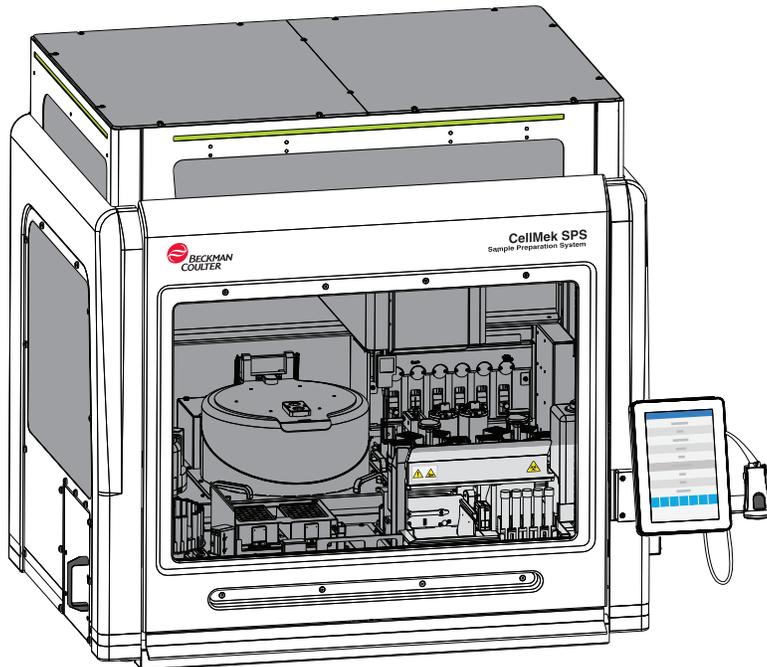


Instructions for Use

CellMek SPS Sample Preparation Instrument Rx Only in the U.S.A.



PN C48507AC
February 2023



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



CellMek SPS Sample Preparation Instrument

PN C48507AC (February 2023)

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EC REP

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare, Ireland
Phone: +353-65-683-1100
FAX: +353-65-683-1122

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

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

Original Instructions

Revision History

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Updates were made to the following sections:

Introduction

- About This Manual
- Conventions
- Safety Symbols

CHAPTER 1, System Overview

- System Components
- Specimen Types
- System Specifications

CHAPTER 2, Operation Principles

- CellMek SPS Modules
- Output Tube Assignment

CHAPTER 4, Sample Processing

- Overview
- Specimen Collection
- Importing Panels
- Loading Output Samples Tubes

CHAPTER 5, Shutdown

- Shutdown
- Shutting Down the Instrument
- Extended Shutdown

CHAPTER 6, Software Setup

- Status
- Setup

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

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.

CHAPTER 7, Troubleshooting

- Safety Precautions
- Power Down the System
- System Error Messages
- Audit Trail Messages

CHAPTER 8, Cleaning Procedures

- Cleaning Biological Spills

CHAPTER 9, Replacement Procedures

- Replacing the IsoFlow Sheath Solution Cubitainer
- Replacing the Waste Container

APPENDIX A, CellMek Panel Designer

- Installing the CellMek Panel Designer Software
- Archive Advanced Search

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- Work Area Minimum Dimensions
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- Specimen Tube 1-Dimensional Barcode Specifications
- Linear Barcode Symbolologies
- Barcode Labels
- Output Tube Barcode Specifications
- Specimen Tube 2-Dimensional Barcode Specifications

APPENDIX F, Consumables and Accessories

- Consumables and Accessories

APPENDIX G, Security Features

- Exiting Kiosk Mode
- Returning to Kiosk Mode
- Password Security

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.

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 and employees 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 instrument.

Alerts for Warning, Caution, Important, and Note

WARNING

WARNING indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury. May be used to indicate the possibility of erroneous data that could result in an incorrect diagnosis.

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. May be used to indicate the possibility of erroneous data that could result in an incorrect diagnosis.

IMPORTANT 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.

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

 **WARNING**

Risk of operator injury if:

- All doors, covers, and panels are not closed and secured in place prior to and during instrument operation.
- The integrity of safety interlocks and sensors is compromised.
- Instrument alarms and error messages are not acknowledged and acted upon.
- You contact moving parts.
- 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. Do not defeat safety interlocks and sensors.
- 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, external hard drives, and CD/DVDs. 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 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, contact your Beckman Coulter Representative.

 **CAUTION**

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.

 **CAUTION**

The instrument is vulnerable to malware, viruses, data corruption, and unauthorized instrument setting changes, or privacy breaches if unauthorized access is gained by malicious personnel. To reduce the risk of such events, only allow authorized laboratory personnel access to the instrument. Contact your institutional security department for assistance.

 **CAUTION**

The instrument is vulnerable to malware and viruses from physical media such as USB drives. To reduce the risk of data corruption or unauthorized setting changes, only use physical media such as USB drives that are known to be free from viruses or malware. Contact your IT professional for assistance.

 **CAUTION**

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

Safety Notice

Alerts for Warning, Caution, Important, and Note

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Overview

This introductory section contains the following information:

- [How To Use Your CellMek SPS Sample Preparation Instrument Manual](#)
- [About This Manual](#)
- [Conventions](#)
- [Safety Symbols](#)
- [Graphics](#)

How To Use Your CellMek SPS Sample Preparation Instrument Manual

Use the Instructions for Use for:

- In-depth information about:
 - What the instrument does
 - Instrument specifications
 - Information about installation
- The day-to-day running of your instrument.
- The cleaning and replacement/adjustment procedures and troubleshooting information.

About This Manual

The information in your Instructions for Use (IFU) manual is organized as follows:

[CHAPTER 1, System Overview](#)

Provides the intended use of the CellMek SPS system, its controls and indicators, and information on using the system's software.

[CHAPTER 2, Operation Principles](#)

Contains a description of the CellMek SPS system's capabilities, functionality, and operating principles.

[CHAPTER 3, Daily Startup](#)

Provides information on starting to power up the CellMek SPS followed by the checks that are required each day.

CHAPTER 4, Sample Processing

Provides information on specimen collection, specimen storage, and how to prepare samples using the autoloader.

CHAPTER 5, Shutdown

Provides information on correctly shutting down the CellMek SPS and the proper way to perform an extended shutdown when needed.

CHAPTER 6, Software Setup

Provides information on customizing the software.

CHAPTER 7, Troubleshooting

Describes safety precautions, operational hazards, general troubleshooting techniques, system messages, and troubleshooting guidelines.

CHAPTER 8, Cleaning Procedures

Describes the cleaning procedures for the instrument.

CHAPTER 9, Replacement Procedures

Describes when, why, and how to perform replacement procedures.

Additionally, this manual includes several appendices that cover a range of topics including the CellMek SPS software screens, pre-installation, tube list, barcode label specifications, Panel Designer Software, and a list of orderable reagents and accessories.

This manual also includes a list of References, a list of Abbreviations (including acronyms), Glossary, and the Beckman Coulter, Inc. Customer End User License Agreement.

Conventions

This manual applies the following conventions:

- **Bold** font indicates a screen icon or menu item on the Workstation screen.
- *Italics* font indicates screen text displayed by the Workstation.
- **Blue** text indicates that you can click on the text to access related information.
- The term 'select' is used to indicate either one or both of the following actions:
 - to tap or touch your finger on the touch screen
 - to click with a mouse
- Instrument or system may be used when referring to the entire CellMek SPS (Sample Prep System, Supply Cart, and Touchscreen).
- Tabs in the software are blue when not selected and inactive. Tabs in the software turn green when selected and active.
- Sections that contain entirely new content are flagged with a New Section icon  at the end of the section title or chapter.

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 and Action
	Consider all materials (specimens, controls, monoclonal antibodies, and so forth) as being potentially infectious. Wear standard laboratory attire and follow safe laboratory procedures when handling any material in the laboratory.
	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.
	To warn of sharp element. Keep fingers or hands away from sharp objects.
	The moving parts symbol indicates that there are moving parts in the area. Only operate the system when all covers are in position and use caution to reduce the risk of personal injury. While the system is operating, do not touch the moving parts of the system. Do not insert fingers or hands into any system opening.
	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.
	The symbol indicates the presence of magnetic fields. Keep metal objects, pacemakers, and implants away from this area.
	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	To signify a general warning.

Symbol	Warning Condition and Action
	<p>Disposal of Electrical Instrumentation</p> <p>It is very important that customers understand and follow all laws regarding the safe and proper disposal of electrical instrumentation.</p> <p>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:</p> <ol style="list-style-type: none"> 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. <p>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 the device.</p>
	<p>RoHS Notice</p> <p>These labels and materials declaration table (the Table of Hazardous Substance's Name and Concentration) are to meet People's Republic of China Electronic Industry Standard SJ/T11364-2006 "Marking for Control of Pollution Caused by Electronic Information Products" requirements.</p> <p>RoHS Caution Label</p> <p>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.</p>
	<p>cNRTLus Certification Mark Canadian Standards Association Symbol</p> <p>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.</p>
	<p>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.</p>
	<p>Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.</p>

Graphics

All graphics, including screens and printouts, are for illustration purposes only and must not be used for any other purpose.

Overview

This chapter contains information about:

- [General](#)
- [Intended Use](#)
- [Intended User](#)
- [System Components](#)
- [System Connections](#)
- [Software](#)
- [Consumables and Supplies](#)
- [System Specifications](#)
- [Uninterruptible Power Manager](#)
- [Limitations](#)

General

The CellMek SPS system is an automated sample preparation workstation that can be programmed to perform a wide variety of liquid handling operations. It is designed to operate in a general use capacity within a clinical setting. The CellMek SPS system offers basic sample preparation capabilities that are summarized as follows:

- Interface for the user to create and implement user-defined preparation panels.
- Specimen batching not required.
- Barcode tracking of specimen, reagents, consumables, and subsequent prepared samples.
- Pipetting of specimen, reagents, and consumables.
- Separation of cells from plasma (specimen wash) or from red-cell lysis solution (sample wash) via the Cell Wash Module (CWM).
- Ability to output samples in a format that can be used with Beckman Coulter flow cytometers.
- Export worklists so they may be used with Beckman Coulter flow cytometers.
- Refrigeration module for liquid antibodies.
- DURACartridge for custom dry reagents.

Intended Use

The CellMek SPS is a sample preparation system designed to automate staining, lysing, and cell washing for a variety of specimen types and applications in the clinical laboratory, including flow cytometry. The system is intended for in vitro diagnostic use.

User environment is expected to be a routine clinical laboratory, a specialized flow cytometry laboratory, or a research flow cytometry laboratory. The user shall be an experienced clinical laboratory professional but may not be proficient in flow cytometry sample preparation.

Intended User

This product is intended for laboratory professional use.

System Components

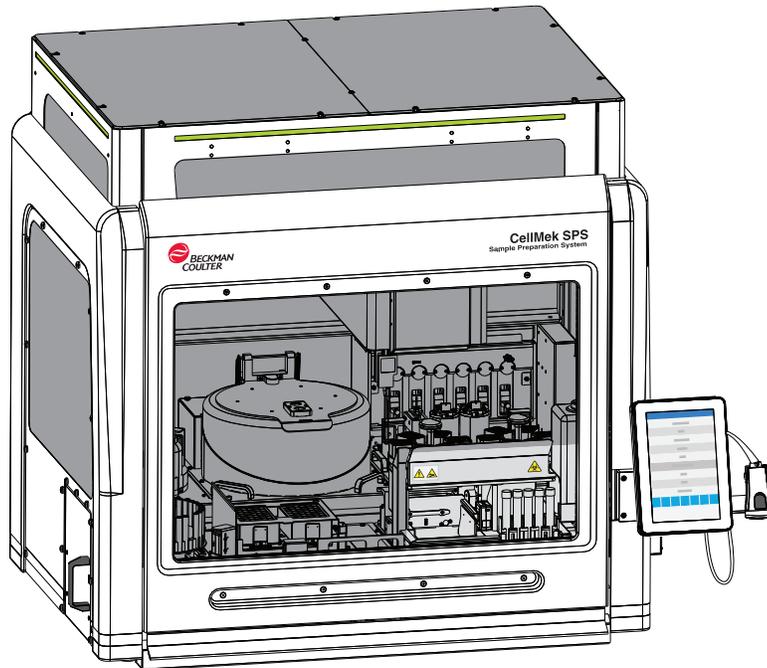
The system components are divided into three groups:

- Sample Preparation System
- Touchscreen
- Supply Cart

CellMek SPS Instrument

The CellMek SPS Instrument is shown in [Figure 1.1](#).

Figure 1.1 CellMek SPS Instrument

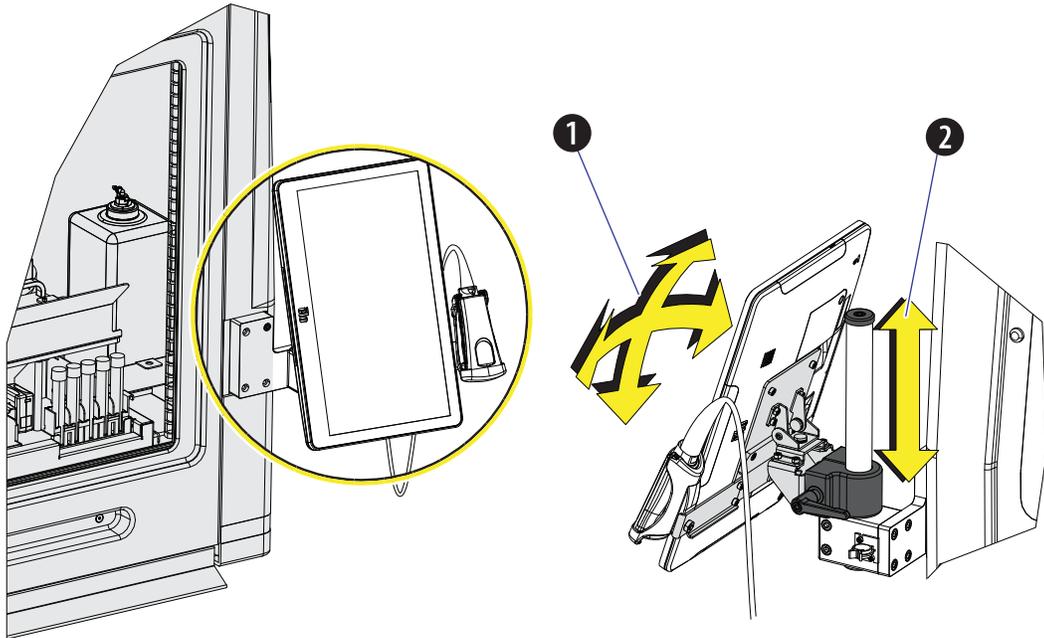


Touchscreen

The user interacts with the CellMek SPS instrument through the touchscreen user interface. This interface uses capacitive touch technology to provide sensitivity when lab gloves are worn.

The touchscreen allows adjustment of the viewing angle and height for the best ergonomic positioning, see [Figure 1.2](#).

Figure 1.2 Touchscreen

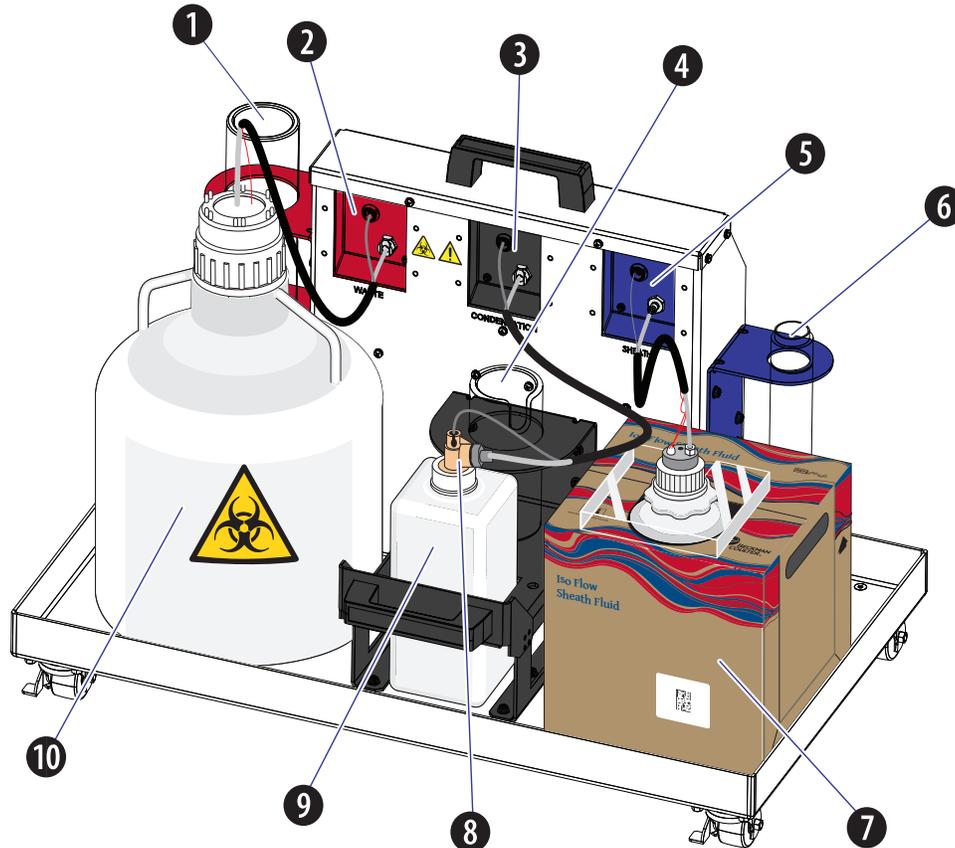


1. Angle adjustment of tablet
2. Adjustment of up and down position of tablet

Supply Cart

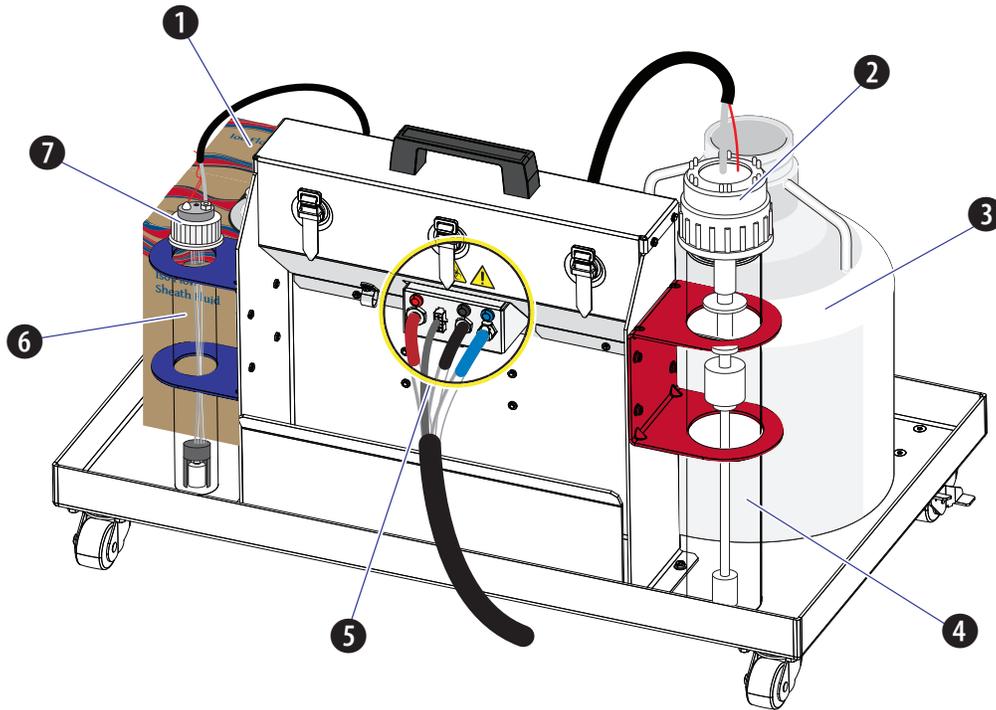
The supply cart contains system waste, sheath, and condensate from the refrigeration module. The cart is placed on the floor near the CellMek SPS instrument.

Figure 1.3 Supply Cart Main Components (front view)



1. Waste Tubing Holder
2. Waste Container Connectors
3. Condensate Bottle Connectors
4. Condensate Tubing Holder
5. Sheath Container Connectors
6. Sheath Tubing Holder
7. IsoFlow Sheath Solution Cubitainer (10 L): Located in the supply cart, this container supplies the sheath fluid needed to operate the prep system.
8. Condensate Bottle Cap/Sensor
9. Condensate Bottle
10. Waste container (15 L): Located in the supply cart, the waste container accumulates the waste generated by the prep system.

Figure 1.4 Supply Cart Main Components (back view)



- | | |
|--------------------------------|--|
| 1. Sheath Fluid | 5. Fluidics/Signal Cable Connections |
| 2. Waste Cap/Sensor | 6. Sheath Pickup Tube Holding Cylinder |
| 3. Waste Container | 7. Sheath Fluid Pickup Tube/Sensor |
| 4. Waste Tube Holding Cylinder | |

Front Door

The front door protects the user from contact with the moving Pod-Arm and probes. It has a gray tinted window that allows visibility to the inside of the instrument while minimizing sample exposure to light.

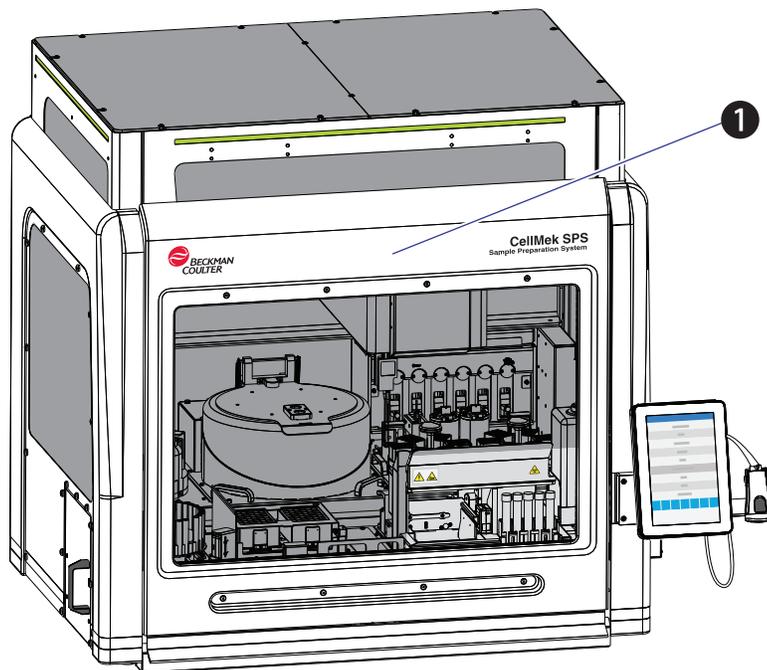
The front door remains locked during sample processing. If the user requests a PAUSE at the user interface, sample processing will be completed for the cassette that is in the Sample Transport Module's rocker before the front door is unlocked. To stop processing immediately, see [CHAPTER 4, Aborting Instrument Actions](#).

Opening the front door turns on the internal light and closing it turns it off.

NOTE There is 10-minute timer that automatically turns off the internal light, this time reduces the light exposure to protect the DURACartridge dry reagents.

Closing the front door initiates an automatic deck scan and inventory check. The Prep Reagents Module, Output Module, Reaction Plate Module, and Dry Reagents Modules are scanned for reagent, reaction plate and output tube changes. The Liquid Antibody Module is also scanned if the lid was opened when the front door is open. The user will be prompted to enter what fluid is in the Cell Wash Fluid container.

Figure 1.5 Front Door

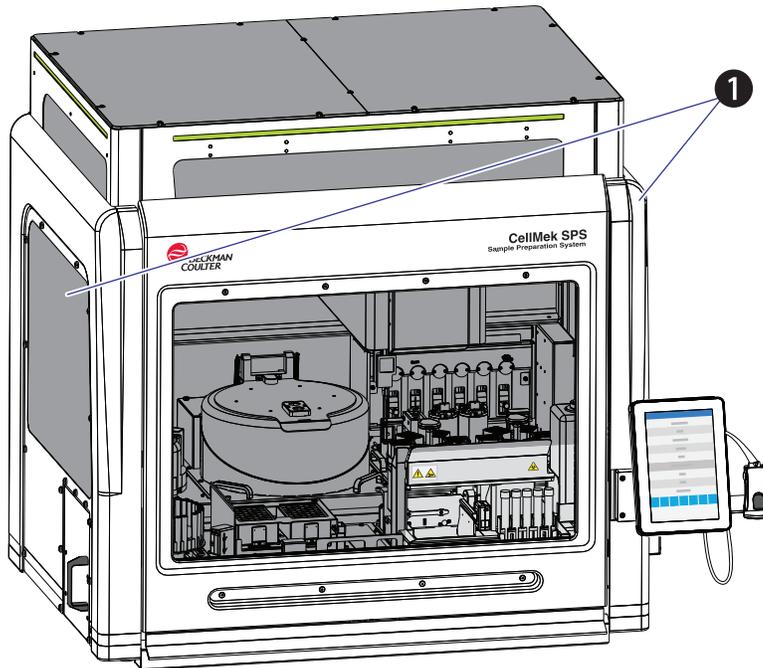


1. Front door

Side Covers

The left and right covers and the rear panel protect users from injury from moving parts. The left and right-side covers have gray tinted windows that allow visibility to the inside of the instrument while minimizing sample and DURACartridge dry reagents exposure to light.

Figure 1.6 Side Covers



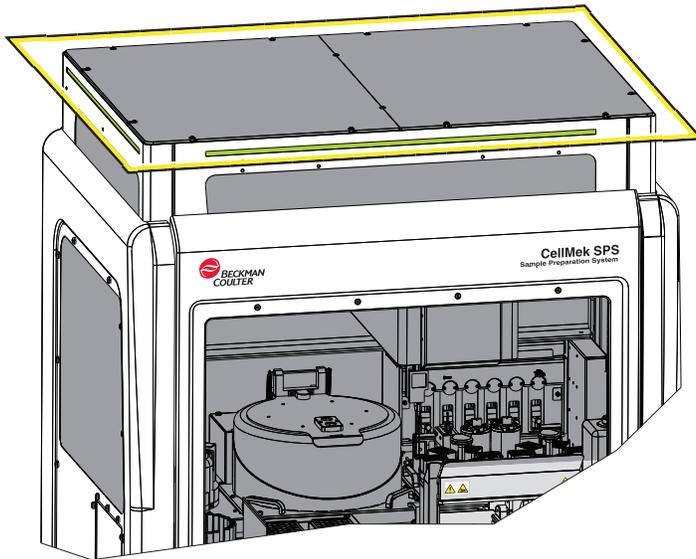
1. Side covers

Halo

The Halo is on the top cover of the CellMek SPS, see [Figure 1.7](#). The halo has 360 degrees of LED lights that signal the instrument status:

- Ready - Blue
- Startup, Shutdown, System Checks, System Prime, Processing - Solid Green
- Not Ready and Processing with Alerts - Bright Amber/ Dim Amber
- Error - Flashing Red
- White - Disconnection from computer

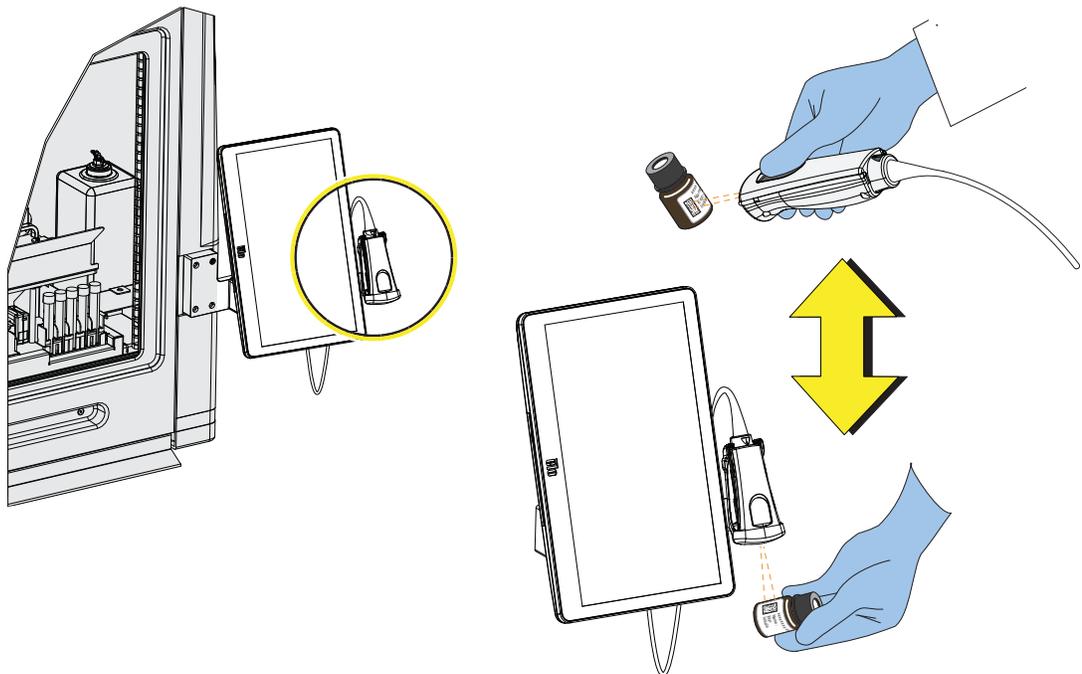
Figure 1.7 Halo Light



Handheld Barcode Scanner

The handheld barcode scanner is shown in [Figure 1.8](#). For more detailed information, see [APPENDIX E, Barcode Labels](#). To initiate the barcode scanning, push the button prior to scanning.

Figure 1.8 Touchscreen with Scanner



Specimen Types

Specimen types may include whole blood, bone marrow, or other single cell suspensions.

Software

For information on the CellMek SPS software, see [APPENDIX B, Software Screen](#).

For information on the CellMek Panel Designer Software, see [APPENDIX A, CellMek Panel Designer](#).

System Connections

For information on System Connections, see [System Connections](#) in [APPENDIX C, Instrument Installation](#).

Consumables and Supplies

 **WARNING**

Risk of erroneous results if reagent container volumes do not match the volume in the system software. The CellMek SPS keeps track of the volume in each bottle and vial as it is used by the system. The CellMek SPS also keeps track of DURACartridge (dry reagent) wells using reagents in CellMek SPS that have been used to prepare samples outside the system will cause the volume tracking to be wrong. Never use reagents in the CellMek SPS system that have been used to prepare samples manually or in another CellMek SPS system.

 **WARNING**

Risk of erroneous results if available DURACartridge wells do not match the wells in the system software. The CellMek SPS keeps track of the wells in each DURACartridge as it is used by the system. Using a DURACartridge in CellMek SPS that has been used to prepare samples outside the system will cause the wells tracking to be wrong. DURACartridge reagents have not been validated for manual sample preparation. Only use DURACartridge per the instructions provided in this manual.

Reagents

 CAUTION

Risk of reporting erroneous results. To avoid problems with reagents or the system, always run an application-specific quality control check before testing with clinical samples.

 CAUTION

Risk of reagent spoilage if the prep reagents are stored with the cap removed. To avoid reagent spoilage, ensure that the prep reagents are re-capped prior to storage.

 CAUTION

Risk of erroneous results. To avoid Dry Reagent deterioration, always store Dry Reagents cartridges, including the packaged product away, from light.

 CAUTION

Risk of reagent spoilage; the onboard refrigerator turns off when condensate container becomes full. It is recommended that you empty the condensate container daily.

CellMek SPS is optimized to operate with supported liquid or dry antibody reagents, lyse and prep solutions, user defined cell wash buffer. The stated analytical characteristics and specifications cited in this manual can only be guaranteed by using IsoFlow Sheath Fluid as the system fluid. IsoFlow Sheath Fluid may also be referred to as diluent.

Additionally, select Beckman Coulter reagents are available with barcoded labels that are used with CellMek SPS to provide tracking of reagent volume, lot number and vial IDs through the Audit Trail function. All reagents cannot be shared between systems. Third-party reagents may be used in Beckman Coulter provided vials and/or bottles in combination with custom defined barcode labeling.

[Contact us](#) if a product is damaged upon receipt. For more information about CellMek SPS supported reagents, visit the Beckman Coulter Web site at www.beckman.com or [contact us](#).

IsoFlow Sheath Solution



Risk of losing in-process samples if IsoFlow Sheath Solution is replaced during sample processing. Only replace the IsoFlow Sheath Solution when the system is in the Ready or Not Ready state.

IsoFlow Sheath Solution is a non-fluorescent, azide-free balanced electrolyte solution for use on the CellMek SPS instrument. It serves as the system fluid for the CellMek SPS.

The IsoFlow Sheath Solution has the following characteristics:

- 0.2 µm filtered
- Transparent and nonfluorescent to 488 nm laser light
- Low background
- Balanced electrolyte solution

NOTE When the IsoFlow Sheath Solution cubitainer is replaced, scan the barcode to ensure that the correct reagent is being loaded and tracked. For more information, see [Replacing the IsoFlow Sheath Solution Cubitainer](#) in [CHAPTER 9, Replacement Procedures](#).

The 10 L IsoFlow Sheath Solution cubitainer is stored on the Supply Cart. The contents of the IsoFlow Sheath Solution cubitainer are supplied to the CellMek SPS through the tubing attached to a connector labeled **SHEATH**.

Material Safety Data Sheets (SDS/MSDS)

To obtain an SDS or MSDS for Beckman Coulter reagents:

- On the Internet, go to www.beckman.com:
 1. Select **Safety Data Sheets (SDS/MSDS)** from the Support menu.
 2. Follow the instructions on the screen.
 3. [Contact us](#) if you have difficulty locating the information.
- If you do not have Internet access, [contact us](#).

Cassettes

The CellMek SPS uses a five-position cassette to load specimen tubes. Specimen cassettes can hold up to five specimen tubes of the same size. The Specimen Transport Module (Autoloader) accommodates up to six different cassettes (30 specimens) at one time. Each cassette is uniquely identified for specimen tracking purposes. Additionally, the barcoded cassette type identifier is used by the CellMek SPS to determine the piercing height for the various supported tube types.

WARNING

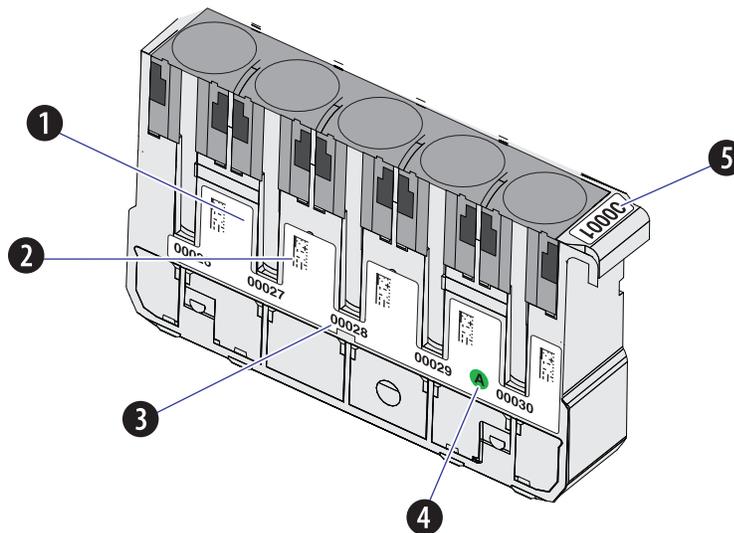
Risk of biohazardous contamination or instrument damage. The use of non-supported tube types or loading tubes in the incorrect cassette type can result in sample loss or instrument damage. See [APPENDIX D, Tube List](#) for the list of supported tubes and the required tube-cassette combination.

Cassette Types

To find the required cassette type for your specimen tube, see [APPENDIX D, Specimen Collection Tube Specifications](#).

Cassette Labels

Each cassette has an identifying label that contains four elements as shown below.



1. Barcode label
2. 2D barcode symbol that can be read by the CellMek SPS barcode reader
3. Visually readable number
4. Cassette type identifier
5. Cassette number

Plates

Sample preparation requires a reaction plate with a 48 pyramidal-shaped reaction plates capable of holding up to 2300 μL during system operation. Each plate has a unique barcode label identifier, which enables the system to keep track of the plate usage and sample location. Only barcoded 48-reaction plates obtained from Beckman Coulter can be used.

Waste Container

Sample Preparation System waste is collected in a waste container on the Supply Cart. Waste travels from the Sample Preparation System to the waste container via tubing attached to a container labeled **WASTE**.

 **CAUTION**

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.

 **WARNING**

Risk of chemical exposure when handling reagents, waste container, or bleach. Use barrier protection, including protective eyewear, gloves, and suitable laboratory attire. Refer to the Safety Data Sheet for chemical exposure.

 **CAUTION**

Risk of losing in-process samples if waste container becomes full during sample processing. Ensure that the waste container is emptied daily.

 **CAUTION**

Risk of losing in-process samples if waste container is disconnected while processing samples. Only replace the waste container when the system is in the Ready or Not Ready state.

Before placing the waste container on the Supply Cart, add 1.0 L of high-quality, fragrance-free, gel-free bleach (5 to 6% solution of sodium hypochlorite - available chlorine) to the empty 15 L waste container. Check with local regulations and acceptable laboratory procedures. The system monitors the waste container and warns you before and when the waste is full. For more information, see [Replacing the Waste Container](#) in [CHAPTER 9, Replacement Procedures](#).

System Specifications

Table 1.1 presents system specifications and requirements for the instrument. Table 1.2 presents the Space and Table Requirements for the Instrument.

 **CAUTION**

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

 **CAUTION**

The sensors in the Specimen Transport Module are sensitive to bright lights that can cause errors. Do not place the instrument in front of a bright light source or directly facing a window that receives direct sunlight.

Table 1.1 System Specifications

Specification	Description
Power Requirements	<ul style="list-style-type: none"> US: 120VAC, 60Hz, 10 Amp, UL recognized, CSA certified, UL File E96454 Europe: 250VAC, 50Hz, 10 Amp, VDE Certificate Number: 40011305 <p>An Uninterruptible Power Manager (UPM) is used with the CellMek SPS and requires a dedicated line. All system components must be plugged into the Uninterruptible Power Manager.</p> <p>For specific details, see the Electrical Requirements in APPENDIX C, Instrument Installation.</p>
Installation Category	Category II (per IEC 61010-1 standard)
Environment	Indoor Use Only
Electrical Environment	100 - 240 VAC, 50/60 Hz, 10 A
Pollution Degree	Pollution degree 2
Acoustic Noise Produced by the System	≤65 dBa
Ambient Operating Temperature	15.5°C to 26.7°C (59.9°F-80.1°F)
Operating Humidity	30-70%
Altitude Restrictions	Up to 3000 m (9880 ft.)

