzer from the outlet and plugging it back in. 2. Turn on the Analyzer. 3. If the problem persists, contact us.
Initialization failure	• Camera failed to initialize • Camera disconnected • Camera failure • Wiring fault	1. Power cycle the system by turning off power, unplugging the Analyzer from the outlet and plugging it back in. 2. Turn on the Analyzer. 3. If the problem persists, contact us.

Table 10.6 Troubleshooting Table - Imaging

Problem	Probable Cause	Corrective Action
No image capture	Camera failure	**1.** Power cycle the system by turning off power, unplugging the Analyzer from the outlet and plugging it back in. **2.** Turn on the Analyzer. **3.** If the problem persists, contact us.
Subsystem: Trigger		
Hardware Error	• Problem with the main board • Faulty main board to camera wiring	**1.** Power cycle the system by turning off power, unplugging the Analyzer from the outlet and plugging it back in. **2.** Turn on the Analyzer. **3.** If the problem persists, contact us.
Subsystem: LED		
Hardware Error	Connection failure to LED module.	**1.** Power cycle the system by turning off power, unplugging the Analyzer from the outlet and plugging it back in. **2.** Turn on the Analyzer. **3.** If the problem persists, contact us.
Initialization error	• LED failure • LED wiring failure	**1.** Power cycle the system by turning off power, unplugging the Analyzer from the outlet and plugging it back in. **2.** Turn on the Analyzer. **3.** If the problem persists, contact us.
Power threshold	• LED power request is out of tolerance • LED intensity output degradation • Imaging path requires cleaning	**1.** Select **Decontaminate** on the Reagent status screen to decontaminate the flow cell. **2.** If the problem persists, contact us.
Communication error	• Communication error to LED module • Wiring failure • LED module failure	**1.** Power cycle the system by turning off power, unplugging the Analyzer from the outlet and plugging it back in. **2.** Turn on the Analyzer. **3.** If the problem persists, contact us.

Table 10.7 Troubleshooting Table - Sample

Problem	Probable Cause	Corrective Action
Subsystem: Analysis		
Unknown type	Software fault	Contact us.
Subsystem: Cell Type		
Unknown type	Software fault	Contact us.
Subsystem: Cell Counting		

Table 10.7 Troubleshooting Table - Sample

Problem	Probable Cause	Corrective Action
Configuration invalid	Software fault	Contact us.
General Population invalid	Software fault	Contact us.
Population of Interest invalid	Software fault	Contact us.
Initialization error	Software fault	Contact us.
Subsystem: General		
Processing error	Sample processing was not completed successfully	Re-run sample.

Debris in Vi-CELL BLU Images

Debris is sometimes observed in the trypan blue reagent as a result of Trypan Blue precipitate. The debris consists of irregularly shaped particles with asymmetrical semi-translucent filaments and a particle size range between five and ninety microns. The contrast between the background image and the debris particles is inconsistent, making identification difficult. The debris is light red when viewed with a brightfield microscope. Refer to Figure 10.1 and Figure 10.2.

Figure 10.1 Trypan Blue Precipitate

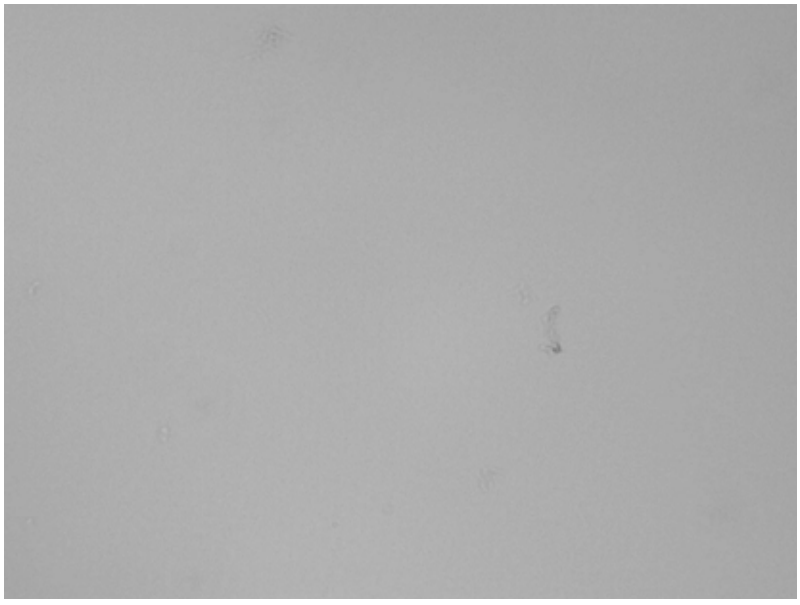
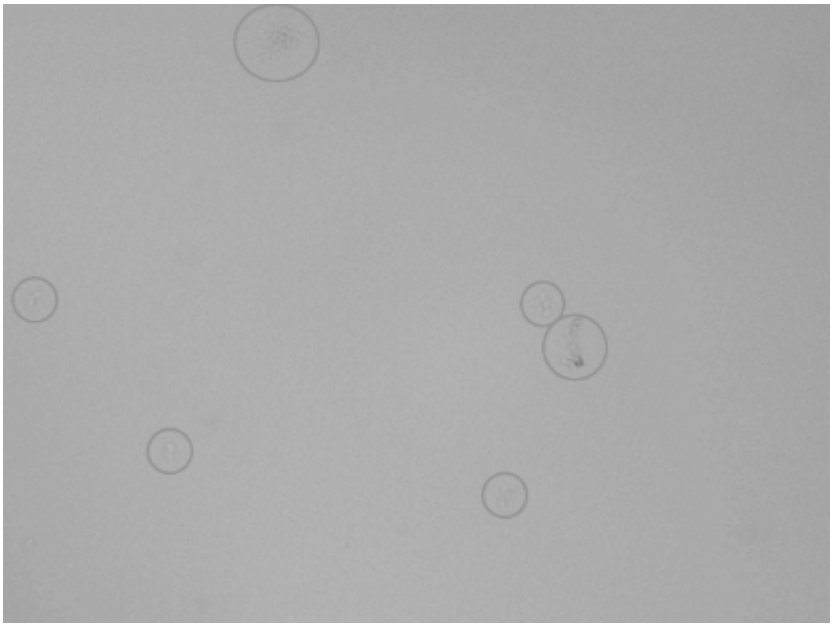


Figure 10.2 Trypan Blue Precipitate Circled



This debris occurs when the trypan blue dye forms an insoluble precipitate. Like any precipitate, the amount of precipitate formed is affected by the concentration of the precipitating molecule, the concentration of non-precipitating molecules, the temperature of the solution, the pH, and the raw material purity. Beckman Coulter's formula controls the concentration, pH, and the raw material purity. The ambient temperature of the laboratory controls the solution temperature. Temperatures below 15° C increase the amount of the precipitate. Evaporation of the solution causes the formation of the precipitate by increasing the reagent concentration.

Beckman Coulter recommends managing all possible causes of trypan blue precipitation as follows:

- The storage location and laboratory should be between 15 and 25° C.
- Bottles should be stored tightly capped with their original lids before use.
- Do not modify the Vi-CELL BLU instrument.

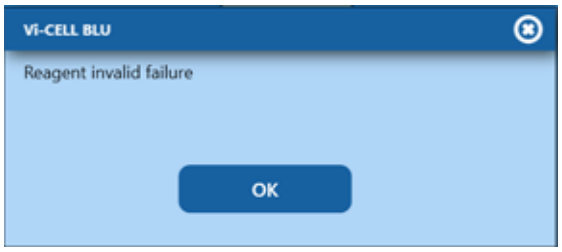
Infrequently, the debris may have an effect on cell viability and concentration results. If the user determines the impact on their results to be unacceptable, they may adjust the Cell Type Definitions in the Vi-CELL BLU software (See CHAPTER 6, Creating a New Cell Type) or filter the Trypan Blue to reduce the effect of the debris on results.

Contact us for assistance with issues related to the presence of trypan blue debris in the trypan blue reagent. Before filtration, read and follow the filter manufacturer's directions, read the trypan blue section of the Vi-CELL BLU Reagent Pack Safety Data Sheet, and wear the appropriate personal protective equipment.

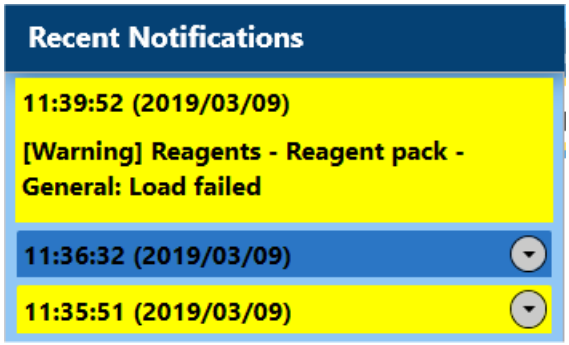
Corrupt Reagent Pack RFID Tag Troubleshooting

Reagent pack validity is checked on two instances; first during Reagent Pack loading and next during bootup with a pack loaded in Reagent bay. Below is the response from Instrument Software to the user on these two scenarios:

When a Reagent pack RFID tag data is corrupted, the following message appears: *Reagent invalid failure*.

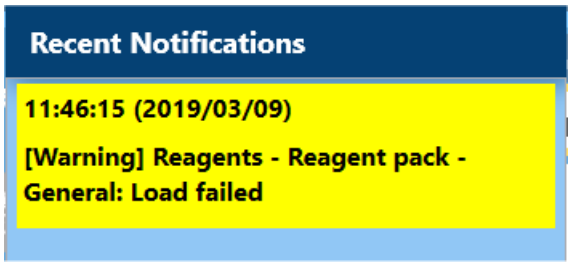


Upon closing the pop-up window, the Replace Reagent window is prompted again. At this point the following System Error notification displays *[Warning] Reagents – Reagent Pack – General : Load failed* in yellow.



If the Reagent pack is left in the Reagent Bay from the previous step, on the next boot up of the Application software, the following System Error notification displays *[Warning] Reagents – Reagent Pack – General : Load failed* in yellow.

NOTE User should re-install the reagent pack. Should they continue to get the error notifications, they should contact customer technical support.



APPENDIX A

System Specifications

Data Acquisition

- Operating principle: analysis of video images
- Sample type: spatial data
- Cell size range of 2 microns to 60 microns
- Analysis rate: up to 100 Images in 130 seconds
- Digitizing resolution: 2048x2048 pixels

Cell Viability/Concentration/Cell Count

- Concentration Range: 5×10^4 to 1.5×10^7 cells/mL
- Viability Range: 0 to 100%
- Recovery Value of Vi-CELL BLU Concentration Control compared to the lot assay value used are ±10%.

NOTE The results for samples at the low end of the concentration range will not be as statistically accurate due to the low number of measured cells. The accuracy at the high end of the concentration range is affected by the difficulty of declustering groups of cells particularly if the cells are large. The sample should be diluted to bring its concentration into range or to improve the accuracy of the results. Multiple cell/bead aggregates can affect results. Aggregates can be reduced by vortexing or sonicating the sample.