Table 1.1 System Specifications (*Continued*)

Specification	Description
Heat Dissipation	Total heat dissipation into the room is approximately 850 W (2900 btu/hour). Provide sufficient air conditioning (see Ambient Operating Temperature shown above).
Drainage	<div style="border: 1px solid black; background-color: #ffcc00; padding: 2px; display: inline-block;"> WARNING</div> <p>Risk of biohazardous contamination if you have skin contact with the waste container, its contents, or its associated tubing. The waste container and its associated tubing might contain residual biological material and must be handled with care. Clean up spills immediately. Dispose of the contents of the waste container in accordance with your local regulations and acceptable laboratory procedures.</p> <p>The waste line from the Sample Preparation System is connected to a 15 L waste container. Dispose of the waste in accordance with your local regulations and acceptable laboratory procedures. For more information, see Replacing the Waste Container in CHAPTER 9, Replacement Procedures.</p>

Table 1.2 Space and Table Requirements for Instrument

Component	Minimum Dimensions Required
Height Clearance ^a	196 cm (77 in.): (84 cm (33 in.) table height + 112 cm (44 in.) instrument)
Rear access clearance	10 cm (4 in.)
Side access clearance	38.1 cm (15 in.)
Weight	187 kg (412 lbs)
Minimum recommended bench necessary to adequately hold the instrument	<p>112 cm x 76.2 cm (44 in. x 30 in.)</p> <div style="border: 1px solid black; background-color: #ffcc00; padding: 2px; display: inline-block;"> WARNING</div> <p>Risk of personal injury or equipment damage. The instrument will overhang the edges of a 112 cm (44 in) x 76.2 cm (30 in) bench. Make sure there are no obstacles that will interfere with placement of the instrument and that the leveling feet are securely positioned on the bench.</p> <div style="border: 1px solid black; background-color: #ffcc00; padding: 2px; display: inline-block;"> WARNING</div> <p>Risk of personal injury or equipment damage. Make sure the bench meets the minimum bench size and can support the total installed weight of the system. Refer to Table 1.2 to determine the total weight of the system.</p>
Aisle and door clearance for delivery	86 cm (34") minimum

a. Consult local fire codes for ceiling clearance requirements.

Uninterruptible Power Manager

The Uninterruptible Power Manager (UPM) incorporates a low impedance isolation transformer which delivers clean, fully conditioned power which is free from noise, voltage spikes and common-mode disturbances. It includes a battery backup in case of brownouts that temporarily disrupt power.

Table 1.3 Uninterruptible Power Manager Specifications

Locale and Model No.	Load Current (Amps)	Load Power (VA)	Input Voltage (VAC)	Output Voltage (VAC)	Frequency (Hz)	Ship Weight (lb)
North America						
ABCE800-11	7.9	800	96-151	120	50/60	47
International						
ABCE800-22	3.9	800	181-290	230	50/60	21.5

The UPM case for both the North America and International model is 8.0 in. x 5.8 in. x 17.5 in. (20.3 cm x 14.7 cm x 44.5 cm).

Performance Characteristics

Carryover

<0.1 % WBCs when tested under the following conditions:

Load three normal whole blood specimens followed by one diluent blank in a cassette on the CellMek SPS, each one assigned with following 4-tube panel: specimen wash (4-wash cycles), 10 μ L CD45-FITC, 15-minute (min) to 45-minute (max) incubation, 2 mL IOTest Lyse with 0.25% Fixative, 10-min (min) to 15-minute (max) incubation, lyse wash (1-wash cycle) with resuspension to 750 μ L. Ensure Cytometer is clean and obtain a background count. Set the acquisition stop count to 300 seconds. Run all 16 tubes, ensuring that the WBCs are gated. Average the total number of WBC events from the 4 tubes of the third whole blood specimen. Average the total number of WBC events from the 4 tubes of the diluent blank. Calculate carryover as follows:

$$\left[\frac{\text{(Average Diluent Blank WBC Count - Cytometer Background)}}{\text{(Average Third Specimen WBC Count - Cytometer Background)}} \right] * 100$$

Sample Preparation Throughput

The CellMek SPS processes 32 output tubes in less than 4 hours and 15 minutes when running a 4-tube panel tested under the following conditions:

Two cassettes with a total of 8 specimen tubes (4 tubes each) with each specimen assigned to a 4-tube panel. Panel consisted of a specimen wash (4-wash cycles), a liquid antibody cocktail of

100 μL , 15-minute (min) to 45-minute (max) incubation, 2 mL lyse, 10-minute (min) to 15-minute (max) incubation, lyse wash (1-wash cycle).

Pipetting Accuracy and Repeatability

For information on pipetting accuracy and repeatability, see [Table 1.4](#).

Table 1.4 Pipetting Accuracy and Repeatability

Specimen/Antibody/Reagent	Range	Accuracy	Repeatability	Comments
Specimen (measured with analytical balance using whole blood)	$25 \mu\text{L} \leq x < 100 \mu\text{L}$	$\pm 7\%$	$\leq 7\% \text{ CV}$	
	$100 \mu\text{L} \leq x \leq 400 \mu\text{L}$	$\pm 5\%$	$\leq 5\% \text{ CV}$	
Liquid Antibody (measured with Artel MSV Multichannel Verification System)	$3 \mu\text{L} \leq x < 10 \mu\text{L}$	$\pm 20\%$	$\leq 10\% \text{ CV}$	Additionally 5 μL of system fluid is dispensed.
	$10 \mu\text{L} \leq x < 50 \mu\text{L}$	+0%/-20%	$\leq 5\% \text{ CV}$	
	$50 \mu\text{L} \leq x < 100 \mu\text{L}$	+0%/-15%	$\leq 5\% \text{ CV}$	
Prep Reagent (measured with analytical balance using DI water)	$100 \mu\text{L} \leq x < 450 \mu\text{L}$	$\pm 5\%$	$\leq 5\% \text{ CV}$	
	$450 \mu\text{L} \leq x < 2000 \mu\text{L}$	$\pm 5\%$	$\leq 3\% \text{ CV}$	

Limitations

- RBC carryover from one sample to the another may occur in the CellMek SPS. If you are preparing samples that are susceptible to RBC interference, do not run them at the same time as samples containing RBCs. Instead, wait until the system has completed processing (is in the **Ready** state) and perform a **Prime and Clean Cell Wash** from the maintenance menu before running these samples. See [CHAPTER 6, Prime and Clean Cell Wash](#). Performing **Prime and Clean Cell Wash** is not needed if samples are run immediately after daily startup.
- Particles due to wash buffer protein aggregation may appear in samples washed by the CellMek SPS. It is recommended that you run blank samples to test the CellMek SPS with your wash buffer formulation.
- The CellMek SPS uses the barcoded information in the Beckman Coulter reagent labels to monitor reagent volumes. The CellMek SPS keeps track of the volume in each bottle and vial as it is used by the system. The CellMek SPS also keeps track of DURACartridge (dry reagent) wells using reagents in CellMek SPS that have been used to prepare samples outside the system will cause the volume tracking to be wrong. Never use reagents in the CellMek SPS system that have been used to prepare samples manually or in another CellMek SPS system.
- The CellMek SPS is best suited for workflows where samples are stained first and lysed later if multiple washing steps are utilized. Panels that specify lyse first and then stain, are limited due to the residual volume of the Cell Wash Module, which is between 330 and 400 μL .
- The CellMek SPS does not contain a means for maintaining bead reagents in suspension or adding beads to samples.

- CellMek SPS does not contain any validated IVD panels. Beckman Coulter recommends that all panels developed by system users should be validated before being published for use.
- For CellMek SPS dead volume of specimen, see [APPENDIX D, Tube List](#).
- For Beckman Coulter liquid antibody reagents, stain reagents, prep reagents, and IsoFlow Sheath Fluid, the system does not use all the usable volume claimed in the reagent product labeling due to system aspiration dead volumes.
- Reports/Data must be reviewed by a laboratory professional before results are reported to ensure sample preparation was performed correctly.
- Only 1 cell wash buffer fluid is supported at a time, see [APPENDIX A, CellMek Panel Designer](#).

Overview

This chapter contains information about:

- [Principles of Operation](#)

Principles of Operation

Overview

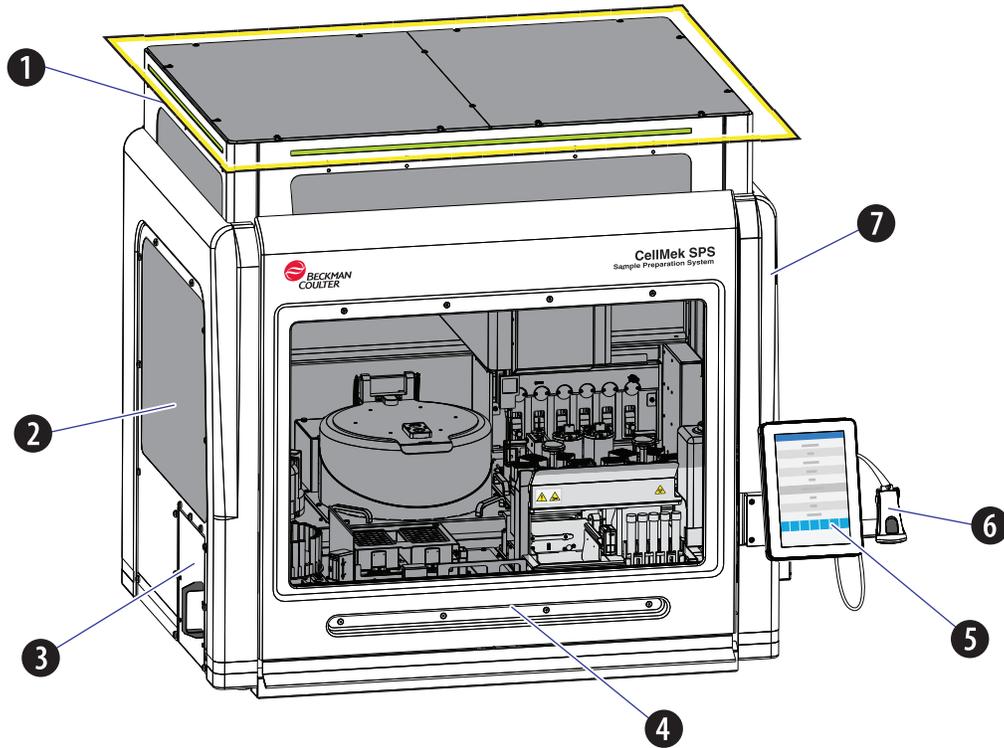
The CellMek SPS automatically prepares samples for a variety of specimen types and applications in the clinical laboratory including flow cytometry. Barcodes are used to provide full chain-of-custody for all samples including the reagents used in the sample preparation. The instrument layout is shown in [Figure 2.1](#) and [Figure 2.2](#).

The CellMek SPS allows users to obtain reports with specimen and sample run data information. Reports are obtained by archiving instrument data and retrieving it using the Panel Designer Software. See [APPENDIX A, CellMek Panel Designer](#).

 **CAUTION**

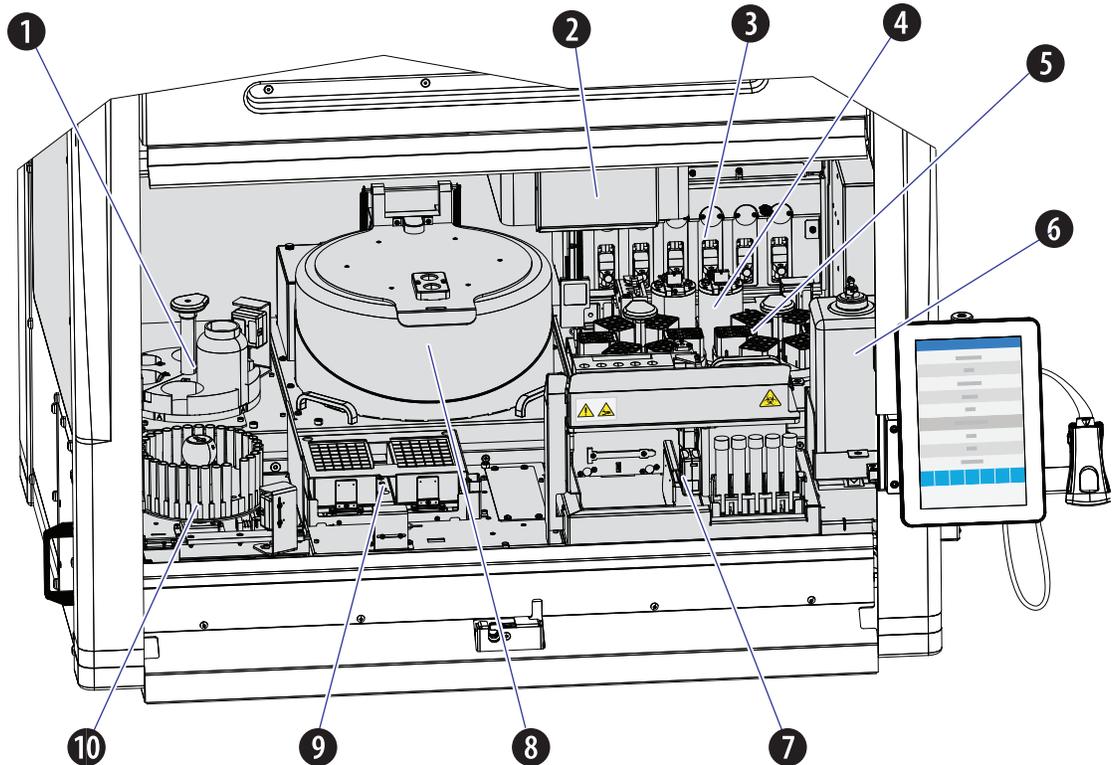
Risk of reporting erroneous results if there are sample prep errors. Flow cytometer data displays for light scatter patterns and antibody staining profiles should be reviewed by a laboratory professional when interpreting the data. If results are suspect, follow your laboratory's procedures to resolve.

Figure 2.1 CellMek SPS Outside Overview



- | | |
|--------------------|---------------------|
| 1. Halo | 5. Touchscreen |
| 2. Left Side Cover | 6. Scanner |
| 3. Output Drawer | 7. Right Side Cover |
| 4. Front Door | |

Figure 2.2 CellMek Inside Overview



- | | |
|------------------------------|------------------------------------|
| 1. Prep Reagent Module (PRM) | 7. Specimen Transport Module (STM) |
| 2. POD Arm | 8. Liquid Antibody Module (LAM) |
| 3. Syringe Pump Bank | 9. Reaction Plate Module (RPM) |
| 4. Cell Wash Module (CWM) | 10. Output Drawer Module (ODM) |
| 5. Dry Reagent Carousels | |
| 6. Cell Wash Buffer Bottle | |

CellMek SPS Modules

Handheld Scanner

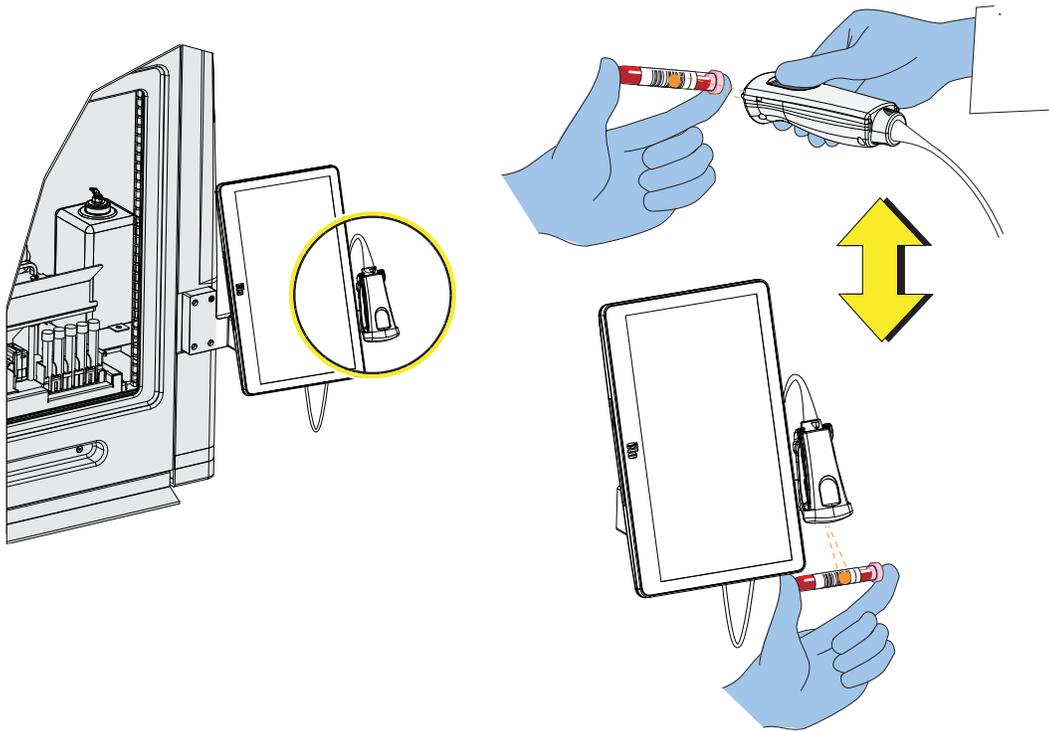
IMPORTANT Specimen tubes must be scanned even if the CellMek SPS is configured with LIS connectivity.

Two or more specimen tubes with the same Specimen ID cannot be loaded at the same time in the CellMek SPS.

The CellMek SPS workflow starts when you scan barcoded specimen tubes with the external handheld scanner, see [Figure 2.3](#). To scan the barcode, you can either scan the barcode by pushing the button with the barcode scanner in the cradle or by holding the barcode scanner and pushing the button and then scanning the bottle. The touchscreen or a Laboratory Information System (LIS) is used to assign up to three panels to each specimen tube.

NOTE The handheld scanner may also be referred to as the external scanner.

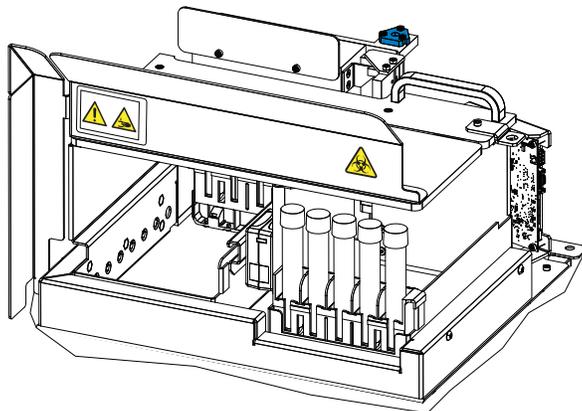
Figure 2.3 Scanning barcodes



NOTE The specimen tubes require barcodes to be run on the system.

Specimen Transport Module (STM)

Figure 2.4 Specimen Transport Module



**WARNING**

Risk of hand injury from the piercing probe and moving parts in the Specimen Transport Module. Never reach into the back of the Specimen Transport Module when the system is processing.

The specimen tubes are loaded into the Specimen Transport Module (Autoloader) using barcoded cassettes, see [Figure 2.4](#). Specimen tubes are re-scanned inside the Specimen Transport Module before moving to the piercing location. This module mixes the specimen tubes by gentle inversions prior to each pierce. Only closed vial sampling is supported.

The Pod-Arm Module uses Probe 3 (closest to the front) to pierce the rubber stopper of the specimen tube, aspirate the specimen, and transfer it to either the Cell Wash Module or the Reaction Plate Module.

Specimen Overhead Volume:

- At least 100 μL of specimen per aspiration is used as overhead when performing transfers from the Specimen Transport Module to the Reaction Plate Module.

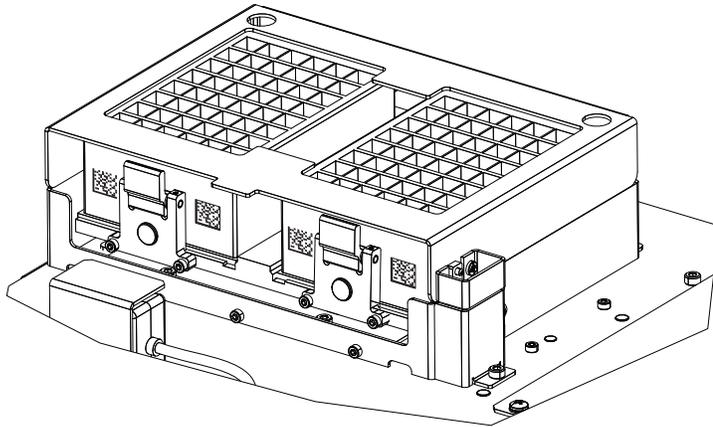
NOTE When transferring the specimen from the Specimen Transport Module (Autoloader) to the Reaction Plate Module, the system will multi-dispense the specimen if a multi-tube panel has been assigned. The system aspirates an additional 100 μL of specimen volume with each specimen transfer. For example: If an eight-tube, no-wash panel with 100 μL per tube is assigned to a specimen, then the system will aspirate 900 μL of specimen, and will add 100 μL to each of eight wells in the reaction plate.

- The specimen overhead consumed when transferring from the Specimen Transport Module to the Cell Wash Module varies depending on the specimen volume required for the sample preparation. For all specimen volumes $\geq 225 \mu\text{L}$, the specimen overhead will be 75 μL . For specimen volumes $< 225 \mu\text{L}$, the total specimen volume (including overhead) that is transferred to the Cell Wash Module will always be 300 μL . For example, if a one-tube 100 μL specimen no wash panel is assigned, then 200 μL of specimen will be transferred to the Cell Wash Module and 100 μL will be consumed as overhead.

Reaction Plate Module

The Reaction Plate Module allows mixing of the specimen or samples with reagents in the reaction plate wells, see [Figure 2.5](#). The CellMek SPS holds one or two disposable 48-well reaction plates simultaneously. The reaction plates are snapped into an orbital mixing device that mixes the samples inside the wells.

Figure 2.5 Reaction Plate Module



The CellMek SPS always adds the reagent to the specimen or sample in reaction plate. For example: Antibodies or lyse reagents are always added to the specimens inside the reaction plate wells.

 **CAUTION**

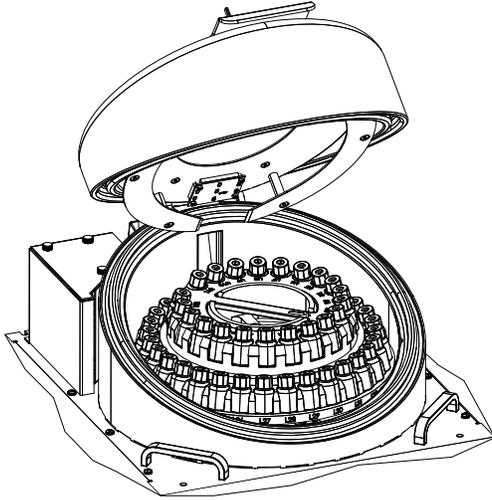
Risk of incorrect results. Reaction plates should not be moved between system if you have more than one CellMek SPS.

Each reaction plate well can only be used once. The reaction plates have barcodes that are used to keep track of the remaining available wells. The barcode on the plate is scanned by the instrument to ensure that the plates are always presented in the same orientation and are not accidentally reused.

Liquid Antibody Module

The Liquid Antibody Module provides on-board refrigeration for liquid antibodies, see [Figure 2.6](#). The temperature inside this module is maintained between 2°C and 8°C (inclusive). The vials are maintained in a dark environment when the module's lid is closed.

Figure 2.6 Liquid Antibody Module

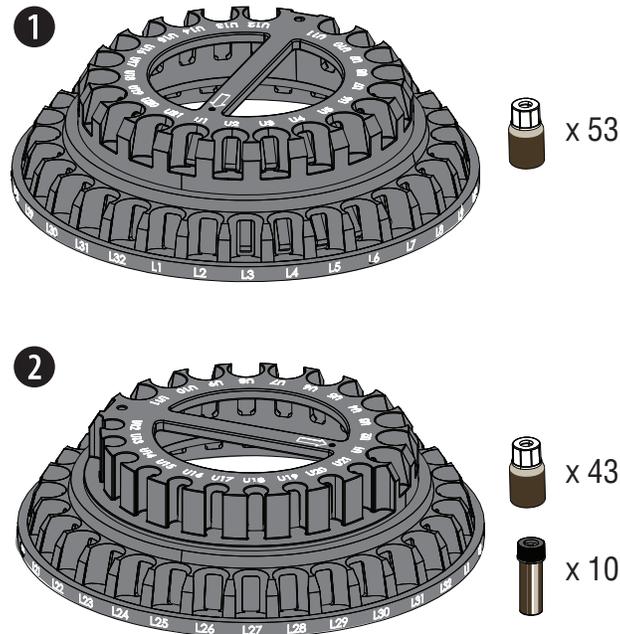


⚠ CAUTION

Risk of reagent spoilage if antibody reagents are stored in the refrigerated antibody module and power is lost. To avoid reagent spoilage, ensure that the system is powered on and connected to an electrical outlet with backup power. Otherwise, store the antibody carousel in a laboratory refrigerator connected to backup power.

The Liquid Antibody Module supports two types of liquid antibody carousels. Carousel type IO53 (1) holds up to 53 IOTest type antibody vials. Carousel type IO43CYT10 (2) holds up to 43 IOTest type vials and up to 10 CytoSTAT type antibody vials, see [Figure 2.7](#).

Figure 2.7 Carousel Types



Liquid antibody reagents that are marketed by Beckman Coulter are available in the following formats: IOTest or CytoSTAT. The format is dependent on the specific reagent. For users that want to use their own custom defined reagents or third-party reagents, Beckman Coulter offers empty IOTest vials along with custom defined reagent barcode labels.

All liquid antibody reagents require barcodes to be used in the CellMek SPS. The barcodes are used to track the remaining volume inside the vials. For Beckman Coulter antibody reagents, the instrument software will subtract the reagent volume usage from an initial fill volume and minus a small buffer for in-accessible volume. For custom defined reagents, the software will subtract reagent volume usage from an initial fill volume entered by the user minus a small buffer for in-accessible volume.

WARNING

Risk of erroneous results if reagent container volumes do not match the volume in the system software. The CellMek SPS keeps track of the volume in each bottle and vial as it is used by the system. Using reagents in CellMek SPS that have been used to prepare samples outside the system will cause the volume tracking to be wrong. Never use reagents in the CellMek SPS system that have been used to prepare samples manually or in another CellMek SPS system.

To minimize contamination, Beckman Coulter provides pierceable caps to replace the caps provided with the antibody reagents. The pierceable caps are color-coded (blue or yellow) to make it easy to inspect and ensure that all non-pierceable caps (white and black) have been replaced. The IOTest are yellow, while the CytoSTAT are blue.

Dry Reagent Module

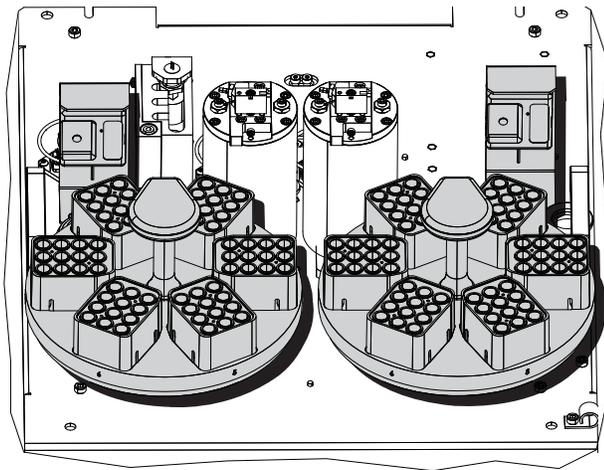
⚠ WARNING

Risk of erroneous results if available DURACartridge wells do not match the wells in the system software. The CellMek SPS keeps track of the wells in each DURACartridge as it is used by the system. Using a DURACartridge in CellMek SPS that has been used to prepare samples outside the system will cause the wells tracking to be wrong. DURACartridge reagents have not been validated for manual sample preparation. Only use DURACartridge per the instructions provided in this manual.

The Dry Reagents Module consists of two carousels, and each carousel can hold up to six DURACartridges.

The Dry Reagents Module provides for the use of up to twelve DURACartridges simultaneously in the CellMek SPS. Each DURACartridge contains 12 identical dry reagent tests, see [Figure 2.8](#). DURACartridges contain barcodes for tracking remaining tests and the reagent lots used to prepare samples.

Figure 2.8 Dry Reagents Module

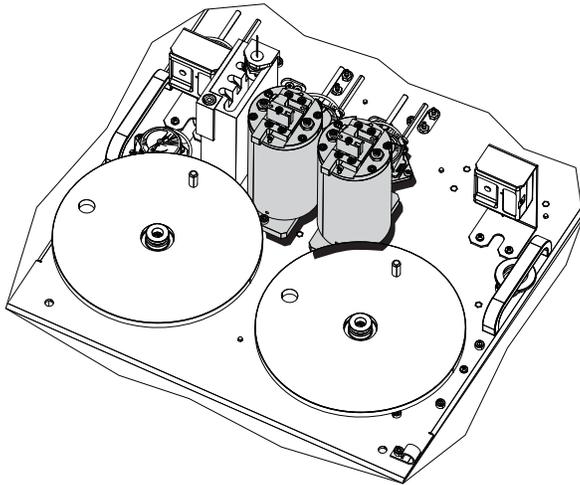


The CellMek SPS uses probe 1 in the Pod-Arm to pierce through the DURACartridge aluminum seal and resuspend the dry reagent with 90 μ L IsoFlow. The Pod-Arm's probe then aspirates the resuspended reagent and adds 50 μ L to the specimen or sample contained in one of the reaction plate wells.

Cell Wash Module

The Cell Wash Module contains two cell wash assemblies, see [Figure 2.9](#). Both assemblies can be used for performing either specimen wash or sample wash. The Cell Wash Module assemblies can perform spin only workflows.

Figure 2.9 Cell Wash Module



The specimen wash occurs when the specimen is directly transferred to the Cell Wash Module from the Specimen Transport Module. Refer to the [Specimen Transport Module \(STM\)](#) for information about the specimen overhead when transferring the specimen to the Cell Wash Module.

Sample Wash occurs when an in-process sample is transferred to the Cell Wash Module from a reaction plate well. The most common reason for performing a sample wash is to remove lytic reagent from the sample to stop the lysing process.

Spin Only occurs when an in-process sample is transferred to the Cell Wash Module from a reaction plate well to undergo concentrating of sample with no additional Wash Buffer added.

To minimize the cell loss due to reaction plate dead volume when transferring a sample from the reaction plate to the Cell Wash Module, the instrument dilutes samples (with volumes < 1000 μ L) to 1000 μ L using system fluid prior to transferring. Spin Only samples (see below) are not diluted.

⚠ WARNING

Risk of red blood cell cross-contamination in the Cell Wash Module if sample wash is performed on samples with un-lysed red cells. To minimize the risk of red cell cross-contamination, only create panels that perform sample wash with samples that have been lysed or have very low red cell concentrations (<100,000 cells per microliter).

Specimen and sample wash are performed using wash buffer that is added into the Cell Wash Buffer bottle. The wash buffer composition is user defined. Wash buffer volume is measured in the wash bottle holder assembly. The instrument keeps track of the remaining wash volume by subtracting volume usage from the initial weighed value.

The CellMek Panel Definition software allows the user to define the number of wash cycles (up to 5) for specimen or sample wash. In addition, users may select the Spin Only option.

Spin Only concentrates samples with a volume $\geq 500 \mu\text{L}$ to an approximate volume of 330 μL .

Table 2.1 shows the volume of wash buffer consumed in Cell Wash operations. Use this table to determine the wash buffer volume needed to prepare your samples. Add an extra 20% for safety margin.

Table 2.1 Wash Buffer Volume Consumption (mL)

Wash Cycles	Specimen Wash	Sample Wash
1	27.5	17.2
2	30.0	19.4
3	32.5	21.6
4	35.0	23.8
5	37.5	26.0
Startup and Wash Buffer Prime		35.0
Initiate Processing (when Start button is pressed)		5.0
Cell wash fluid bottle inaccessible (dead) volume		100.0

CELL WASH MODULE OPERATING PRINCIPLES

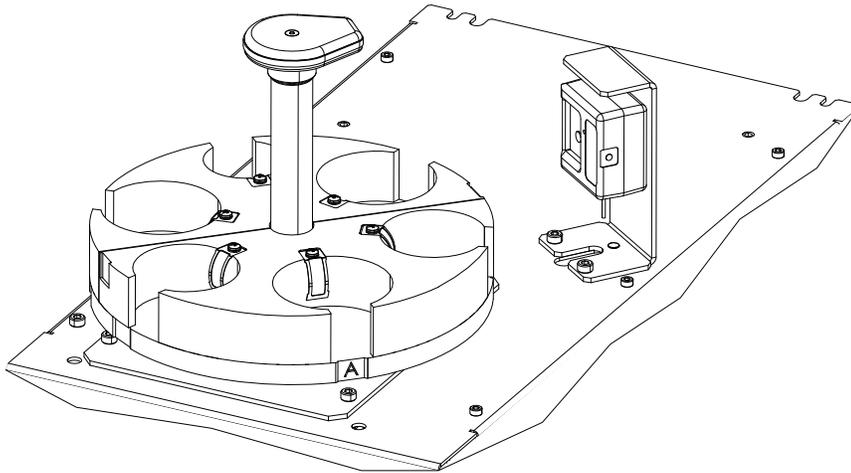
Specimen Wash — The Cell Wash Module contains two spin wash assemblies that operate independently of each other. After adding the specimen to a Cell Wash Module assembly, the wash buffer is added to dilute the specimen. The Cell Wash Module is then rotated on its axis to create a centripetal force that pushes the cells toward the Cell Wash Module walls. The Cell Wash Module walls have pockets to collect and pellet the cells. After the cells have completely pelleted in the Cell Wash Module pockets, a fluidic pump is used to remove the liquid from the spinning center of the Cell Wash Module. This effectively removes the supernatant without removing the cells. When rotation stops, cells and buffer solution fall to the bottom of the Cell Wash Module. At this point, additional buffer is added and another cell wash cycle is performed if desired. The number of cell wash cycles is selectable by the user. Increasing the number of wash cycles has a positive effect when the goal is to remove plasma proteins (as with a Kappa and Lambda assays) but negatively affects system throughput due to the additional cycles.

Sample Wash — Sample wash works similarly to Specimen Wash. The main difference is that the initial sample is not diluted in the wash buffer before it is spun and the supernatant is removed. After the initial supernatant removal cycle has completed, then the wash buffer is added and the wash cycles are performed similarly to specimen wash. The number of cell wash cycles is selectable by the user including Spin Only (see above).

Prep Reagents Module

The Prep Reagents Module supports a removable carousel which holds the prep reagents and presents them for aspiration as needed during the sample preparation process. See [Figure 2.10](#).

Figure 2.10 Prep Reagents Module

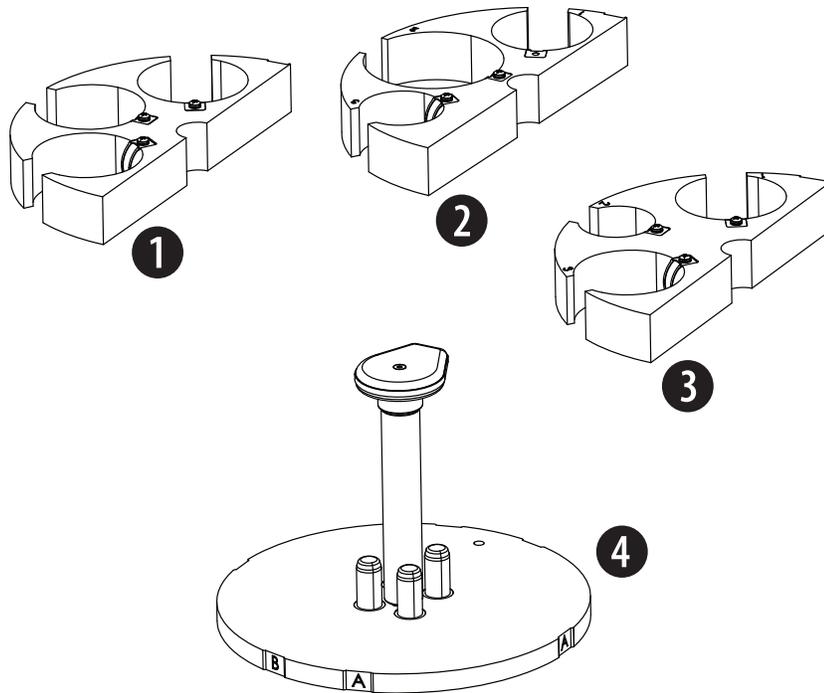


The Prep Reagents are lyse or buffer reagents that are used to condition, fix, or otherwise prepare the sample for analysis. Prep Reagents do not include instrument support reagents such as the IsoFlow Sheath Fluid (contained in the Cart Module) or Wash Buffer (contained in the Cell Wash Module).

There are three types of prep reagent adapters to support different reagent systems, see [Figure 2.11](#).

Any two adapters can be placed on-board the carousel simultaneously, see [Figure 2.11](#).

Figure 2.11 Adapter Types



1. P01 Custom Defined Reagent, Versalyse, and Optilyse C
2. P02 Immunoprep 300 Test
3. P03 Perfix NC, Optilyse B, Optilyse C, and Custom Defined Reagent
4. Adapter Holder

For users that want to use their own custom defined reagents or third-party reagents, Beckman Coulter offers empty Nalgene bottles and caps along with custom defined reagent barcoded labels. These bottles can be used with all the positions in Adapter 1 and in two of the positions in Adapter 3.

All prep reagents require barcodes to be used in the CellMek SPS. The barcodes are used to track the remaining volume inside the bottles. For Beckman Coulter prep reagents that are known based on the reagent barcode, the instrument software will subtract the reagent volume usage from an initial fill volume, minus a small buffer of inaccessible volume. For custom defined prep reagents, the software will subtract the reagent usage volume from an initial fill volume entered by the user minus a safety buffer. The system uses liquid level sensing to verify the volume entered by the user during the reagent inventory check; if the volume detected by the system is less than the volume entered by the user, then the volume detected by the system is used.

NOTE The reagent volume is automatically verified by the system only for custom defined prep reagents, level sensing is not used with antibody reagents or Beckman Coulter prep reagents.

 **WARNING**

Risk of erroneous results if reagent container volumes do not match the volume in the system software. The CellMek SPS keeps track of the volume in each bottle and vial as it is used by the system. Using reagents in CellMek SPS that have been used to prepare samples outside the system will cause the volume tracking to be wrong. Never use reagents in the CellMek SPS system that have been used to prepare samples manually or in another CellMek SPS system.

 **CAUTION**

Risk of reagent spoilage if the prep reagents are stored with the cap removed. To avoid reagent spoilage, ensure that the prep reagents are re-capped prior to storage.

To aspirate the prep reagent from the prep reagent bottles, the bottles must be placed un-capped in the instrument. Each time the instrument front door is closed, a reagent inventory is performed and the Pod-Arm uses one of its probes to check that all prep reagent caps have been removed.

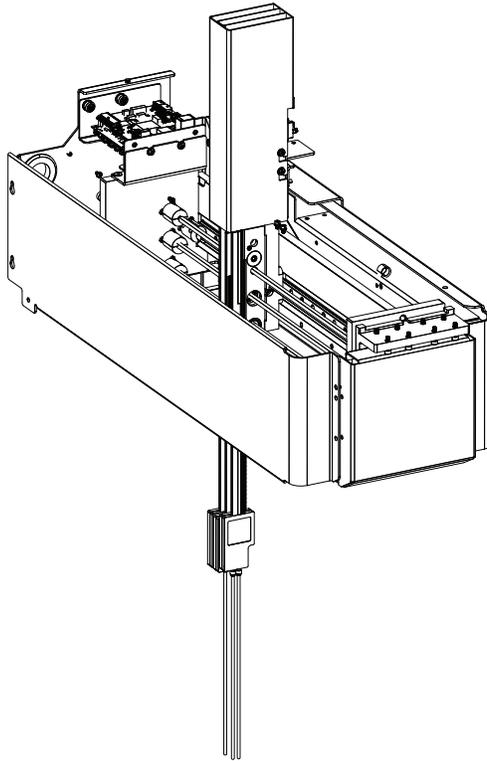
 **CAUTION**

Risk of injury from inhalation of Prep Reagent vapors. Refer to [CHAPTER 1, Material Safety Data Sheets \(SDS/MSDS\)](#) for information about inhalation hazards for specific reagents. To minimize airborne concentration of chemical vapors, install your CellMek SPS in a well-ventilated area. A qualified professional should evaluate the chemical vapor levels to determine if your laboratory ventilation is adequate to maintain operator comfort and safety.

Pod-Arm Module

The instrument transfers the specimen, sample, and reagents from one location to another using the Pod-Arm Module, see [Figure 2.12](#).

Figure 2.12 Pod-Arm Module



The Pod-Arm Module consists of a robotic arm that is capable of movement along three axes:

- **Left/Right:** Parallel to the front of the system - X-Axis Motion
- **Front/Back:** Parallel to the sides of the system - Y-Axis Motion
- **Up/Down:** Z-Axis Motion

The Pod-Arm Module contains the three probes for transferring specimen, sample, and reagent. All probes move together in the x and y axes, but each probe is capable of independent z-axis motion.

The probes are numbered as follows:

- **Probe 1:** Metallic finish; Farthest from front - does not pierce specimen tube rubber stoppers
- **Probe 2:** Metallic finish; Middle - does not pierce specimen tube rubber stoppers
- **Probe 3:** Black finish - pierces specimen tube rubber stoppers

The probes are fluidically connected to precision syringe pumps and the fluidic lines are primed with IsoFlow.

During transfer of the specimen, reagents, or sample, the syringes pull an air gap to separate the IsoFlow from the fluid being transferred in order to minimize dilution.

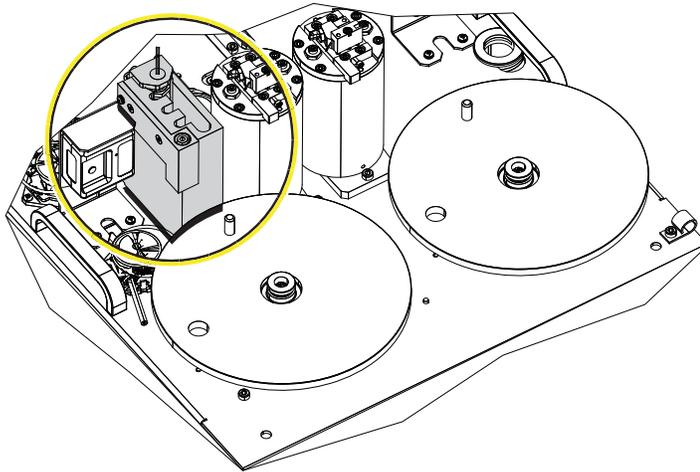
To optimize the small volume transfers, an additional 5 μL chase volume of IsoFlow is dispensed in all reagent transfers from 3 μL and 9 μL (inclusive).

While all three probes are connected to 1 mL precision syringes, Probe 1 is also connected to a 2.5 mL precision syringe. Therefore, Probe 1 is used for all sample and reagent transfers of $\geq 875 \mu\text{L}$.

Probe Wash Module

The Probe Wash Module is used to clean the probes in between use to avoid cross-contamination, see [Figure 2.13](#).

Figure 2.13 Probe Wash Module



The Probe Wash Module has two sides: the flush side and the wash side.

In the flush side of the Probe Wash Module (the large opening in the right), the probes flush their internal contents. The flush side is used to clean the inside of the probes.

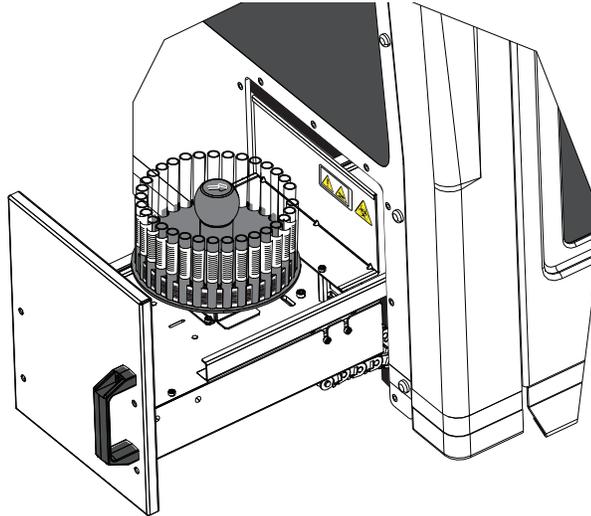
In the wash side of the Probe Wash Module, the probes dispense IsoFlow inside three separate channels. This causes the IsoFlow to flow up around the outside surface of the probe before pouring into the flush side of the module. The wash side is used to clean the outside of the probes.

A pump moves waste from the Probe Wash Module into the waste container in the Cart Module.

Output Module

The Output Module holds the output carousel which holds 32 daughter tubes. Once the prepared samples of completed panels are transferred to tubes, the carousel can be removed and brought to a flow cytometer for analysis, see [Figure 2.14](#).

Figure 2.14 Output Module



The output carousel can be used in Beckman Coulter Navios, Navios EX, and DxFLEX cytometry systems. However, Navios and Navios EX carousels cannot be used with the CellMek SPS. The CellMek SPS is a precision robotic system, it uses an output carousel that more precisely supports output tubes than the carousels included with the above flow cytometry systems. A pin in the output carousel hub ensures that carousels will not fit in the CellMek SPS instrument. The output carousel hub is different than the carousels located on cytometer devices.

CAUTION

Risk of sample misidentification or erroneous results if order of sample analysis panels does not match the samples in the output carousel. The CellMek SPS may rearrange the order of panels to achieve efficient workflows, therefore the order of panels in the output carousel will not always match the order of specimen loading. To avoid samples run in the wrong order:

1. Use the Worklist created by the CellMek SPS to transfer sample information to the flow analyzer. For more information Setting Up the Worklist, see [CHAPTER 6, Worklist Setup](#).
2. If Worklists are not utilized in the laboratory workflow, use the human readable (HTML) worklist created by the CellMek SPS to manually enter sample information to the flow analyzer. The human readable (HTML) worklist can be opened with any web browser.

NOTE [Contact us](#) to confirm if the DxFLEX and this feature are available in your geography.

All output carousels and output tubes require barcodes so that they can be used in the CellMek SPS. The barcodes are used to track the presence of an acceptable output tube (i.e., one that has not been used before).

NOTE Barcode values must be unique. Barcode values on output tubes that were previously used on the system may not be used again.

CellMek SPS compatible output tubes containing the proper barcodes are available from Beckman Coulter. Beckman Coulter also gives users the option of printing their own CellMek SPS compatible output tube labels. See [APPENDIX E, Barcode Specifications](#) for output barcode specifications.

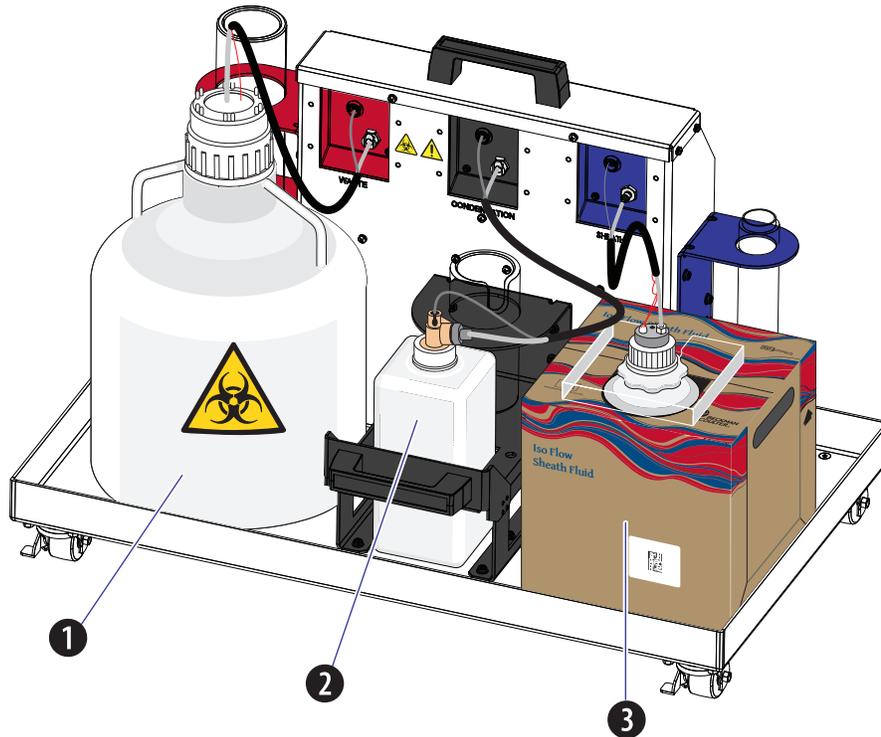
The output carousel is mounted on an output drawer that can be opened independently of the front door. This allows users to safely remove and add new carousels without interrupting sample processing.

NOTE The CellMek SPS moves samples to the output carousel as panels are completed. The instrument will not allow the output drawer to be opened during the time that a panel is being transferred to the output carousel. An output carousel with an adequate number of valid output tubes is not required to start sample processing, but it is required for prepared samples to be transferred to output tubes. The system alerts the user if there are not enough output tubes available, when additional tubes are added, the system will continue to transfer the panel. Opening and closing the output carousel door triggers a scan of the output carousel.

Supply Cart Module

The Supply Cart Module provides a location to hold the IsoFlow cubitainer, the waste container, and the condensate container. The Supply Cart Module is mounted on wheels for easy access and placement under a lab bench, see [Figure 2.15](#).

Figure 2.15 Supply Cart Module



1. Waste Container
2. Condensate Container
3. IsoFlow Cubitainer

⚠ CAUTION

Risk of losing in-process samples if the waste container becomes full during sample processing. Ensure that the waste container is emptied daily. Refer to [CHAPTER 9, Replacing the Waste Container](#) procedure for detailed instructions.

⚠ CAUTION

Risk of losing in-process samples if waste container is disconnected while processing samples. Only replace the waste container when the system is in the Ready or Not Ready state.

⚠ CAUTION

Risk of losing in-process samples if IsoFlow Sheath Solution is replaced during sample processing. Only replace the IsoFlow Sheath Solution when the system is in the Ready or Not Ready state.

 **CAUTION**

Risk of reagent spoilage; the onboard refrigerator turns off when condensate container becomes full. It is recommended that you change the condensate container daily.

The Supply Cart Module provides the following components to monitor the liquid levels in the containers:

- Waste container float assembly - The instrument tracks the waste level in the waste container by adding all the effluent volume during usage. Based on the volume tracking, the instrument will notify when the waste is full and requires replacement. As a backup, in case the user does not change the waste when required by the volume tracking, the waste container has an over-fill float. When the over-fill float is triggered, the system will not perform any processes that produces effluent. The float assembly also detects if the waste cap is not installed and will not perform any processes that produce effluent until it is re-installed.
- IsoFlow container float assembly - The instrument tracks the use of IsoFlow by subtracting from the IsoFlow initial volume every time it consumes IsoFlow. As a backup, an IsoFlow empty float is used to detect insufficient IsoFlow to continue sample processing. This float will safeguard against air being aspirated into the system, therefore preventing incorrect fluid transfers, and it will abort all in-process samples if it is triggered.

 **WARNING**

Risk of erroneous results if reagent container volumes do not match the volume in the system software. The CellMek SPS keeps track of the volume in each bottle and vial as it is used by the system. Using reagents in CellMek SPS that have been used to prepare samples outside the system will cause the volume tracking to be wrong. Never use reagents in the CellMek SPS system that have been used to prepare samples manually or in another CellMek SPS system.

- Condensate container float assembly. The instrument contains a float to detect if the condensate container is over-filled. If the condensate container float is tripped, the system will alert the user and not start processing any new specimens.

Output Tube Assignment

The CellMek SPS has two tube assignment modes for you to control how output tubes are allocated in the output tube carousel.

- **Auto Assigned Mode:** This mode uses the Beckman Coulter provided output tubes with pre-existing output tube ID labels or third-party tubes with labels printed per the instructions in [APPENDIX E, Output Tube Identification 1-Dimensional Barcode Label](#). Completed panels are transferred to output tubes in the order they are completed. The criteria for transferring samples to output tubes are provided that there are sufficient sequential tubes in the carousel to transfer the whole panel (no partial panels). The electronic worklist contains the information mapping the output tube IDs to the specimen ID, panel name, and tube name.

Upload the electronic worklist to a Navios, Navios EX, or DxFLEx cytometer and load the tube carousel to process samples. The flow cytometer will use the electronic worklist data to analyze samples and associate the results with the specimen ID and panel. In this mode, output tubes cannot be manually labeled prior to processing because the sample assignment is done by the CellMek SPS during processing. The specimen ID and panel names for individual output tubes can also be viewed after processing by scanning the tube ID with the hand-held scanner.

- **Barcode Assigned Mode:** This mode uses the Beckman Coulter provided output tubes with pre-existing output tube ID labels and an additional specimen information label printed by the lab. Alternatively, you can use third-party tubes and apply laboratory printed labels containing both the specimen information and the output tube ID. Specifications for printing these labels are provided in [APPENDIX E, Output Tube Identification 1-Dimensional Barcode Label](#). Completed panels are transferred only to output tubes with matching specimen ID and panel codes. In this mode, you can control how panels are assigned to output tubes. This allows pre-labeling of barcode tubes with human readable information such as specimen ID, panel name, tube name, or other identifiers used in your lab to track samples.

Overview

This chapter contains information about:

- [Startup](#)

Startup



WARNING

Risk of biohazardous contamination. To avoid contamination when handling CellMek SPS carousels, cassettes, reaction plates, or reagent bottles, wear barrier protection including gloves, eye protection, and a laboratory coat.

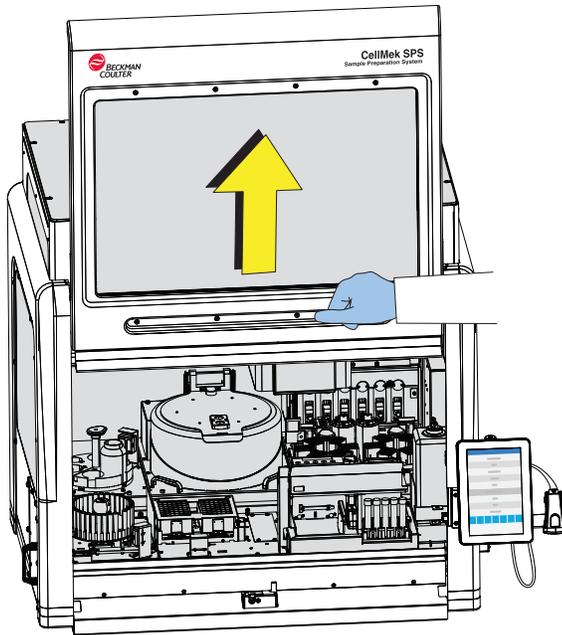
CAUTION

Risk of losing in-process samples if the waste container becomes full during sample processing. Ensure that the waste container is emptied daily. Refer to [CHAPTER 9, Replacing the Waste Container](#) procedure for detailed instructions.

After your system is set up and configured at installation, follow the procedures below to prepare for sample analysis.

IMPORTANT Any specimen requests in the first tab (Processing Samples tab) are removed after Startup, see [CHAPTER 6, Processing Samples](#). The status is changed to Error and the panel and tube status is skipped.

- 1 Open the front door.



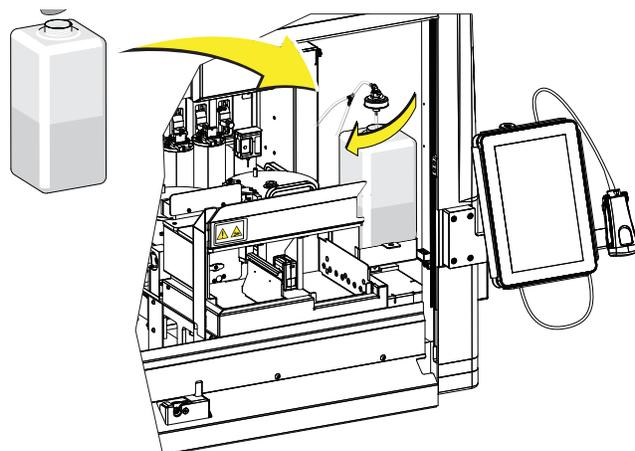
WARNING

Risk of personal injury or biohazardous contamination when contacting CellMek SPS including work area components, carousels, cassettes, reaction plates, reagent bottles, and waste container. To prevent possible injury or biohazardous exposure, always wear proper laboratory attire, including gloves, a laboratory coat, and eye protection. Refer to [CHAPTER 1, Material Safety Data Sheets \(SDS/MSDS\)](#) for chemical exposure details.

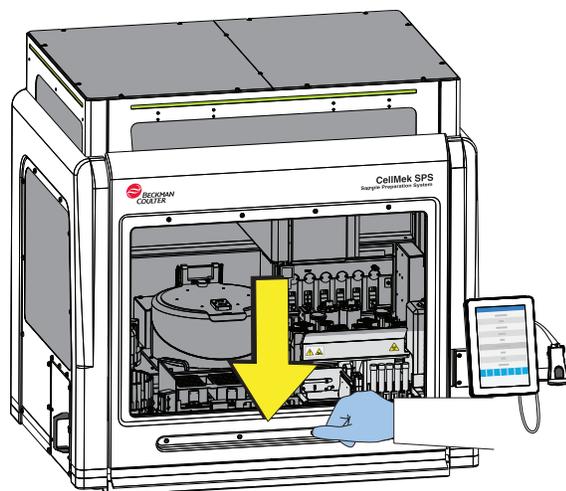
- 2 Load the cell wash fluid.

If planning to perform cell washes as part of the sample processing, load the cell wash buffer solution used for your samples. If cell washes will not be performed, the cell wash bottle should contain deionized water. Refer to instructions for replacing cell wash fluid. See [CHAPTER 8, Cleaning the Cell Wash Bottle](#).

Figure 3.1 Loading the Cell Wash Fluid



- 3** Close the front door.



- 4** Select **Cell Wash Fluid** and enter information in the status.

- 5** Select the  icon located at the bottom left of your screen. The halo will turn green during Startup. The instrument status displays **Starting**.
- 6** Startup primes the fluidic lines, checks that status of all system modules, and performs integrity checks of the Cell Wash Module.

-
- 7** The system displays **Ready** status upon completion:
- a.** The system shows **Ready** in the lower left corner of the screen if Startup was successful. The halo turns blue when the system is ready.
 - b.** The system shows **Error** or **Not Ready** in the lower left corner of the screen if Startup was unsuccessful. The halo flashes red if the system fails. If an error is displayed, see [CHAPTER 7, Troubleshooting](#).
-

Overview

This chapter contains information about:

- Specimen Collection
- Workflow Overview
- Importing Panels
- Publishing Panels
- Checking Reagents
- Before Running Specimens
- Loading Specimens
- Deleting Specimen Requests
- Pausing Processing
- Ejecting Cassettes
- Aborting Instrument Actions
- Loading Output Samples Tubes

Specimen Collection



Risk of misleading results and/or biohazard spills if specimen tubes are underfilled or overfilled with specimen. The adequate ratio of specimen to anticoagulant must be observed. A space must be left between the cap and the specimen to allow for proper mixing and to prevent any specimen spills while piercing the sample.

For sample collection methods and safety procedures, refer to:

- CLSI document H3 – Procedures for the Collections of Diagnostic Blood Specimens by Venipuncture.
- CLSI document M29 – Protection of Laboratory Workers From Occupationally Acquired Infections.

Workflow Overview

To run specimen panels, they need to be created with the CellMek Panel Designer Software and imported into the CellMek SPS.

Depending on the user's permissions, panels can be run in either development or published mode. Only users with Import Panel permissions may run panels that are in development mode. All users may run published panels.

The CellMek SPS is designed for simplicity and minimal interaction by the user. To operate the CellMek SPS, follow the workflow overview described in [Workflow Steps](#).

Workflow Steps

1. Perform Startup. See [Startup](#) in [CHAPTER 3, Daily Startup](#).
2. Import panels created in the CellMek Panel Designer Software (as needed).
3. Publish panels in the CellMek SPS (as needed).
4. Load and/or check reagents.
5. Load and process the specimens.
6. Unload the carousel with prepared samples and transfer to a supported cytometer.
7. Unload the specimens.
8. If you need to perform a shutdown, refer to [Shutdown](#) in [CHAPTER 5, Shutdown](#).

Importing Panels

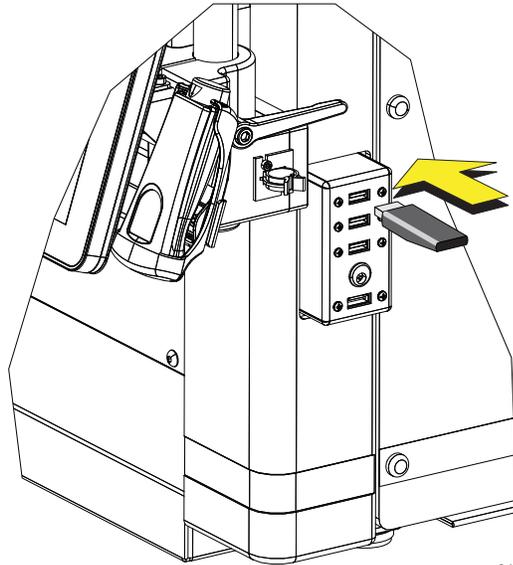


Risk of reporting erroneous results. To avoid problems with reagents or the system, always run an application-specific quality control check before testing with clinical samples.

Panels are created using the CellMek Panel Designer software. This software only works using a Windows 10 computer. Panels can only be transferred from the CellMek Panel Designer computer to the CellMek SPS using a portable USB drive.

Importing Panels into CellMek SPS

- 1 Connect the USB drive to one of the slots on the power panel of the CellMek SPS.



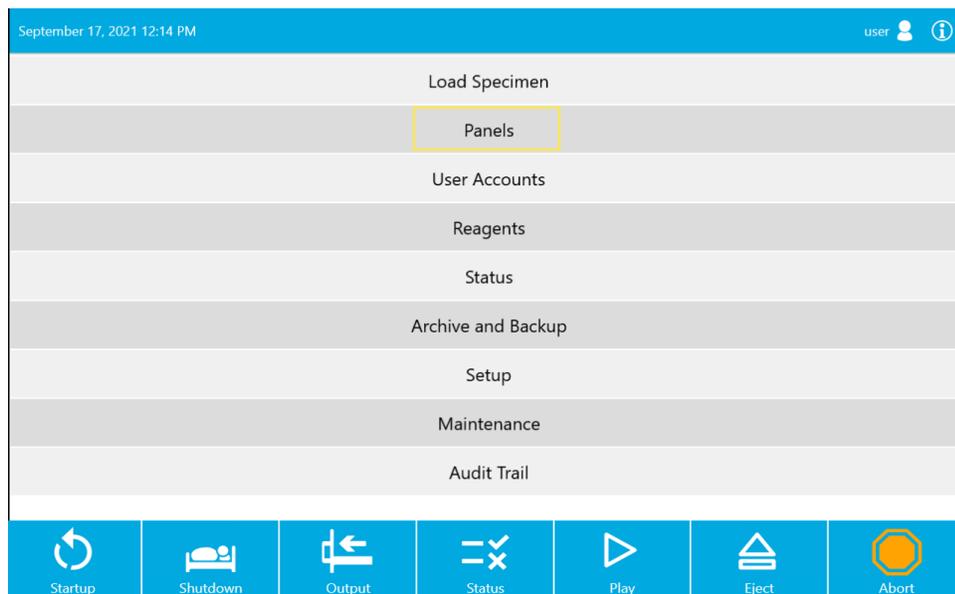
8455107AB

NOTE For information on accessing a BitLocker encrypted USB drive in Kiosk Mode, see [APPENDIX G, Using BitLocker Encrypted Media in Kiosk Mode](#).

Only use USB media that has been verified to be free of malware to transfer files between CellMek SPS and other systems.

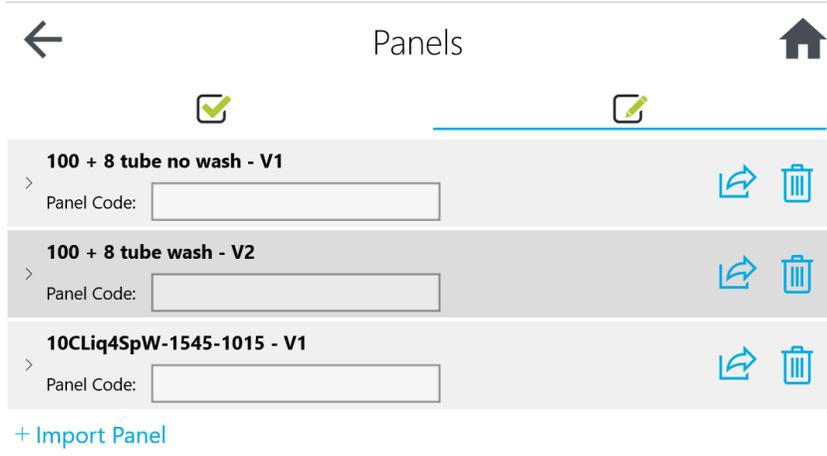
- 2 Select **Panels** from the CellMek SPS Home Screen. See [Figure 4.1](#).

Figure 4.1 CellMek SPS Home Screen



- 3 Select  to access imported panels. The screen shows the list of panels that were imported by the active user.

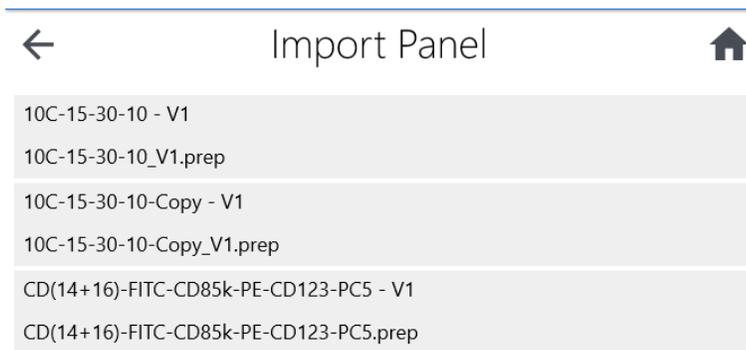
Figure 4.2 Accessing the Panels



- 4 Select +Import Panels.

IMPORTANT The system allows for unique panels to be published. If you duplicate the name, the panel will not be allowed to be published. Panels need to be stored in a folder named **CellMek** to be imported into the system.

- 5 Select the panel names to import. Panels that have already imported have a check mark.



NOTE The screen shows both the panel name and the file name.

- 6 Enter the panel code:

- a. If the output tube mode is set to **Barcode Assigned**, the system will prompt you to enter a panel code. Panel codes are 1-5 character alpha-numeric codes defined by your lab to link in-process panels to their designated output tubes.

NOTE You will need to program your barcode printer to print output tube labels with matching panel codes. Refer to [APPENDIX E, Output Tube Labels for Barcode Assigned Mode](#).

- b. The system will not prompt you to enter a panel code when the output tube mode is set to Auto Assigned Mode.
- c. Panel codes can be added or edited in the Panel screen. Only users with Publish Permission can edit panel codes for published panels.

-
- 7 Remove the USB drive if you are only importing panels.

NOTE If you are exporting worklists after processing samples, you may want to leave the USB in the drive.

-
- 8 The newly imported panels are now shown.

NOTE Only users with import panels permissions may import panels or run specimens with unpublished panels. Users without the import panels permissions can only run published panels.

Once you have validated a panel, you may publish the panel to make it available for general use.

Publishing Panels

CAUTION

Risk of incorrect results. To avoid incorrect panel designs, validate all panels prior to publishing or using to report clinical results.

-
- 1 Select **Panels** from the CellMek SPS Home Screen. See [Figure 4.1](#).

-
- 2 Select  to access imported panels, see [Figure 4.2](#). The screen shows the list of panels that were imported by the active user.

-
- 3 Select  to select the panel you want to publish.

NOTE The gray arrow signifies that a panel with the same name has already been published, while the blue arrow indicates a panel has not been published.

- 4 Confirm that you have selected the right panel. A message will appear *Are you sure?*, select **Yes, publish this panel.**

- 5 Select  to view published panels.

All the published panels are displayed in the Published Panel tab. Published panels are available for running by all users.

Checking Reagents



Risk of reporting erroneous results. To avoid problems with reagents or the system, always run an application-specific quality control check before testing with clinical samples.



Risk of reagent spoilage if antibody reagents are stored in the refrigerated antibody module and power is lost. To avoid reagent spoilage, ensure that the system is powered on and connected to an electrical outlet with backup power. Otherwise, store the antibody carousel in a laboratory refrigerator connected to backup power.

Prior to running specimens, all the consumables including reagents and reaction plates need to be loaded in the CellMek SPS. The instrument front door and output drawer must be closed.

- 1 Select **Status** from the CellMek SPS Home Screen. Alternatively, you can select the icon located at the bottom of your screen.

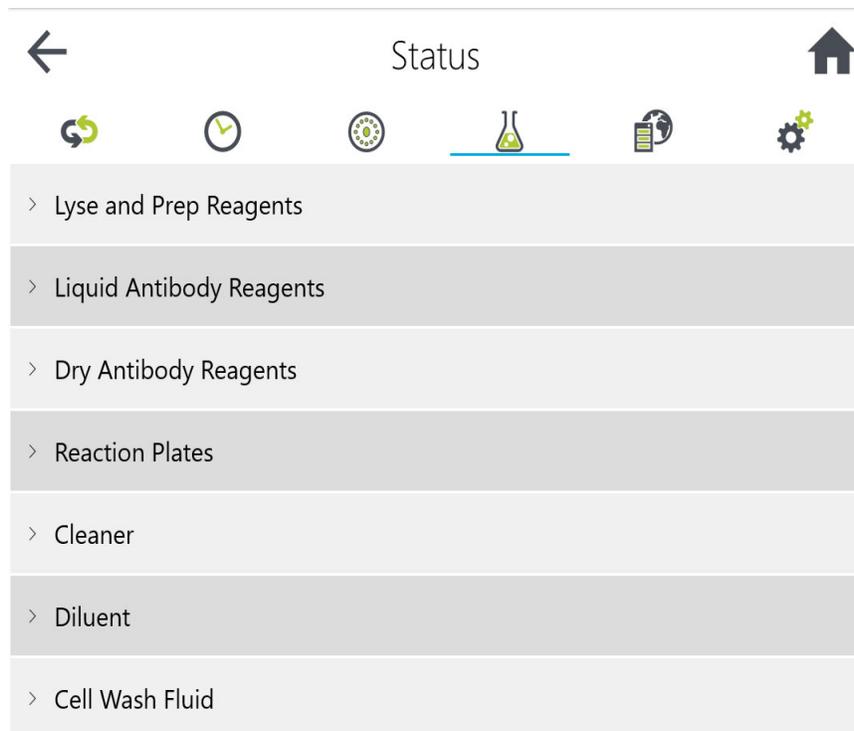


- 2 Select  to view reagents/consumables.

CAUTION

Risk of injury from inhalation of Prep Reagent vapors. Refer to [CHAPTER 1, Material Safety Data Sheets \(SDS/MSDS\)](#) for information about inhalation hazards for specific reagents. To minimize airborne concentration of chemical vapors, install your CellMek SPS in a well-ventilated area. A qualified professional should evaluate the chemical vapor levels to determine if your laboratory ventilation is adequate to maintain operator comfort and safety.

IMPORTANT Ensure there are sufficient reagents and reaction plate wells for panels that are planned. If the number of panels is unknown, it is recommended to maintain excess volumes of reagents onboard to handle unexpected workloads.



- 3 Select each consumable type to see all the consumables onboard or that are connected to the system.

Table 4.1 Consumable Type Information

Consumable Type	Consumable Information
Reagents	<p>The status screen displays the remaining volume and expiration date for each reagent (except for the DURACartridge) that is onboard and that is connected to the system.</p> <p>For Lyse and Prep Reagents, Liquid Antibody Reagents, selecting a reagent shows the QC Status, Part Number, Lot Number, Vial ID, and Onboard Hours.</p> <p>Dry Antibody Reagents, selecting dry reagents shows the QC, Part Number, Lot Number and Cartridge ID.</p> <p>For Diluent, the status screen displays the lot number, expiration date, and remaining volume.</p>
Reaction Plate	The status screen displays the location of the plate and number of the remaining wells.
Cell Wash Fluid	The status screen displays the name of the currently selected cell wash fluid with the lot number, remaining volume, and the expiration date. If the selected Cell Wash Fluid is deionized water or bleach solution, then the expiration date will not be displayed.

Before Running Specimens

 CAUTION

Risk of reporting erroneous results. To avoid erroneous results, ensure there is sufficient volume in the specimen tube for specimen processing. Ensure the specimen tubes are filled with the required volumes specified prior to processing, see [APPENDIX D, Tube List](#) to find the dead volume for the specimen tube type that you are using. Add the dead volume to the volume required for the assigned panels to determine the minimum required specimen tube volume.

 CAUTION

Risk of inaccurate results. The CellMek SPS prepared sample may contain insufficient cells for accurate results due to clots or fibrin strands in the input specimen. To avoid this, inspect specimen tubes to ensure they do not contain clots or fibrin strands.

IMPORTANT To reduce the occurrence of clogs, specimens should be free of particle clumps larger than 0.125 mm in size. Specimen types (for example: bone marrow) that may contain particles larger than 0.125 mm should be filtered prior to loading in the CellMek SPS.

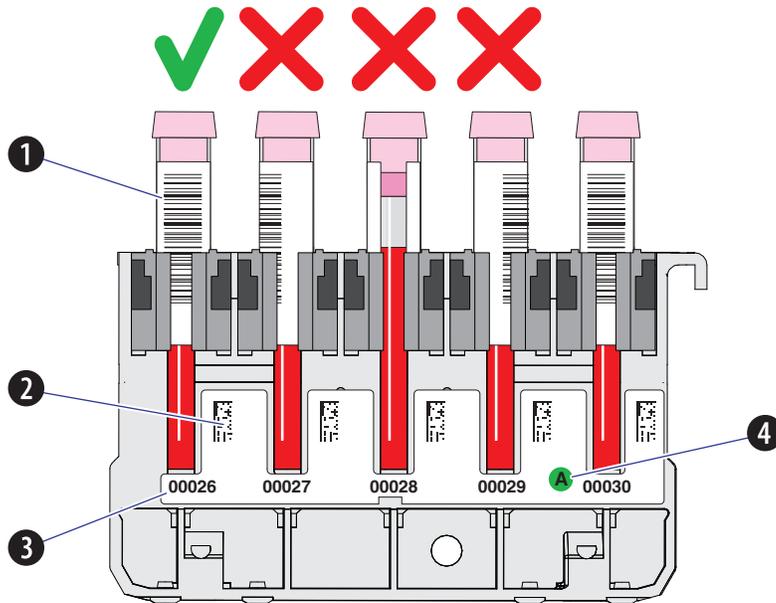
Before proceeding to load specimens, verify the following:

- That Daily Startup was performed. See [Startup](#) in [CHAPTER 3, Daily Startup](#) for more information.
- That the CellMek SPS reagents and reagent levels are suitable for the number of samples to be run. If you need to replace reagents, see [Replacing Reagents and Consumables](#) in [CHAPTER 9, Replacement Procedures](#). It is recommended to replace reagents before starting the workload.
- That the specimen to be loaded complies with the minimum running volume. See [Specimen Collection](#).

Specimen Cassettes

The specimen cassette holds five tubes. Position the tubes with the barcode facing to the front, see [Figure 4.3](#). Refer to [APPENDIX D, Tube List](#) for the different types of cassettes.

Figure 4.3 Cassette Holder



1. Tube with barcode
2. Barcode of cassette
3. Cassette and position identifier
4. Cassette type

Loading Specimens



WARNING

Risk of biohazardous contamination. To avoid contamination when handling CellMek SPS carousels, cassettes, reaction plates, or reagent bottles, wear barrier protection including gloves, eye protection, and a laboratory coat.

- 1 Select `Load Specimen` from the CellMek SPS Home Screen. See [Figure 4.1](#).

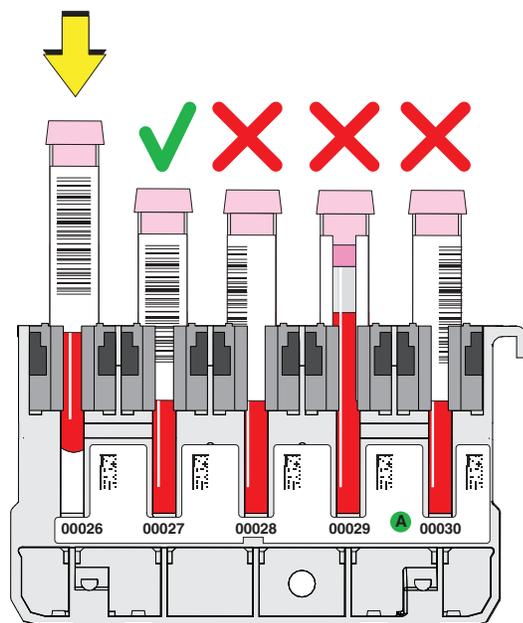
WARNING

Risk of insufficient specimen transfer if specimen tubes contain vacuum or pressure. Specimen tubes that were under filled at the time of specimen collection or which have been opened and re-capped should be vented to atmospheric pressure prior to processing.

- 2 Load specimen tubes into the cassettes with the barcode facing outward. Ensure that the tube you are putting in the cassette is the appropriate tube type and contains its pierceable stopper, see [APPENDIX D, Tube List](#).

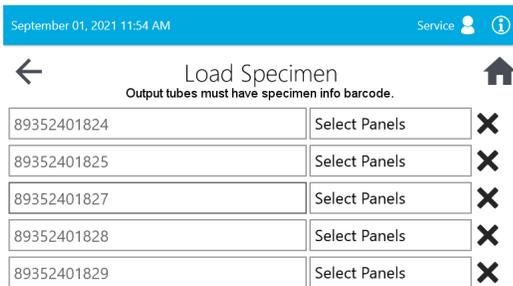
CellMek SPS only supports closed vial sampling.

Figure 4.4 Loading Specimen Tubes



- 3 Use the handheld barcode scanner to scan all the specimen tubes in the cassette.
 - a. Users may assign panels one-by-one as tubes are scanned, or wait until all the tubes are scanned before assigning panels. The order of scanning does not matter.
 - b. Specimen barcodes will appear in the load specimen screen in the order they are scanned, not in the order that they are loaded in the cassette.
 - c. [Figure 4.5](#) shows the load specimen screen after five specimen tubes have been scanned, but prior to assigning panels.

Figure 4.5 Loading Specimens after Scanning



NOTE The example above is for Barcode Assigned Mode while the message in [Figure 4.6](#) shows the message for Auto Assigned Mode.