Physical Requirements

- Power 200 watts max.
- Voltages 100-240V AC, 50-60 Hz
- Temperature: 13 to 37°C (55 to 99°F)
  Temperature Variation of: ±3°C over 8 hours.
- Humidity: 10 to 90%

Unit Dimensions

See CHAPTER 2, Unpacking and Setup.

APPENDIX B

Regulatory Compliance – 21 CFR Part 11

21 CFR Part 11

The Electronic Records and Electronic Signatures Rule (21 CFR Part 11) was established by the FDA to define the requirements for records in electronic form and the criteria for approved electronic signatures.

This section describes the relevant portions of the 21 CFR Part 11 regulations and their implementation using the Vi-CELL BLU control software. The implementation and compliance of 21 CFR Part 11 remains the responsibility of the organization or entity creating and signing the electronic records in question. Proper procedures and practices, such as GLP and GMP, are as much a part of the overall compliance with these regulations as are the features of the Vi-CELL BLU control software.

Electronic Records

Per Section 11.3 subpart A of 21 CFR Part 11, an electronic record is 'any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system'. This refers to any digital computer file submitted to the FDA, or any information not submitted but that needs to be archived. Public docket No. 92S-0251 of the Federal Register (Vol. 62, No. 54) identifies the types of documents acceptable for submission in electronic form and where such submissions may be made.

FDA Requirements

The general comments section of the ruling states that 'The agency emphasizes that these regulations do not require, but rather permit, the use of electronic records and signatures'. The introduction to the final ruling states that 'The use of electronic records as well as their submissions to FDA is voluntary'.

If electronic submissions are made, Section 11.2 explains that 'persons may use electronic records in lieu of paper records or electronic signatures in lieu of traditional signatures provided that: (1) The requirements of this part are met; and (2) The document or parts of a document to be submitted have been identified in public docket No. 92S-0251'.

The Vi-CELL BLU control software has been designed to enable users to comply with the electronic records and signatures rule.

Implementing Electronic Records and Signatures

Section 11.3 Subpart A describes two classes of systems:

Closed Systems

A closed system is one 'in which system access is controlled by persons who are responsible for the content of electronic records'. In other words, the people and organization responsible for creating and maintaining the information on the system are also responsible for operating and administering the system.

Open Systems

An open system is one 'in which system access is not controlled by persons who are responsible for the content of electronic records'.

The Vi-CELL BLU is an open system.

The Vi-CELL BLU control software is designed to ensure the proper operation, maintenance and administration for system security and data integrity. Anyone who interacts with the Vi-CELL BLU, from administrators to users, must abide by these procedures. Therefore, the ultimate responsibility is with the organization generating electronic records and signatures. The Vi-CELL BLU software is a component, albeit a vital one, of the overall process.

Controls for Electronic Records

Subpart B, Section 11.10 describes the controls to be applied to a "closed system". Section 11.30 describes the controls for an "open system", which include "those identified in Section 11.10, as appropriate, and additional measures such as document encryption and use of appropriate digital signature standards". Since a typical Vi-CELL BLU system can be regarded as an open system, additional controls for closed systems will not be discussed in this document. The primary thrust of these controls is "to ensure the authenticity, integrity, and, when appropriate, the confidentiality of electronic records, and to ensure that the signer cannot readily repudiate the signed record as not genuine". In other words, to protect the data and to make it difficult for someone to say that this is not their "signature". Many of the controls described in Section 11.10 refer to written procedures (SOPs) required of an organization by the agency, for the purpose of data storage and retrieval, access control, training, accountability, documentation, record keeping, and change control. The other controls are addressed either by the Vi-CELL BLU software itself, or in combination with end-user procedures.

Establishing an Electronic Record

The Vi-CELL BLU software employs a system of usernames and passwords, consistent with the specifications of Subpart C, Section 11.300, "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".

21 CFR Part 11 Compliance

Security needs to be enabled to access more advanced options for compliance.

To turn on the security option, select  > 

> 

.
See CHAPTER 2, Set Security settings.

NOTE Inactivity timeout is set to prevent unofficial access to the system, as when the system is left unattended directly after starting the Sample Set.

The system will prompt you to log in. On the **Log In** dialog, enter your user name and password.

If the security is set to local, new users can only be created and passwords reset by users with Administrator rights. If security is set to Active Directory, the User Accounts are managed by the customer's Information Technology organization.

File History

The Vi-CELL BLU software also performs data input and "operational checks", as specified in Subpart B, Section 11.10, "to determine, as appropriate, the validity of the source of data input or operational instruction", and "to enforce permitted sequencing of steps and events". These two features ensure that valid data are being entered into the system, and all required steps have been completed to perform the task at hand.

The purpose of all such data checking and validation is described in Section 11.10, Paragraph (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". Vi-CELL BLU software data records are all automatically saved upon creation.

Section 11.10, paragraph (e) requires “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 must be retained for a period at least as long that required for the subject electronic records and must be available for agency review and copying.” The Vi-CELL BLU software complies with this rule by generating an audit trail which records the time a user was logged on. The audit trail is encrypted and checksummed for added security. The audit trail also will record and time-stamp: failed login attempts, switching users, turning security on or off, adding new user, enable/disable user, change password, reset password, lock instrument and failed checksums. Refer to Table 6.5 for a list of audit trail events and the related descriptions.

NOTE Change password and reset password are not audited for Active Directory users.

When a data file is created, the Vi-CELL BLU system software provides a computer-generated time-stamped record that documents actions taken to create a record. This information is stored within the actual data file itself, not in the Audit Trail file. Each data file contains a computer-generated time-stamped record, the date and time of operator entries, and the actions taken to create the data file.

The system software does not allow a data record to be modified or deleted within the normal operation of the system software.

If the integrity of a data file is compromised in some way, the file is rendered unusable by the system and it can no longer be used by the Vi-CELL BLU software. Each data file contains an embedded checksum that is used to check the integrity of the file each time the file is loaded. If the data file is compromised, an error message is displayed and the file does not load.

Electronic Signature

In Subpart A, Section 11.3, an electronic signature is defined as "a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature". Subpart C, Section 11.100 of the regulation defines the general requirements of such a manifestation. Paragraph (a) states that "each electronic signature must be unique to one individual and must not be reused by, or reassigned to, anyone else". These two paragraphs, taken together, mean that an electronic signature is a representation of a user's identity, developed to ensure the distinct and unique identity of that user. The procedural aspect of Section 11.100 requires that before any such electronic representation is applied, the organization first must "verify" the identity of that individual.

Subpart C, Section 11.200, refers to biometric and non-biometric forms of electronic signature. Non-biometric signatures are those that are computer generated and, as per Section 11.200, "Employ at least two distinct identification components such as an identification code and password". It is this form of electronic signature that is supported by the Vi-CELL BLU software.

Generating Electronic Signatures

The Vi-CELL BLU software employs User IDs and passwords to verify the identification of each user logging into the system. When using this technique, Subpart C, Section 11.300 of the regulation requires "maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password". This section also requires that the "identification code and password issuances are periodically checked, recalled, or revised". Vi-CELL BLU software supports both of these provisions.

NOTE To support 21 CFR Part 11 compliance the user name entered should be the full user display name.

The administration of the system requires that individuals are added to the list of valid Vi-CELL BLU users via the **Add a New User** dialog box. The "identification code" or username of each Vi-CELL BLU user must be unique. No two users on the same Vi-CELL BLU system can have the same user name. It is also required that these users supply a password to access the Vi-CELL BLU software, thus satisfying the requirement to "employ at least two distinct identification components such as an identification code and password". Passwords can be controlled to prohibit the use of duplicates and to force the selection of new passwords after a prescribed period of time.

NOTE In Active Directory mode **Add a New User** is performed by the customer's Information Technology organization.

By the implementation of these features, the Vi-CELL BLU software can satisfy the requirement that "identification code and password issuances are periodically checked, recalled, or revised".

Applying Electronic Signatures

Subpart C, Section 11.200 stipulates several requirements for the control of electronic signatures. Procedurally, the regulations require that electronic signatures "be used only by their genuine owners" and that they "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". Through the application of Vi-CELL BLU user and password configuration procedures, the system can be configured to "ensure" that inappropriate use of these identifiers can be performed only by the intentional divulgence of security information.

Section 11.200 further specifies the use of electronic signature components during a period "when an individual executes a series of signings during a single, continuous period of controlled system access", and "when an individual executes one or more signings not performed during a single, continuous period of controlled system access". To comply with these provisions, the Vi-CELL BLU software uses the application of the username and password to authenticate the user making and saving the changes, in conjunction with file history.

APPENDIX C

Statistics

Circularity

A value from 0 to 1, with 1 representing a perfect circle. Computed as Da/Dp, where Da = square root (4 A / π), Dp = P / π ; A = pixel area, P = pixel perimeter.

The circularity distribution is based on individual cells, not cells that are part of clusters. Cells that are declustered in Vi-CELL BLU are currently included in the average circularity calculation as well as in the circularity histogram.

System Performance

Run Statistics

Cell Count — The number of cells counted per image and for the total number of images.

Viable Cells — The number of viable or "live" cells per image and for the total number of images.

Viability — The percentage of viable or "live" cells per image and for the total number of images.

Total Cells/mL — The sample cell concentration, expressed in units of cells per mL.

Viable Cells/mL — The concentration of viable or "live" cells in the sample, expressed in units of cells per mL.

Avg. Diameter — The average size of cells per image and for total images.

Avg. Circularity — The average circularity of the cells. See Circularity above.

Images — The total number of images analyzed.

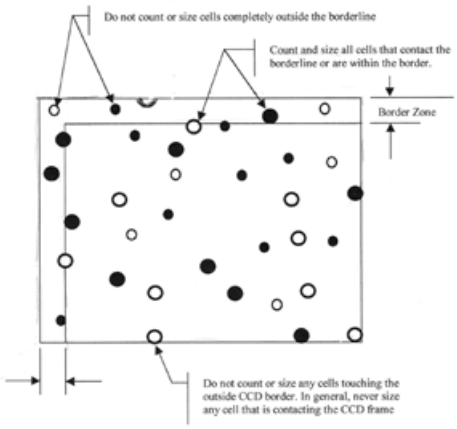
Average Cells/Image — The number of cells captured per image.

Background Intensity — The average pixel value, from 0 to 255, of the image background.

Effective Field of View

"Effective Field of View" is the size of the area inside the reduced measurement frame, and it most accurately represents the actual counting area. It is the area that should be used in computing cell concentrations.

The Effective Field of View value in the configuration or calibration screens permits the cell or particle concentration calculation to be compared against reported values.



The border zone offsets on the top and left borders of the image are used to balance out the cells that are not counted due to contact with the bottom and right borders of the image.

- Objects intersecting the bottom or right edge are not counted.
- Objects that are partially in the main counting area and partially in the border zone are counted.
- Objects that are entirely within the border zone are not counted.

With this method, larger objects that would have gotten rejected are now counted. Smaller objects are not affected (the correction varies in proportion to particle size). The border indent is 30 microns, which is large enough to handle all actual cell sizes that are encountered.

APPENDIX D

Decontaminate with Vaporized Hydrogen Peroxide

Decontaminate with Vaporized Hydrogen Peroxide

Beckman Coulter recognizes that you may need to occasionally decontaminate the instrument.

The instrument is a high performance instrument with sensitive electronic, optical and mechanical components. Beckman Coulter has determined that the only approved method of decontamination for the instrument is to use Vaporized Hydrogen Peroxide (VHP). VHP decontamination is supported by the National Institutes of Health, is more personnel friendly than other methods, does not leave carcinogenic residue, and is accepted in countries around the world.

⚠ CAUTION

Methods that utilize any decontamination method other than Vaporized Hydrogen Peroxide (formaldehyde, etc.) are not supported by Beckman Coulter and could cause substantial damage to the instrument. This damage is not covered by the instrument warranty.

⚠ WARNING

Proper and successful application of a Vaporized Hydrogen Peroxide decontamination cycle is the responsibility of the Laboratory Safety Officer and the personnel performing the decontamination protocol. Only trained and certified personnel should perform decontamination activities.

⚠ CAUTION

By their nature, decontamination methods are aggressive in order to kill pathogens. It is important that the following items be considered when the instrument is decontaminated:

- **VHP decontamination methods will cause slight and progressive aesthetic damage to items such as anodized aluminum, some paints and other coatings.**
- **Labels, including warning labels, may come loose and may need to be replaced after one or more decontamination cycles. Inspect the instrument after decontamination to determine if new labels should be applied. If additional labels are needed, contact your Beckman Coulter Representative.**
- **The serial and part number labels on the instrument may show degradation after the decontamination process. These values should be noted in your laboratory's device history documentation and/or other permanent records. Contact the manufacturer for replacement serial and part number labels if needed.**
- **Decontamination methods can be dangerous to those in the area; observe all safety rules presented by the decontamination provider.**
- **The application of VHP does not leave carcinogenic residue. Other, unsupported decontamination methods may.**
- **Do not allow the VHP decontamination cycle to condense. This could cause equipment damage that would not be covered under the warranty. Decontamination providers will develop a process cycle that should effectively decontaminate the instrument without condensing. A higher concentration decontamination cycle is shorter in duration, but very high concentrations run the risk of condensing. It is best to run lower concentrations in exchange for a longer decontamination cycle.**
- **Decontamination methods may not be effective against pathogens that are suspended in liquids. Liquids may be present due to leaks or spills and the instrument system must be inspected in order to assure that they are not present before a decontamination cycle is performed.**
- **The Laboratory’s Safety Officer is the responsible for the choice, application and efficacy of any decontamination protocols. Any application notes or information from Beckman Coulter is for informational purposes only.**
- **The instrument has been designed to be tolerant of VHP decontamination; however, an excessive number of applications may cause damage.**
- **Due to its sealed nature, the optical module of the Vi-CELL BLU does not receive sufficient concentrations of VHP to decontaminate it. Contact your Beckman Coulter Representative if you feel the optical module requires decontamination.**

⚠ CAUTION

For the instrument to be sufficiently decontaminated, the following steps must be taken:

- **The Vi-CELL BLU Reagent Pack must be removed from the instrument and the reagent bay door left open for the duration of the decontamination cycle.**
- **The waste tube tray must be removed from the instrument and the waste tube tray bay door left open for the duration of the decontamination cycle.**
- **The carousel must be removed from the instrument.**
- **The instrument must be powered down.**

APPENDIX E

Offline Analysis

Offline Analysis Software Operation

The Vi-CELL BLU instrument software can be installed and configured to operate in an offline analysis mode when installed on a personal computer running the Windows 10 operating system.

When running in offline analysis mode the Vi-CELL BLU software supports a subset of the total instrument software functionality. The supported functionality in offline analysis mode primarily includes sample review and reanalysis.

Any functionality in the offline analysis software that requires any non-software related component, such as instrument hardware or reagents, is not supported.

The user experience of the offline analysis software is identical to the instrument software user experience for all supported functionality. Please refer to the instrument instructions for use for instructions on running the software.

The offline analysis software allows for the import of a single data set exported from an instrument. When importing a new data set the data set present in the offline analysis software, if any, will be discarded and replaced by the new data set.

Any new data created within the offline analysis software, such as by reanalysis in the offline analysis software, should be exported and saved before a new data set is loaded.

All data and configuration information in the offline analysis software will be discarded and replaced when a new data set is loaded into the offline analysis software.

NOTE The export file is not altered after importing into the offline software.

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 500 MB 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 or later; this .NET version is compatible with the listed OS versions. The installer for the .NET 4.8 package is included in the Offline Analysis installation package. The Offline Analysis package installer provides the option during installation to install the .NET component, or save it 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.

Offline Analysis Installation

The most current version Vi-CELL Offline Analysis software is supplied on a USB drive. The USB drive contains the Application Set Assy, Vi-CELL BLU Offline Analysis. This PN contains the application set installer binary object with all components for installation to a non-instrument environment.

The application installer file name may contain a version number reference embedded in the file name.

The Vi-CELL Offline Analysis package has been developed to run on computers running the Windows 10 operating system. The software should be compatible with earlier Windows versions back to Windows 7, if the appropriate tools are added to those earlier systems, but operation on those earlier systems has not been verified.

Apply the application software installation to the target workstation using the following steps. Note that administrative privileges may be required to install software. The installation may not complete without the proper permissions.

NOTE Version numbers are in the format: vW.X.Y.Z where 'W', 'X', 'Y', and 'Z' represent version designator elements that will change . An example would be: v1.3.5.1245.

Offline Analysis Installation

1. Logout of the Windows current user, then login to Windows using a Windows administrative user ID.

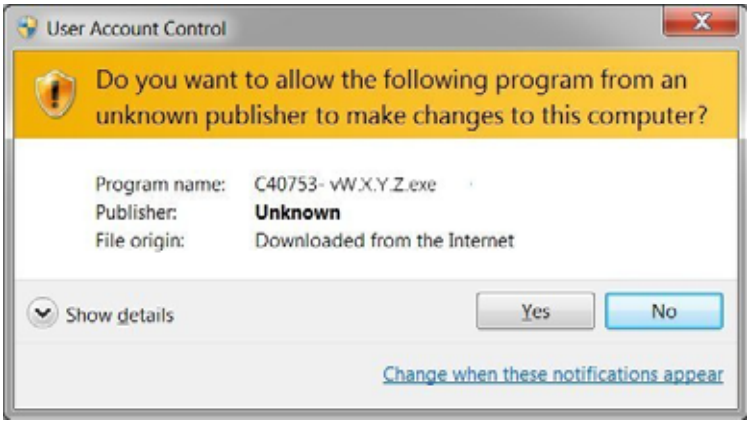
2. Insert the USB drive into an available USB port.

3. Use File Explorer to locate the drive letter representing the USB drive.

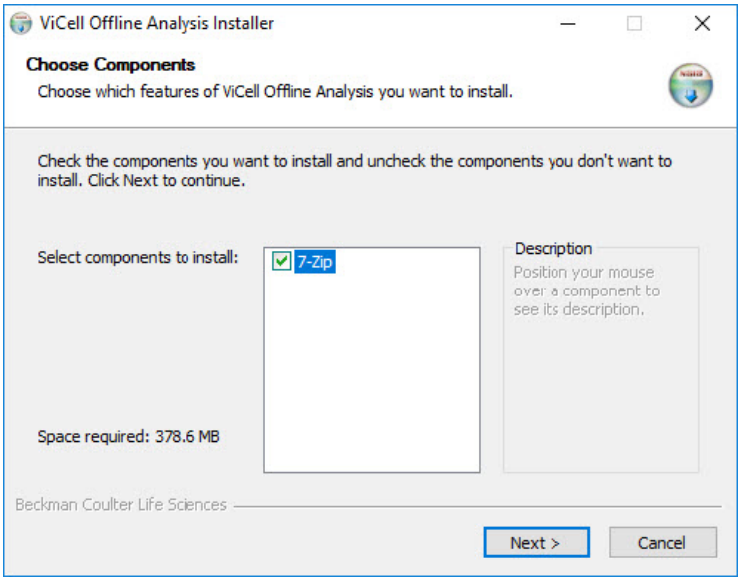
4. Using File Explorer, locate the installer file. The installer should be located in the <drive>:\ folder, where <drive>; is the drive letter of the USB drive.

5. Double-click the installer application to begin the installation.

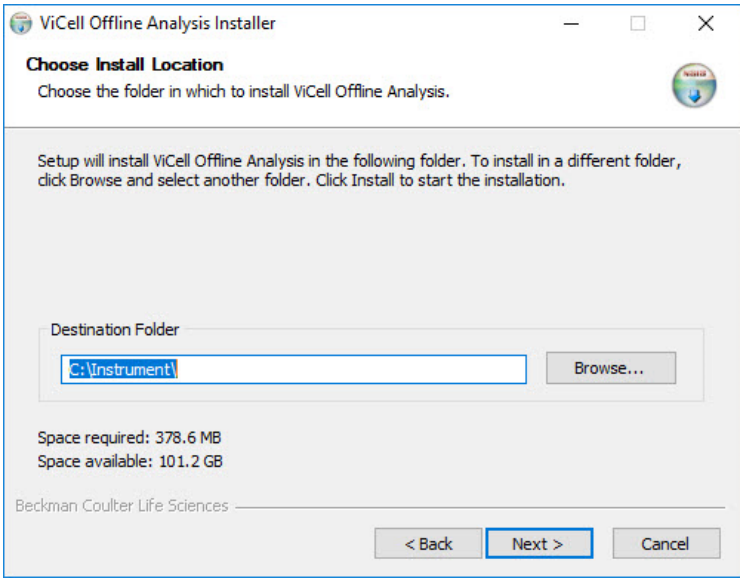
6. If the system prompts to allow modifications, select **Yes** to allow the installation and proceed, or **No** to cancel the installation and exit.



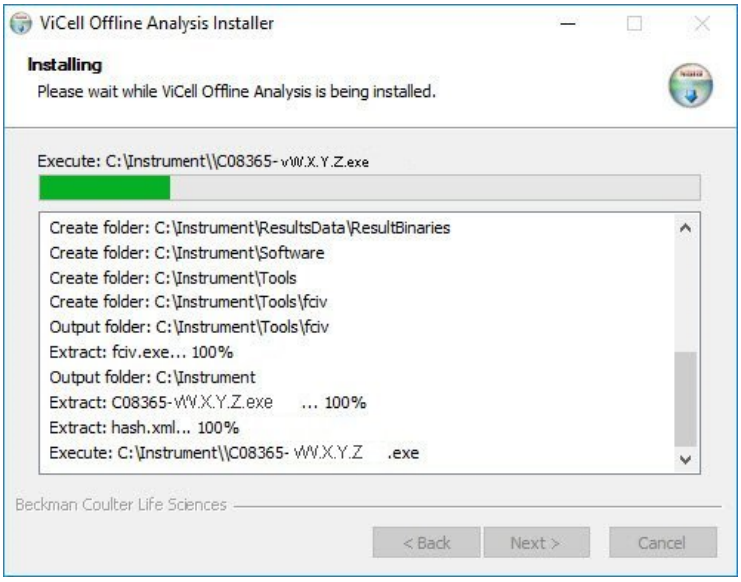
7 You will be given the option to install 7-Zip. If 7-Zip is not already installed on your system, select 7-Zip for installation. When done, select **Next** to proceed.