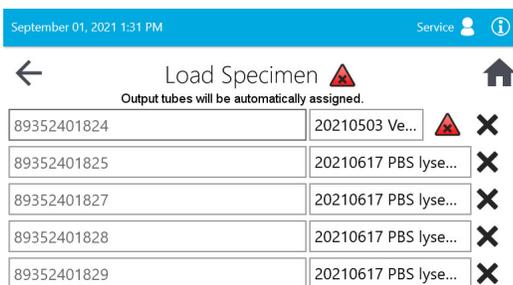
- 4 Choose **Select Panels** for each specimen tube ID. Assign one to three panels for each specimen. See [Figure 4.6](#).

The screen will show any errors associated with your panel assignments with a red triangle.

Select and expand the error to see the details. Panels with errors will not be prepared, therefore, correct any errors before proceeding.

NOTE If valid order information (panel) was received from the LIS, the panel will be preselected.

Figure 4.6 Specimens with Assigned Panels



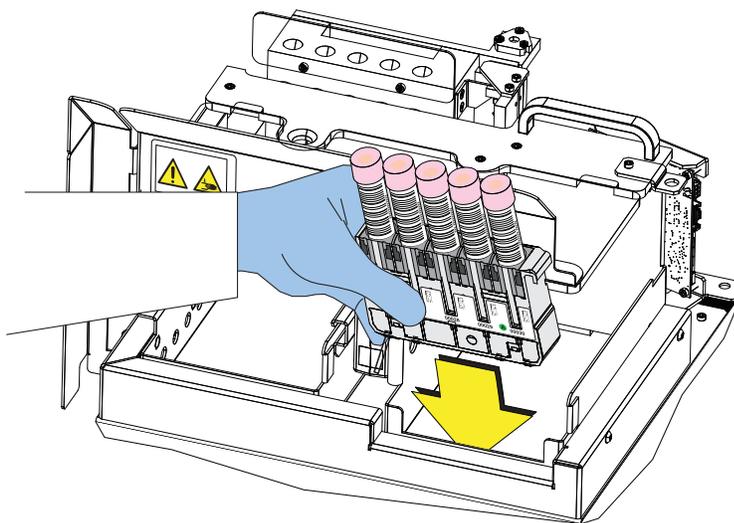
- 5 Select each specimen to view the specimen volume required. This is the minimum volume required in the specimen tube to process all the panels that have been assigned to it. Refer to [APPENDIX D, Tube List](#) for dead volumes for specimen tube types.

Verify that the specimen tubes have the required specimen volume before proceeding to loading specimens.

⚠ WARNING

Risk of hand injury from the piercing probe and moving parts in the Specimen Transport Module. Never reach into the back of the Specimen Transport Module when the system is processing.

- 6 Place the cassette in the input buffer of the Specimen Transport Module.



IMPORTANT Once the Load button is selected, the specimens on the cassette they created in the Load Specimen screen get added to the Processing Samples screen with the status of Loaded, see [CHAPTER 6, Processing Samples](#).

- 7 Select **Load** .

The Load button will be **Load**  (grey) until the cassette is placed into the input position, then the button will turn to **Load**  (blue) when the cassette can be loaded.

NOTE The system will move the cassette toward the back of the input buffer and a new load specimen screen will appear.

- 8 Continue to load specimen tubes and assign panels until all specimen tubes are loaded.

- 9 Select  to start processing the specimens.

While the samples are processing, the **Play** icon will change to **Pause** icon.

The CellMek SPS will start processing the specimens. The system will continue to process all the specimens that were loaded until there are no specimens remaining to be processed or wells and support reagents become insufficient in volume/number.

NOTE Specimens may not be processed in the order that they are loaded in the cassette or were scanned. The CellMek SPS will determine the order of processing for high workflow efficiency.

The specimen tube barcode is scanned by an internal tube scanner when it moves from the input buffer to the tube rocker. When a specimen tube is ready to be pierced, the system will evaluate if there are sufficient available resources (reagents and reaction plate wells) to prepare the sample. The system will also evaluate if there is sufficient volume available in the waste container to process the sample. If there are insufficient resources available or if there is insufficient waste volume available, the specimen will be skipped and the system will attempt to process the next specimen. The user will be notified that the specimen was skipped and the reason.

-
- 10** While the system is processing samples, more specimens may be added for sample processing following the steps outlined above.
Since the system is already processing, it is not necessary to select **Play** icon again unless the **Pause** icon is visible. If the **Play** icon is visible, select **Play**.
-

Deleting Specimen Requests

IMPORTANT Scheduled panels in the rocker cannot be cancelled.

- 1** Select the **X** next to the specimen that you want to remove in the Load Specimen screen.
The system must be in **Pause** state (the **Play** icon is visible).
-

Pausing Processing

Processing of specimen cassettes that are loaded in the STM but have not yet been transferred to the tube rocker can be stopped at any time by pressing **Pause** on the Home menu.

Samples that are in-process and specimens loaded in the tube rocker will not be stopped when **PAUSE** is pressed. However, the next cassette will not be transferred to the rocker after the current cassette is completed.

Processing of the cassettes waiting in the input buffer will resume when **Play** is pressed.

Pausing allows users to make changes to the panel assignments for cassettes that have not yet been loaded onto the tube rocker.

Pause Processing Specimens

- 1 Select  to pause processing samples.
 - 2 Select .
 - 3 On the touchscreen, swipe to the left or right to find the desired Specimen ID.
 - 4 Use the Panel Assignment screen to make changes.
-

Resume Processing Specimens

- 1 Select  to resume processing samples.
-

Ejecting Cassettes

To eject cassettes from the input buffer to the output buffer without processing, press  on the  menu.

All specimens in the cassette located in the tube rockers will continue to be processed.

The completed cassette in the tube rocker will be ejected and then all the remaining unprocessed cassettes from the input buffer will also be ejected.

The output buffer must be empty to be able to eject the cassettes.

Aborting Instrument Actions

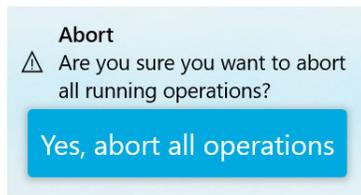
At any time during sample processing, the user may select the abort icon to stop all the samples being prepared, see [Abort Cassettes](#). This will also stop Startup and Shutdown. Any samples that were already completed and taken to the output carousel can be taken to the flow cytometer for analysis. All samples that were still in process, such as in the reaction plate or cell wash, will be aborted. The cassette that was in the tube rocker when the abort icon was pressed will be ejected; but all other cassettes that are in the input buffer will remain there.

After an abort is performed, the system will be in **Error** state and the halo will be red. To restore the system, see [Restoring the System](#).

Abort Cassettes

- 1 Select  .

A message will be displayed “Are you sure you want to abort all running operations?”



- 2 Select  to abort all operations.
-

Restoring the System

- 1 Select  the on the status bar.

The system will check for errors and attempt to return to the **Ready** state. This is displayed on the status bar on the bottom of the screen.

If it doesn't return to ready state, review the Notifications in the software  and follow the instructions provided. If that doesn't not resolve the problem, see [CHAPTER 7, Troubleshooting](#) for more instructions. If the problem persists, [contact us](#).

- 2 Go to the Status screen to see the status of your samples.
-

Loading Output Samples Tubes

At any time during sample processing, you may exchange an output tube carousel. The carousel should contain sufficient barcoded output tubes to process at least one full panel.

CAUTION

Risk of sample misidentification or erroneous results if order of sample analysis panels does not match the samples in the output carousel. The CellMek SPS may rearrange the order of panels to achieve efficient workflows, therefore the order of panels in the output carousel will not always match the order of specimen loading. To avoid samples run in the wrong order:

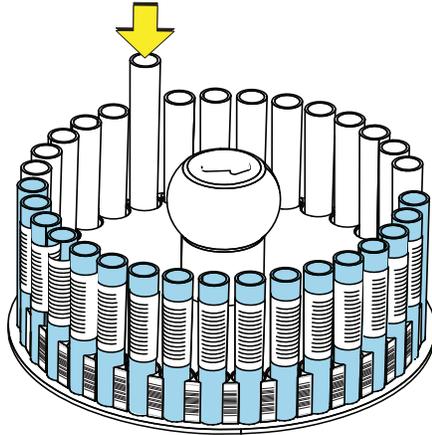
1. Use the Worklist created by the CellMek SPS to transfer sample information to the flow analyzer. For more information [Setting Up the Worklist](#), see [CHAPTER 6, Worklist Setup](#).
2. If Worklists are not utilized in the laboratory workflow, use the human readable (HTML) worklist created by the CellMek SPS to manually enter sample information to the flow analyzer. The human readable (HTML) worklist can be opened with any web browser.

Loading an Output Tube Carousel

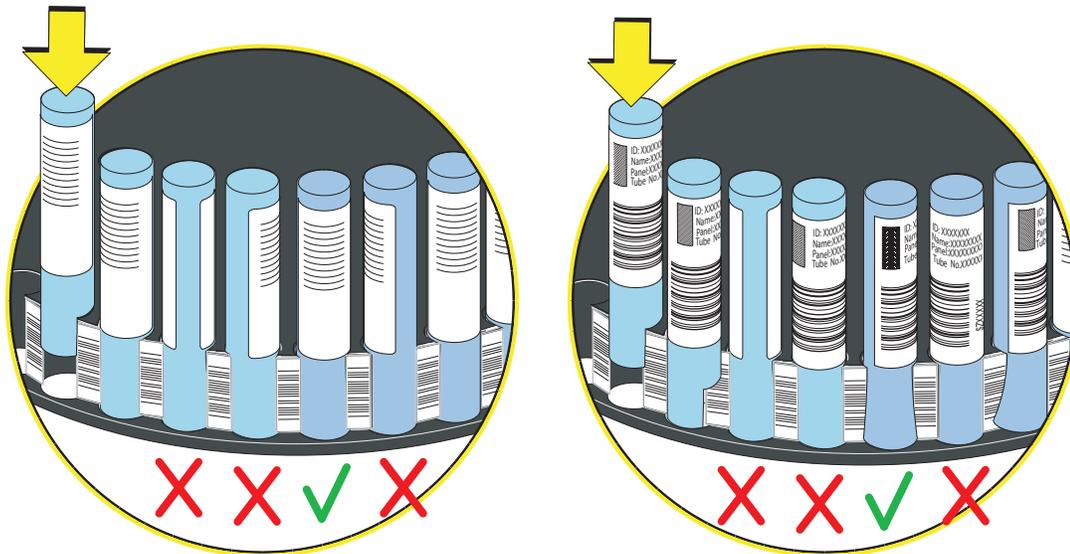
IMPORTANT If you are not using output tubes provided by Beckman Coulter, you should validate your output tubes for proper functioning in the CellMek SPS and your flow cytometer.

- 1 Load sufficient unused barcoded output tubes into an output tube carousel. Tubes that are intended to contain a panel must be contiguous (no empty spaces in between).
 - If output tube mode is set to **Auto Assigned**, ensure that you are using pre-labeled output tubes available from Beckman Coulter or third-party tubes with labels printed per [APPENDIX E, Output Tube Barcode Specifications](#) and [APPENDIX E, Output Tube Identification 1-Dimensional Barcode Label](#). In this mode, the CellMek SPS will transfer panels to the next available output tubes. Refer to [CHAPTER 2, Output Tube Assignment](#) for more information.
 - If the output tube mode is set to **Barcode Assigned**, ensure that the output tubes are labeled per Output tube labels for Barcode Assigned mode. Ensure output tubes within a panel are arranged in the corresponding panel order. In this mode, the CellMek SPS will only transfer panels to the tubes that you have assigned for them. Refer to [CHAPTER 2, Output Tube Assignment](#) for more information.

Figure 4.7 Loading Unused barcoded Output Tubes



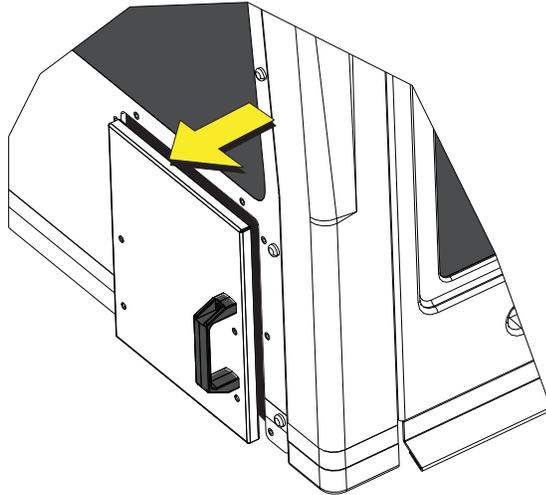
- 2 Load the tubes with the barcode facing outwards. Refer to graphic below for correct orientation (Auto Assigned/Barcode Assigned).



IMPORTANT Selecting Output will generate instrument worklist(s). Ensure your worklist destination is configured and accessible prior to selecting the output button. See [CHAPTER 6, Worklist Setup](#).

- 3 Select  .

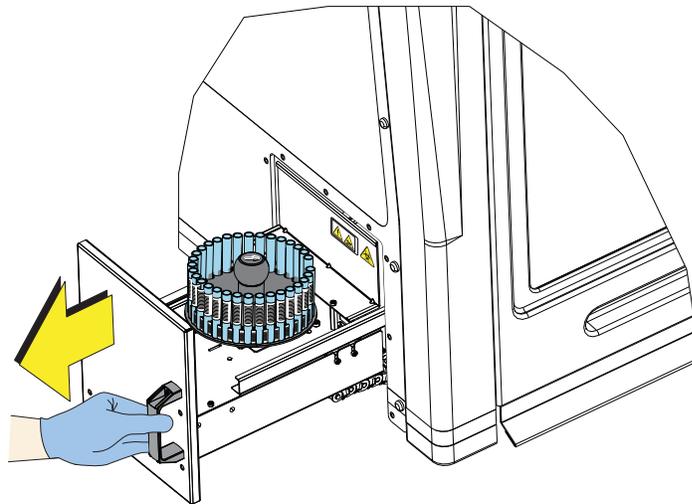
- 4 If the CellMek SPS is not currently accessing the output module, the output drawer will unlock and open slightly. If the output module is busy, the output drawer will not unlock. Wait until the output module unlocks to open it.



NOTE The CellMek SPS will only transfer a prepared panel to the output carousel if there are sufficient tubes available for the entire panel.

Once all the samples in a panel are prepared, if there are insufficient tubes available for the panel in the output carousel, the system will notify the user of insufficient tubes.

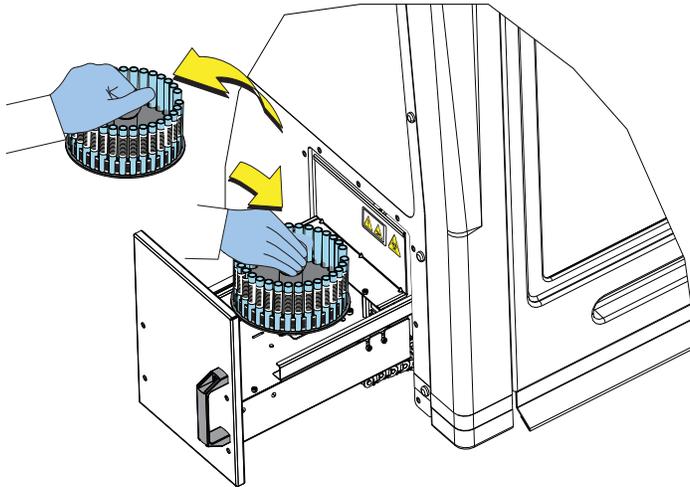
- 5 Holding the handle, open the drawer completely.



WARNING

Risk of erroneous results. After removing the sample carousel from the CellMek SPS for processing in a flow cytometer, do not change the order of the sample tubes in the output carousel.

- 6 Remove the carousel currently in the output modules and replace with the new carousel with sufficient tubes.



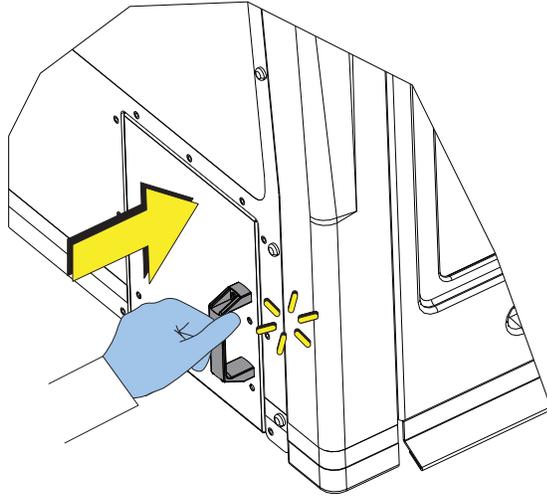
NOTE For any Output Tubes, scanning the 1-D Output Tube barcode with the external scanner will automatically display the Output Tube information screen. Screen will vary if the tube has not been used or has been archived.

Output tube has been used	
Tube ID:	\$N10FQR
Specimen ID:	126556878
Panel:	Ab1
Tube:	Tube 1
Prepared On:	26 Aug 2022 6:56:50 AM
Comments:	Specimen with comments.

OK

IMPORTANT Ensure there is a carousel in the output drawer before closing the door.

7 Close the output drawer until you hear it click in place.



8 The CellMek SPS will scan all the output tubes when the drawer is closed.

Shutdown

This chapter contains information on the following:

- [Shutdown](#)
- [Extended Shutdown](#)



IMPORTANT The CellMek SPS requires a shutdown to be performed within 24 hours after it has completed a Startup and entered the Ready state. For example: If a Startup was completed at 9 a.m., then the system will require a Shutdown before 9 a.m. the next day. Beckman Coulter recommends that you perform a Shutdown after daily system use in order to avoid workflow interruption during the following shift.

 **CAUTION**

Risk of losing in process samples if the waste container becomes full during sample processing. Ensure that the waste container is emptied daily.

 **WARNING**

Risk of personal injury or contamination. To prevent possible injury or biohazardous exposure, always wear proper laboratory attire, including gloves, a laboratory coat, and eye protection.

 **WARNING**

Risk of biohazardous contamination. Clean up any biological spill as quickly as possible. Dispose of all contaminated disposable cleaning materials in accordance with your local regulations and acceptable laboratory practices.

 **CAUTION**

Risk of erroneous results due to reagent spoilage. The liquid antibody refrigerator will shut off after several hours if the CellMek SPS software is not running. To avoid reagent spoilage, ensure that the CellMek SPS software is running after restarting the computer. You can know that the CellMek SPS software is running if the log in screen is displayed and the system says Not Ready.

Cleaning the Cell Wash Module Fluid Pathways



IMPORTANT If the Cell Wash Module was not used, it does not have to be cleaned prior to [Shutting Down the Instrument](#).

WARNING

Risk of personal injury or biohazardous contamination when contacting CellMek SPS including work area components, carousels, cassettes, reaction plates, reagent bottles, and waste container. To prevent possible injury or biohazardous exposure, always wear proper laboratory attire, including gloves, a laboratory coat, and eye protection. Refer to [CHAPTER 1, Material Safety Data Sheets \(SDS/MSDS\)](#) for chemical exposure details.

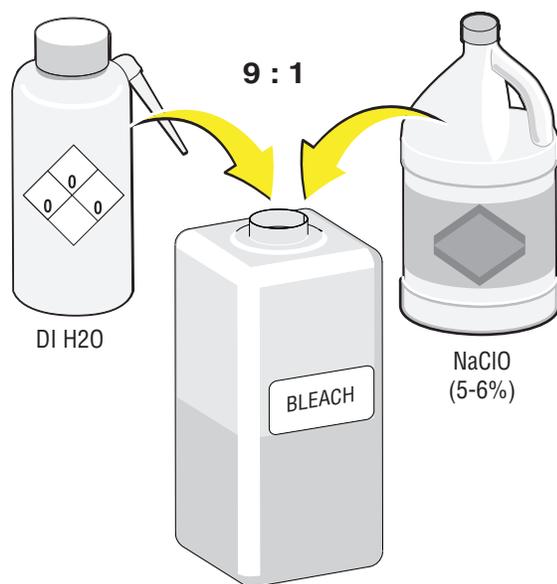
This procedure should be performed prior to shutdown at the end of daily system use if the cell wash module was used to wash samples.

CAUTION

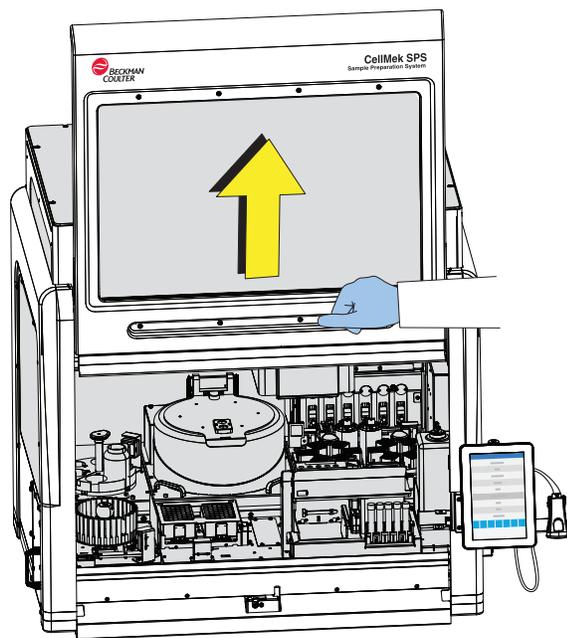
Risk of chemical injury from bleach. To avoid contact with the bleach, use barrier protection, including protective eyewear, gloves, and suitable laboratory attire. Refer to the Safety Data Sheet for details about chemical exposure before using the chemical.

Cleaning the Cell Wash Module Fluid Pathways

- 1 Add 500 mL of a dilution consisting of 9-parts water and 1-part high quality, fragrance-free, gel-free bleach (5 to 6% solution of sodium hypochlorite - available chlorine) to the Cell Wash Fluid bottle; label bottle as the Bleach Solution.

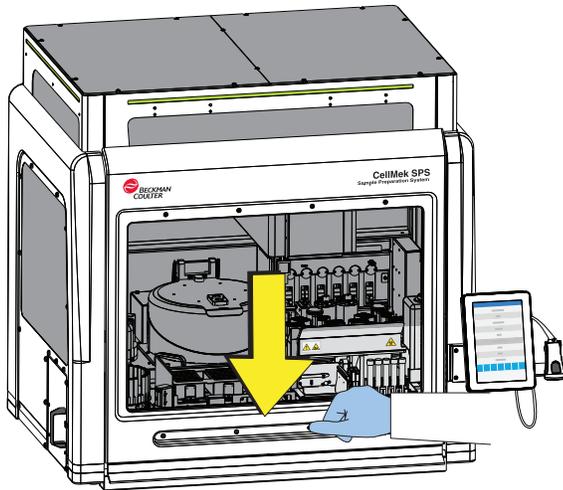


- 2 Open the front door.



- 3 Replace the Cell Wash fluid bottle containing Wash Buffer with the one containing the bleach solution.

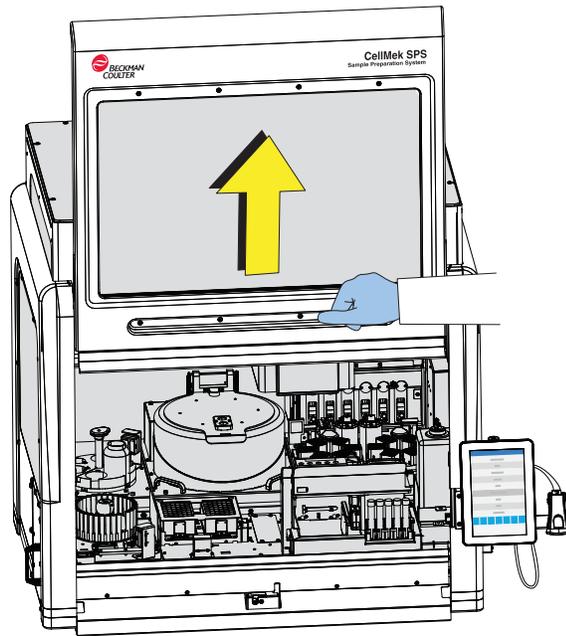
-
- 4 Close the front door.



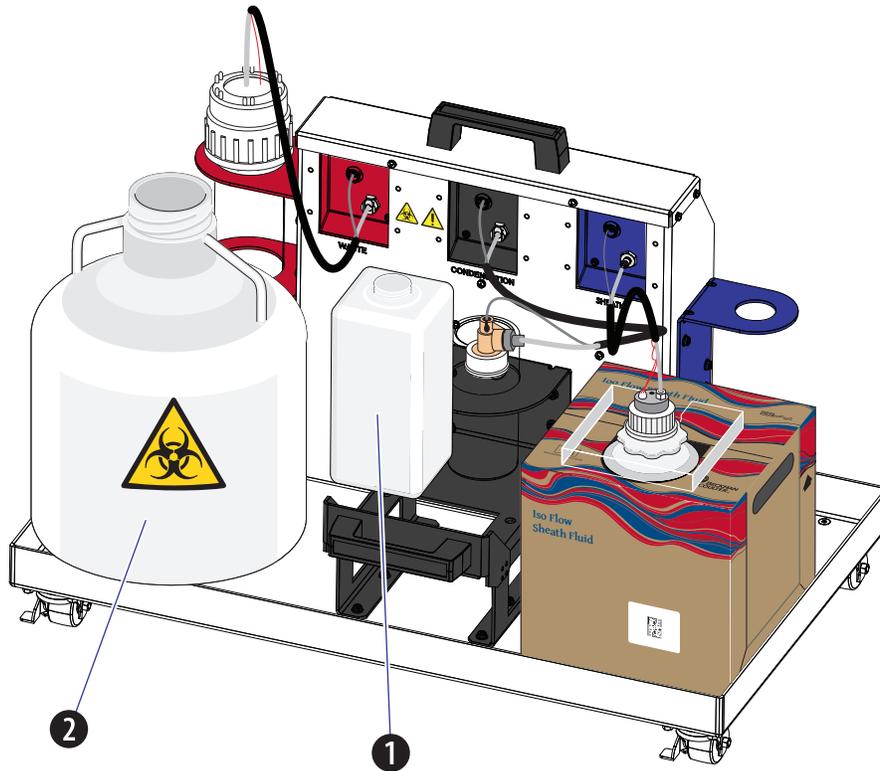
-
- 5 Select **Bleach Solution** when the software prompts the user to select the Cell Wash fluid in the system.
-
- 6 Select **Maintenance**, select **Prime and Clean Cell Wash**.
-
- 7 When the cycle finishes, replace the bleach bottle with a Cell Wash fluid bottle that has at least 500 mL of DI water.
-
- 8 Perform Shutdown, see [CHAPTER 5, Shutting Down the Instrument](#).
-

Shutting Down the Instrument

- 1 Open the front door.



- 2 Empty the condensate and waste containers. See [CHAPTER 9, Replacement Procedures](#) for [Replacing the Waste Container](#) and [Replacing the Condensate Container](#) instructions.

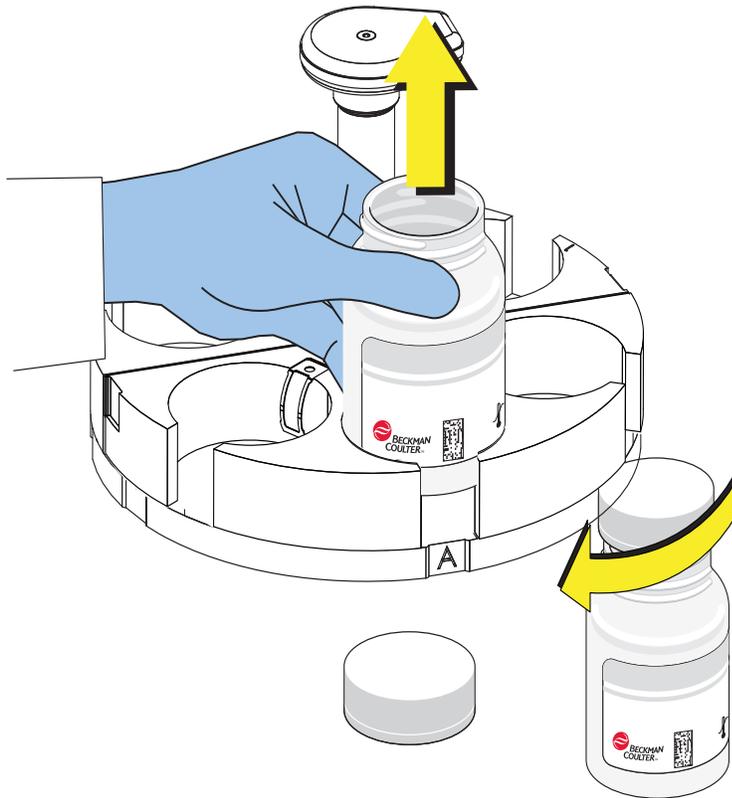


1. Condensate container
2. Waste container

CAUTION

Risk of reagent spoilage if the prep reagents are stored with the cap removed. To avoid reagent spoilage, ensure that the prep reagents are re-capped prior to storage.

- 3 Remove the reagents from the Prep Reagents module, reinstall the caps, and store per the appropriate reagent Instructions for Use.



CAUTION

Risk of reagent spoilage if antibody reagents are stored in the refrigerated antibody module and power is lost. To avoid reagent spoilage, ensure that the system is powered on and connected to an electrical outlet with backup power. Otherwise, store the antibody carousel in a laboratory refrigerator connected to backup power.

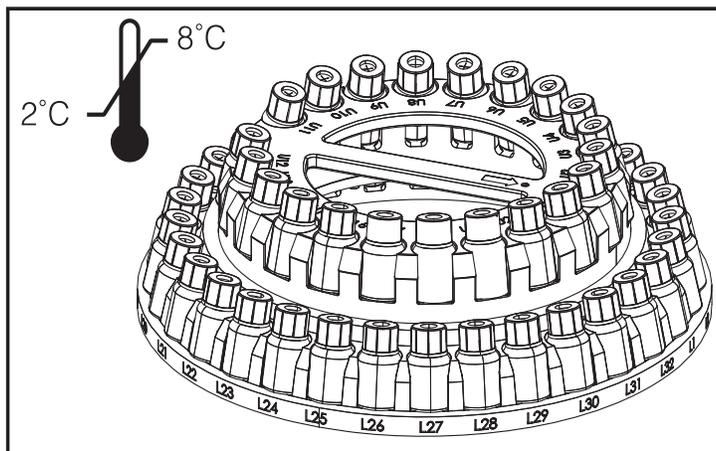
WARNING

Risk of erroneous results if reagent container volumes do not match the volume in the system software. The CellMek SPS keeps track of the volume in each bottle and vial as it is used by the system. The CellMek SPS also keeps track of DURACartridge (dry reagent) wells using reagents in CellMek SPS that have been used to prepare samples outside the system will cause the volume tracking to be wrong. Never use reagents in the CellMek SPS system that have been used to prepare samples manually or in another CellMek SPS system.

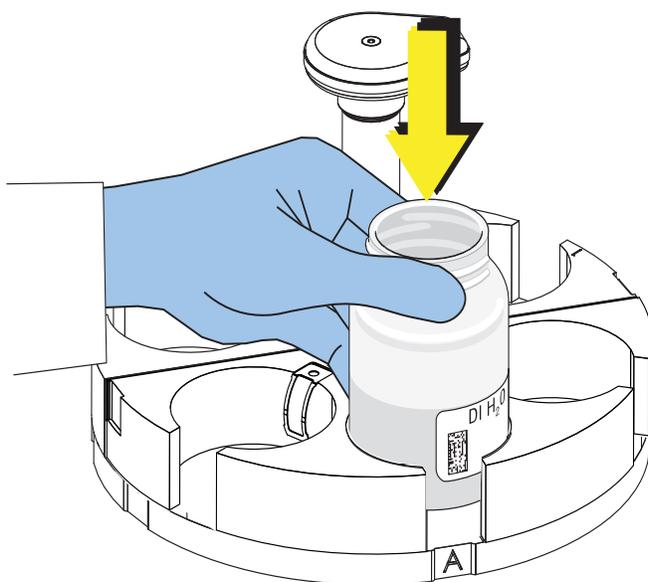
WARNING

Risk of inaccurate counts. To avoid inaccurate counts ensure that if a vial is removed that it is returned to the same system if your laboratory has more than one system. Additionally, if vials are stored in the refrigerator, return the vials to the same system.

- 4 Antibody reagents can be kept on-board on a regular basis. If antibody reagents will be stored off-board, remove the antibody carousel and place in a refrigerator maintained between 2°C and 8°C.



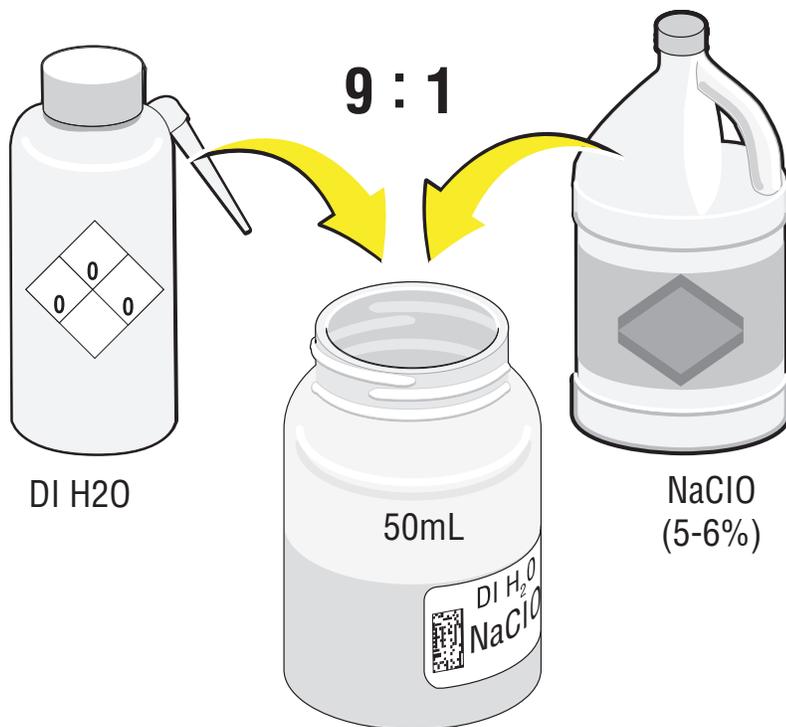
- 5 Add 50 ml of deionized water to the deionized water bottle (about half full). The deionized water bottle should be enrolled in the software as a Custom Defined bottle with a Custom Defined reagent label. For more information on custom defined reagent information, see [CHAPTER 6, Custom Defined Reagents](#).
- 6 Place the deionized water bottle in the Prep Reagents module in one of the positions reserved for Custom Defined reagents. These are all three positions of the Custom Defined reagents adapter and positions 1 and 3 of the Perfix-NC reagent adapter. Ensure that the 2D barcode is visible through the opening in the adapter.



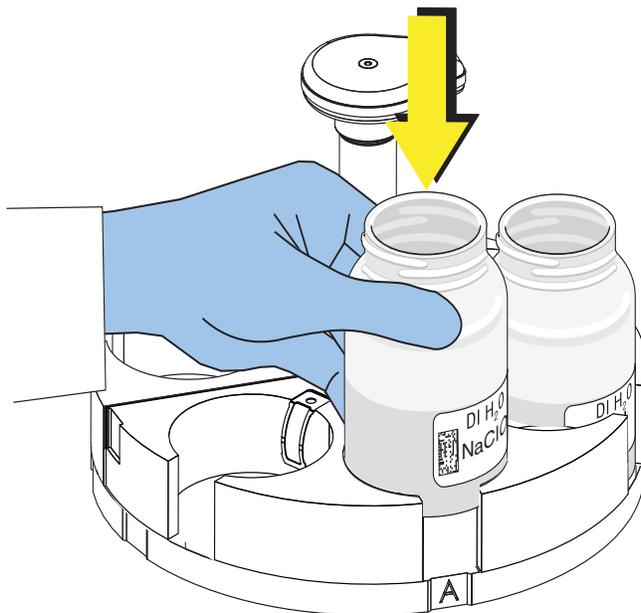
CAUTION

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.

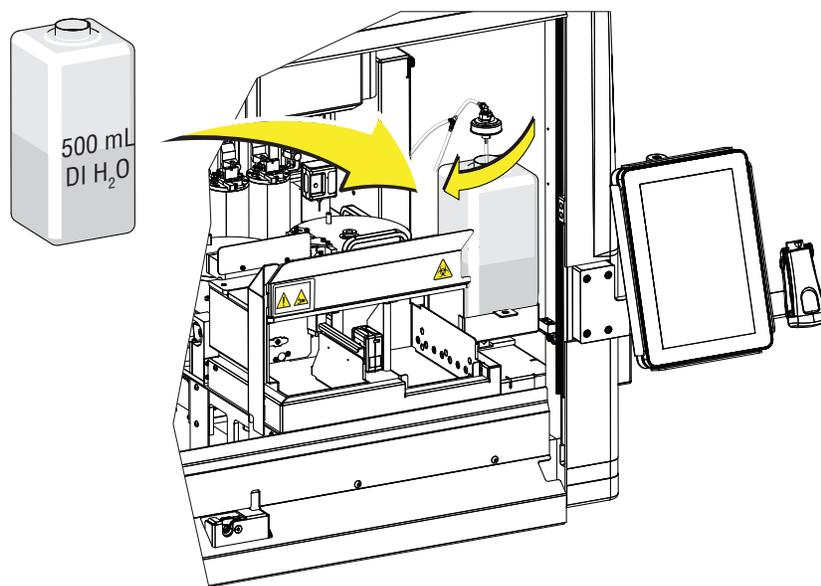
- 7 Prepare 50 mL of bleach solution in the bleach solution bottle (about half full). Bleach solution should be prepared by mixing 1-part bleach (sodium hypochlorite, 5 - 6 % available chlorine) with 9-parts deionized water. The bleach solution bottle should be enrolled in the software as a Custom Defined bottle with a custom reagent label. For more information on custom defined reagent information, see [CHAPTER 6, Custom Defined Reagents](#).



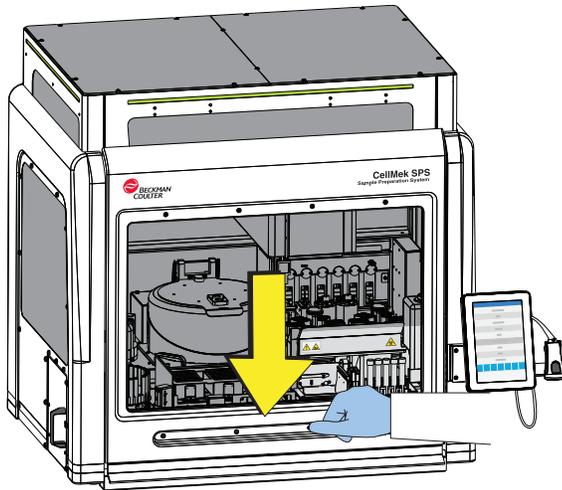
- 8 Place the bleach solution bottle in the Prep Reagents module in one of the positions reserved for the Custom Defined reagents. These are all three positions of the Custom Defined reagents adapter and positions 1 and 3 of the Perfix-NC reagent adapter. Ensure that the barcode is visible through the opening in the adapter.