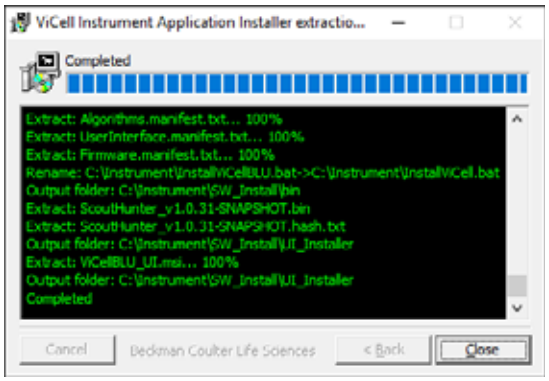
8 When the installer presents the installation destination folder, accept the default folder location and select **Next** to proceed.



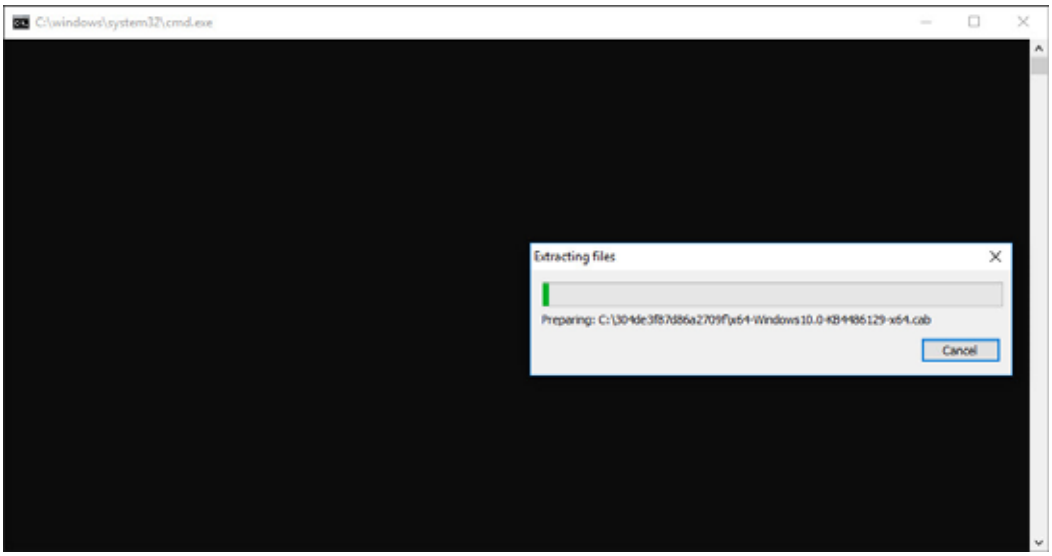
The installer now extracts various sub-components and installers.



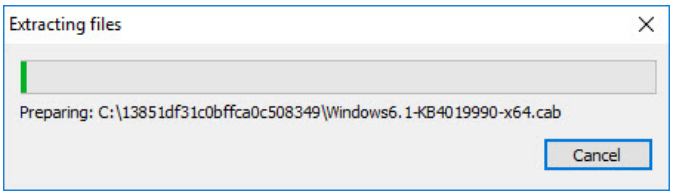
9 When the Vi-CELL Instrument Analysis Software extraction has completed, select **Close** to continue.

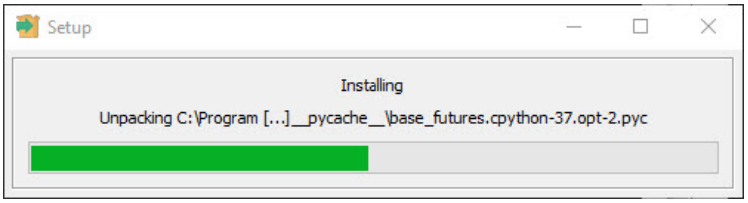


10 The required sub-components will now be automatically installed or repaired if needed. You will see various installer windows flashing by on the screen. You will see a black window in the background with Installation progress bars displayed for several components that are being installed.



Here are a couple of examples of the progress bars that you might see:

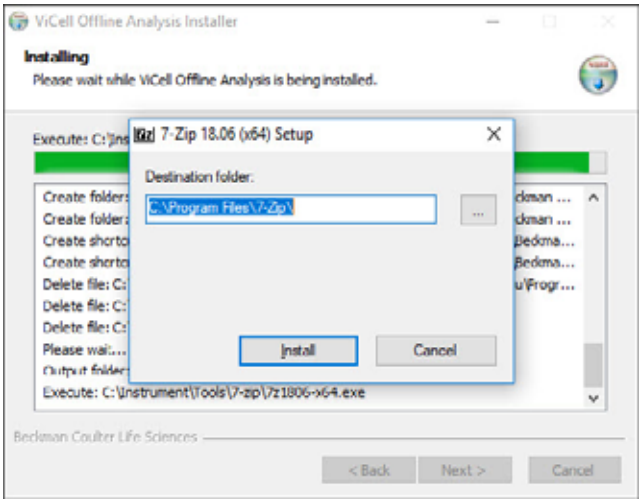




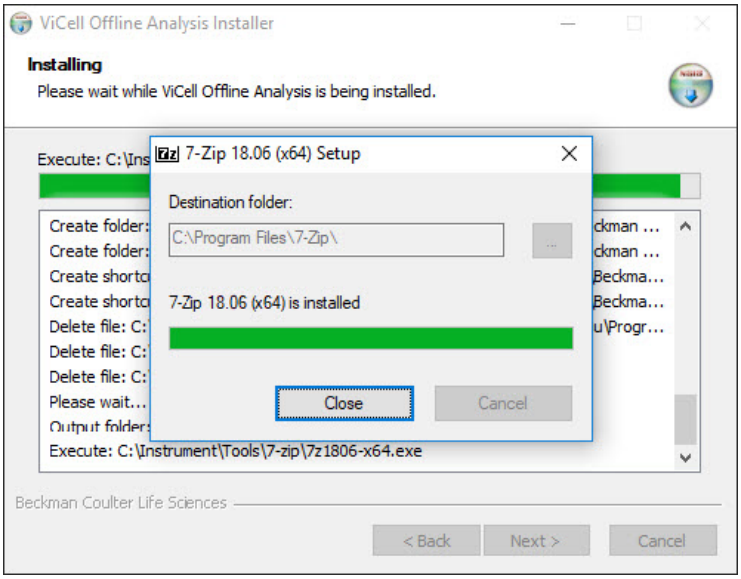
11 If prompted to restart the computer after the .NET installation completes, select **Restart Later** to allow the main application installation and component installation to proceed.

12 7-Zip Installation – if selected.

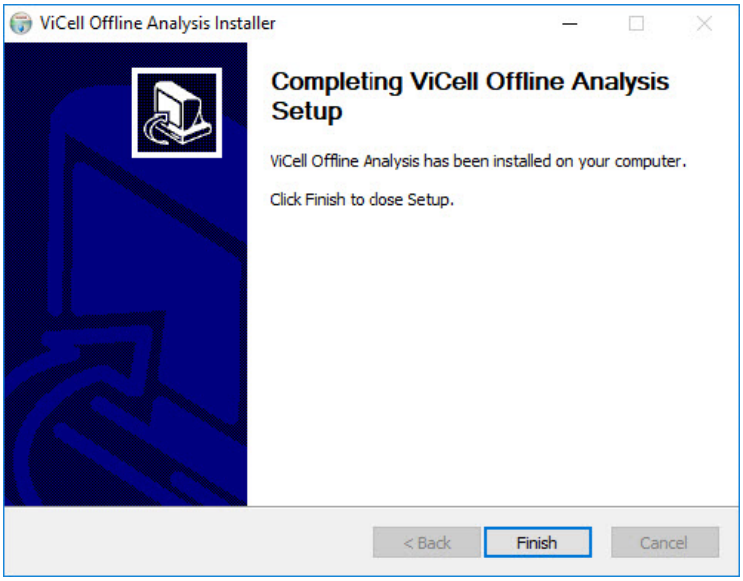
Select the installation location and then select **Install**.



When the installation is complete, select **Close**.



13 All installation steps have completed. Select the **Finish** button to exit the installation.



14 At this point, the USB drive may be removed, or the copy of the installer program may be deleted from the copied location.

15 To start the application, open the start menu and locate the Beckman Coulter section.

16 Expand the Beckman Coulter section to display the Vi-Cell section.

17 Expand the Vi-Cell section to display the Vi-Cell application control items.

18 Locate and select ViCell Offline Analysis to start the application.
Enter the default login credentials:

- Username - factory_admin
- Password - Vi-CELL#0

NOTE After the first successful login, the user will be prompted to change the default password. The instrument ships with Security enabled and passwords are set to expire automatically. After changing the password, record the new password.

NOTE The ViCell section also contains an Uninstall option. Select Uninstall to remove the application and the associated folder structure. Note that some folders may not be removed if they contain user data.

On successful startup, the Offline Analysis application will start a full-screen window presenting the application login screen.

NOTE Once started, the application only allows closure by an administrative user after login. Closure by other means may corrupt data.

Exporting Data to the Offline Software

When a data set is exported from an instrument for use in the offline analysis software, the complete instrument configuration is exported. This will include the instrument operating security mode and the user list for that mode. When imported into the offline workstation, the imported instrument security mode and user list replaces the security mode and user list in the offline workstation instrument application database. Any user login information present from the previous application login sessions will be erased.

For a user at the offline workstation to be able to login to the application, the workstation must have access to the same instrument security authentication mode and the user list present in the exported data set. In particular, if the instrument security mode was using the Active Directory user authentication, this will require that the offline workstation be connected to a network with access to the same Active Directory user list as used by the instrument from which the export was generated.

If the offline workstation cannot be connected to the same authentication system (i.e., Active Directory server), it is recommended that the instrument be placed in the **No Security** mode prior to the data set being exported. The local security mode may be used in situations where the local user list contains login credentials known to the offline user.

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1 On an instrument, select  > 

.

---

2 Select the **Storage** tab.

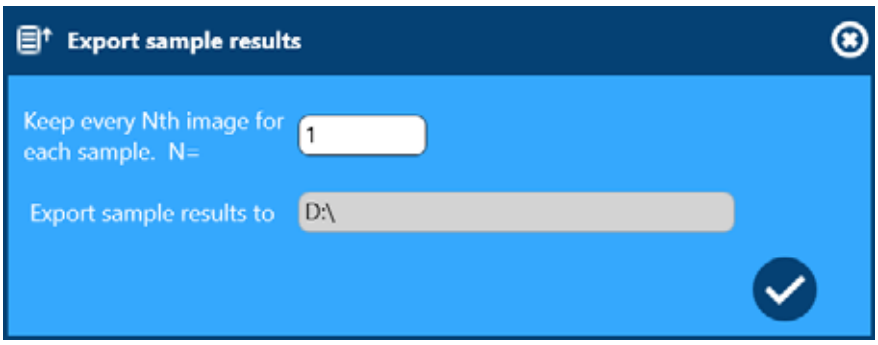
---

3 Enter the desired search criteria in the **User name**, **From**, and **To** fields.

---

4 Select the desired results by checking the box in the left column.

5 Select  . The Export Sample Results screen appears.



6 Select the number of images to export with the samples.

NOTE Selecting N=1 exports all images. Selecting N>1 exports every "Nth" image. For example, N=5 exports images, 1, 5, 10, 15...100. The first and last images are always included in the exported datasheet.