- 9 If not done previously, replace the cell wash fluid bottle with one filled with at least 500 ml of deionized water. Each bottle will have an individual cap with a quick-connect fitting on top.



10 Close the front door.



11 The system will scan the onboard reagents and will ask you to select the reagent that was added in the cell wash fluid bottle.

12 Select **Deionized Water**.

13 Select  .

NOTE The halo will turn solid Green during Shutdown.

14 The system flashes the halo Amber when the shutdown completes.

 **CAUTION**

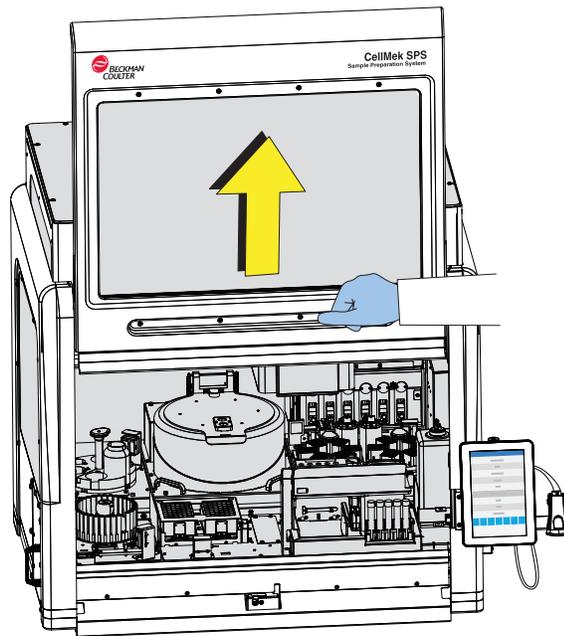
Risk of inaccurate results. To avoid inaccurate results, Beckman Coulter recommends that you create fresh wash buffer daily and thoroughly clean the bottle and cap after use. Some wash buffer formulations may begin to grow bacteria after just a few hours and these may in turn interfere with your flow cytometry results.

15 Discard unused wash buffer following your laboratory's procedure for discarding biological waste.

Extended Shutdown

Perform this procedure whenever the instrument will not be in use for a period of 7 days or longer.

- 1 Perform a regular shutdown, see [Shutdown](#).
- 2 Open the front door.

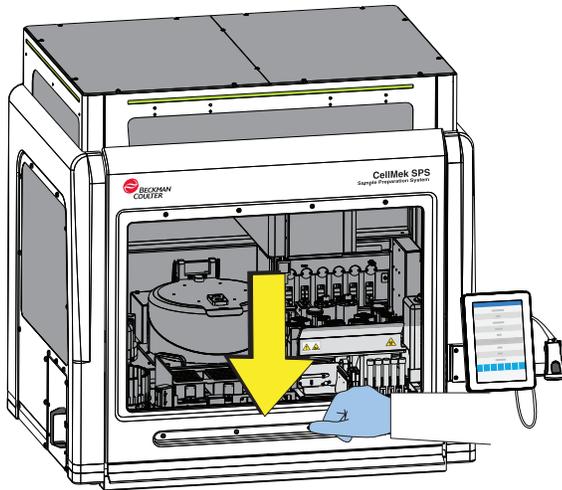


CAUTION

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.

- 3 Remove the bleach and DI water bottles from the prep carousel.
- 4 Remove the liquid antibody carousel and store in a refrigerator.

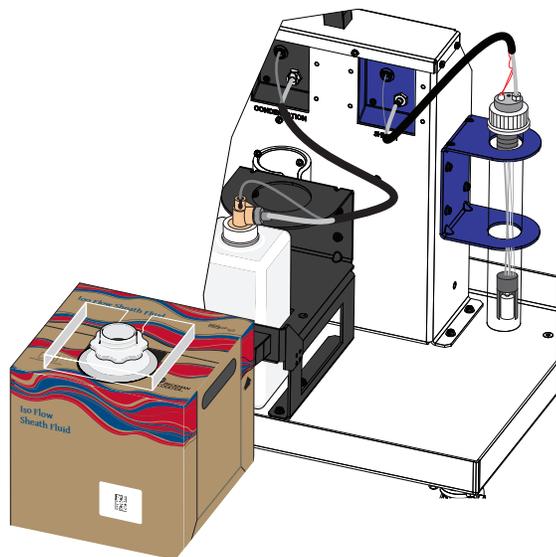
-
- 5 Close the front door.



-
- 6 The system will scan the onboard reagents and will ask you to select the reagent that was added in the cell wash buffer bottle.

-
- 7 Select **Deionized Water** from the reagent screen.

-
- 8 Remove the IsoFlow Sheath cubitainer from the supply cart.



-
- 9 Pour out the IsoFlow Sheath according to your laboratory's procedures and local regulations.

IMPORTANT Use standard laboratory procedures to label the cubitainer as containing deionized water.

- 10** Fill the IsoFlow cubitainer with at least 2 L (or fill about 1/3 of the emptied IsoFlow sheath container) of deionized water and place on the supply cart and insert of the IsoFlow pickup tube inside the container.
-



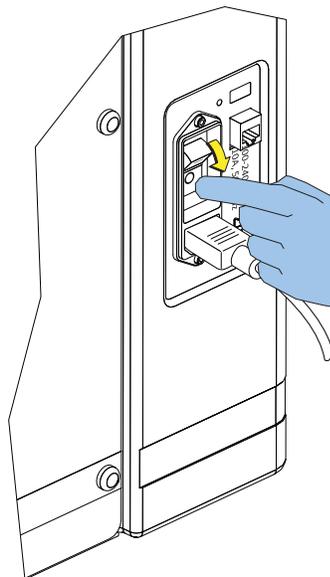
- 11** Select **Check System** to reset the sheath container sensor.
-

- 12** Select **Maintenance**, perform Prime System Probes, see [CHAPTER 6, Prime System Probes](#). The halo will turn solid green during Prime System Probes.
-

- 13** Once the Prime Pod Syringes is completed and is in ready state select **Maintenance**, and select **Prime and Clean Cell Wash**. The halo will turn solid green during **Prime and Clean Cell Wash**.
-

- 14** Select  in the top right corner of the software screen and select **Shutdown Computer**.
-

- 15** Turn off the power switch on the right back side of the system to power off the system.



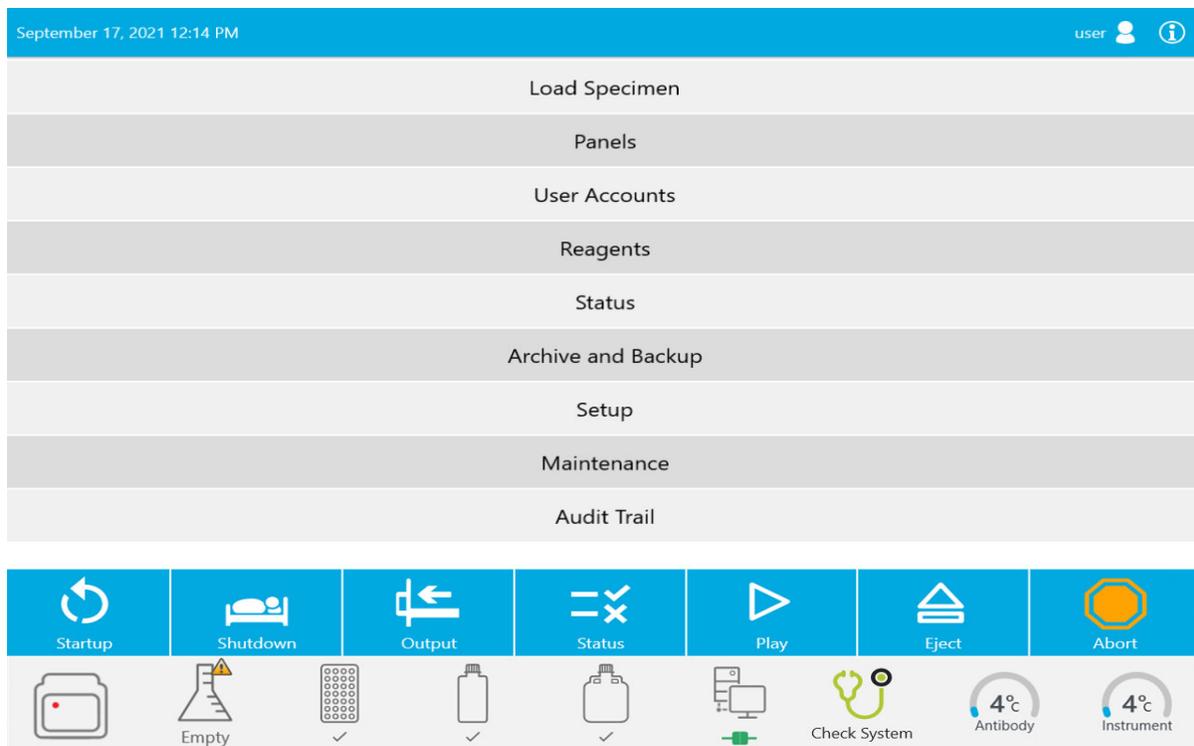
- 16** Empty the waste container, see [CHAPTER 9, Replacing the Waste Container](#).
-

Main Software Screens

This chapter contains information on the following:

- Load Specimen
- Panels
- User Accounts
- Reagents
- Status
- Archive and Backup
- Setup
- Maintenance
- Audit Trail

Figure 6.1 CellMek SPS Software Screen



Load Specimen

For information on the Load Specimen setup screen, see [CHAPTER 4, Loading Specimens](#).

Panels

For information on the Panels setup screen, see [CHAPTER 4, Importing Panels](#).

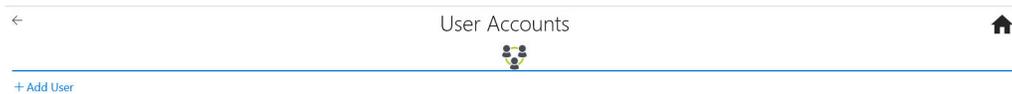
User Accounts

The User Accounts screen ([Figure 6.2](#)) can only be accessed by users with the Manage Users permission. It allows you to add and manage user accounts. Set up users according to your laboratory's policies and procedures for data security. Do not disclose your password to anyone. Use

 to access the User Accounts screen.

NOTE If the user's password expires they will be prompted for a new password when they log in. Passwords expire after 90 days.

Figure 6.2 User Accounts Screen

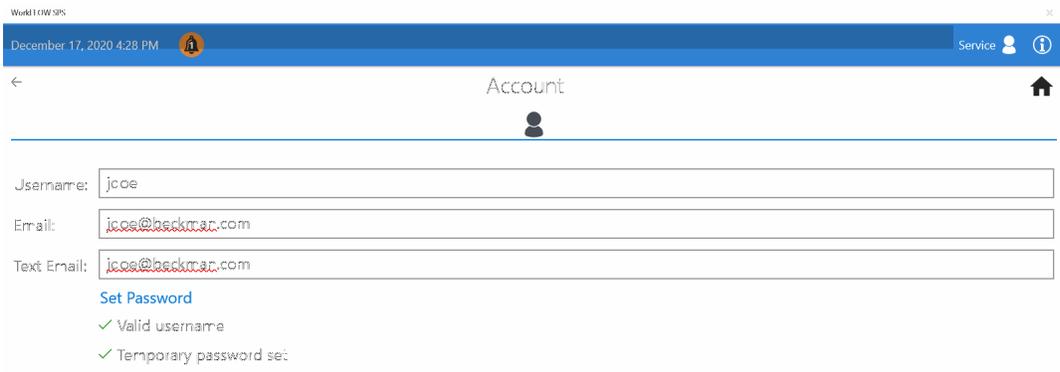


All users can access the Change Password, Change Username and Emails through the  (User Menu) in the upper right of the software while logged in.

Create an Account for Administrator or Operator Accounts

NOTE Only users with the Manage Users permission can add, edit, delete, or disable users.

- 1 Select **+ Add User** and the following screen will be displayed.



Workflows SPS
December 17, 2020 4:28 PM Service ⓘ

Account

Username: jcoe

Email: jcoe@heckmar.com

Text Email: jcoe@heckmar.com

[Set Password](#)

- ✓ Valid username
- ✓ Temporary password set

NOTE Text email addresses are used to send a message via email to your phone as a text message. Contact your provider to obtain the text email address for your phone if you would like to use this feature. If you do not have or want to use a text email, you may leave this field blank.

- 2 Enter Details for the new user (Username)

The password is entered here by selecting **Set Password**. The user is prompted to enter and confirm a new password on their first login session.

IMPORTANT Refer to [APPENDIX G, Password Security](#) for requirements for creating your password.

- 3 Select **Set Password** to setup the temporary password. When logging in for the first time, enter the password twice.

Change Password

Set temporary password

New password

Confirm new password

- ✓ Must have at least 10 characters
- ✓ Must have at least one non alphanumeric character
- ✓ Must have at least one lowercase ('a'-'z')
- ✓ Must have at least one uppercase ('A'-'Z')
- ✓ Must have at least one digit
- ✓ Passwords must match

Save Password

NOTE A red X is displayed next to any requirements that is not met. A green checkmark is displayed next to any requirement that has been satisfied.

- 4 Enter the new password and confirm the password, and select **Save Password**.
- 5 Select **Save** and the new account will be visible.
- 6 Setup the user permissions.

Manage User

- 1 Select **User Accounts**.
- 2 Select the User.

3 Select what the user has access to by selecting the White/Green toggle switch for the following:

- Manage Users
 - Import Panels
 - Publish Panels
 - Access All Panels
 - Manage Reagents
 - Archive and Backup
 - Manage Settings
 - Exit Kiosk Mode
-

Lock User

1 Select **User Accounts** .

2 Select the User.

3 Select **Lock User**.

Unlock User

1 Select **User Accounts** .

2 Select the User.

3 Select **Unlock User**.

Reset User Password

1 Select **User Accounts** .

2 Select the User.

3 Scroll down to Account, which is highlighted in blue.

4 Select **Account**.

IMPORTANT Refer to [APPENDIX G, Password Security](#) for requirements for creating your password.

5 Select **Reset Password** to setup the temporary password.

Change Password

Set temporary password

New password

Confirm new password

- ✓ Must have at least 10 characters
- ✓ Must have at least one non alphanumeric character
- ✓ Must have at least one lowercase ('a'-'z')
- ✓ Must have at least one uppercase ('A'-'Z')
- ✓ Must have at least one digit
- ✓ Passwords must match

Save Password

NOTE A red X displays for requirements that are not met, otherwise a green checkmark will be displayed. The user will have to change their password the next time they login.

6 Enter the new password and confirm the password, and select **Save Password**.

7 Select **Save**.

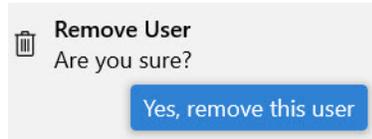
Delete User

NOTE You must have administrator permissions to delete a user.

1 Select **User Accounts**.

2 Select the User.

-
- 3 Select . The *Remove User, Are you sure?* message appears.



-
- 4 Select **Yes, remove this user.**

NOTE User names cannot be reused even if the user was removed.

Reagents

Setup Antibody Reagent Warning Levels

- 1 Select **Reagents**.

-
- 2 Select the antibody reagent to change the remaining volume warning level.

-
- 3 Scroll down to the Warning Level section, and drag the Warning Level bar to the left or right to the desired percentage of starting volume. Moving to the left will lower the warning level, while moving to right will increase the warning level. Moving warning level to 0, removes the warning for this reagent.



NOTE The comment button will only appear for custom defined reagents.

- 4 Select the Comments label to enter any comments.

-
- 5 To change any other antibody reagent warning levels continue with Steps 2 through 4 until completed.
-

Custom Defined Reagents



Risk of erroneous results or instrument damage. Only use reagent vials and bottles provided by Beckman Coulter for custom designed reagents on the CellMek SPS.

Initial enrollment of custom defined reagents establishes a link between a barcoded Product ID and a reagent name. After initial enrollment, whenever the CellMek SPS scans a reagent with the same Product ID, it will associate this reagent with the product name to which it was initially enrolled.

NOTE Beckman Coulter reagents do not require enrollment; their product name and usable volume is downloaded to the CellMek Panel Designer software and the lot number and expiration date are encoded in the 2D barcode.

IMPORTANT Custom reagents must be defined in the CellMek Panel Designer software and transferred to CellMek SPS software before use. See [APPENDIX A, CellMek Panel Designer](#).

For custom defined liquid antibody, lyse, and prep reagents, Beckman Coulter provides preprinted sheets of barcode labels, empty liquid antibody vials, and empty prep reagent bottles.

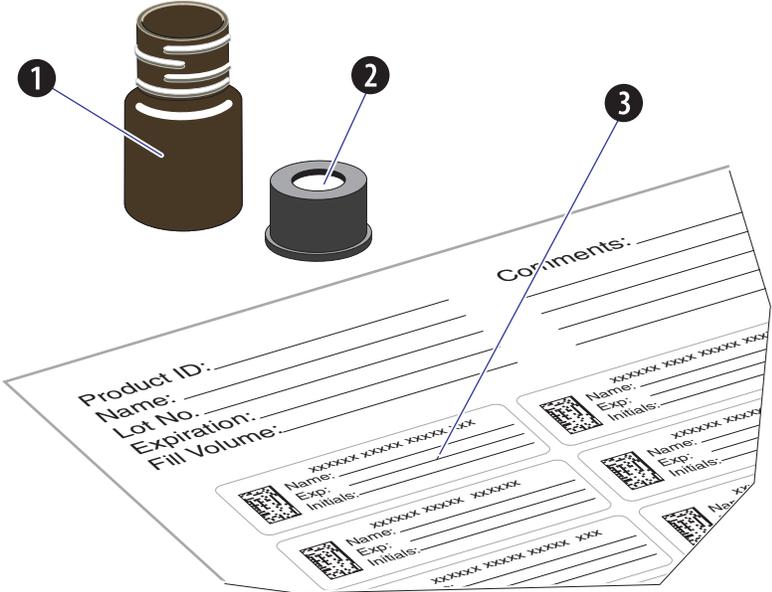
Enrolling Custom Defined Reagent Information

1 Fill a custom antibody vial or prep reagent bottle with the required custom reagent. If filling an antibody vial, place a pierceable cap on the vial. If filling a prep reagent, remove cap before placing the reagent in the Prep Reagent module. The example shows an antibody vial but the same steps apply to custom defined prep reagents.

NOTE Measure and note the volume used to fill the container.

NOTE For custom defined prep reagents, place the barcoded label approximately 13 mm (.5 inches) from the bottom of the bottle.

2 Enter the Name of the Reagent, Expiration Date, Volume and Lot number on the pre-printed custom defined reagent sheets. (If this sheet's product ID had been enrolled, then skip to the next step.)



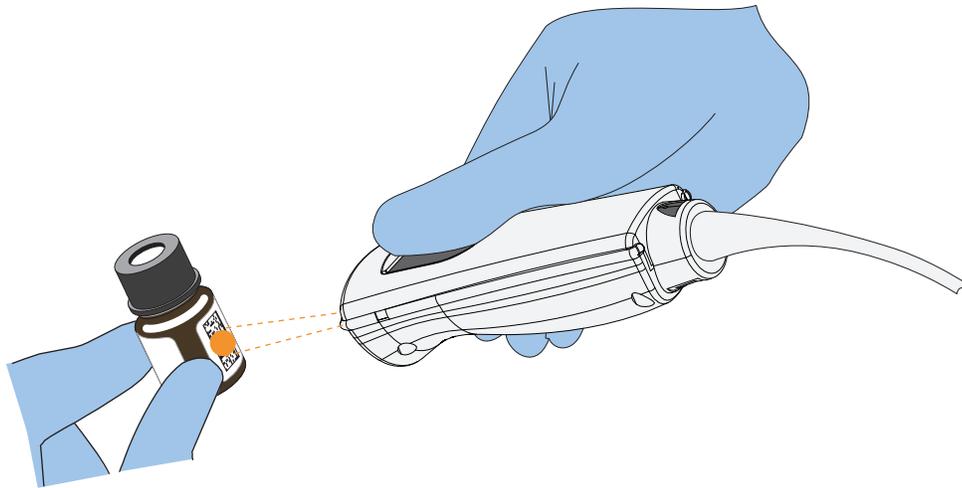
- 1. Custom Defined Antibody Vials
- 2. Pierceable Cap for Antibody Vials
- 3. Preprinted barcode Labels

3 Apply the label to the antibody vial or prep reagent bottle to be enrolled.



NOTE When adding the custom defined reagent pre-printed label to the prep reagent bottle, place the label near or flush with the bottom of the bottle.

-
- 4 Scan the label with the barcode scanner.

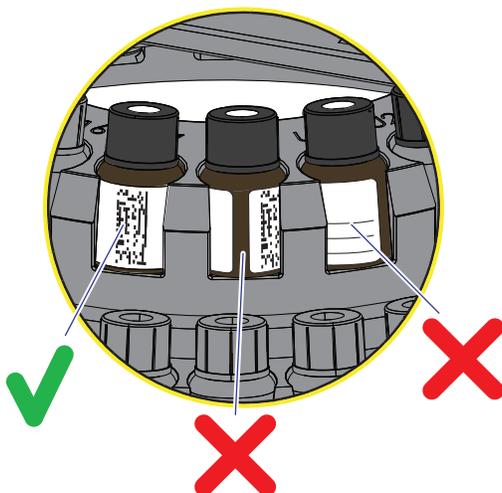


-
- 5 Once the barcode is scanned, it will be displayed on the Custom Defined Reagent screen. Select the Reagent Name (Bleach and DI Water are included as default reagent names) and enter the Expiration, Fill Volume, and Lot Number.

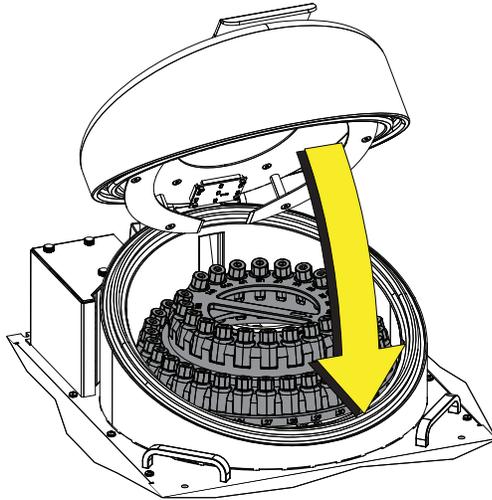
-
- 6 Select **Save**.

-
- 7 Review the Enrollment information and select **Confirm**. If you need to make a change, select the **X** in the upper right-hand corner to close the window. Refer to Step 6.

-
- 8 Place the antibody vial in the carousel with the barcode facing outwards, in either lower or upper deck.

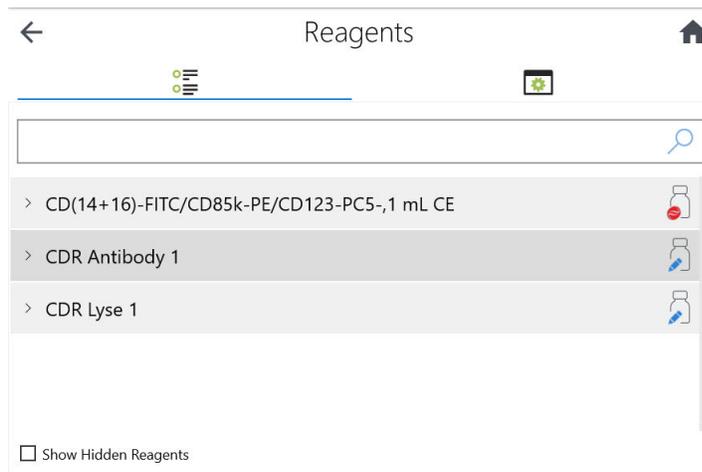


- 9 Close the Antibody Module lid after adding reagents to maintain the reagents at refrigeration temperatures.



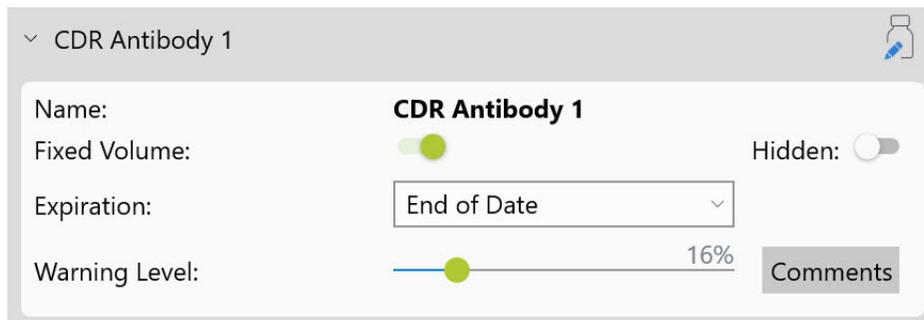
Verifying Custom Defined Reagents

- 1 Select **Reagents** from the main Software Screen.



- 2 Select  or anywhere in the reagent block to see more detailed information on the reagent.

This icon is a custom defined reagent.



CDR Antibody 1

Name: **CDR Antibody 1**

Fixed Volume: Hidden:

Expiration: End of Date

Warning Level: 16%

Comments

NOTE Beckman Coulter Reagents will be displayed with the  icon. It is not necessary to manually scan the Beckman Coulter reagents.

Enrolling Dry Reagent (DURACartridge) Information

DURACartridge (dry) reagents are available through Custom Design Service. DURACartridges must be enrolled in the CellMek SPS before the cartridge can be used.

Enrollment links the barcoded product identification number in DURACartridge label with a Reagent Name.

- 1 Scan the DURACartridge label with the barcode scanner, see [CHAPTER 9, Replacing the DURACartridge Reagents](#).
- 2 Once the barcode is scanned, the DURACartridge Reagent screen will be displayed.
- 3 Use the drop-down menu to select the Reagent Name.
For DURACartridges, the only information entered at the time of enrollment is the Reagent Name. Lot Number and the Date of Manufacture is obtained from the barcode.
- 4 Select **Save**.

Status

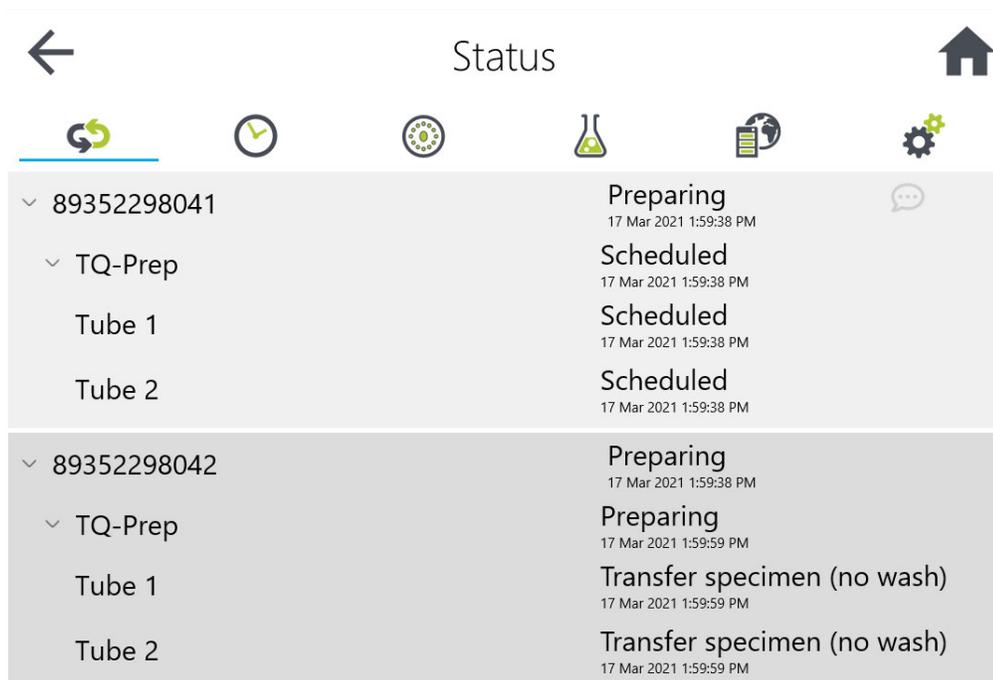
Processing Samples



This screen displays the status of samples that are in-process. **Preparing** shown below means the sample is in the reaction well; while **Completed** means the sample is in the output tube.

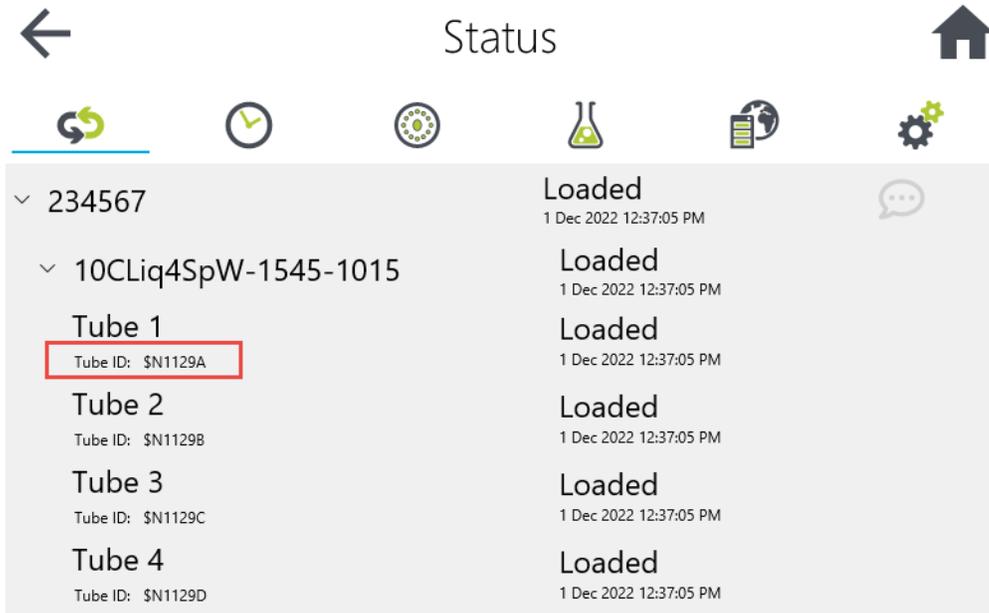
Select  or anywhere in the row to expand the field to provide more details.

When the Output Tube Mode is set to Auto Assigned, the screen will show the samples that are being processed, but it will not show the output tube IDs that will receive the samples. The system will not determine the output tube IDs until the moment immediately prior to transferring the samples from the reaction plate to the output tubes. Refer to the graphic below.



When the Output Tube Mode is set to Barcode Assigned, and the corresponding output tubes have been loaded in the output carousel in their appropriate order, the screen will show the samples that

are being processed and it will show the output tube IDs where the samples will be transferred as shown below.



IMPORTANT All specimen requests in the first tab (Processing Samples tab) are removed after Startup, see [Processing Samples](#). The status is changed to Error and the panel and tube status is skipped.

Any tube that is not scanned by the internal scanner will remain in the Processing Samples screen.

If the barcode is not found on any cassette when scanned in the STM it will be described as Loaded in the Processing Sample screen as shown below.



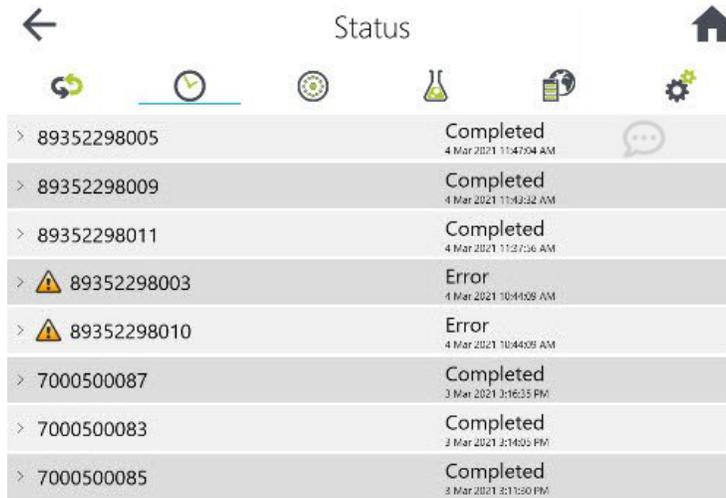
Status of Processed Samples



This displays the status of samples, either completed or with errors. **Completed** shown below means the sample has been transferred to the output tubes.

Select  to display a popup with a list of any run flags or notifications.

Select  or anywhere in the row to expand the field to provide more details.



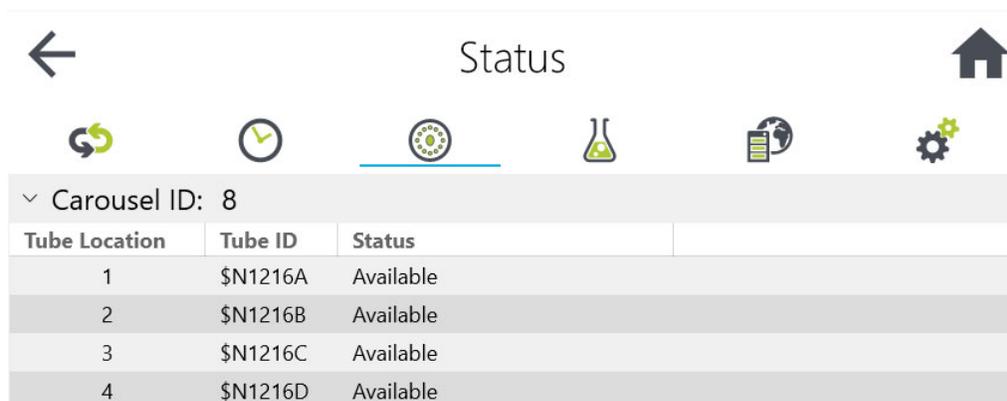
ID	Status	Timestamp
> 89352298005	Completed	4 Mar 2021 11:47:04 AM
> 89352298009	Completed	4 Mar 2021 11:42:32 AM
> 89352298011	Completed	4 Mar 2021 11:27:36 AM
>  89352298003	Error	4 Mar 2021 10:44:09 AM
>  89352298010	Error	4 Mar 2021 10:44:09 AM
> 7000500087	Completed	3 Mar 2021 3:16:35 PM
> 7000500083	Completed	3 Mar 2021 3:14:05 PM
> 7000500085	Completed	3 Mar 2021 3:11:30 PM

Carousel ID and Location List



The Carousel ID and Location List screen shows the Carousel ID and the Output Tube IDs, locations, and status of all the output tubes loaded in the output tube module.

- If the Output Tube Mode is set to Auto Assigned, and if samples have not yet been transferred from the reaction plate well to the output tubes, the status column will only show tubes are “Available”. After the sample has been transferred, the status will update to “Prepared” and will show the Specimen ID, panel name, tube name, status, and comments.



Carousel ID: 8		
Tube Location	Tube ID	Status
1	\$N1216A	Available
2	\$N1216B	Available
3	\$N1216C	Available
4	\$N1216D	Available

- If the Output Tube Mode is set to Barcode Assigned, then the status will show the Specimen ID, panel code, panel name, and tube name obtained from the specimen information 2D barcode in

the output tube. In addition, the status of the tubes (Specimen Not Loaded, In Progress, and Completed) is provided.

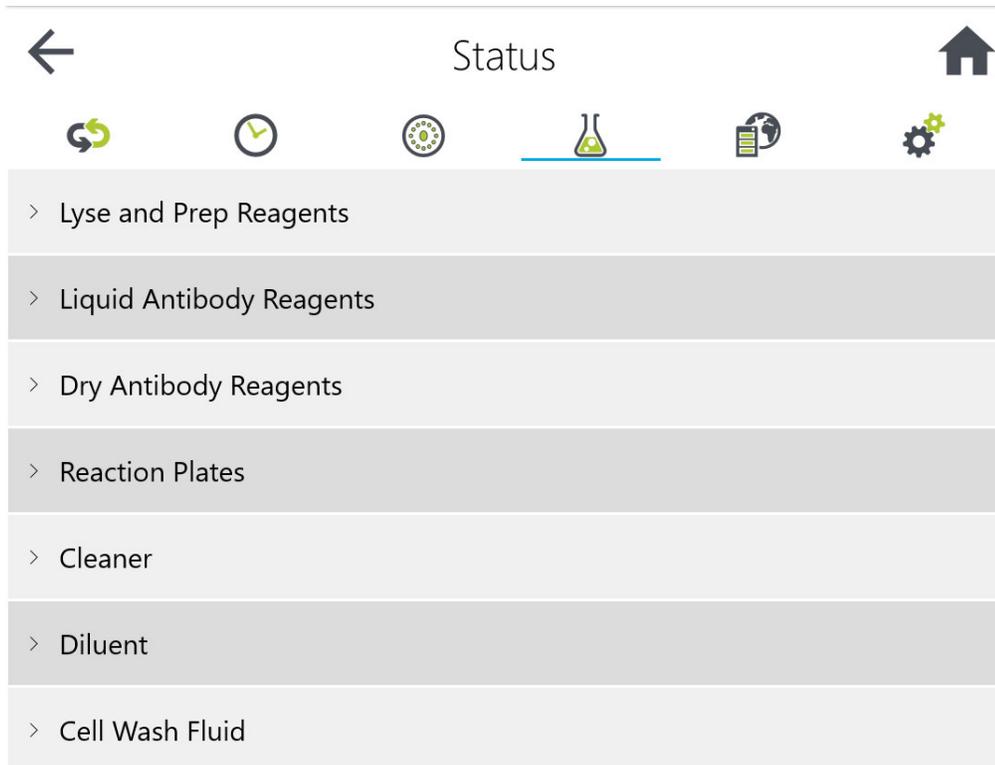
Tube Location	Tube ID	Status
1	\$N1216A	Specimen ID: 234567 Panel Code: LIQ1 Panel: 10CLiq4SpW-1545-1015 Tube 1 Status: In Progress Comments
2	\$N1216B	Specimen ID: 234567 Panel Code: LIQ1 Panel: 10CLiq4SpW-1545-1015 Tube 2 Status: In Progress Comments

Reagent Information



This screen displays the reagent and consumables that are currently loaded in the system.

Select  or anywhere in the row to expand the field to provide more details.



LIS and Incomplete Specimens

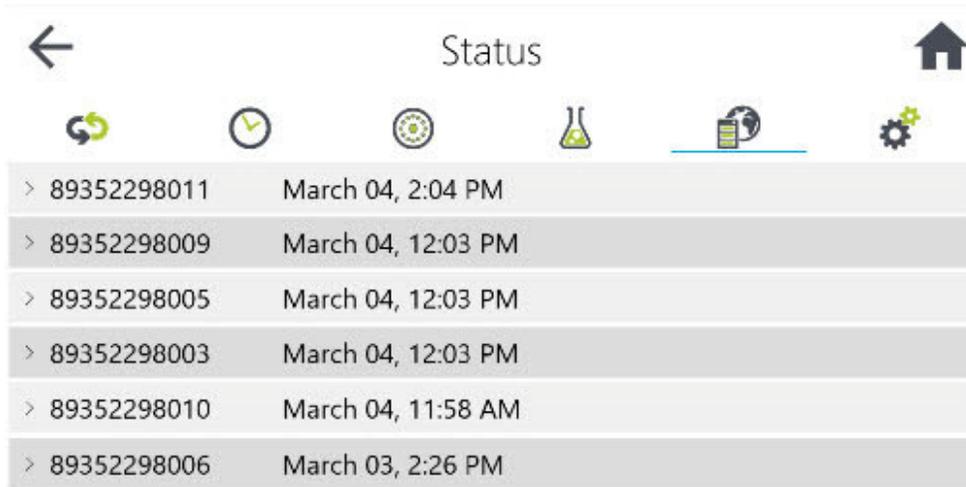


This screen displays the specimens with valid order requests (panels) that were received from the

LIS and specimens that were aborted due to a system error or were ejected using



Select  or anywhere in the row to expand the field to provide more details.