7 Select the desired export location then select  .

Choose to export to C:\Instrument\Export or to any removable drive. Exporting to any other location on the C: drive is not permitted.

A command window appears and displays the status of the export process.

NOTE Depending on the number of samples being exported, this process may take anywhere from a few seconds to several minutes. To cancel the export process, select  in the command window.

The exported data is saved as a .zip file.

Importing Data to the Offline Software

1 Save the .zip file created during the export process to a removable drive and insert the drive into a computer with the Offline Analysis software installed.

2 If necessary, exit the Offline Analysis software.

3 Double-click the import_data.bat script included with the Offline Analysis software.

NOTE The import_data.bat script file is located in the chosen directory for the Offline Analysis installation in the following folders: Instrument\Software\import_data.bat.

4 The script prompts for the drive and full name of the exported data file (for example: G:\ 20190320-221020_ViCELLBLU_SNC1919619B02.zip). Enter the location and full name and press (Enter).

The script checks for the correct installation of the Offline Analysis tool and then unpacks the exported data into the Offline Analysis environment.

NOTE This process removes any existing data and configuration from the Offline Analysis tool and replaces it with the new data. Ensure that any data you wish to retain has been backed up to a different location.

5 When the script is complete, the following notification appears: *Successfully imported the data.* Press (Enter) to complete the import process.

6 Start the Offline Analysis tool.

NOTE The offline application will be updated and start-up in the same Security Mode and with the same user list the instrument was using at the time that the sample data file was exported. Application user login information may not match what existed prior to import. Sample data exported while running in a different security mode than the current security mode will result in an import failure.

APPENDIX F

Vi-CELL BLU Software Installation

Tools/Supplies Needed

- USB software flash drive with appropriate software version.
- Wireless Mouse
- Wireless Keyboard

NOTE Removing unrequired data before upgrading the software can significantly reduce the installation time. It is recommended that you export and then delete any data records that are no longer needed before you start the upgrade.

Vi-CELL BLU Software Upgrade Installation

NOTE Upgrading the Vi-CELL BLU application software to version 1.4 from any earlier version cannot be reversed.

Before upgrading the software, users should consider performing a complete system backup using a backup technique capable of restoring the entire system to its previous state. For systems being upgraded from application version 1.2 or earlier, a backup of the entire C:\Instrument folder should be performed, at a minimum, to preserve system data.

If upgrading from version 1.2, the available free storage space must be greater than the amount of sample data on the instrument to avoid issues with migration of existing data files. CHAPTER 6, Software Administration provides guidance on determining this. If insufficient free space is available, follow the instructions in CHAPTER 6, Software Administration to remove or export unwanted files before proceeding with the upgrade.

The installation process will calculate the amount of free space required at the time of installation, both for the installer and for the data upgrade, if required. If the amount of free space is insufficient to perform the installation, the installer will display a message and the installation process will terminate.

When the installer terminates due to insufficient free space, it does not alter data or configuration files. This allows the installation to be repeated after any system management needed to make the instrument ready for the new application version installation has been performed.

If the installer finds that more than 60% of disk space has been used, it will display a warning message indicating that system maintenance may be required, but will continue the installation process.

Instruments running versions of the Vi-CELL BLU application software older than the 1.2 version must be upgraded to the 1.2 version prior to upgrading to any later application version.

Instruments running a Vi-CELL BLU application software version of 1.2 or later may be upgraded

directly to version 1.4.2 or newer.

---

1 Exit the Vi-CELL BLU application through the main menu of the instrument software.

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2 Logout of the Windows default instrument user, then login to Windows using the windows administrative credentials.

Sign in to Windows using the following credentials:

Username: ViCellAdmin

Password: Vi-CELL#0

NOTE The password provided is the initial password. The user will be prompted to change the password upon the first login. If someone has already logged in as Admin, the password would have been changed.

---

3 Insert the USB software flash drive into an available USB port.

---

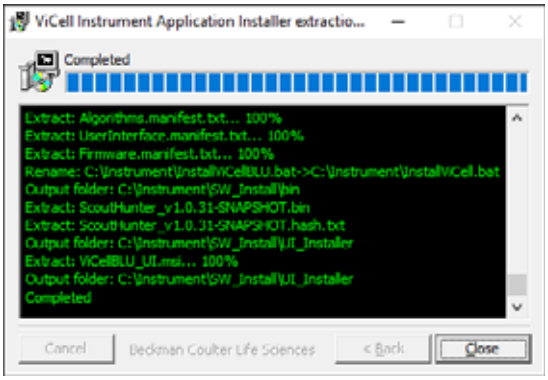
4 On the administrator/service desktop, double-click the 'Load Vi-CELL Software' shortcut, typically located in the upper, right area of the desktop.

A command window appears for the installation process.

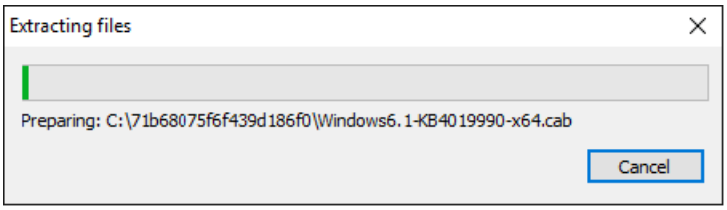
When the initial steps of the installation process have copied necessary files, a secondary auto-extracting zip archive begins.

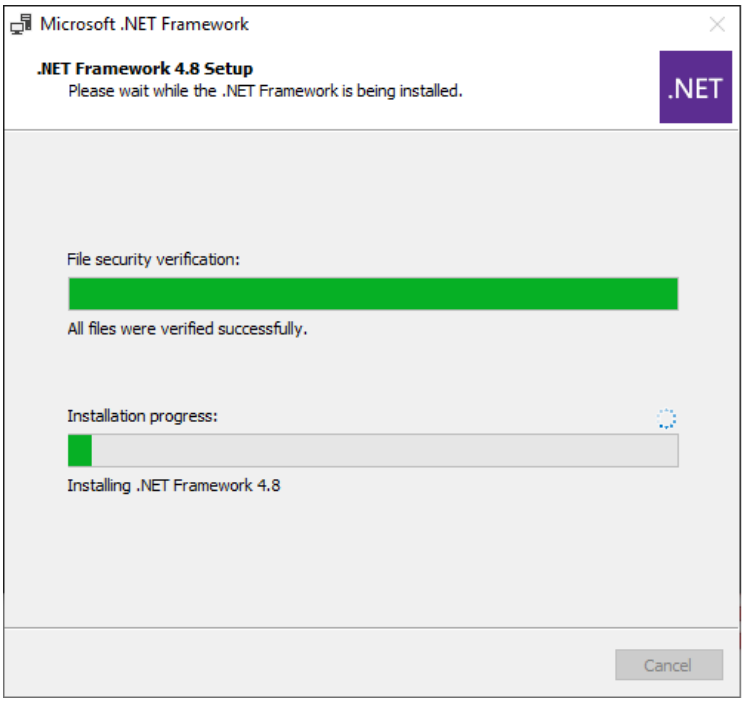
The first window you see should be a **DOS** or **Command** window that looks like:

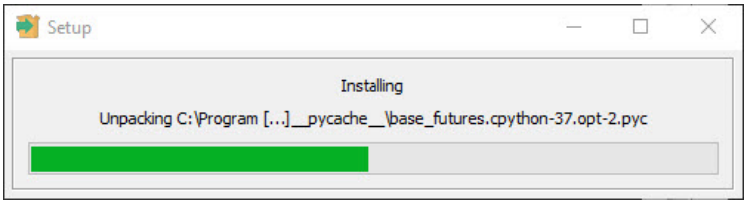
When the extraction of the installers has completed you will see the following screen:



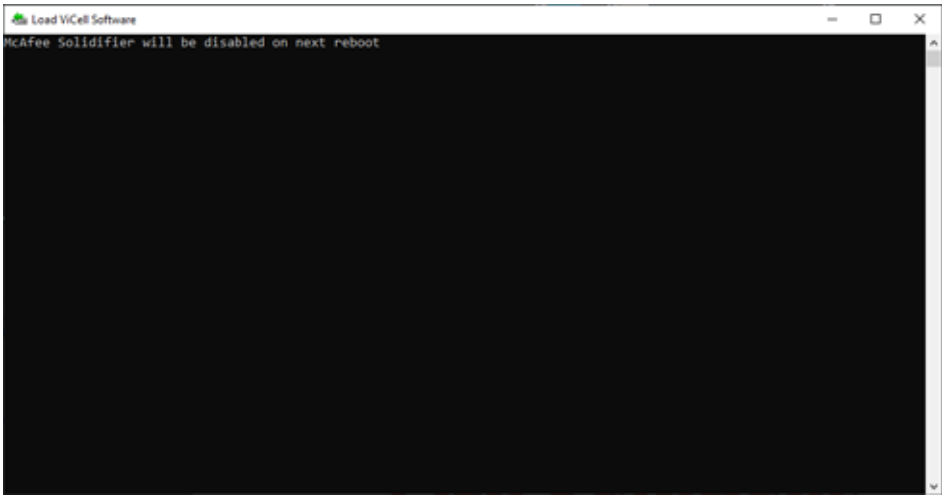
5 Select **Close**. The rest of the installation process is automated. Several software packages are installed as part of this process. All of these installers are run and automatically determine if they need to be installed, repaired or upgraded as required. Many different windows will flash on and off the screen during this process. An example of some of the screens are shown below:.