The panels sent in the LIS order request may be accessed in the details screen.



LIS order requests may not be removed from within the CellMek software. Orders will be purged automatically after 30 days. Incorrect order requests may be removed by the LIS sending a cancel request or the order (panel) may be corrected when the specimen barcode is scanned with the external reader.

Instrument Module Status



This screen displays the health status of the instrument modules.

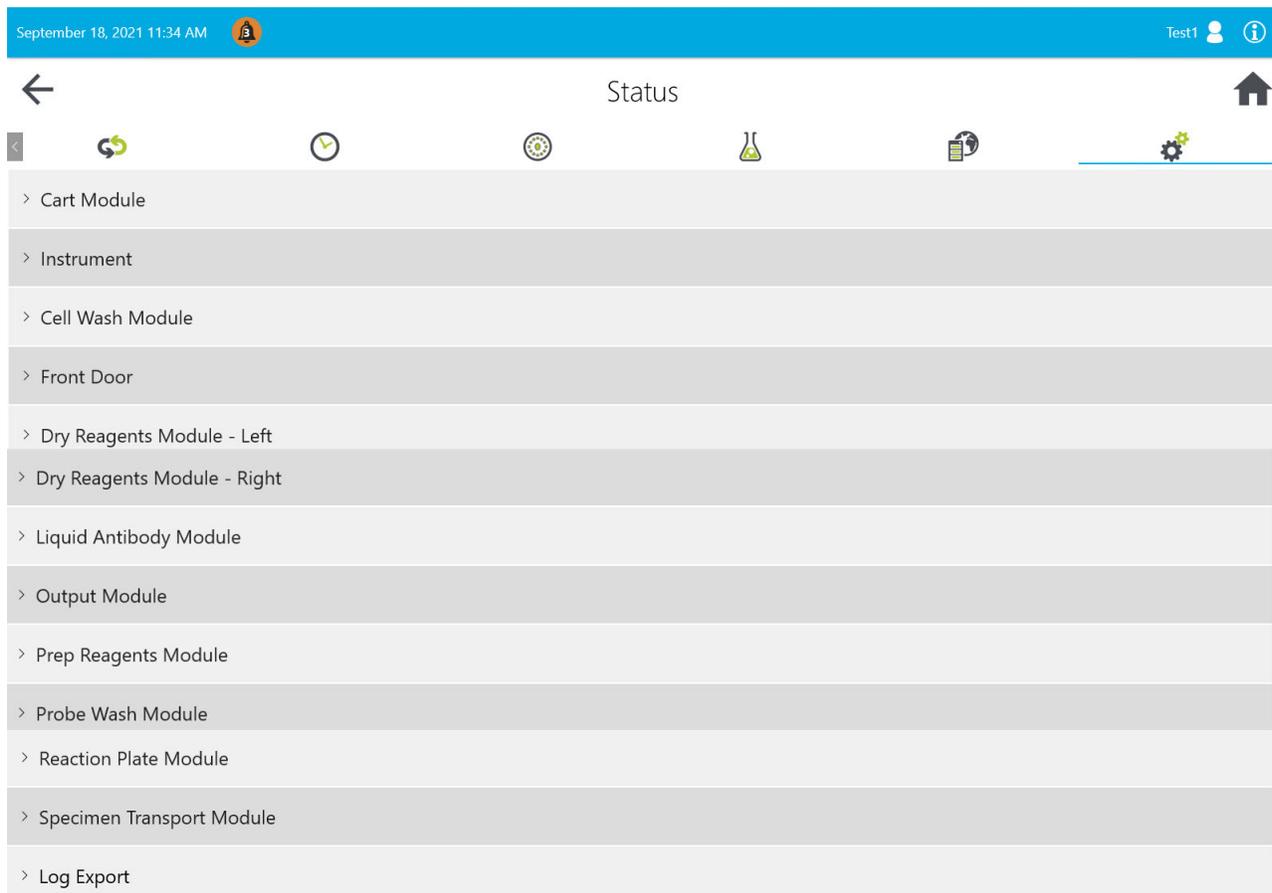
Select  or anywhere in the row to expand the field to provide more details.

The Cart Module, Instrument, Cell Wash Module, Front Door, Dry Reagents - Left and Right, Prep Reagents and Probe Wash Module, Specimen Transport Module display whether the module is working properly. If the modules are not working properly the system displays the errors.

The Liquid Antibody Module displays whether the module is working properly. The user can also export the antibody module temperature data. From the Liquid Antibody Module, the user can export the antibody temperature data. The system retains up to 6 months of temperature data.

The Reaction Plate Module displays whether the module is working properly. The user can also export the instrument temperature data. The system retains up to 6 months of temperature data.

From the Log Export, the user can export the system, scheduler, and hardware logs for service to troubleshoot issues. An encrypted USB will need to be inserted to export these log files.



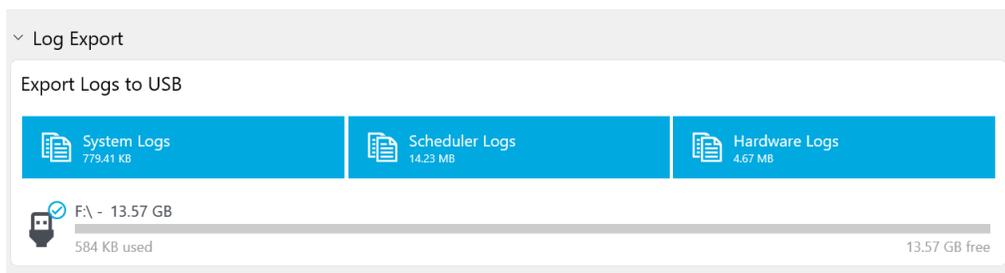
Exporting Logs

- 1 Insert a malware free USB to the CellMek SPS.

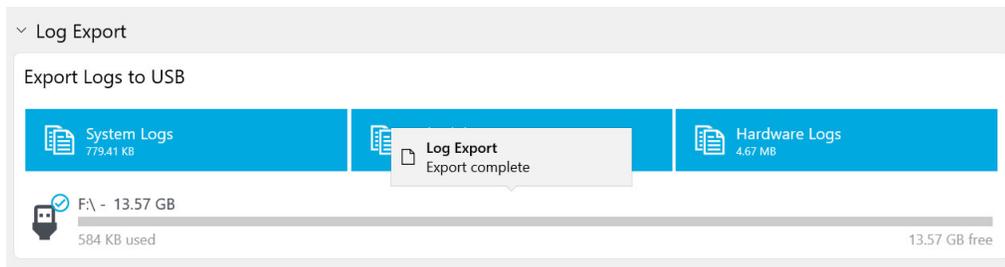
NOTE For information on saving to a BitLocker encrypted USB drive in Kiosk mode, see [APPENDIX G, Using BitLocker Encrypted Media in Kiosk Mode](#).

- 2 Select **Log Export**.

The export screen will display the free space available on the USB and space needed for each of the log exports.



- 3 Select the log type to export to USB and successful message displays.



Archive and Backup

Archiving Data

Archive saves sample runs or audit trail data to a file on an inserted USB drive and deletes the archived data from the database if selected to remove the data. Only sample runs or audit trail data between the From and To dates are archived when All is not selected.

Archive

Time Period

All ~

Contents

Archive runs
 Remove run data after archival

Archive audit trail
 Remove audit trail after archival

Archive

IMPORTANT A USB drive is required to use the archive function.

Archiving History

1 Attach a malware-free USB to the CellMek SPS.

2 Select **Archive and Backup** from the Home screen.

NOTE For information on saving to a BitLocker encrypted USB drive in kiosk mode, see [APPENDIX G, Using BitLocker Encrypted Media in Kiosk Mode](#).

3 Select .

4 Select **Archive** to expand the section.

5 Enter the From and To dates. Runs and/or Audit Trails between these dates, including those dates, are archived.

NOTE Alternatively, you can select ALL. This will grey out the date fields.

 **CAUTION**

Risk of data loss. Archive files contain all the run and/or audit trail data. If this data is removed, the archive files will be necessary to view this information. Ensure the files are transferred to a safe location and kept for the duration required by the laboratory's data retention policy.

6 Select Archive runs.

NOTE If you want to remove the data run after archival, select the **Remove run data after archival** checkbox.

7 Select Archive Audit Trail.

NOTE If you want to remove the audit trail after archival, select the **Remove audit trail after archival** checkbox.

8 Select .

Archive History

1 Select  from the Home screen.

2 Select .

3 Select **Archive History** to see when the data was previously archived. The history displays the date and time the archive was performed, as well as the Username and Record, which includes the location of where it was archived to.



Backing Up Data

Select  to make a backup copy of the software database.



Daily Backup

IMPORTANT Daily Backups can only be saved to a network drive location. Network drive must access must be configured before performing these steps. See [Network Share Configurations](#).

1 Select  to enter you Daily Backup Location.

2 Enter a network location and select **Test** to test the network location to ensure the software can write to that location.



NOTE The Test button will change from gray to **Test** (blue) once you enter a location and the OK button will turn to **OK** blue.

NOTE UNC path or IP must be used to access drive. (i.e. \\server\share or \\192.168.0.1\share). Network drive mapping may not be utilized.

3 Select **OK**.

4 Toggle the toggle switch to on to enable the daily backup.

NOTE If this is not on, the Daily Backup will not be performed.

Manual Backup

1 Select **Archive and Backup** from the Home screen.

2 Select .

3 The instrument should not be in **Processing** state.

4 Ensure that a malware-free USB drive is attached with free space.

NOTE For information on saving to a BitLocker encrypted USB drive in kiosk mode, see [APPENDIX G, Using BitLocker Encrypted Media in Kiosk Mode](#).

5 Select  to start the manual backup.

6 The backup will begin.

Backup History

1 Select **Archive and Backup** from the Home screen.

2 Select .

3 Select **Backup History** to see when previous backups were created by Date and Time, Username and Record which includes the location of where it was backed up.

Backup History		
Date and Time	Username	Record
29 Mar 2021 2:05:02 PM	Marvin	Backed up database successfully to USB Drive: \CellMek \EP00019_20210329140451.wfsb.
29 Mar 2021 2:08:55 PM	Marvin	Backed up database successfully to USB Drive: \CellMek \EP00019_20210329140845.wfsb.

Restoring Database

Restoring your database is only performed by Service Personnel, [contact us](#) if you need assistance with this function.

Setup

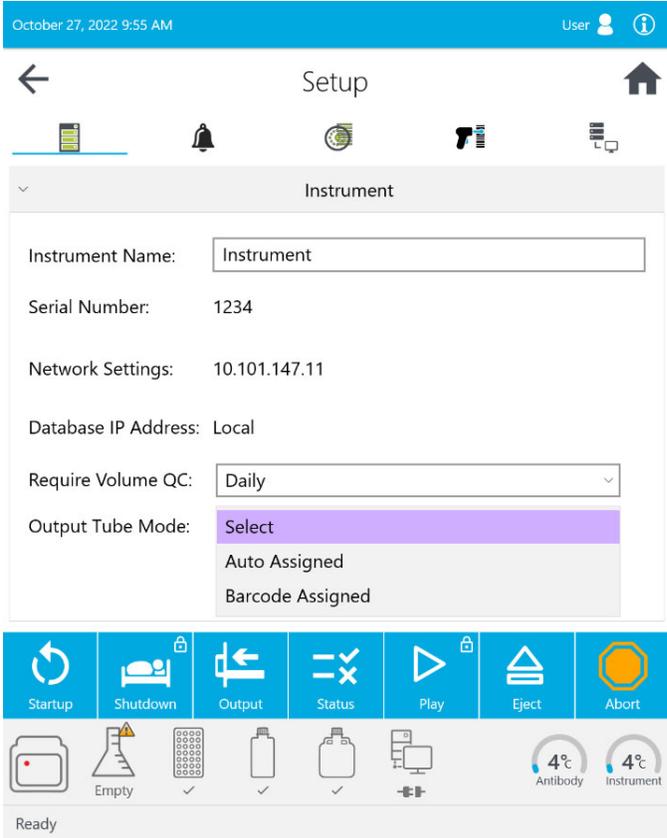
The System Setup screen defines the system preferences throughout the software. You must be logged in as a user with the Manage Settings permission to make changes to the setup screen. Other users cannot view the settings.

The System Setup screen allows you to configure the software settings including instrument name, alerts, worklists, barcodes, and LIS settings.

View Instrument Serial Number, Setup Frequency of Probe and Syringe Volume QC and Select Output Tube Mode

1 Select **Setup**.

2 Select  and Instrument screen displays as shown below.



October 27, 2022 9:55 AM User

Setup

Instrument

Instrument Name: Instrument

Serial Number: 1234

Network Settings: 10.101.147.11

Database IP Address: Local

Require Volume QC: Daily

Output Tube Mode: Select

Auto Assigned

Barcode Assigned

Startup Shutdown Output Status Play Eject Abort

Empty Antibody 4°C Instrument 4°C

Ready

NOTE Only a Beckman Coulter Representative can change the serial number. The serial number can be found on the instrument serial number plate or the supply cart serial number plate.

3 Select **Daily** or **Weekly** under Require Volume QC field.

4 Select **Auto Assigned** or **Barcode Assigned** under Output Tube Mode. Refer to [CHAPTER 2, Output Tube Assignment](#) for an explanation of the output tube modes.

The following message appears if the output tube mode has not been selected prior to loading the sample cassette.

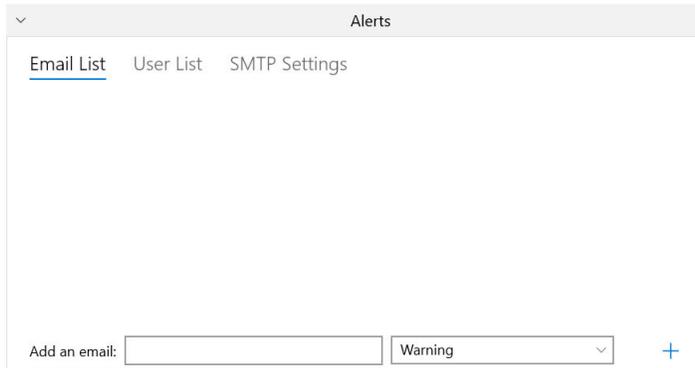
Output tube mode must be set before loading cassettes. Set the output tube mode in the Setup Screen.

Alerts

The alert list is used to notify the user of any notifications.

1 Select **Setup**.

2 Select  and Alert screen displays.



The screenshot shows the 'Alerts' screen with three tabs: 'Email List', 'User List', and 'SMTP Settings'. The 'Email List' tab is selected. Below the tabs, there is a form to add an email. It includes a text input field for the email address, a dropdown menu currently set to 'Warning', and a plus sign button to the right.

3 Enter an e-mail address and choose the level of message and select the + button.

The E-mail List allows the user to specify an e-mail to send notifications to. An alternative to the email list, the User List tab allows for selection of users to notify. The emails in the user account will be used for notifications.

The Level of Message is: **All Notifications** (Information, Warnings, Error); **Warning** (All warning and error notification); **Error** (Only Error Notifications).

4 Configure the SMTP e-mail server settings that should be used to send e-mails from the CellMek SPS e-mail notifications to users or e-mails on the E-mail List and User List.

- a. Enter the SMTP Server.
- b. Enter the SMTP Port.
- c. Enter the SMTP Username.
- d. Enter the SMTP Password (if required).
- e. Enable TLS/SSL if the e-mail server requires this feature.
- f. Enter the Test E-mail Address.

g. Select **Apply**.

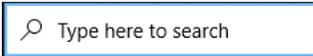


Network Share Configurations

NOTE Use the instructions below to configure network drive access for the CellMekKiosk user.

Saving Network Credentials

- 1 Exit the Kiosk mode, see [APPENDIX G, Exiting Kiosk Mode](#).
- 2 Open My PC (file explorer) and navigate to C:\windows\system32\cmd.exe.
- 3 Hold **(Shift)** and right-click on cmd.exe and select **Run as different user**.
If you do not have a keyboard and mouse, follow the instructions below.

- a. Select  on the task bar.
- b. Tap the search field to open the keyboard.

- c. Type **OSK**.
- d. Select **On-screen Keyboard** and this will open a new keyboard.
- e. Select **(SHIFT)** on this keyboard.



- f. Long press (press and hold until a square appears) and open C:\windows\system32\cmd.exe.

- g. Select **Run as different user**.

- 4 Login as CellMekKiosk. Enter username CellMekKiosk and the password configured for CellMekKiosk, see [APPENDIX G, Changing Your Windows Password](#) or use the default password *cellmekkiosk*.



- 5 Enter the command below and press **(Enter)**. This will cache network credentials for network drive use for the kiosk user.

Cmdkey /add:{network share server name or IP} /user:{"username"} /pass:{password}

Example: ***cmdkey /add:Flowfiles /user:testuser /pass:password*** or

cmdkey /add:192.168.1.100 /user:testuser /pass:password

You will receive the message ***CMDKEY: Credential added successfully*** if the credential is saved.

NOTE If domain user credentials are necessary to access the share, the domain name must be entered as part of the user parameter.

Example: ***cmdkey /add:Flowfiles /user:domain1\testuser /pass:password***

- 6 Close the command windows and login as *CellMekKiosk*.

Removing Network Drive Credentials

- 1 Repeat Steps 1 - 4 from [Saving Network Credentials](#).

- 2 Enter the command below and press enter. This will cache network credentials for network drive use for the kiosk user.

Cmdkey /delete:{servername}

Example: ***cmdkey /delete:flowfiles***

You will receive the message **CMDKEY: Credential deleted successfully** if the credential is removed.

Worklist Setup

This section is for configuring your Worklist Export preferences, for information on importing your instrument worklist into your cytometer software, refer to the cytometer Instructions for Use manual.

1 Select **Setup**.

2 Select  and Worklist options displays.



3 Under **Format**, select Navios/Navios EX, DxFLEX or/and Human Readable (HTML) using the toggle switch.

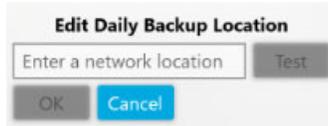
NOTE The human readable worklist provides an HTML worklist that can be viewed by the user using a standard web browser.

NOTE [Contact us](#) to confirm if the DxFLEX is available in your geography.

4 Under **Destination**, select either USB using the toggle switch or enter the Network Location.

IMPORTANT Network drive access must be configured before performing these steps, see [CHAPTER 6, Network Share Configurations](#). UNC path or IP must be used to access drive. (i.e. \\server\share or \\192.168.0.1\share). Network drive mapping may not be utilized.

- 5 If instrument worklist will be exported to a network location, select **Test** to test the network location to ensure the software can write to that location.



NOTE The Test button will change from gray to **Test** (blue) once you enter a location and the OK button will turn to **OK** blue.

- 6 If exporting to USB, ensure a USB drive with free space is attached to the CellMek SPS.

NOTE For information on saving to a BitLocker encrypted USB drive in kiosk mode, see [APPENDIX G, Using BitLocker Encrypted Media in Kiosk Mode](#).

Barcode Checksum Option

- 1 Select **Setup**.

- 2 Select  and the barcode screen displays.



- 3 Select the toggle switch for **Code 39 Checksum**, **Codabar** or **Interleaved 2 of 5 Checksum Options** to enable checksum check for the barcode symbology. Beckman Coulter recommends to use checksums for barcodes when available. If the checksum option is off for **Interleaved 2 of 5**, a barcode length must be set.

LIS Setup

The LIS connection on the CellMek SPS is only used to receive panel orders from a Laboratory Information System (LIS) and specimen draw and patient information.

The CellMek SPS (Client) will only connect to the LIS (Server) when the CellMek SPS software is open. A user does not need to be logged into the CellMek SPS software for the LIS connectivity to be established.

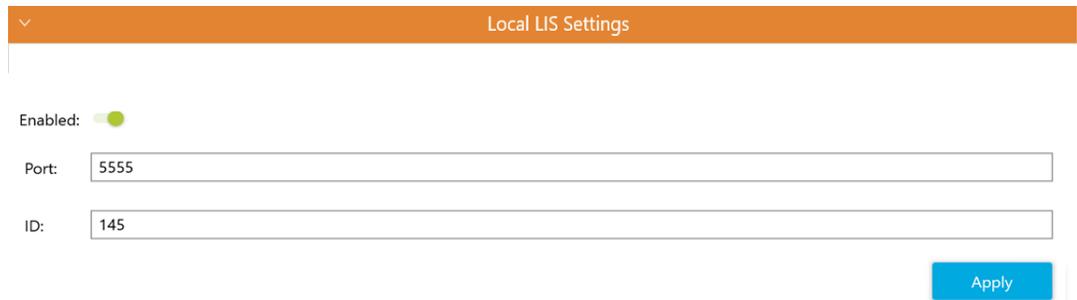
Setting Up Local LIS

1 Login to the CellMek SPS software as a user with **Manage Settings** to alter settings. See [Create an Account for Administrator or Operator Accounts](#).

2 Select **Setup**.

3 Select  from the Setup menu bar.

4 Select **Local LIS Settings** to begin setting up LIS and the screen displays. See [Table 6.1](#).



- a. Enter the Port and ID number.
- b. Select Enabled button to turn on the LIS feature.
- c. Select .

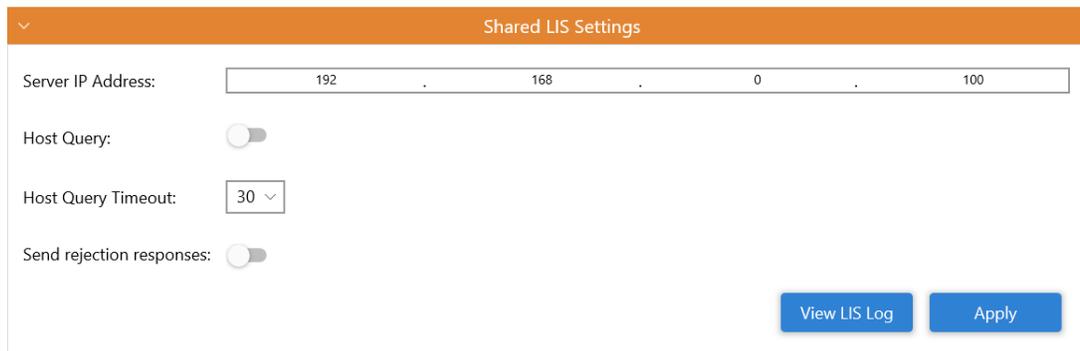
Table 6.1 Local LIS Settings

IP Port — Specifies the port number on the LIS (server) available for the incoming connection from the CellMek (client).

ID — This number is used to identify CellMek SPS workstations when more than one is present.

Setting Up Shared LIS Settings

- 1 Login to the CellMek SPS software as user with **Manage Settings** permission to alter settings. See [Create an Account for Administrator or Operator Accounts](#).
- 2 Select **Setup** from the Home screen.
- 3 Select  icon.
- 4 Select **Shared LIS Settings**, enter LIS server settings and access the LIS communication trace logs. See [Table 6.2](#).



- a. Enter the **Server IP Address** and select the appropriate settings for **Host Query**, **Host Query Timeout** (if applicable), and **Send Reject Response**.
- b. Select  .

Table 6.2 Shared LIS Settings

Server IP Address — Enter the LIS (Server) IP address.

Host Query — If Enabled on CellMek (Client) and LIS (Server), the software transmits a host query request message to the LIS upon scanning a specimen with the handheld scanner. It waits for this test order, if no response is received after the amount of time specified in the Host Query Timeout, the software will consider that the LIS did not send a response and no longer wait for the response.

Host Query Timeout — The number of seconds the software waits for a response from the LIS after transmitting a host query message. If the Host Query is enabled, a host query time out value is required.

Send Rejection Response — If enabled, a rejection message is transmitted to the LIS when an improperly formatted specimen order message is received from the LIS.

Viewing the LIS Trace Log

1 Login to the CellMek SPS software as a user with manage settings permission. See [Create an Account for Administrator or Operator Accounts](#).

2 Select **Setup** from the Home screen.

3 Select  icon.

4 Select **View LIS Log** to view the LIS trace log.



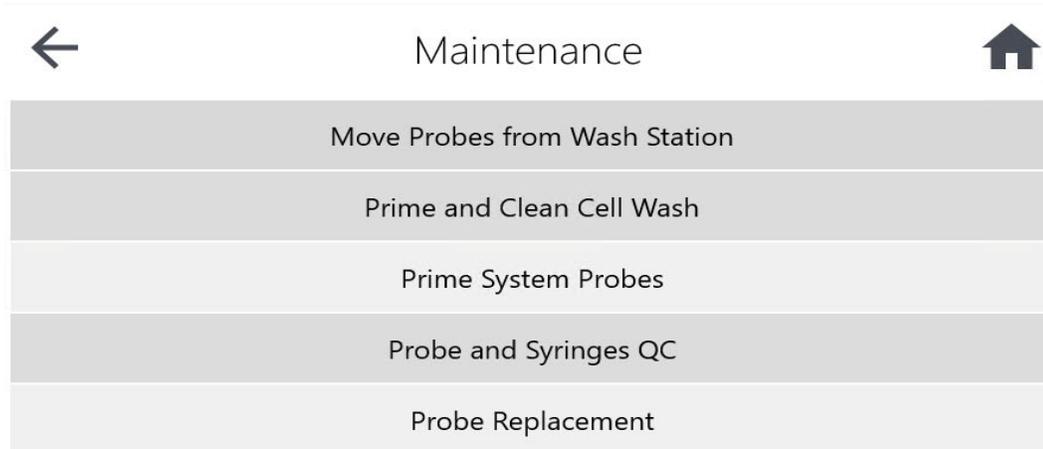
5 Select from available log files base the time stamp range. Logs older than 60 days will automatically be deleted.



Maintenance

The Maintenance screen (Figure 6.3) contains the Move Probes from Wash Station, Prime and Clean Cell Wash, Prime System Probes, Probe and Syringes QC, and Probe Replacement.

Figure 6.3 Screen



Restarting the Computer

 **CAUTION**

Risk of erroneous results due to reagent spoilage. The liquid antibody refrigerator will shut off after several hours if the CellMek SPS software is not running. To avoid reagent spoilage, ensure that the CellMek SPS software is running after restarting the computer. You can know that the CellMek SPS software is running if the log in screen is displayed and the system says Not Ready.

- 1 Enter the Username and Password at the login screen.

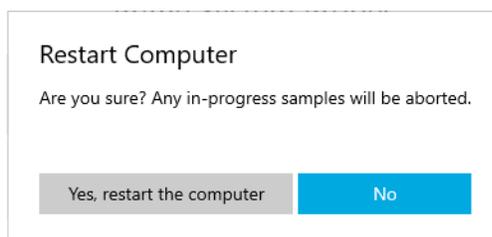
NOTE This step is not necessary if you already logged in.

- 2 Select the User Menu  on the top right of the screen.

- 3 Select **Restart Computer** from drop-down menu.

IMPORTANT Ensure no samples are currently being processed.

4 Select **Yes**, restart the computer.



5 The system software starts running when the CellMek SPS screen is displayed.

Move Probes from Wash Station

The Move Probes from Wash Station feature makes it possible to clean the probe wash station, see [CHAPTER 8, Cleaning the Probe Wash Station](#).

Prime and Clean Cell Wash

The Prime and Clean Cell Wash is used for the following:

- Adding diluted bleach to clean the Cell Wash Module. See [CHAPTER 5, Cleaning the Cell Wash Module Fluid Pathways](#).

1 Select **Maintenance** .

2 Select **Prime and Clean Cell Wash** and this will automatically start running.

This process uses the fluid in the Cell Wash fluid bottle to prime the Cell Wash module tubing and clean inside surfaces of the Cell Wash.

3 Wait for the process to complete.

Prime System Probes

The Prime System Probes is used for the following:

- Priming the system probes after IsoFlow Sheath Fluid has been replaced.
- Priming the system probes with deionized water, see [CHAPTER 5, Extended Shutdown](#).

1 Select **Maintenance** .

2 Select **Prime System Probes** and this will start automatically.

This process uses the fluid in the cubitainer located in the supply cart to prime the probes.

3 Wait for the process to complete.

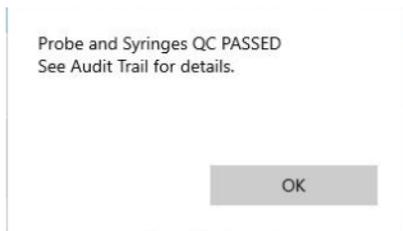
Probe and Syringes QC

The Probe and Syringe QC is a function that checks the integrity of the fluidic pathways containing the system probes and their associated syringes. This function needs to be performed at least once per week to confirm that these pathways are functioning correctly. The system allows you to set up the time interval for performing this function, see [View Instrument Serial Number, Setup Frequency of Probe and Syringe Volume QC and Select Output Tube Mode](#). If this function is not performed within the selected interval, the system will display an alert (Yellow Triangle) during panel assignment with the following message: System has not passed Probe and Syringe Volume QC.

1 Select **Maintenance** > **Probe and Syringes QC** and this will automatically start running.

2 Wait for the process to complete.

3 Confirm that the system displays a message that **Probe and Syringes QC PASSED**.



-
- 4 If you receive a message *Probe and Syringes QC FAILED*, perform the following steps:
- Perform [Prime System Probes](#) and rerun [Probe and Syringes QC](#) procedure.
 - If Probe and Syringe QC fails again, review the results in the Audit Trail to identify if one probe is causing the failure. Refer to [CHAPTER 9, Replacing the Probes](#) to replace the probe.
 - If Probe and Syringe QC continues to fail, use [Move Probes from Wash Station](#) to safely access the QC well (round hole in wash station metal attachment). Use a cotton swap with Isopropyl Alcohol to clean the well and repeat the [Probe and Syringes QC](#) procedure.

- 5 If the Probe and Syringe Volume QC fails again, [contact us](#).

Probe Replacement

Refer to [CHAPTER 9, Replacing the Probes](#) for detailed instructions on Probe Replacement.

Audit Trail

- 1 Select **Audit Trail** from the CellMek SPS Home Screen and the audit trail opens, it defaults to the current date. The refresh button reloads the data with the latest data available.

Date/Time	Category	User	Description
25 Oct 2021 1:10:23 PM	User	user	User signed in successfully: user.
25 Oct 2021 1:07:46 PM	Error	System	[ATLAS_WORKFLOW_ERROR] System execution error. Press the Check System button on the status bar. If the problem continues power the instrument off and on and perform a startup. Contact service representative if problem continues. { "description": "connect ()", "error": "No available device of type 0x00FA" }
25 Oct 2021 1:07:27 PM	External Resources	System	Waste tank full.

CHAPTER 7

Troubleshooting

Overview

This chapter contains information about:

- [Safety Precautions](#)
- [EMC Information](#)
- [Hazard Labels and Locations](#)
- [Powering Up / Powering Down](#)
- [Troubleshooting Procedures](#)
- [System Error Messages](#)
- [System Warning Messages](#)
- [Audit Trail Messages](#)

Safety Precautions

Operational

 **WARNING**

Risk of injury. To avoid injury, ensure the left and right covers, back cover and front door cover are installed before operating the CellMek SPS; otherwise blunt force trauma could occur including crush, pinch, or puncture injuries.

IMPORTANT Risk of clogging probes due to sheath fluid crystallization if Extended Shutdown is not performed when not using or turning off the instrument for more than seven days. Follow the [Extended Shutdown](#) in [CHAPTER 5, Shutdown](#) when turning off the instrument for more than seven days.

Electronic

 **WARNING**

Risk of personal injury from electrical shock or fire. Electronic components can cause shock and or injury. To prevent possible injury or shock, do not tamper with the instrument and do not remove any covers, doors, or panels unless otherwise instructed in this manual. Use the breaker switch in the right-rear side of the instrument if an emergency power down is needed. Do not use an extension cord or power strip; otherwise overheating, melting, and burning of the extension cord or power strip can occur. Always connect the CellMek SPS into the Uninterruptible Power Supply (UPS) provided with your system and then plug the UPS into the dedicated outlet with an isolated ground.

 **WARNING**

Risk of personal injury from electrical shock or fire. Use the detachable power cord on the right-rear side of the instrument, or power plug at the rear of the UPS, if an emergency power down is needed. Ensure that the power connection to the instrument is always accessible and un-obstructed.

 **WARNING**

Risk of personal injury if electronic equipment is used near fumes or flammable gases. Avoid this risk by never operating electronic equipment near fumes or flammable gases. Do NOT USE flammable liquids on this device.

Biological

Use universal precautions when working with pathogenic materials.

WARNING

Risk of personal injury or biohazardous contamination when contacting CellMek SPS including work area components, carousels, cassettes, reaction plates, reagent bottles, and waste container. To prevent possible injury or biohazardous exposure, always wear proper laboratory attire, including gloves, a laboratory coat, and eye protection. Refer to [CHAPTER 1, Material Safety Data Sheets \(SDS/MSDS\)](#) for chemical exposure details.

WARNING

Risk of personal injury and/or contamination:

- To prevent possible injury or biohazardous exposure, wear proper laboratory attire, including gloves, a laboratory coat, and eye protection.
- Operating the instrument while the waste level sensor is disconnected can cause biohazardous exposure due to waste overflow. To prevent biohazardous exposure, do not operate the instrument while the waste level sensor is disconnected.

WARNING

Risk of possible biohazardous contamination. All biological specimens should be treated as potentially infectious. Adequate precautions and safety attire should be used when handling a biological sample. For details on handling potentially infectious samples, refer to document "CLSI M29 Protection of Laboratory Workers From Occupational Acquired Infections".

WARNING

Risk of biohazardous contamination. Clean up any biological spill as quickly as possible. Dispose of all contaminated disposable cleaning materials in accordance with your local regulations and acceptable laboratory practices.

WARNING

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

EMC Information

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.



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.

This equipment is designed for use in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT. It is likely to perform incorrectly if used in a HOME HEALTHCARE ENVIRONMENT. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.

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:

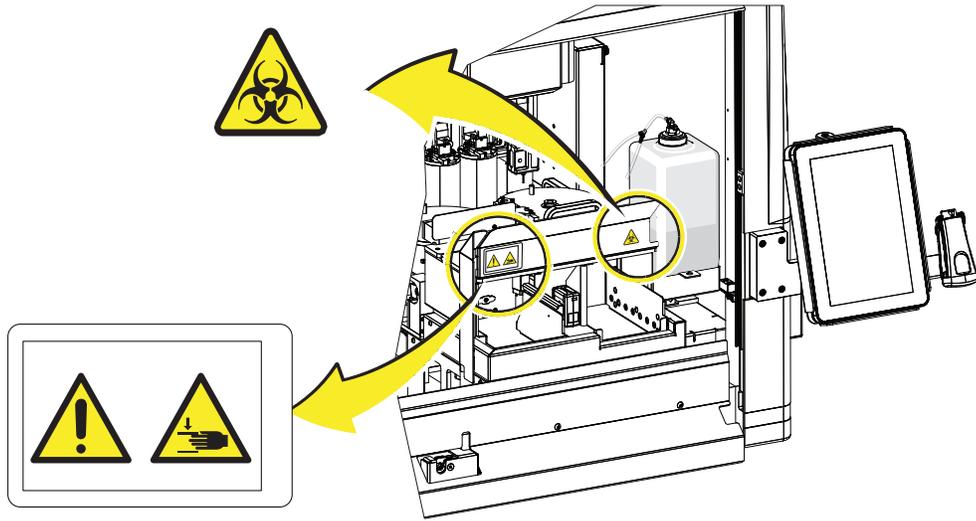
- Evaluate the electromagnetic environment before installation and operation of this device.
- Do not operate this device close to sources of strong electromagnetic radiation (for example: unshielded intentional RF sources), as these can interfere with proper operation. Examples of unshielded intentional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

Hazard Labels and Locations

Carefully read the hazard warning labels on the instrument. The hazard labels are located on the instrument as indicated. See Introduction, [Safety Symbols](#) for more detailed information on label.

NOTE If a label is missing or unclear, [contact us](#).