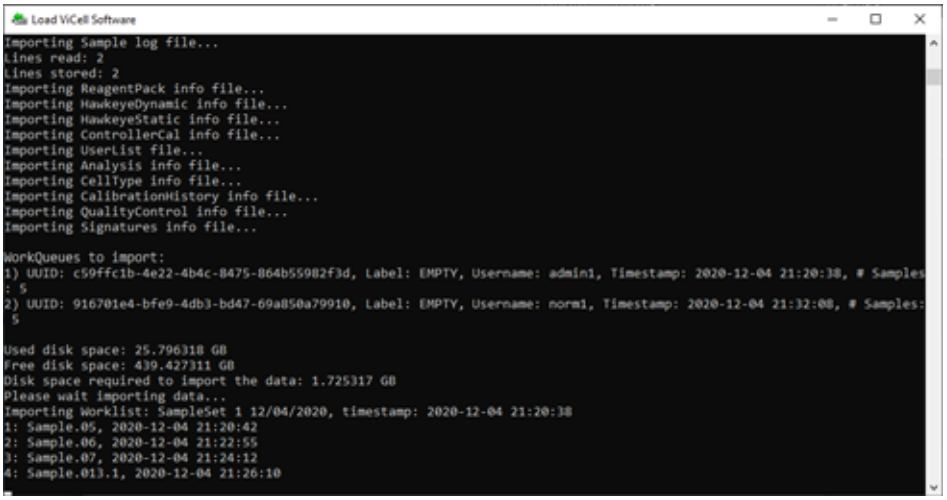




6 After the various software packages are installed, the anti-virus software "McAfee Solidifier" will be prepared for an update and then reboot. This information will briefly be displayed on-screen:



7 Importing of existing data to the database. If there is existing data, samples, users, Cell Types etc., it will be imported into the new software / database. This process can take a significant amount of time depending on the number of sample records to be imported. During this process you will see a screen similar to:



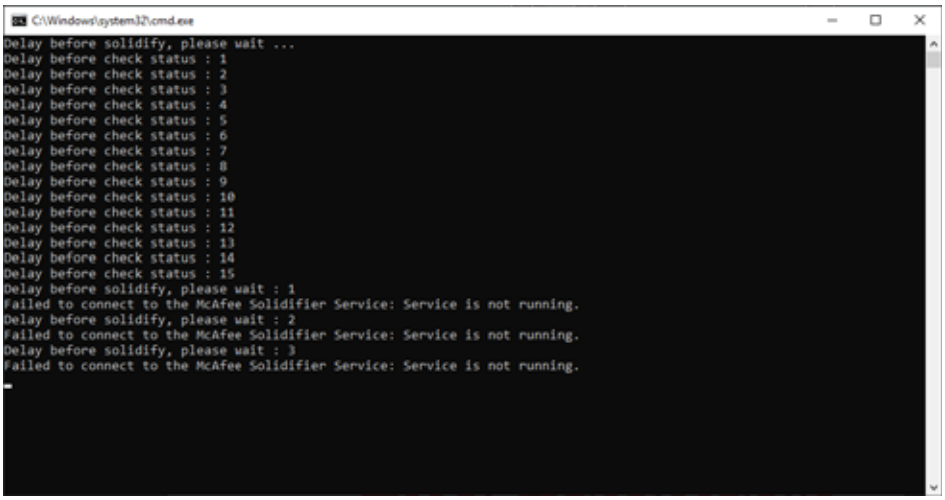
8 When importing of data is done the installation will complete without user input required. If there is an error during installation, the command window will not automatically close and will display the error message.

Upgrading from Version 1.2 or Higher

If upgrading from version 1.2 to a higher application version, the system will automatically reboot. When the instrument restarts you may be presented with a Windows login prompt. At this point login to Windows as a windows administrator. This will automatically launch the final step in the upgrade process. The McAfee anti-virus software needs to analyze the newly installed software in a process called 'solidifying'.

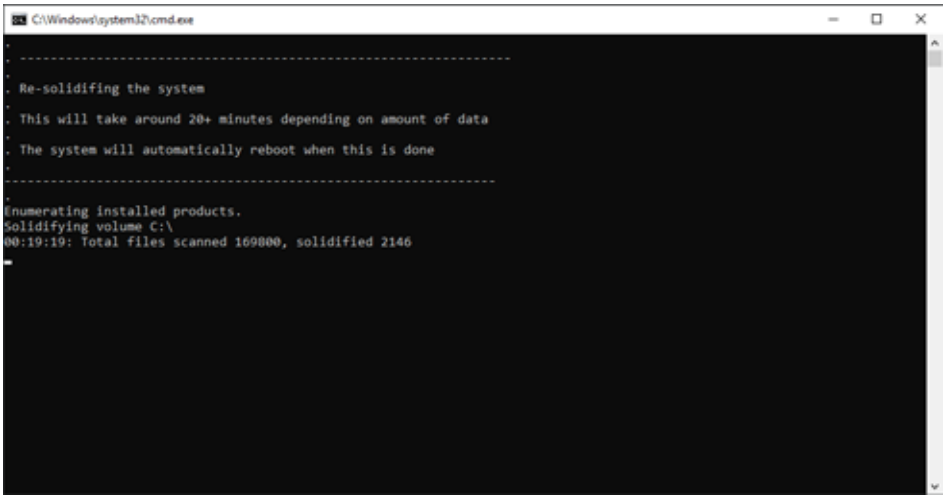
---

1 The first screen shows the connection process to the McAfee software. It takes a little less than a minute to connect to the McAfee software service.



---

2 The process of "solidifying" takes at least 20 minutes to complete. The following screen will be displayed during this process:



3 Automatic restart when complete.

After the “solidifying” process is complete, the system will automatically reboot. After rebooting, the instrument will then run normally.

Vi-CELL BLU Software Installation Troubleshooting

IMPORTANT If errors are encountered by the installation process, the command window will remain open to indicate that errors were detected. The details of any installation errors are located in the "C:\Instrument\Install.log" file. Note any errors, copy the log file for examination by BEC personnel, and contact us if you need assistance.

In case of errors during installation, perform the following troubleshooting steps:

1 Ensure that the Vi-CELL UI application has been shut down properly.

A running Vi-CELL UI process holds files open and blocks the update process. You will see access violations, sharing violations, or similar copy failure notifications under these circumstances.

If in doubt about the Vi-CELL UI shutdown process, or if you see any of the noted errors indicated, check for leftover processes using the task manager, and end those processes prior to performing or repeating the installation.

2 Using the Operating System (OS) desktop, open Apps & Features to remove the 'ViCell Blu' software.

3 Display the contents of the C:\Instrument\Software folder. Delete all contents of the folder.

4 Repeat the installation of the software. Refer to Vi-CELL BLU Software Upgrade Installation.

5 If software fails to install, collect the log files including install.log from the C:\Instrument\Logs folder and contact us.

APPENDIX G

Instrument Configuration Guidelines

OS-Level Login

Whenever signing-out of an OS-level login, a keyboard is required to login to a different OS user account. The touch panel keyboard is not accessible on the OS login lock screen. Returning to normal instrument operations may be accomplished by restarting the instrument through the on-screen power button if present, the Start menu power options, or by use of the power button to power-cycle the instrument.

Installing or upgrading software, as well as OS-level instrument configuration operations requires the user be logged in under an administrative OS user account.

The default OS user administrative account login is:

- Username - ViCellAdmin
- Password - Vi-CELL#0

On first login to the admin account, the user will be prompted to change the password.

Users should avoid changing the desktop backgrounds, as these changes may result in system operations which use significant system resources (CPU time, network IO, or additional storage space usage). Common activities which should be avoided are desktop slideshows, desktop animations (e.g. screensavers), or OS scheduled tasks which may run during times when sample processing is normally expected to occur.

NOTE The instrument control computer configuration should never be altered to allow the instrument to 'sleep' or 'hibernate', or to allow USB devices to be suspended, as these states will occur without regard for any background or unattended processing being performed by the instrument application. Incomplete sample processing may occur, resulting in incomplete or inconsistent sample result data, and potential degradation and/or loss of samples due to prolonged time on the instrument.

Third-Party Software

Beckman Coulter does not support the installation of third-party software on the Vi-CELL BLU system. Installation of third-party software may impact the performance of the Vi-CELL BLU, specifically, real-time active antivirus which reads all data being written to the hard drive.

The Vi-CELL BLU instrument is not a standard computer and should not be treated as such. The OS license does not grant use as a standard computer.

The Vi-CELL BLU instrument is configured with software to prevent running of unknown malicious software. Because this software is preconfigured to recognize the software provided on the instrument, attempts to install additional third-party software may fail, or may cause the system to reject some component of the installed software. This may result in a system with reduced stability.

Remote Connectivity

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.

To download the BeckmanConnect installer, navigate to https://www.beckman.com/beckmanconnect. Or, locate the shortcut in the C:\Instrument\Tools\BeckmanConnect folder, and double-click to navigate to the download site.

After downloading the installer, login to the onboard Vi-CELL PC as an administrative user, and navigate to the hard drive location containing the downloaded installer. Run the installer from the hard drive, following the on-screen prompts.

For additional technical documentation, visit https://www.beckman.com/support/technical/beckmanconnect.

APPENDIX H

Vi-CELL BLU Networking

Overview

The Vi-CELL BLU may be used in a network environment with little additional configuration. The instrument is configured to automatically acquire a network address and expose the 'Export' folder as a read-only network-accessible share.

Installing or upgrading the Vi-CELL BLU application software, as well as OS-level instrument configuration operations requires the user be logged in under an administrative OS user account.

Whenever signing-out of an OS-level login, a keyboard is required to login to a different OS user account. The touch panel keyboard is not accessible on the OS login lock screen. Returning to normal instrument operations may be accomplished by restarting the instrument through the on-screen power button if present, the Start menu power options, or by use of the power button to power-cycle the instrument.

The default OS user administrative account login is:

- Username - ViCellAdmin
- Password - Vi-CELL#0

On first login to the admin account, the user will be prompted to change the password. Record the password for future use.

Access standard network settings through the Start Menu > Settings > Network and Internet > Ethernet to customize network connectivity.

Configuration Tips

- The first configuration tip is that each instrument should be given a unique identification name. The Vi-CELL BLU instrument is configured during manufacturing to use a standardized common name, which may cause conflicts on networks, or may make discrete access to individual instruments difficult. This change is accomplished through the standard Windows computer networking configuration screens.
- Change the instrument workgroup to the desired local workgroup. This change is accomplished through the standard Windows computer networking configuration screens.
- Configuration of static IP addresses is also performed under an OS administrative account. Use the standard tools provided by the operating system, found under the 'Setting - Network & Internet' category.
- Configuring additional mapped network drives is performed under an OS administrative login, using the standard Windows computer technique. Mapped drives may be used as export locations, or for report output destinations when the automation option is enabled.

IMPORTANT The following changes should be undertaken with increased caution, as they may reduce the security of the system.

- Modify group policies to allow registry editing. This may be necessary in certain environments to allow application of changes. If possible, this change should be a temporary change, and the restriction re-enabled after completion of the desired actions.
- Join the instrument to a domain. There are several potential side effects of this change. Those changes are discussed in the section below on Joining an instrument to a domain.
- Modify Group policies to re-enable Command prompt access. This change may also require related changes to provide access to the command prompt, so caution should be exercised.

  NOTE Even though the interactive command prompt is disabled, scripts may still be used to perform actions, if the user has appropriate permissions to perform the scripted actions or has access to the password for an administrative OS user account. NOTE that the PowerShell command prompt is accessible through admin OS accounts and provides command-level access under a more advanced interactive command shell. Whenever possible, it should be the command prompt used.

Configuring Active Directory

The instrument can be configured to use Active Directory login accounts to login into the Vi-CELL BLU application. Most of the configuration is performed through the Vi-CELL BLU application.

The Vi-CELL BLU application cannot create groups on the AD server, nor can it create, configure, or modify user accounts on the AD server. The creation of Active Directory groups, which can be used by the Vi-CELL BLU application to map to the internal roles, is left to the user or their IT department.

Within the Vi-CELL BLU application, AD groups may be mapped to each of the application internal roles. Users belonging to a mapped group will gain all the permissions associated with that application role. Users belonging to multiple mapped groups will gain the permissions granted by the group mapped to the highest-level application role.

Refer to Active Directory Configuration for instructions on configuring the Vi-CELL BLU application.

NOTE For server and domain information, use the appropriate tools to determine the server name and domain for the configuration. These values may not be displayed fully by common tools like 'ipconfig'.

NOTE Active Directory server names, domain names and group names must be entered EXACTLY. In particular, group name entries are case sensitive.