Figure 7.1 Hazard Labels



Biohazardous and Caution/Warning Label and Locations

Figure 7.2 Caution/Warning Label on the Front Panel of the Instrument

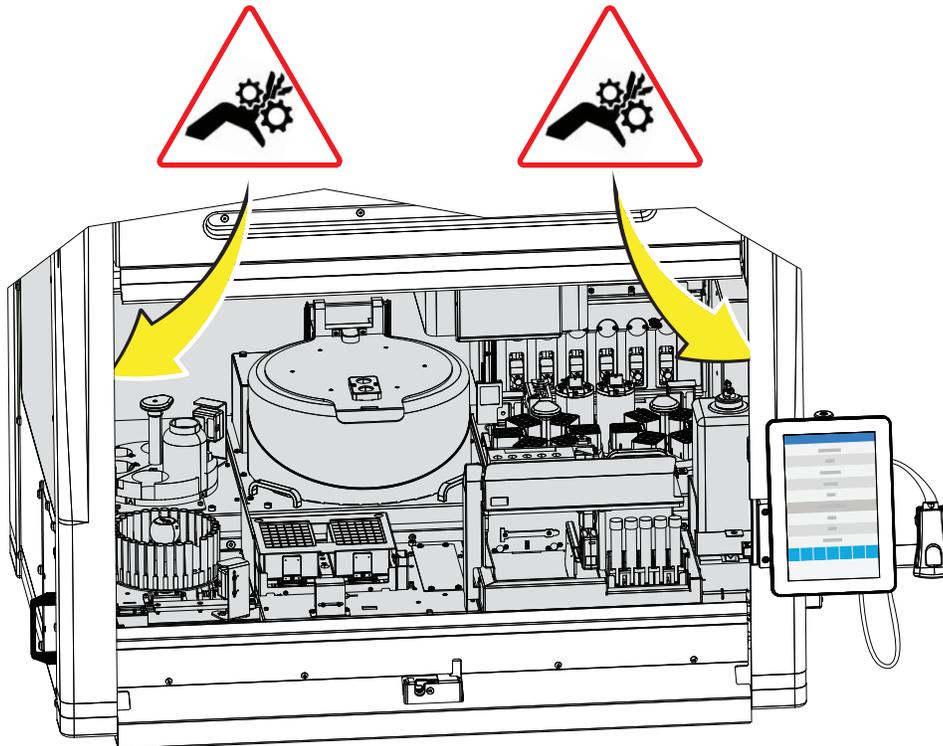


Figure 7.3 Caution/Warning Label on the Back Panel of the Instrument

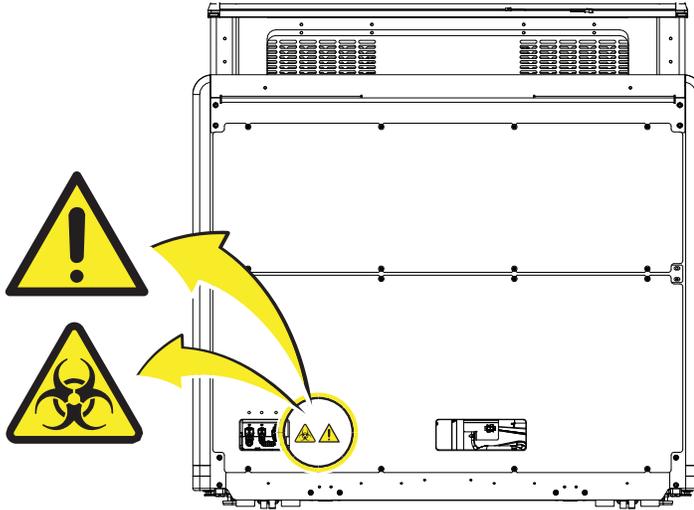


Figure 7.4 Caution/Warning Label on the Side Panel of the Instrument

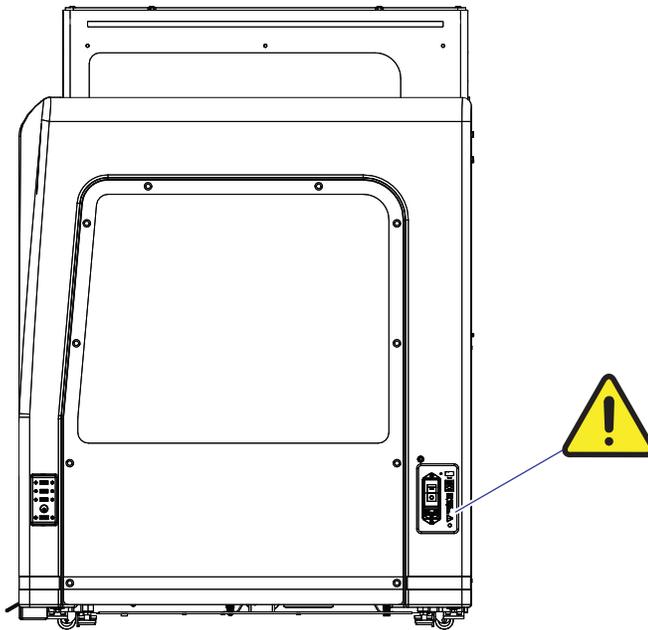


Figure 7.5 Caution/Warning Label on the Supply Cart (Front View)

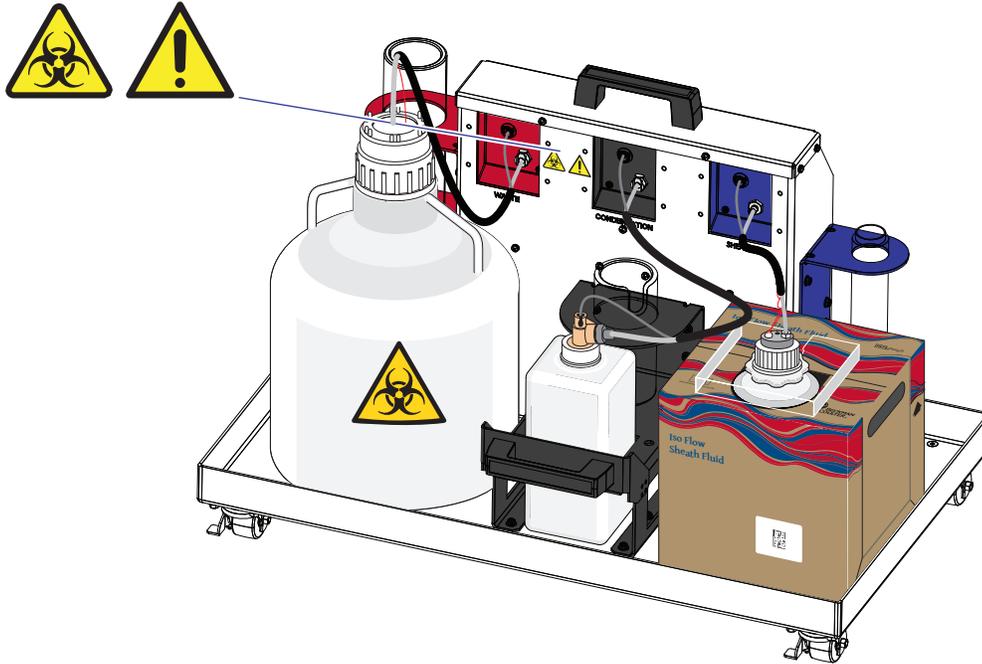


Figure 7.6 Caution/Warning Label on the Supply Cart (Rear View)

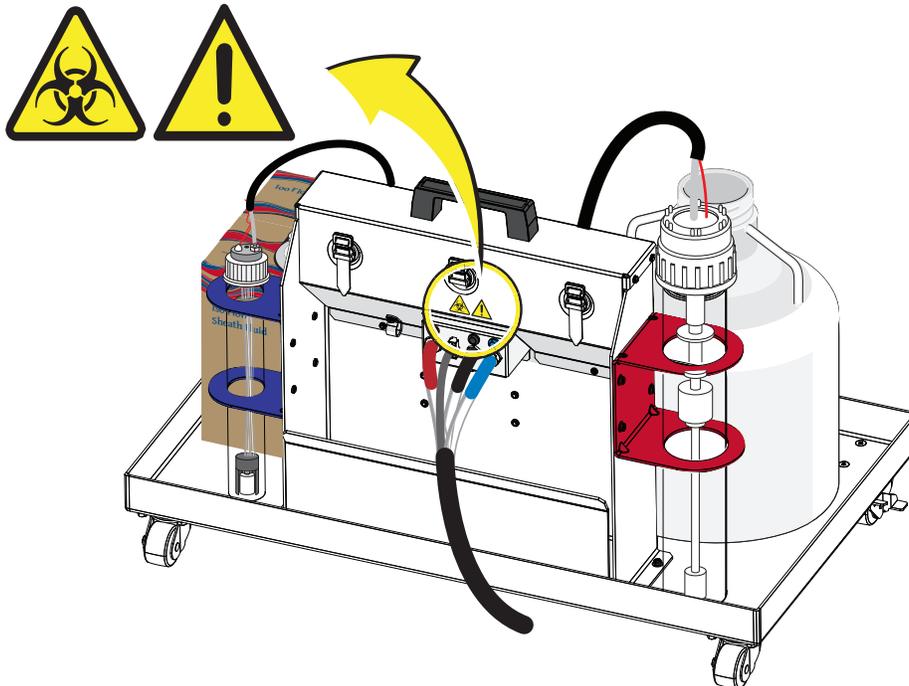
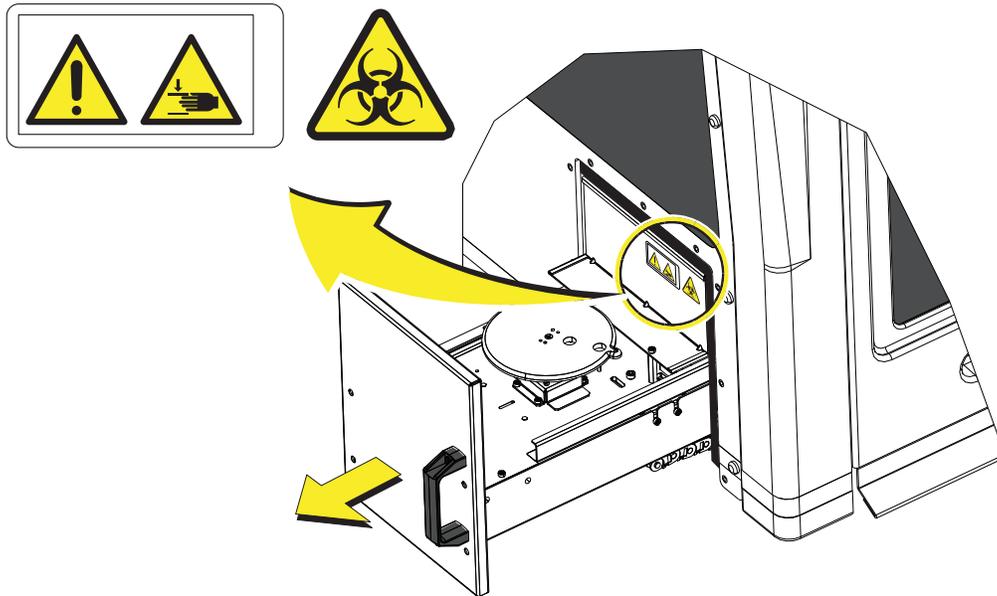


Figure 7.7 Caution/Warning Label on the Side Output Drawer



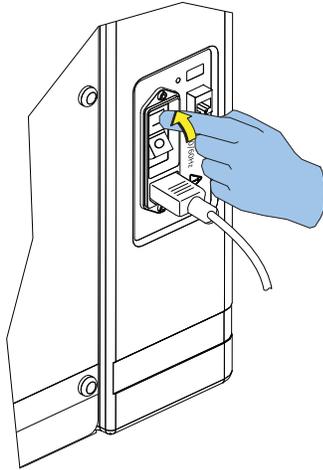
Powering Up / Powering Down

When performing or troubleshooting your CellMek SPS, it may be necessary to turn off the power. When the task is completed, the power to major components must be restored and the instrument properly prepared for operation.

Power Up the System

- 1 Plug the Uninterruptible Power Manager (UPM) into the wall outlet.
- 2 Press the ON/OFF button on the UPM for more than 3 seconds to turn the UPM on.

- 3 Turn **ON** the instrument by pressing the power switch on the right side.



- 4 When the Login screen appears, enter your **User name** and **Password**.

- 5 The system is now available for use.

Power Down the System

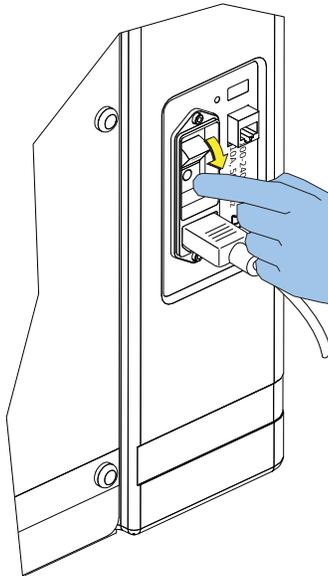
CAUTION

Risk of reagent spoilage if antibody reagents are stored in the refrigerated antibody module and power is lost. To avoid reagent spoilage, ensure that the system is powered on and connected to an electrical outlet with backup power. Otherwise, store the antibody carousel in a laboratory refrigerator connected to backup power.

IMPORTANT Always perform a shutdown cycle before powering down the unit. See [Shutdown](#) in [CHAPTER 5, Shutdown](#).

- 1 Turn **OFF** the touchscreen by selecting  in the top right corner of the software screen and select **Shutdown Computer**.

- 2 Turn **OFF** the instrument by pressing the power switch on the right side.



IMPORTANT When cycling power on the unit, wait 15 seconds before turning the unit back on. If this is not done, the computer may not come back on.

- 3 Press the **ON/OFF** button on the UPM for more than 3 seconds to turn the UPM off.

Troubleshooting Procedures

The troubleshooting topics in this chapter include:

- [System Error Messages](#)
- [System Warning Messages](#)

Before following the suggested actions in these sections, review handling procedures, warning labels, and Beckman Coulter Material Safety Data Sheets (SDS/MSDS). For further assistance and/or repairs, contact your Beckman Coulter Representative.

System Error Messages

System Error Messages are messages that appear in the notification drop-down as well as on the Status Screen. See [Table 7.1](#) for such messages.

Table 7.1 CellMek System Error Messages

Error Message	Probable Cause	Corrective Action
[Error Code: ATLAS_COMM_ERROR] Failure connecting to module. Ensure system is not in Processing state, then press the Check System button on the status bar. If problem continues power the instrument off and on and perform a startup. Contact service representative if problem continues.	Communication failure with module controller.	<ol style="list-style-type: none"> 1. Press the Check System button on the status bar. 2. If the problem continues power the instrument off and on and perform a startup, see CHAPTER 3, Startup. 3. If problem persists, contact us.
[Error Code: BARCODE_READER_ERROR] Failure detected connecting to barcode reader. Power the instrument off and on and perform a startup. Contact service representative if problem continues.	Communication failure with barcode reader.	<ol style="list-style-type: none"> 1. Power the instrument off and on and perform a startup, see CHAPTER 3, Startup. 2. If problem persists, contact us.
[Error Code: FE_WORKFLOW_ERROR_QC_FAILED_SPW] Cell Wash QC failure. Open door and ensure that the cell wash fluid bottle is connected and is not empty. Close door and press the Check System button on the status bar. Contact service representative if problem continues.	Spin Wash QC failure.	<ol style="list-style-type: none"> 1. Open door and ensure that the cell wash fluid bottle is connected and is not empty. 2. Close the door. 3. Select Check System on the status bar. 4. If problem persists, contact us.
[Error Code: FE_WORKFLOW_ERROR_WASTE_SHEATH_EMPTY] Diluent is empty. Ensure system is not in processing state, change the diluent container, scan the barcode, and press the Check System button on the status bar. Contact service representative if problem continues.	<ol style="list-style-type: none"> 1. IsoFlow Sheath container is empty. 2. IsoFlow Sheath sensor cable is disconnected from the reagent cart. 3. IsoFlow Sheath sensor malfunction. 	<ol style="list-style-type: none"> 1. Ensure system is not in processing state. 2. Change the diluent container. 3. Scan the barcode. 4. Select Check System on the status bar. 5. If problem persists, contact us.
[Error Code: FE_WORKFLOW_ERROR_WASTE_OVERFLOW] Waste container full. Ensure system is not in processing state, empty the waste container, and press the Check System button on the status bar. Contact service representative if problem continues.	<ol style="list-style-type: none"> 1. Waste container is full. 2. Waste container sensor cable is disconnected. 3. Waste sensor malfunction. 	<ol style="list-style-type: none"> 1. Ensure system is not in processing state. 2. Empty the waste container. 3. Select Check System on the status bar. 4. If problem persists, contact us.

Table 7.1 CellMek System Error Messages (Continued)

Error Message	Probable Cause	Corrective Action
[Error Code: FE_WORKFLOW_ERROR_WASTE_CAP_OFF] Waste container cap removed. Ensure system is not in processing state, replace the waste container cap securely and press the Check System button on the status bar. Contact service representative if problem continues.	<ol style="list-style-type: none"> 1. Waste cap was removed or not tight. 2. Waste container sensor cable is disconnected. 3. Waste cap sensor malfunction. 	<ol style="list-style-type: none"> 1. Ensure system is not in processing state. 2. Turn the waste container cap clockwise and ensure it is securely attached to the waste container. 3. Select Check System on the status bar. 4. If problem persists, contact us.
[Error Code: BARCODE_READER_NOT_CONFIGURED] Barcode reader not configured. Ensure system is not in Processing state, then power the instrument off and on and perform a startup. Contact service representative if problem continues.	Barcode reader incorrectly configured.	<ol style="list-style-type: none"> 1. Ensure system is not in Processing state. 2. Power the instrument off. 3. Power the instrument on. 4. Perform a startup, see CHAPTER 3, Startup. 5. If problem persists, contact us.
[Error Code: FE_WORKFLOW_ERROR_WASTE_CONDENSATION_OVERFLOW] Condensate container full. Empty the condensate container.	<ol style="list-style-type: none"> 1. Condensate container is full. 2. A condensate sensor cable is disconnected. 3. Condensate sensor malfunction. 	<ol style="list-style-type: none"> 1. Empty the condensate container. 2. If problem persists, contact us.
[Error Code: ACED_CONTROL_ERROR_UNKNOWN] Instrument communication failure. Ensure system is not in Processing state, then power the instrument off and on and perform a startup. Contact service representative if problem continues.	<p>Communication failure with the instrument.</p> <p>Cannot connect to pump.</p>	<ol style="list-style-type: none"> 1. Ensure system is not in Processing state. 2. Power off the instrument. 3. Power on the instrument. 4. Perform a startup, see CHAPTER 3, Startup. 5. If problem persists, contact us.
[Error Code: ACED_CONTROL_ERROR_PUMP] Failure detected in module. Ensure system is not in processing state and press the Check System button on the status bar. Contact service representative if problem continues.	Communication failure with the module.	<ol style="list-style-type: none"> 1. Ensure system is not in processing state. 2. Select Check System on the status bar. 3. If problem persists, contact us.
[Error Code: ACED_CONTROL_ERROR_BARCODE_WHITE_LIGHT] Barcode flash failed. Open the door and antibody lid then close antibody lid and door. Contact service representative if problem continues.	Liquid antibody barcode flash failed to activate.	<ol style="list-style-type: none"> 1. Check reagent inventory. 2. If antibody reagents are not scanned. 3. Slide open the door. 4. Open and close the antibody lid. 5. Slide the door down. 6. If problem persists, contact us.

Table 7.1 CellMek System Error Messages (Continued)

Error Message	Probable Cause	Corrective Action
[Error Code: ACED_CONTROL_ERROR_HOLD_CURRENT, ACED_CONTROL_ERROR_HOME] Failure detected in module. Ensure system is not in processing state, open door and check that the carousel is seated correctly. Close door and press the Check System button on the status bar. Contact service representative if problem continues.	Communication failure with the module.	<ol style="list-style-type: none"> 1. Ensure system is not in processing state. 2. Slide open door. 3. Ensure that the carousel is seated properly. 4. Close the door. 5. Select Check System on the status bar. 6. If problem persists, contact us.
[Error Code: FE_WORKFLOW_ERROR_PROBEWASH_OVERFLOW] Overflow detected in Cell Wash. Ensure system is not in processing state and press the Check System button on the status bar. Contact service representative if problem continues.	<ol style="list-style-type: none"> 1. A sensor cable is disconnected. 2. Sensor malfunction. 3. Probe wash not draining properly (possible clog). 	<ol style="list-style-type: none"> 1. Ensure system is not in processing state. 2. Check the Fluidics Tubing / Cable connection at back of instrument and at cart. 3. Check waste container tubing connection. 4. Select Check System on the status bar. 5. If problem persists, contact us.
[Error Code: FE_WORKFLOW_ERROR_CRITICAL_MODULE] Critical module error, system stopped. Check hardware status screen.	<p>Hardware error with the Probe Wash, Output, Door Latch, Reaction Plate, or Pod module.</p> <p>NOTE The hardware status screen shows the error details. This error code is accompanied with other errors.</p>	<ol style="list-style-type: none"> 1. Check Hardware Status Screen. 2. Perform the recovery process for any module errors. 3. If problem persists, contact us.
[Error Code: ACED_CONTROL_ERROR_TRUCK] Failure detected moving cassettes. Ensure system is not in the Processing state, then remove all cassettes and perform a Check System. Contact service representative if problem continues.	STM truck is unable to move freely.	<ol style="list-style-type: none"> 1. Wait for the system to complete any ongoing samples. 2. Clear any obstructions and remove all cassettes. 3. If failures continue, clean the STM, see CHAPTER 8, Cleaning the Specimen Transport Module. 4. Verify the STM is not in front of a bright light source or directly facing a window that receives direct sunlight. 5. If problem persists, contact us.

Table 7.1 CellMek System Error Messages (Continued)

Error Message	Probable Cause	Corrective Action
[Error Code: ACED_CONTROL_ERROR_ROCKER] Failure detected rocking cassette. Ensure system is not in the processing state, then remove all cassettes and perform a Check System. Contact service representative if problem continues.	STM rock is unable to move freely.	<ol style="list-style-type: none"> 1. Wait for the system to complete any ongoing samples. 2. Clear any obstructions and remove all cassettes. 3. If failures continue, clean the STM, see CHAPTER 8, Cleaning the Specimen Transport Module. 4. If problem persists, contact us.
[Error Code: ACED_CONTROL_ERROR_STRIPPER] Failure locking tubes. Ensure system is not in the Processing state, then remove all cassettes and perform a Check System. Contact service representative if problem continues	STM stripper is unable to move freely.	<ol style="list-style-type: none"> 1. Wait for the system to complete any ongoing samples. 2. Clear any obstructions and remove all cassettes. 3. If failures continue, clean the STM, see CHAPTER 8, Cleaning the Specimen Transport Module. 4. If problem persists, contact us.
[Error Code: FE_MODULE_EXCEPTION] System execution error. Press the Check System button on the status bar. If the problem continues power instrument off and on and perform a startup. Contact service representative if problem continues.	An exception has taken place executing the module.	<ol style="list-style-type: none"> 1. Select Check System on the status bar. 2. If the problem continues, power off the instrument. 3. Power the instrument on. 4. Perform a startup, see CHAPTER 3, Startup. 5. If problem persists, contact us.
[Error Code: FE_MODULE_WORKFLOW-ERROR] System execution error. Press the Check System button on the status bar. If the problem continues power instrument off and on and perform a startup. Contact service representative if problem continues.	<p>Module is unable to complete its operation.</p> <p>Example: STM is unable to move cassettes due to obstruction.</p>	<ol style="list-style-type: none"> 1. Select Check System on the status bar. 2. If the problem continues, power off the instrument. 3. Power the instrument on. 4. Perform a startup, see CHAPTER 3, Startup. 5. If problem persists, contact us.
[Error Code: FE_INST_MANAGER_EXCEPTION] System execution error. Press the Check System button on the status bar. If the problem continues power instrument off and on and perform a startup. Contact service representative if problem continues.	Instrument failed to successfully complete operation (Startup, Shutdown, Maintenance).	<ol style="list-style-type: none"> 1. Select Check System on the status bar. 2. If the problem continues, power off the instrument. 3. Power the instrument on. 4. Perform a startup, see CHAPTER 3, Startup. 5. If problem persists, contact us.

Table 7.1 CellMek System Error Messages (Continued)

Error Message	Probable Cause	Corrective Action
[Error Code: ATLAS_EXECUTION_ERROR] System execution error. Press the Check System button on the status bar. If the problem continues power instrument off and on and perform a startup. Contact service representative if problem continues.	Instrument error occurred while performing operation (Startup, Shutdown, Sample Processing, or Maintenance).	<ol style="list-style-type: none"> 1. Select Check System on the status bar. 2. If the problem continues, power off the instrument. 3. Power the instrument on. 4. Perform a startup, see CHAPTER 3, Startup. 5. If problem persists, contact us.
[Error Code: ATLAS_WORKFLOW_ERROR] System execution error. Press the Check System button on the status bar. If the problem continues power instrument off and on and perform a startup. Contact service representative if problem continues.	Operation failed because one of the modules is in error state. See Hardware Status Screen to find modules in error.	<ol style="list-style-type: none"> 1. Select Check System on the status bar. 2. If the problem continues, power off the instrument. 3. Power the instrument on. 4. Perform a startup, see CHAPTER 3, Startup. 5. If problem persists, contact us.
[Error Code: ACED_CONTROL_ERROR-DECK_LIGHT] Error occurred operating the deck light. Press the Check System button on the status bar. Contact service representative if problem continues.	Open or closing of the front door.	<ol style="list-style-type: none"> 1. Select Check System on the status bar. 2. If problem persists, contact us.
[Error Code: ATLAS_CONTROL_ERROR_INTERLOCK] Failed to secure main door. Ensure door is closed secured. Press the Check System button on the status bar. If the problem continues power instrument off and on and perform a startup. Contact service representative if problem continues.	Opening and closing the front door.	<ol style="list-style-type: none"> 1. Ensure door is closed securely. 2. Select Check System on the status bar. 3. If the problem continues, power off the instrument. 4. Power the instrument on. 5. Perform a startup, see CHAPTER 3, Startup. 6. If problem persists, contact us.
[Error Code: ACED_CONTROL_ERROR_HALO] Error occurred operating the status light. Press the Check System button on the status bar. Contact service representative if problem continues.	Halo light failure.	<ol style="list-style-type: none"> 1. Select Check System on the status bar. 2. If problem persists, contact us.
[Error Code: ACED_CONTROL_ERROR_LATCH] Latch failure. Ensure door is closed securely. Press the Check System button on the status bar. If the problem continues power the instrument off and on and perform a startup. Contact service representative if problem continues.	Front door latch failure.	<ol style="list-style-type: none"> 1. Ensure the front door is closed properly. 2. Select Check System on the status bar. 3. If problem persists, contact us.

Table 7.1 CellMek System Error Messages (Continued)

Error Message	Probable Cause	Corrective Action
[Error Code: FE_MODULE_WORKFLOW_ERROR_ABORTED_OPERATIONS] Operations have been aborted. Press the Check System button on the status bar.	User pressed the Abort button.	<ol style="list-style-type: none"> 1. Select Check System on the status bar. 2. If problem persists, contact us.
[Error Code: FE-STM_MODULE_WORKFLOW_ERROR] Remove all cassettes from module. Clean sliding surfaces. (Refer to Cleaning Procedures in User's Manual). Ensure moving parts of module are free of obstructions. Press the Check System button on status bar. If problem continues power the instrument OFF and ON and perform Startup. Contact Service representative if problem continues.	Error performing operation in STM that does not involve hardware failure.	<ol style="list-style-type: none"> 1. Ensure that the module is clear of cassettes and that all moving parts are clear of obstructions.

System Warning Messages

The System Warning and Status messages are listed in [Table 7.2](#).

Table 7.2 System Warnings and Status Messages

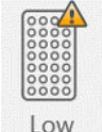
Message	General Category	Corrective Action
<p>Low</p>  <p>Low</p>	Status Bar	<ol style="list-style-type: none"> 1. Allow samples in progress to complete preparation. 2. Replace the reagents as needed. See Replacing Reagents and Consumables in CHAPTER 9, Replacement Procedures.
<p>Empty</p>  <p>Empty</p>	Status Bar	<ol style="list-style-type: none"> 1. Allow samples in progress to complete preparation. 2. Replace the reagents as needed. See Replacing Reagents and Consumables in CHAPTER 9, Replacement Procedures.
<p>Low</p>  <p>Low</p>	Status Bar	<ol style="list-style-type: none"> 1. Allow samples in progress to complete preparation. 2. Replace the reaction plates as needed. See Replacing the Reaction Plate in CHAPTER 9, Replacement Procedures.

Table 7.2 System Warnings and Status Messages (Continued)

Message	General Category	Corrective Action
<p>Empty</p>  <p>Empty</p>	Status Bar	<ol style="list-style-type: none"> 1. Allow samples in progress to complete preparation. 2. Replace the reaction plates as needed. See Replacing the Reaction Plate in CHAPTER 9, Replacement Procedures.
<p>Disabled</p>  <p>Enabled and Not Connected</p>  <p>Enabled and Connected</p> 	Status Bar	<ol style="list-style-type: none"> 1. Turn on the LIS and configure its settings. See LIS Setup in CHAPTER 6, Software Setup. 2. If the problem persists, contact your LIS administrator.
<p>Condensate Full</p>  <p>Full</p>	Status Bar	<ol style="list-style-type: none"> 1. If the condensate container needs to be replaced, see CHAPTER 9, Replacing the Condensate Container.
<p>Waste Low</p>  <p>Low</p>	Status Bar	No action required.

Table 7.2 System Warnings and Status Messages (*Continued*)

Message	General Category	Corrective Action
Waste Full 	Status Bar	1. If the waste container needs to be replaced, see CHAPTER 9, Replacing the Waste Container .
Instrument Warning 	Status Bar	1. Check the error message table for the appropriate action.
Instrument Temperature 	Status Bar	Displays the temperature inside the instrument.
Antibody Temperature 	Status Bar	Displays the antibody temperature.

Audit Trail Messages

The list of Audit Trail Messages is not a comprehensive list as there are some hardware and/or sub components messages that may not appear in the following Audit Trail Messages.

Consumables Audit Trail Messages

Items in the message text enclosed in curly brackets are substituted with the parameter at run time. For all these items **Lot Yes/No** refers to whether a previous vial of the same reagent was enrolled already when the current vial is enrolled.

Action Performed	Audit Trail Message Results
BCI reagent definition updated during panel import. This occurs when a panel has imported the reagent, the catalog definition of the reagent (as identified uniquely by part number) has changed name or type, then import a new panel/updated version of the panel with the updated name/type for that part.	BCI reagent with part number '{Part Number}', updated FROM name '{Previous Name}', type '{Previous Type }' TO name '{New Name}', type '{New Type}'
Cell Wash Fluid was set to a wash buffer. (Set Cell Wash Fluid, also performed when user prompted after closing doors).	Cell Wash fluid updated: Reagent: {Name}, Remaining Volume: {Volume} L
Cell Wash Fluid was set to DI water or bleach solution (Set Cell Wash Fluid, also performed when user prompted after closing doors).	Cell Wash fluid updated: Reagent: {Name}, Remaining Volume: {Volume} L
Update Custom Defined Reagent vial updated. When the user scans the barcode for an already enrolled vial and saves.	Custom Defined reagent vial updated. Reagent: {Reagent Name}, Type: {Type}, Part: {Part Number}, Lot: {Lot} (new: {Yes/No}), Vial: {Vial}, Expires: {Exp Date}, Fill Volume: {Volume} L, Remaining volume: {Rem. Volume} L, Comments: {Comments}
Custom Defined reagent name changed during panel import (affects name casing only). Example: User fixes a typo accidentally saying mYReagent and renames it MyReagent then imports a new version of their panel.	Custom Defined Reagent updated, name changed from '{Previous Reagent Name}' to '{New Reagent Name}'.
DURACartridge reagent updated using reagent enrollment by scanning a barcode for a cartridge already enrolled.	DURACartridge updated. Reagent: {Reagent Name}, Type: {Type}, Category: {Category}, Part: {Part Number}, Lot: {Lot} (new: {Yes/No}), Vial: {Vial Number}, Date of Manufacture: {Date}, Expires: {Exp Date}, Starting Tests: {Count}, Remaining Tests: {Count}
Diluent reagent scanned and enrolled by user.	New Diluent vial enrolled. Reagent: {Reagent Name}, Type: {Type}, Part: {Part Number}, Catalog reagent type: {Catalog Type}, Product Line: {Product Line}, Regulator status: {Status}, Lot: {Lot} (new: {Yes/No}), Vial: {Vial Number}, Expires: {Exp Date}, Initial volume: {Fill Volume} L, Remaining volume: {Remaining Volume} L
New BCI reagent definition added during panel import. Occurs any time a panel is imported with a BCI reagent part number not yet installed in the database.	New BCI reagent imported. Reagent: {Reagent Name}, Type: {Type}, Is kit: {Yes/No}, Warning level: {Warning Level}, Part: {Part Number}, Initial Volume: {Volume} ?L, Open vial stability: {Days}, Product Line: {Product Line}, Regulatory status: {Status}, Catalog reagent type: {Catalog Type}
First time a BCI reagent vial is found to be onboard (scanned by an internal scanner).	New BCI vial enrolled. Reagent: {Reagent Name}, Type: {Type}, Part: {Part Number}, Catalog reagent type: {Catalog Type}, Product Line: {Product Line}, Regulator status: {Status}, Lot: {Lot} (new: {Yes/No}), Vial: {Vial Number}, Expires: {Exp. Date}, Initial volume: {Fill Volume} ?L, Remaining volume: {Remaining Volume} ?L

Action Performed	Audit Trail Message Results
First time a custom defined reagent barcode is scanned (with the external scanner) and a reagent is assigned to it by the user.	New Custom Defined reagent vial enrolled. Reagent: {Reagent Name}, Type: {Type}, Part: {Part Number}, Lot: {Lot} (new: {Yes/No}), Vial: {Vial Number}, Expires: {Exp Date}, Fill Volume: {Volume} ?L, Remaining volume: {Rem. Volume} ?L, Comments: {Comments}
First time a DURACartridge reagent barcode is scanned (with the external scanner) and a reagent is assigned to it by the user.	New DURACartridge enrolled. Reagent: {Reagent Name}, Type: {Type}, Category: {Category}, Part: {Part Number}, Lot: {Lot} (new: {Yes/No}), Vial: {Vial Number}, Date of Manufacture: {Date}, Expires: {Exp Date}, Starting Tests: {Count}, Remaining Tests: {Count}
DURACartridge reagent definition added during panel import. Occurs any time a panel is imported with a DURACartridge reagent not yet installed in the database.	New DURACartridge reagent imported. Reagent: {Reagent Name}, Type: {Type}, Is kit: {Yes/No}, Warning level: {Warning Level}, Part: {Part Number}, # Tests: {Number of Tests}
Custom Defined reagent definition added during panel import. Occurs any time a panel is imported that includes a Custom Defined Reagent name not yet installed in the database (upper/lower case differences are considered the same name).	New Custom Defined reagent imported. Reagent: {Reagent Name}, Type: {Type}, Is kit: {Yes/No}, Warning level: {Warning Level}, Comments: {Comments}, Expiration Type: {Exp. Type}, Is fixed volume: {Yes/No}

Database Audit Trail Messages

Items in the message text enclosed in curly brackets are substituted with the parameter at run time.

Action Performed	Audit Trail Message Results
Archive Runs and/or audit trail.	Archived data successfully to USB Drive: {Drive Letter}. Start date: {Start Date}, End date: {End Date}, Archive runs: {Yes/No}, Remove run data after archival: {Yes/No}, Archive audit trail: {Yes/No}, Remove audit trail after archival: {Yes/No}.
Backup - Auto	Backed up database successfully to '{Backup file location}'.
Backup - Manual	Backed up database successfully to USB Drive: {Backup file location}.
Backup failed - Auto	Failed to backup database to '{Backup file location}' because of no appropriate permissions.
Backup failed - Auto	Failed to backup database to '{Backup file location}' because of the insufficient disk space.
Backup failed - Auto	Failed to backup database to '{Backup file location}'. Instrument is busy.
Backup failed - Auto	Failed to backup database. The backup location '{Backup file location}' is not available.
Restore - Success	Restored database successfully from '{File location}'.
Restore - Success	Restored database successfully from USB Drive: {Backup file location}.

External Resource Audit Trail Messages

Items in the message text enclosed in curly brackets are substituted with the parameter at run time.

Action Performed	Audit Trail Message Results
Condensate full	Condensate container full.
Diluent empty	Diluent empty.
Waste full	Waste tank full.

Instrument Access Audit Trail Messages

Items in the message text enclosed in curly brackets are substituted with the parameter at run time.

Action Performed	Audit Trail Message Results
Close front door.	Front door closed.
Open front door.	Front door opened.
Liquid antibody module lid closed.	Liquid antibody module lid closed.
Liquid antibody module lid opened.	Liquid antibody module lid opened.
Output carousel drawer opened.	Output module drawer closed.
Output carousel drawer closed.	Output module drawer opened.
RPM lid opened.	Reaction plate module lid closed.
RPM lid closed.	Reaction plate module lid opened.
LAM lid remained open beyond time limit.	Liquid antibody module lid opened for over 5 minutes.

Instrument Monitoring Audit Trail Messages

Items in the message text enclosed in curly brackets are substituted with the parameter at run time.

Action Performed	Audit Trail Message Results
Software is started (computer restarted or instrument powered on).	Days since last Liquid Antibody Module temperature reading: {Days}
Software is started (computer restarted or instrument powered on).	Days since last RPM temperature reading: {Days}
Liquid Antibody Module temperature is outside the range of 2°C to 8°C (inclusive).	Liquid Antibody Module inside temperature recorded at {Temperature}°C, which is out of acceptable range.

LIS Audit Trail Messages

Items in the message text enclosed in curly brackets are substituted with the parameter at run time.

Action Performed	Audit Trail Message Results
LIS Host Query failure - no orders	LIS Host Query found no records for specimen '{Specimen ID}'.
LIS Host Query failure - timeout	LIS Host Query timed out after '{Timeout Setting}' seconds for specimen '{Specimen Barcode}'.
System rejected a message from LIS (example reasons: Too many Test IDS (panels) in order, Field [Test.ID] required but not supplied, Invalid action code)	LIS Message Rejected: {LIS Message}

Maintenance Audit Trail Messages

Items in the message text enclosed in curly brackets are substituted with the parameter at run time.

Action Performed	Audit Trail Message Results
Maintenance Replace Back Probe Started.	Back probe replacement initiated.
Maintenance Replace Back Probe Failed.	Back probe replacement failed. Probe failed to move to replace position.
Maintenance Replace Front Probe Started.	Front probe replacement initiated.
Maintenance Replace Front Probe Failed.	Front probe replacement failed. Probe failed to move to replace position.
Maintenance Replace Middle Probe Started.	Middle probe replacement initiated.
Maintenance Replace Middle Probe Failed.	Maintenance Replace Middle Probe Failed. Probe failed to move to replace position.
Shutdown completed successfully.	Instrument shutdown completed successfully.
Shutdown started by user.	Instrument shutdown initiated.
Startup started by user.	Instrument startup initiated.
Startup completed successfully.	Instrument startup completed successfully.
Maintenance Prime Clean Cell Wash Completed.	Prime and Clean Cell Wash procedure completed successfully.
Maintenance Prime Clean Cell Wash Failed.	Prime and Clean Cell Wash procedure failed.
Maintenance Prime Clean Cell Wash Started.	Prime and Clean Cell Wash procedure initiated. Diluent empty: {Yes if diluent missing or empty, no if available}.
Maintenance Prime System Probes Completed.	Prime System Probes procedure completed successfully.
Maintenance Prime System Probes Failed.	Prime System Probes procedure failed.
Maintenance Prime System Probes Started.	Prime System Probes procedure initiated. Diluent empty: {Yes if diluent missing or empty, no if available}
Maintenance Replace Probe Finish command failed	Replace Probes Finish failed.
Maintenance Replace Probes Finish command succeeded.	Replaced Probes completed successfully.

Action Performed	Audit Trail Message Results
Maintenance Move Probes from Wash Station Completed.	Move Probes from Wash Station procedure completed successfully.
Maintenance Move Probes from Wash Station Failed.	Move Probes from Wash Station procedure failed.
Maintenance Move Probes from Wash Station Started.	Move Probes from Wash Station procedure initiated.
Maintenance Probe and Syringes QC completed.	Probe and syringes QC method ended.
Maintenance Probe and Syringes QC started.	Probe and syringes QC method initiated.
Maintenance Probe and Syringes QC completed (results calculated).	Probe and Syringes QC: [Pass/Fail]. Results: {measurement data and results}

Panel Audit Trail Messages

Items in the message text enclosed in curly brackets are substituted with the parameter at run time.

Action Performed	Audit Trail Message Results
Publish Panel	Panel '{Panel Name}' version {Version} imported by user '{Username}' published.
Import Panel	Panel '{Panel Name}' version {Version} imported from file '{File Name}'.
Development Panel Deleted	Panel '{Panel Name}' version {Version} in development by user '{Username}' deleted.
Update Panel LIS Code	Panel '{Panel Name}' version {Version} LIS Code set to: {LIS Code}.
Panel Published Deleted	Published panel '{Panel Name}' version {Version} deleted.

Run Panel Audit Trail Messages

Items in the message text enclosed in curly brackets are substituted with the parameter at run time.

Action Performed	Audit Trail Message Results
Abort button selected by user.	Abort all initiated.
Eject button selected by user.	Eject all cassettes initiated.
Panel added to specimen. Yes/No on LIS Order will be Yes if the order came from LIS. It will be No if: <ul style="list-style-type: none"> A user assigned the panel to the specimen. A user assigned the panel to a specimen and that specimen was not completed, so the assignment was recovered when the barcode was entered again. 	Panel '{Panel Name}' was added to specimen '{Specimen Barcode}' (LIS Order: {yes/no}).
Panel removed from specimen (by user).	Panel '{panel name}' was removed from specimen '{Specimen Barcode}'.