NOTE When specifying a 'secure' connection to the AD server (typically using port number 636), a certificate must be installed on the instrument to allow the instrument to authenticate to the server and support secure, encrypted communications. The certificate must be obtained from the host server. The Vi-CELL BLU cannot automatically pull the certificate. An authorized IT admin must perform the certificate retrieval and installation on the Vi-CELL BLU.

Joining An Instrument To A Domain

In environments requiring additional configuration, the information provided below should assist in the configuration of instruments.

In environments requiring the instrument be joined to the network domain, the instrument may no longer perform automatic login under the standard instrument OS user account. This will require the customer to manually login to the system and then manually start the Vi-CELL BLU application. Alternatively, a shortcut link may be placed in designated user startup folders to allow the application to auto-start when a user logs into the instrument.

NOTE This will typically involve the customer IT department modifying the configuration of the default user account to provide appropriate desktop shortcuts or startup folder alterations.

APPENDIX I

Automation Mode

Overview

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.

Automation control is performed through an OPC UA server on the Vi-CELL BLU instrument which listens for a specified set of commands or queries sent from external automation clients.

The addition of the automation control software does not affect the ability to use the Vi-CELL BLU instrument as a standalone instrument. All instrument capabilities are retained.

Automation control requires the use of external automation robotics clients which support our control interface. Beckman Coulter is not responsible for the development of the external automation control client software.

System Components

Basic Components

The main components of the automation option are software modules providing an OPC UA server which listens for commands or queries sent from external automation clients and performs the actions requested through the software present on the instrument.

Since the software on the Vi-CELL BLU is the recipient of commands generated by a customer application, we provide an example application demonstrating typical configuration of the customer-side client application. The example is provided to demonstrate the use of the control interface and is not intended to replace a dedicated customer application. The programming guide and use of the control interface are discussed separately in the documents included with the Vi-CELL BLU Automation Kits.

Hardware Components Options

The automation control option supports two methods for external sample introduction.

- Vi-CELL BLU Automation Kit 1 with Sample Introduction Cup (C57876), is intended to provide a configurable introduction point for delivery of a single sample to the instrument. This option includes external tubing, a sample introduction cup and attachment components to mount the sample introduction cup.

- Vi-CELL BLU Automation Kit 2 with Plate Holder (C57877) allows the system to be configured to accept 96 well plates from an automation robot. The modified plate holder is designed to have clearance for the robot to reach into and place 96 well plates into the instrument.

Installation

Space Requirements

The automation software does not alter the physical dimensions or clearance requirements of the instrument.

If the instrument will be used with an external sample delivery robot, the placement of that mechanism must not interfere with full, unobstructed access to the Vi-CELL BLU instrument touch panel, reagent bay, or waste bin and should not restrict the normal movement of the instrument sample carrier platen during system initialization.

The optional Sample Introduction Cup (A-Cup) may be installed on either the left or right side of the instrument to allow flexible placement of the associated fluid handling and delivery systems. Placement of those systems must not prevent full, unobstructed access to the instrument touch panel, reagent bay, or waste bin and should not restrict the normal movement of the instrument sample carrier platen during system initialization. Depending upon the configuration of the sample introduction cup and the Vi-CELL BLU, the addition of the external sample introduction tubing will extend the required instrument clearance. The minimum clearance on the side of the instrument selected for installation of the Sample Introduction Cup is 40 mm (1.55”) to allow for the tube bending radius. When installed and connected, the A-Cup should be mounted in an upright position at all times. If the A-Cup has been disabled, the external connections should be capped to prevent fluid leakage. Refer to Figure I.1 below.

Figure I.1 Vi-CELL BLU with Carousel

1. Touchscreen

   NOTE The touchscreen has an independent power button on the bottom-right corner of the screen.

2. Sample Station
3. Carousel
4. Waste Tube Tray Door
5. Reagent Door
6. USB 3.0 Ports
7. Power Button
8. USB 2.0 Port (rear)
9. Ethernet Port
10. Power Connector

Bench Requirements

There must be adequate bench space to allow placement of the Vi-CELL instrument and the sample delivery robot or fluid delivery system, if those systems will reside on the same bench. Placement of the external systems may be on the left or right of the Vi-CELL Instrument

If the optional A-Cup is installed, the pre-measured sample tubing allows for a separation of up to 815 mm (32") between the instrument and the A-cup at the end of the tubing. The external fluid delivery system may be located up to 850mm (33.5") above the base of the instrument. The length of the sample cup tubing is precise and must not be altered.

External System Accuracy

External plate delivery systems must be capable of accuracy to within +/- 1.25 mm for placement on the instrument plate carrier. External fluid delivery systems must be capable of accurate delivery of sample volumes of 200 +/- 20 uL.

Operation

Samples supplied to the Vi-CELL BLU instrument through an automation mode must meet the sample concentration limitations stated in the Vi-CELL Instruction manual. Follow the guidelines for dilution and filtration to ensure proper sample handling.

⚠ CAUTION

Risk of instrument damage if you use any non-Beckman Coulter control bead products. To prevent damage to the instrument, ensure the proper dilution and/or filtration to meet guidance in the following table.

Particle Size	Concentration
2µm ≤ d ≤ 6µm	≤ $1.5x10^7$ particles/mL
6µm ≤ d ≤ 11µm	≤ $2.0x10^6$ particles/mL
11µm ≤ d ≤ 22µm	≤$1.0x10^6$ particles/mL

⚠ WARNING

Risk of biohazard contamination. Toxicity, safety, and proper handling procedures for controls and reagents used should be adhered to at all times. To prevent biohazard contamination, consult appropriate Safety Data Sheets for the items.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

Configuration Changes

The automation option is installed, configured, and enabled by Beckman Coulter service personnel.

At the time of the installation and configuration of the automation option, the service representative will configure the communications port and communications module on the Vi-CELL BLU. Input from the customer's IT representative or external automation system specifications may also be required if the default interface parameters are not appropriate for the customer environment or the automation system being used.

Table I.1 Communications Configuration

Control communications protocol:	OPC UA
Vi-CELL BLU Communications listening port:	62641

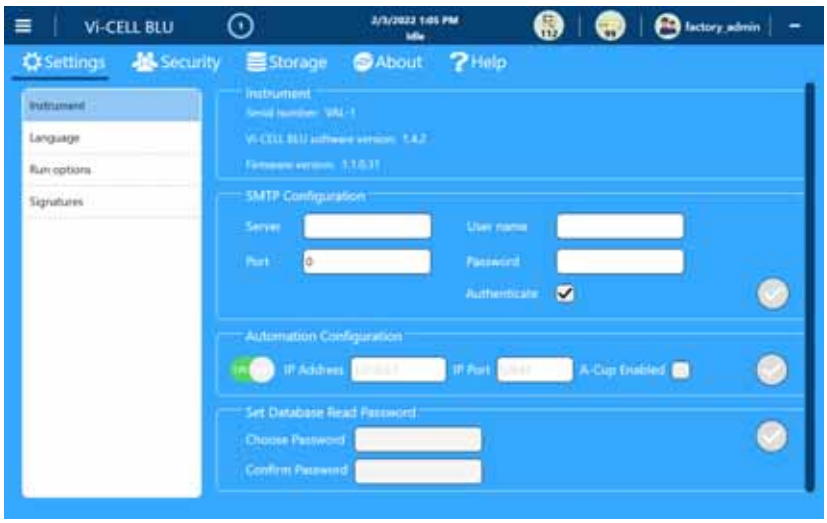
Configuration of the automation communications port also requires configuration of the OS firewall to open the selected port for bi-directional communications (inbound and outbound rules). Firewall configuration can only be performed under an administrative OS user account. The application installation is run under an administrative account and configures the OS firewall appropriately to open the default port number. Changes to the port configuration through the

Vi-CELL BLU application do not configure the OS firewall. The changes to the OS firewall must be made separately. The inbound and outbound firewall rules for the automation port should be given a unique name (identical names for the inbound and outbound rules are allowed). Do not modify the default firewall port rules or re-use the default firewall port rule names created by the installation, as those rules will are recreated each time the application installation is run, and any custom port information will be lost.

After the installation, the following illustration shows the configuration screens accessible through the instrument application. These screens are accessible to users logged into the instrument under admin-level application user accounts. The port field is not editable. Administrative users may disable the A-Cup or disable automation (also disables A-Cup) but may not re-enable them. Enabling automation or the A-Cup is performed only by Beckman Coulter service personnel.

Figure I.2 shows the Automation section when automation has been installed and enabled, but the A-Cup option has not been installed or enabled.

Figure I.2 Automation Enabled



The 'A-Cup' option may only be enabled if the automation control software option has been installed and enabled but is not required by the automation option.

Figure I.3 shows the automation configuration screen when automation is enabled and the A-Cup option has also been installed and enabled.

Figure I.3 Automation Enabled with A-Cup

NOTE Once installed and enabled, an Administrator user may disable the use of the 'A-Cup' or automation. Disabling use of the 'A-Cup' does not disable other use of the automation software interface. Disabling automation will also disable use of the 'A-Cup'. Once disabled, these options can only be re-enabled by Beckman Coulter service personnel.

Figure I.4 shows the automation configuration screen when both automation and the A-Cup are disabled.

Figure I.4 Automation Disabled

If the A-Cup is disabled, the external tubing and receptacle may be disconnected from the system.

Automation Mode Screen Changes

After automation is installed and enabled, several screens will show different content. Starting with the login screen, the illustrations below will demonstrate the differences expected.

Figure I.5 Automation Login Screen

NOTE The modified login screen displays a lock icon on the top icon bar. The icon will display in the locked state when the automation control client has locked the instrument for sample processing or other operations requiring exclusive access. The bottom status bar also indicates the instrument is locked for exclusive access by the automation client. Some menu selections will not show the bottom status indication, but will show the top lock icon.

Figure I.6 illustrates the changes to the Home screen, showing the lock icon and the status shown when the automation client has control of sample processing.

Figure I.6 Automation Login Screen

Figure I.7 illustrates the changes to the Home screen, showing the lock icon and the status shown when the automation client has control of sample processing.

Figure I.7 Automation Mode Completed Sample Sets

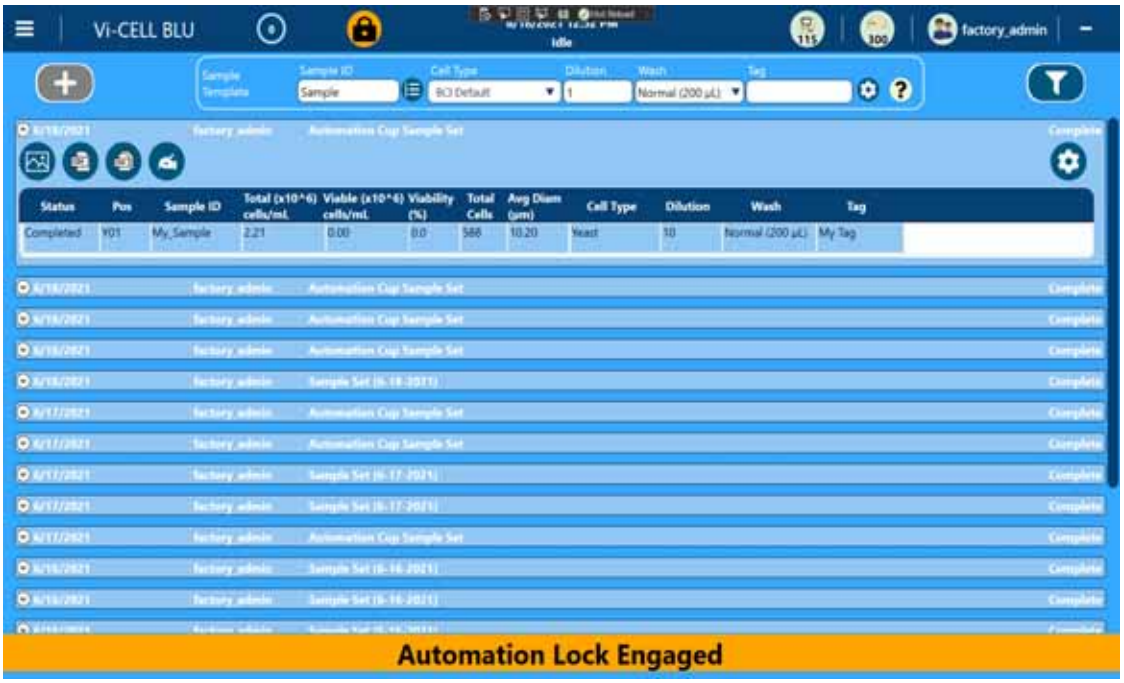


Figure I.7 shows the Home Screen when a user is logged in and automation is on.

Local Exclusions Under External Control

The following list presents those instrument functions that are prohibited when an automation client has the instrument locked for exclusive use. These prohibitions extend to users logged in locally to the instrument, as well as to other automation clients connected to the instrument:

- Cannot select  to open the Create Sample Set dialog
- Cannot run Set Focus
- Cannot run Dust Reference
- Cannot perform Storage Export
- Cannot delete a cell type
- Setting->Instrument is disabled
- Setting->Run Options is disabled
- Setting->Security is disabled
- Setting->Storage is disabled
- Cannot access the Maintenance functions
- Cannot exit the application

Functions Accessible To External Control

The following list presents the instrument automation control interface functions that are available to the automation client when the automation client has enabled the exclusive lock:

- Run single A-Cup sample or 96 plate samples
- Pause, resume and stop sample processing
- Eject the stage
- Get sample results
- Retrieve exported samples
- Delete sample results
- Create Celltype
- Delete Celltype
- Create Quality Control
- Import instrument configuration
- Export instrument configuration

NOTE An automation client cannot access the Maintenance functions.

Local Sample Definition and Processing

When the automation client has control of the system, the sample definition screen will not be displayed when the external client is creating the sample worklist.

When the system is not locked for use by an automation client, normal local sample definition and processing may be performed. The following information applies to local sample definition and processing.

The local user interface will support sample definition using the 96-well plate or carousel. There are no changes to the sample definition process for those sample sources.

If the system has the A-Cup option installed, the sample definition screen will contain the option to use the A-Cup for a single sample. The figure below shows the carrier selection drop-down including the A-Cup option. Generally, manual use of the A-Cup will not be supported except for service personnel.

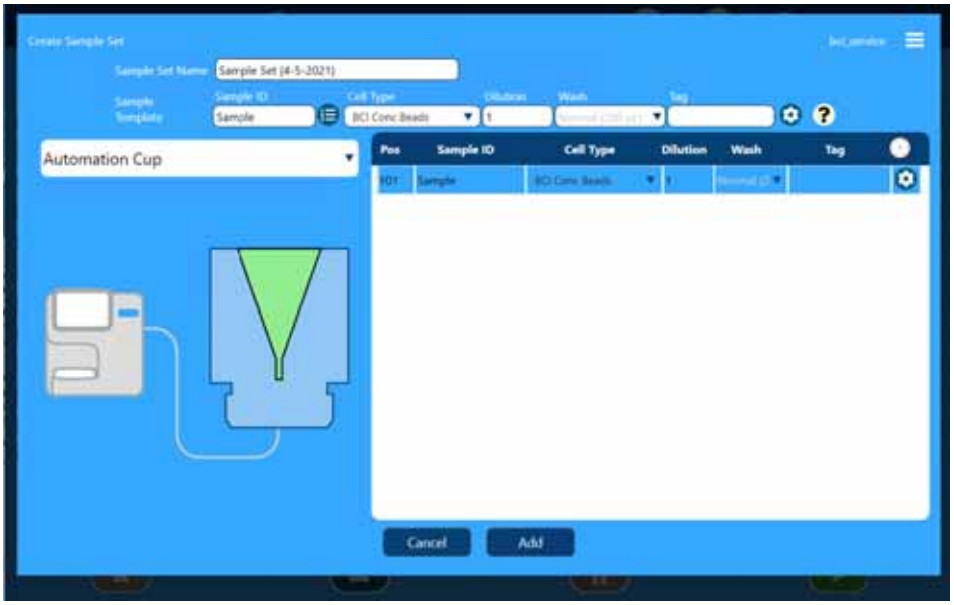
To Create a sample definition using the A-Cup as the source of a sample to be analyzed, select  from the home screen to enter the Create Sample Set screen. In the Create Sample Set screen select the sample carrier selection drop down list and select **Automation Cup** as the sample source.

Figure I.8 Automation Mode Create Sample Set

Once **Automation Cup** has been selected as the source, the Automation Cup connection displays as shown in Figure I.9, and the system will automatically populate the sample list with a single entry. Only a single entry is allowed.

Configure the sample definition information and parameters as you would for a Carousel or Plate sample definition.

Figure I.9 Automation Cup Create Sample Set



Manual Use of the A-Cup

1 Prepare the sample to be run.

2 Create the sample definition for your sample, and add that sample definition to the sample worklist.

3 Using a pipette, aspirate 200 µL ±20 µL of sample and dispense into the automation cup.

4 Select  on the Home Screen displaying the created sample set to begin processing the sample.

Figure I.10 Home Screen with A-Cup Sample

IMPORTANT The system can aspirate a fully filled automation cup. If the automation cup is accidentally overfilled, a single sample can be processed to clear the fluid. Run a subsequent sample of cleaning fluid to avoid carryover.

Maintenance

Nightly Clean Operation

The nightly clean operation runs normally when automation is enabled. If the A-Cup is installed and enabled, the nightly clean cycle will also perform a cleaning cycle for the A-Cup. Please ensure

that the A-Cup receptacle is connected and mounted in an upright orientation to prevent reagent spillage during the nightly clean operation.

Weekly Decontamination

Decontaminate the instrument with bleach on a weekly basis. It is also recommended to run a decontaminate cycle if the background in the images becomes darker over time. Running the decontaminate with bleach cycle removes staining from the flow cell.

1 Select and **Decontaminate**.

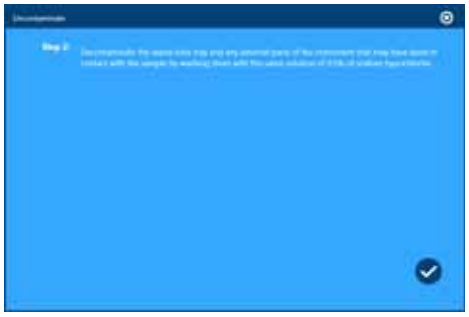
WARNING

Risk of chemical injury from bleach. To avoid contact with the bleach, use barrier protection, including protective eyewear, gloves, and suitable laboratory attire. Refer to the Safety Data Sheet for details about chemical exposure before using the chemical.

2 Prepare a bleach solution according to the instructions on the screen and select .

NOTE In cases of significant staining, undiluted household bleach can be used. Ensure you use pure bleach with no commercial additives.

3 Decontaminate the rest of the instrument per the instructions displayed and tap .



4 Run three or four sample tubes of deionized water to ensure the bleach is flushed from the system.

NOTE If run as "controls", the results will appear in the quality controls report and associated logs.

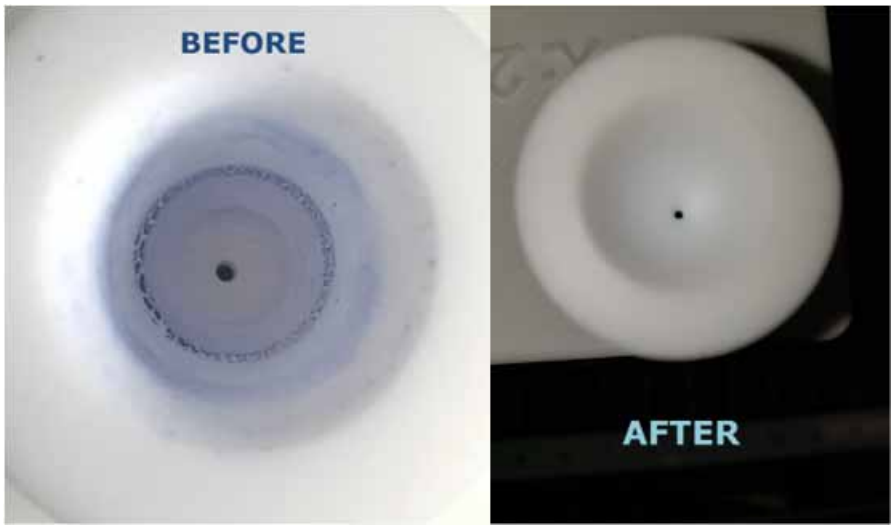
A-Cup Cleaning Procedure

Tools/Supplies Needed

- ❑ Pointed tip lint free swab
- ❑ 70% isopropyl alcohol (IPA)
- ❑ Deionized water (DI water)

1 Thoroughly wet a lint-free swab with IPA and wipe down the well of the A-Cup. Ensure that the entire well is cleaned. Use more than one swab if needed.

Figure I.11 Automation Cup Cleaning



2 Fill the A-Cup with DI water (fill to the top) and run a single sample to clear.

A-Cup Maintenance

Replacement of the external A-Cup tubing or receptacle should be performed by a Beckman Coulter service representative. The service representative will replace the tubing with the precise length required, replace the receptacle with the exact replacement, and may perform a Concentration Calibration to ensure proper operation of the system.

Abbreviations

CM — centimeters

cn — common name

D — depth

H — height

Hz — hertz

IEEE — Institute of Electrical and Electronics Engineers

lb — pound

mL — milliliter

mm — millimeter

OS — operating system

PN — part number

PPE — Personal Protective Equipment

RoHS — Restriction of Use of Hazardous Substances

TBD — to be determined

UI — user interface

µL — microliters

X — times

VAC — Voltage in Alternating Current

VHP — Vaporized Hydrogen Peroxide

W — width

WEEE — Waste Electrical and Electronic Equipment Directive

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Numerics

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Related Documents

Vi-CELL BLU Cell Viability Analyzer, Instructions for Use
PN C13232

- Introduction
- Introducing the Vi-CELL BLU
- Installation and Verification
- Quick Start Guide
- Software Menus
- Special Software Features
- Exporting Results
- Regulatory Compliance - 21 CFR Part 11
- Appendices

Vi-CELL BLU Quick Start Guide
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