Service Audit Trail Messages

Items in the message text enclosed in curly brackets are substituted with the parameter at run time.

Action Performed	Audit Trail Message Results
Module Setup page, Update Offset Position Failed	Failed to update an offset position for module {Module Name}.
Module Setup page, Barcode Device Location Assigned	The barcode device {Barcode ID} has been assigned to location {Module Name}.
Module Setup page, Barcode Device Location Unassigned	The barcode device {Barcode ID} has been unassigned from location {Module Name}.
Service Atlas Method Call Completed	The service call to Atlas method {Method Name} on module {Module Name} completed.
Service Atlas Method Call Failed	The service call to Atlas method {Method Name} on module {Module Name} failed.
STM Diagnostic Started	The STM diagnostic has been initiated.
STM Diagnostic Succeeded	The STM diagnostic has completed successfully.
STM Diagnostic Failed	The STM diagnostic has failed.
Service Atlas Method Call Started	The user initiated a service call to the Atlas method {Method Name} on module {Module Name}.
Module Setup page, Update Aspirate Offset Position Started	Update of aspirate offset position for module {Module Name} to {Offset} initiated.
Module Setup page, Update Frame Offset Position Started	Update of frame offset position for module {Module Name} to {Offset} initiated.
Module Setup page, Update Scan Offset Position Succeeded	Update of offset position for module {Module Name} succeeded.
Module Setup page, Update Scan Offset Position Started	Update of scan offset position for module {Module Name} to {Offset} initiated.
Module Setup page, Capture - Barcode Window Updated	Updated the barcode window {Window Number} for {Module} to ({Left}, {Top}), ({Right}, {Bottom}).

Setup Audit Trail Messages

Items in the message text enclosed in curly brackets are substituted with the parameter at run time.

Action Performed	Audit Trail Message Results
Alert e-mail added.	Alert notification email added: Address: {Email Address}, Notification level: {Notification Level}
Change notification level of alert e-mail.	Alert notification email level changed: Address: {Email Address}, Notification level: {Notification Level}
Alert e-mail removed.	Alert notification email removed: Address: {Email Address}

Action Performed	Audit Trail Message Results
Alert SMTP settings updated.	Alert settings updated: SMTP Server: {Address}, SMTP Username: {Username}, Uses TLS/SSL: {Yes/No}, password changed: {Yes/No}
Alert user added.	Alert user notification added: User: {Username}, Notification level: {Notification Level}
Change notification level of alert user.	Alert user notification level changed: User: {Username}, Notification level: {Notification Level}
Modify barcode checksum settings.	Barcode reader settings update: Code 39 checksum: {Yes/No}, Codabar checksum: No, Interleaved 2 of 5 checksum: {Yes/No}, Interleaved 2 of 5 barcode length: {Barcode Length}
Database daily backup enabled (On Archive and Backup page, Backup tab)	Daily database backup settings changed. Backup enabled: {Yes/No}
Database daily backup location (On Archive and Backup page, Backup tab)	Daily database backup settings changed. Backup location: {Network URL}
IP address changed.	Instrument IP Address updated: Serial number: {Serial Number}, Nickname: {Nickname}, IP Address: {IP Address}
Instrument name changed.	Instrument nickname updated: Serial number: {Serial Number}, Nickname: {Nickname}
Instrument serial number changed.	Instrument nickname updated: Serial number: {Serial Number}, Nickname: {Nickname}
Local LIS settings changed.	Local LIS settings updated: LIS Enabled: {Yes/No}, Port: {Port Number}, ID: {ID Number}
Shared LIS settings changed.	Shared LIS settings updated: IP Address: {IP Address}, Host query enabled: {Yes/No}, Host query timeout seconds: {Seconds}, Send reject replies: {Yes/No}
Worklist export to USB changed.	Worklist export destination changed. Export to USB: {Yes/No}
Worklist export network location changed.	Worklist export destination changed. Network location: {Network URL}
Worklist export in Navios format changed.	Worklist export format changed. Navios format: {Yes/No}
Worklist export in DxFLEX format changed.	Worklist export format changed. DxFLEX format: {Yes/No}
Worklist export in human readable (HTML) format changed.	Worklist export format changed. Human readable/HTML format: {Yes/No}
Change Output Tube Mode to Auto Assigned	Output mode has changed to Auto Assigned.
Change Output Tube Mode to Barcode Assigned	Output mode has changed to Barcode Assigned.

User Account Audit Trail Messages

Items in the message text enclosed in curly brackets are substituted with the parameter at run time.

Action Performed	Audit Trail Message Results
Change User Account username.	Account username changed from '{Previous Username}' to '{New Username}'.
User Account added.	Created user account: {Username}
User Account deleted.	Removed user account: {Username}
Sign out by timeout.	System signed out user '{Username}' due to inactivity.
User setting changes.	User account '{Username}' email changed from '{Old Address}' to '{New Address}'.
User rights changed.	User account '{Username}' permissions updated. Added: {Permission as s/w name}
User rights changed.	User account '{Username}' permissions updated. Removed: {Permission as s/w name}
User settings changed.	User account '{Username}' text email changed from '{Old Address}' to '{New Address}'.
User settings changed.	User account '{Username}' password changed.
User password reset.	User account '{Username}' password reset.
User Account locked out (User is either System if the user failed 5 times, or User if someone with Manage Users permissions locks out a user).	User account locked: {Locked Username}
User Account unlocked by user with Manage Users permissions.	User account unlocked: {Unlocked Username}
User exited Kiosk Mode	User exited kiosk mode: {Username}.
User signed in successfully.	User signed in successfully: {Username}.
User signed out.	User signed out successfully: {Username}.
Invalid username and/or password on login attempt.	Failed login attempt: {Username}
User initiates restart from software.	User restarted computer: {Username}.
User initiates shutdown from software.	User shutdown computer: {Username}.

Worklist Audit Trail Messages

Items in the message text enclosed in curly brackets are substituted with the parameter at run time.

Action Performed	Audit Trail Message Results
Worklist created successfully (configured to output to USB).	Worklist file successfully generated to USB Drive: {Path on USB drive}
Worklist created successfully (configured to output to network path).	Worklist file successfully generated to: {The network path}

Cleaning

 **CAUTION**

Risk of damage to DURACartridges. Always remove and protect DURACartridges prior to extended cleaning times.

 **CAUTION**

Risk of chemical injury from bleach. To avoid contact with the bleach, use barrier protection, including protective eyewear, gloves, and suitable laboratory attire. Wipe down any bleach on surfaces. Follow specific cleaning instructions in this chapter when cleaning with bleach. Refer to the Safety Data Sheet for details about chemical exposure before using the chemical.

Maintenance must be performed on a regular basis in order to maintain the CellMek SPS. The schedule below outlines the proper intervals to check or clean components of the instrument. See [Table 8.1](#) for the cleaning schedule.

This chapter contains information on the following:

- [Cleaning the Probe Wash Station](#)
- [Cleaning the Specimen Transport Module](#)
- [Cleaning the Cell Wash Bottle](#)
- [Cleaning the Barcode Readers](#)
- [Cleaning the Carousels, Cassettes, and Adaptors](#)
- [Cleaning the System Doors and Covers](#)
- [Cleaning the Deck and Metal Carousel Hubs](#)
- [Cleaning Biological Spills](#)
- [Cleaning The Holding Cylinders](#)

Table 8.1 Cleaning Schedule

Component	Daily	Weekly	Monthly
Probe Wash Station	As needed	As needed	As needed
Specimen Transport Module	As needed	As needed	As needed
Cell Wash Bottle	As needed	As needed	As needed
Barcode Readers	As needed	As needed	As needed

Table 8.1 Cleaning Schedule

Component	Daily	Weekly	Monthly
Carousels, Cassettes, and Adapters	As needed	As needed	As needed
System Doors and Covers	As needed	As needed	As needed
Cleaning the deck and metal carousel hubs	As needed	As needed	As needed
IsoFlow, Waste, and Condensate Holding Cylinders	As needed	As needed	As needed

Cleaning the Probe Wash Station



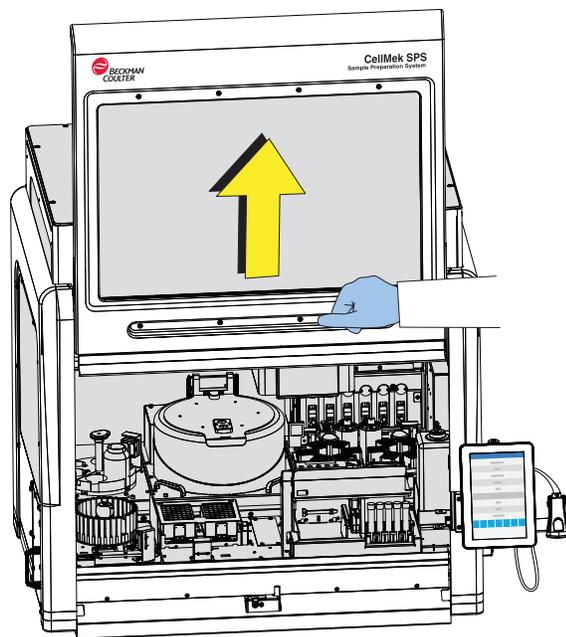
WARNING

Risk of personal injury or biohazardous contamination when contacting CellMek SPS including work area components, carousels, cassettes, reaction plates, reagent bottles, and waste container. To prevent possible injury or biohazardous exposure, always wear proper laboratory attire, including gloves, a laboratory coat, and eye protection. Refer to [CHAPTER 1, Material Safety Data Sheets \(SDS/MSDS\)](#) for chemical exposure details.

This procedure should be performed on a monthly basis. See [Cleaning Schedule](#).

- 1 Select **Maintenance** and select **Move Probes from Wash Station**.

- 2 Open the front door.



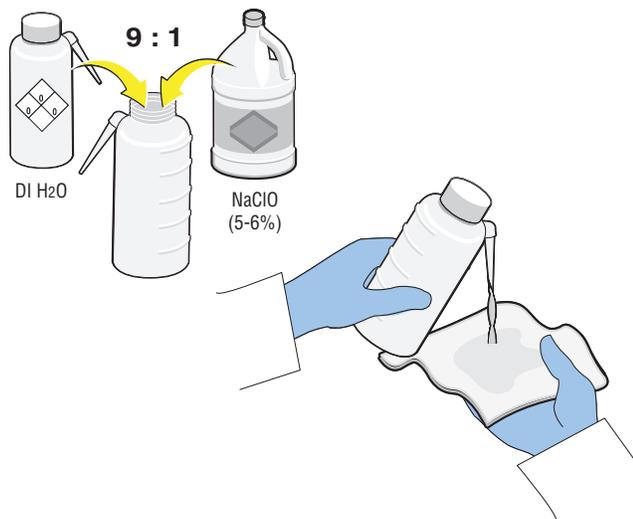
IMPORTANT Decontaminate and clean the brush prior to storing.

- 3 Scrub the well and rim of the probe wash station with a small brush with firm bristles.

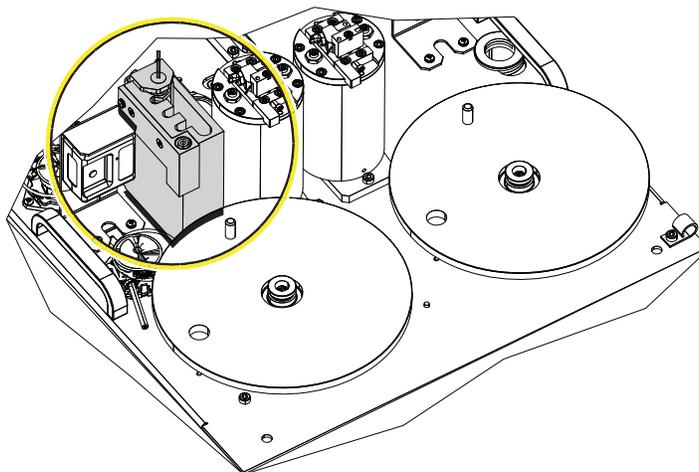
CAUTION

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.

- 4 Dampen a lint free tissue with a dilution of 9-parts water and 1-part high quality, fragrance-free, gel-free bleach (5 to 6% solution of sodium hypochlorite - available chlorine).



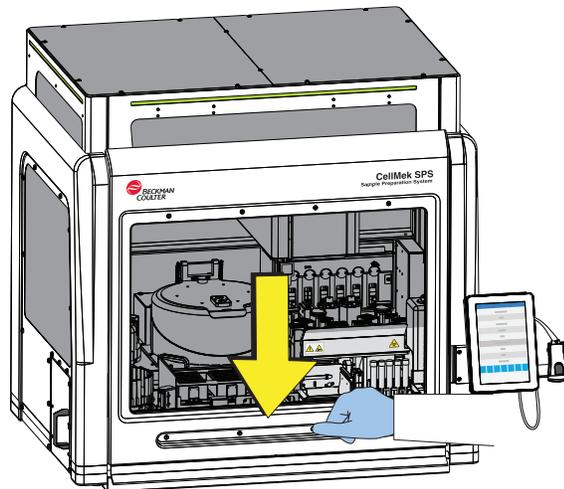
- 5 Wipe down the outside of the probe wash station, including its top surface with the dampened tissue.



6 Use a lint free tissue dampened with DI water, wipe off any residual bleach solution.

7 Close the front door.

The system will scan after the door is closed. The probes will move back to the wash station, and if there are reagents in the prep modules it will check to ensure that they are not capped.



Cleaning the Specimen Transport Module

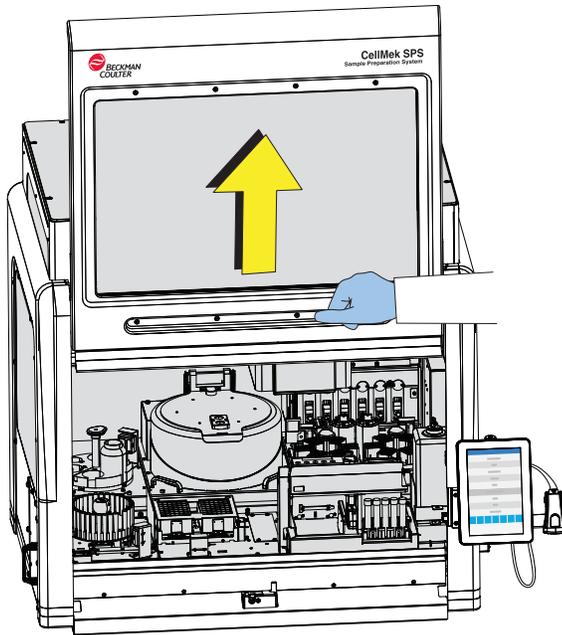


WARNING

Risk of personal injury or biohazardous contamination when contacting CellMek SPS including work area components, carousels, cassettes, reaction plates, reagent bottles, and waste container. To prevent possible injury or biohazardous exposure, always wear proper laboratory attire, including gloves, a laboratory coat, and eye protection. Refer to [CHAPTER 1, Material Safety Data Sheets \(SDS/MSDS\)](#) for chemical exposure details.

This procedure should be performed on a monthly basis or as needed. See [Cleaning Schedule](#).

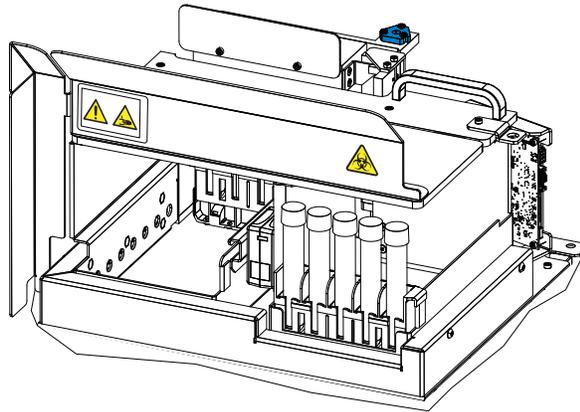
- 1 Open the front door.



NOTE Opening the front door removes all power from the Specimen Transport Module. This allows for cleaning the module without triggering sensors or motor movements.

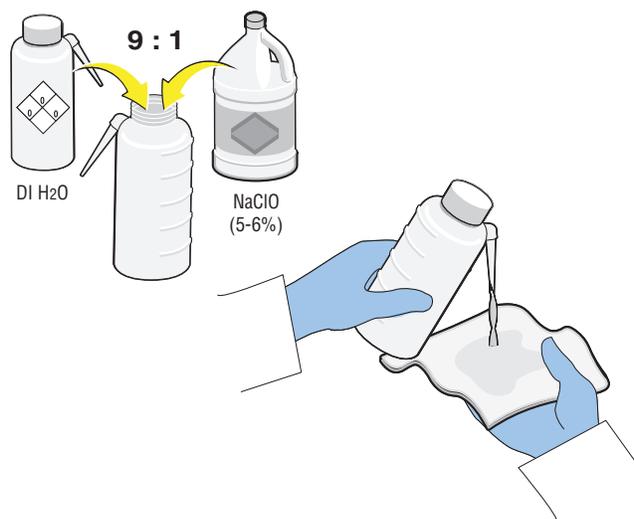
- 2 Inspect for blood, if so, proceed to Step 5.
- 3 Dampen a lint free tissue with a deionized or distilled water.

- 4 Wipe down the metal surfaces of the Specimen Transport Module including the tube stripper, continue to step 7.

**CAUTION**

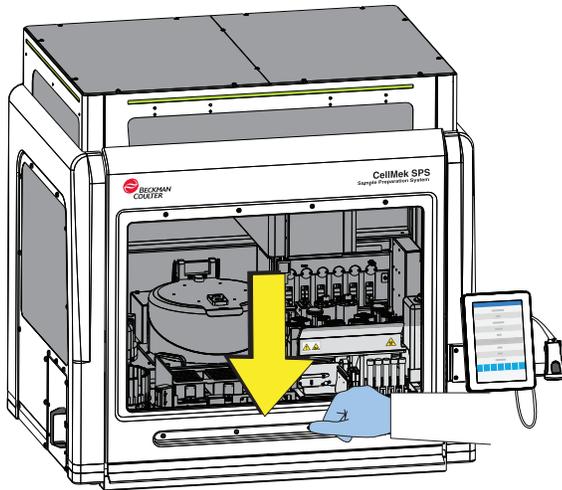
Risk of chemical injury from bleach. To avoid contact with the bleach, use barrier protection, including protective eyewear, gloves, and suitable laboratory attire. Refer to the Safety Data Sheet for details about chemical exposure before using the chemical.

- 5 If there is any blood build-up in the tube stripper, use a lint free tissue dampened with a dilution of 9-parts water and 1-part high quality, fragrance-free, gel-free bleach (5 to 6% solution of sodium hypochlorite - available chlorine) to wipe the tube stripper.



- 6 Use a lint free tissue dampened with DI water, wipe off any residual bleach solution.

7 Close the front door.



Cleaning the Cell Wash Bottle

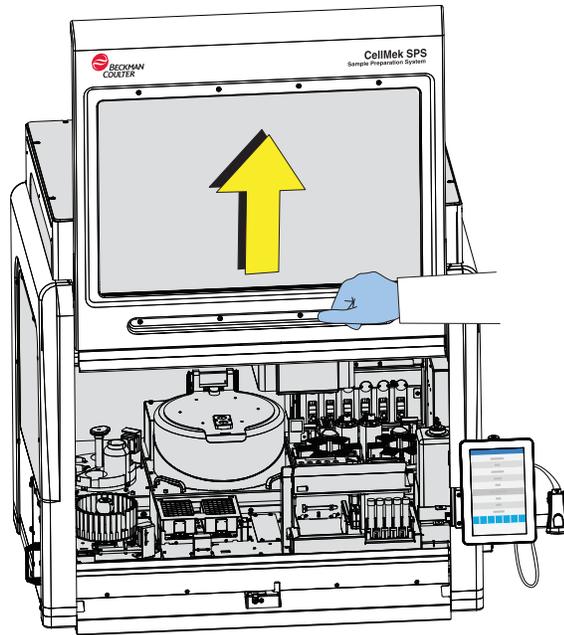


WARNING

Risk of personal injury or biohazardous contamination when contacting CellMek SPS including work area components, carousels, cassettes, reaction plates, reagent bottles, and waste container. To prevent possible injury or biohazardous exposure, always wear proper laboratory attire, including gloves, a laboratory coat, and eye protection. Refer to [CHAPTER 1, Material Safety Data Sheets \(SDS/MSDS\)](#) for chemical exposure details.

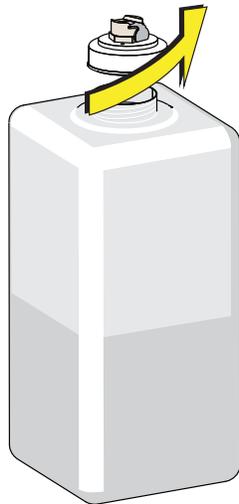
The cell wash bottle used to contain the wash buffer should be cleaned after use. See [Cleaning Schedule](#).

- 1 Open the front door.

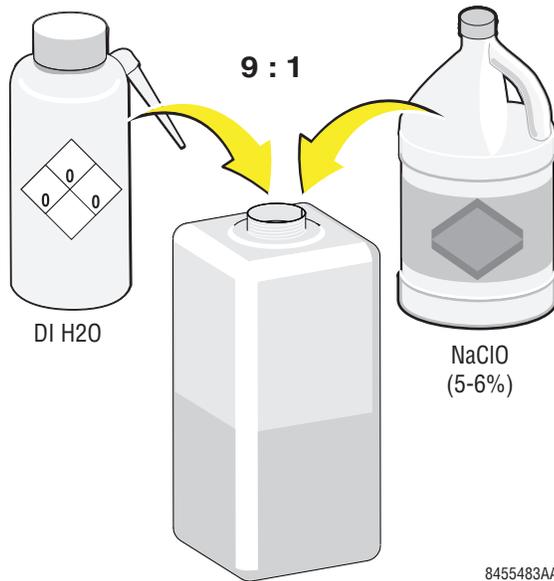


- 2 Remove the Cell Wash Bottle and discard contents in accordance with your local regulations.

- 3 Remove the bottle cap.



- 4 Add 200 mL of a dilution consisting of 9-parts water and 1-part high quality, fragrance-free, gel-free bleach (5 to 6% solution of sodium hypochlorite - available chlorine) to the Cell Wash Fluid bottle.



- 5 Replace the bottle cap.



- 6 Block the cap opening to avoid spillage, and shake the bleach solution inside the bottle to wet all the internal surfaces.



- 7 Allow the bottle to sit for 10 minutes or longer.
- 8 Remove the bleach and thoroughly rinse with deionized water.

Cleaning the Barcode Readers

Built-up dust or uncleaned fluid spills can interfere with the barcode scanning process. If the barcode reader is failing to read barcode labels, clean the barcode reader window and attempt to scan the barcode again.



WARNING

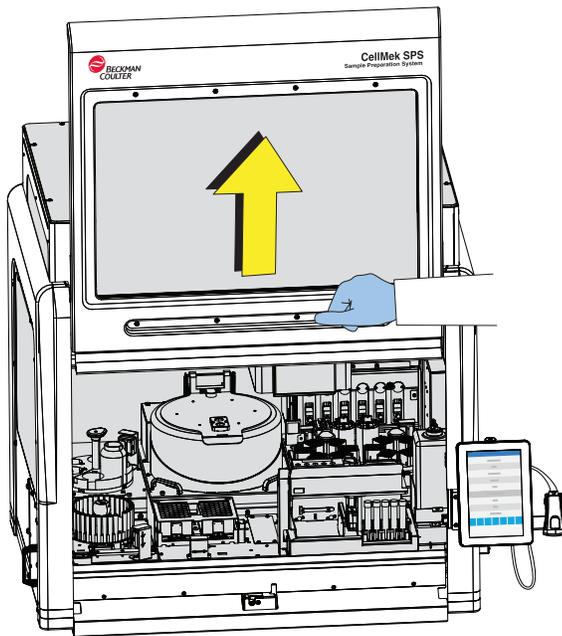
Risk of personal injury or biohazardous contamination when contacting CellMek SPS including work area components, carousels, cassettes, reaction plates, reagent bottles, and waste container. To prevent possible injury or biohazardous exposure, always wear proper laboratory attire, including gloves, a laboratory coat, and eye protection. Refer to [CHAPTER 1, Material Safety Data Sheets \(SDS/MSDS\)](#) for chemical exposure details.

CAUTION

Risk of damaging the barcode reader window when using abrasive or corrosive cleaners such as bleach. Only use the suggested products in this procedure to ensure that the sensitive barcode reader window is not damaged.

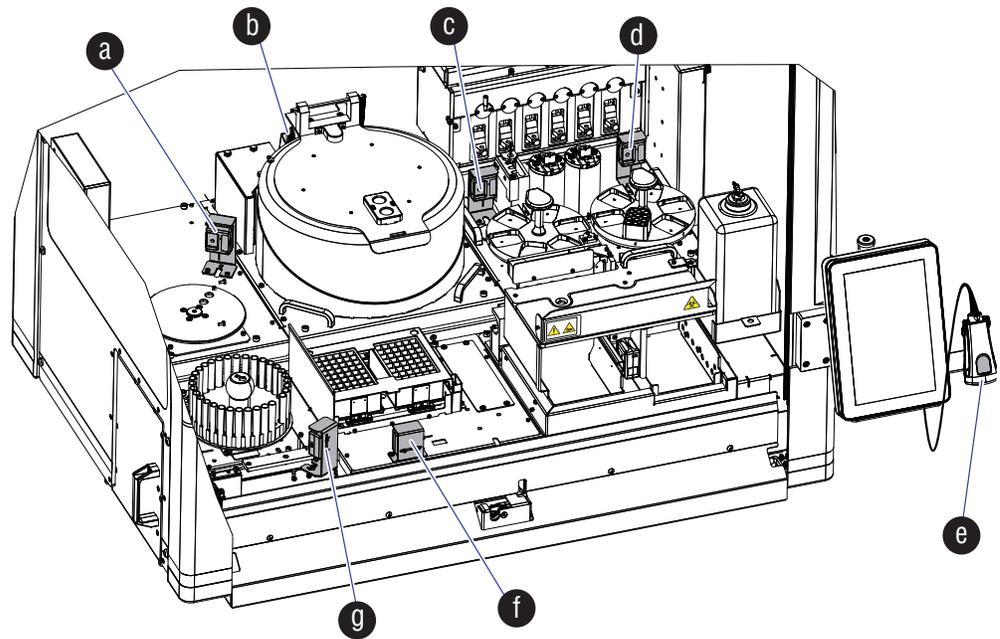
This procedure should be performed as needed. See [Cleaning Schedule](#).

- 1 Open the front door.

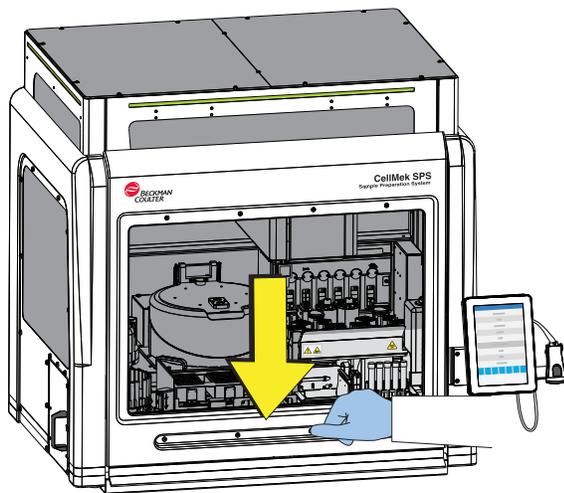


- 2 Dampen a lint free tissue with a deionized solution or distilled water.
- 3 Carefully wipe the barcode reader window. Do not apply excessive force when cleaning the barcode readers. Listed below are the accessible barcode readers:
 - a. Prep Reagent Module Barcode Reader
 - b. Liquid Antibody Barcode Reader
 - c. Left Dry Reagent Module Barcode Reader
 - d. Right Dry Reagent Module Barcode Reader
 - e. Handheld Barcode Reader
 - f. Reaction Plate Module Barcode Reader

g. Output Module Barcode Reader



4 Close the front door.



Cleaning the Carousels, Cassettes, and Adaptors

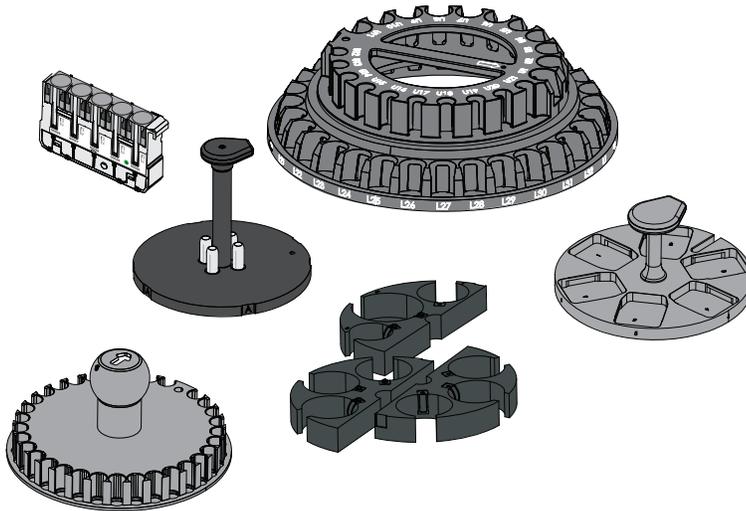


WARNING

Risk of personal injury or biohazardous contamination when contacting CellMek SPS including work area components, carousels, cassettes, reaction plates, reagent bottles, and waste container. To prevent possible injury or biohazardous exposure, always wear proper laboratory attire, including gloves, a laboratory coat, and eye protection. Refer to [CHAPTER 1, Material Safety Data Sheets \(SDS/MSDS\)](#) for chemical exposure details.

This procedure should be performed as needed. See [Cleaning Schedule](#).

- 1 Wash specimen cassettes, prep reagent bottle adaptors, dry reagent carousels, and output carousels with warm soapy water. Do not use an abrasive cleaner. These components should be free of dried blood, reagent, bleach, or diluent.



- 2 Rinse and with DI water to remove any deposits.
- 3 Inspect the barcode labels after cleaning. Replace loose or worn labels before putting back into the CellMek SPS.

Cleaning the System Doors and Covers



WARNING

Risk of personal injury or biohazardous contamination when contacting CellMek SPS including work area components, carousels, cassettes, reaction plates, reagent bottles, and waste container. To prevent possible injury or biohazardous exposure, always wear proper laboratory attire, including gloves, a laboratory coat, and eye protection. Refer to [CHAPTER 1, Material Safety Data Sheets \(SDS/MSDS\)](#) for chemical exposure details.

This procedure should be performed on a as needed basis. See [Cleaning Schedule](#).

- 1 Dampen a lint free cloth with a non-abrasive plastic and glass safe cleaner.
- 2 Wipe the door and cover surfaces.

Cleaning the Deck and Metal Carousel Hubs

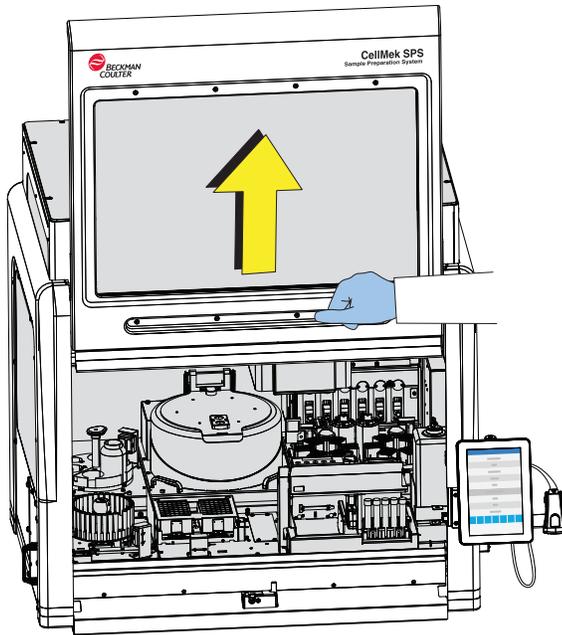


WARNING

Risk of personal injury or biohazardous contamination when contacting CellMek SPS including work area components, carousels, cassettes, reaction plates, reagent bottles, and waste container. To prevent possible injury or biohazardous exposure, always wear proper laboratory attire, including gloves, a laboratory coat, and eye protection. Refer to [CHAPTER 1, Material Safety Data Sheets \(SDS/MSDS\)](#) for chemical exposure details.

This procedure should be performed on a as needed basis. See [Cleaning Schedule](#).

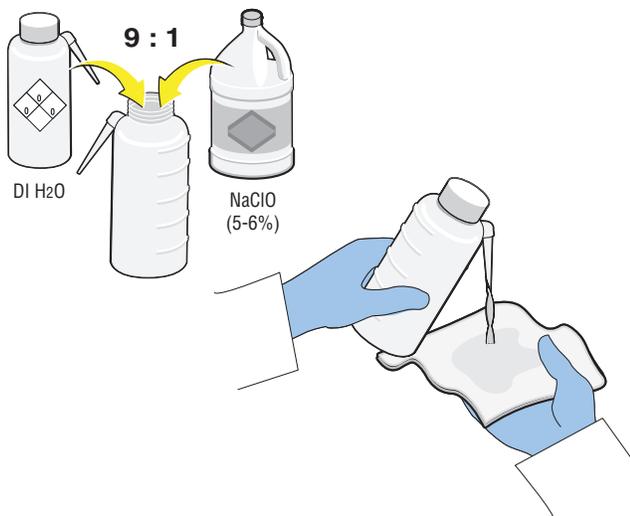
- 1 Open the front door.



CAUTION

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 Dampen a lint free tissue with a dilution of 9-parts water and 1-part high quality, fragrance-free, gel-free bleach (5 to 6% solution of sodium hypochlorite - available chlorine).



-
- 3 Wipe down instrument deck or carousel hub surfaces that require cleaning. When cleaning the carousel hubs (output, prep reagent, or dry reagent), hold the hub with one hand to prevent it from rotating and wipe the surface using your other hand.
-
- 4 Dampen a lint free tissue with deionized or distilled water and wipe off any residual bleach solution.
-

Cleaning Biological Spills



WARNING

Risk of injury and biohazardous contamination if biological spills occur and are not immediately and properly cleaned up. In the event of a biological spill, clean the area according to your laboratory protocol and follow all safety precautions.

-
- 1 Disinfect the area using a disinfectant solution according to your laboratory's procedures.
-
- 2 Dispose of all materials in your laboratory's biohazard waste containers.
-

IMPORTANT If liquid has spilled in an inaccessible area, [contact us](#).

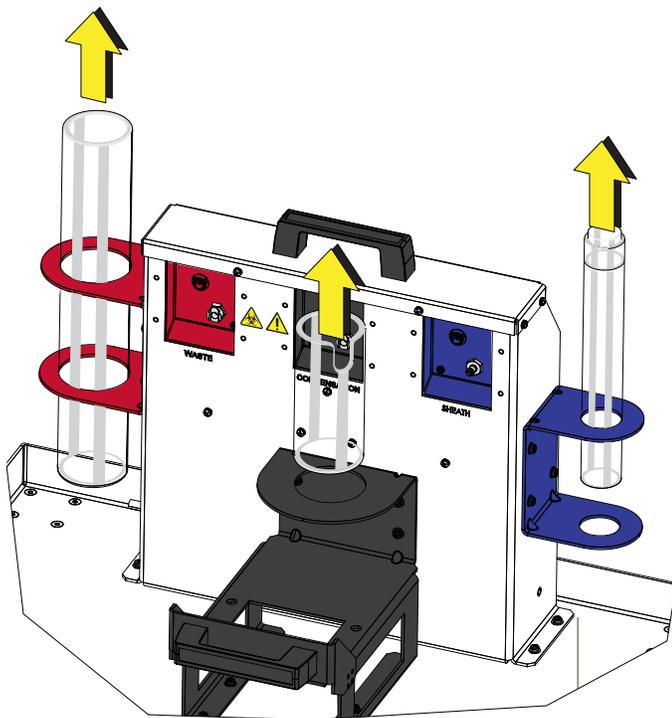
- 3 Refer to CLSI/CCCLS document GP17 - Clinical Laboratory Safety for additional information.
-

Cleaning The Holding Cylinders



WARNING

Risk of personal injury or biohazardous contamination when contacting CellMek SPS including work area components, carousels, cassettes, reaction plates, reagent bottles, and waste container. To prevent possible injury or biohazardous exposure, always wear proper laboratory attire, including gloves, a laboratory coat, and eye protection. Refer to [CHAPTER 1, Material Safety Data Sheets \(SDS/MSDS\)](#) for chemical exposure details.



- 1 Ensure that no samples/specimens are running.
- 2 Clean the waste, sheath, and condensate holding cylinders with detergent and by scrubbing with a bottle brush.
- 3 Rinse with deionized or distilled water.

CHAPTER 9

Replacement Procedures

Overview

This chapter contains information on the following:

- Replacing Reagents and Consumables
- Replacing the Reaction Plate
- Replacing the Prep Reagents
- Replacing the Antibody Reagents
- Replacing the DURACartridge Reagents
- Replacing the IsoFlow Sheath Solution Cubitainer
- Replacing the Wash Buffer in the Cell Wash Fluid Bottle
- Replacing the Waste Container
- Replacing the Condensate Container
- Replacing the Probes

Replacing Reagents and Consumables

Barcoded Reagents

Scan Reagent Information From Barcode

The following reagents need to be scanned by using the handheld barcode scanner when loading a new reagent:

- IsoFlow Sheath Solution
- Custom Antibody Vials when new product ID is enrolled
- Custom Prep Reagents when new product ID is enrolled
- Each DURACartridge (dry reagents)

NOTE Be sure to scan the reagent barcode before using the reagents listed above.

Beckman Coulter reagents, custom reagents that have already been enrolled, and consumables are automatically scanned by the system once they are loaded in the respective holder:

- Antibody Vials
- Prep Reagents
- DURACartridge (dry reagents)

- Reaction Plates
- Output Tubes

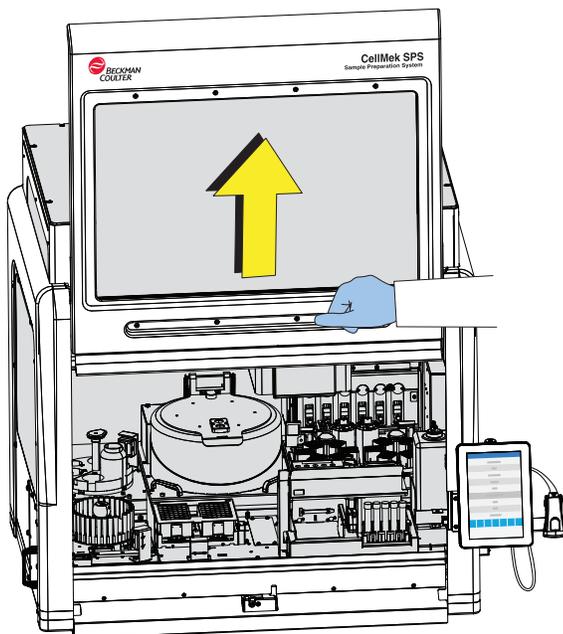
Replacing the Reaction Plate



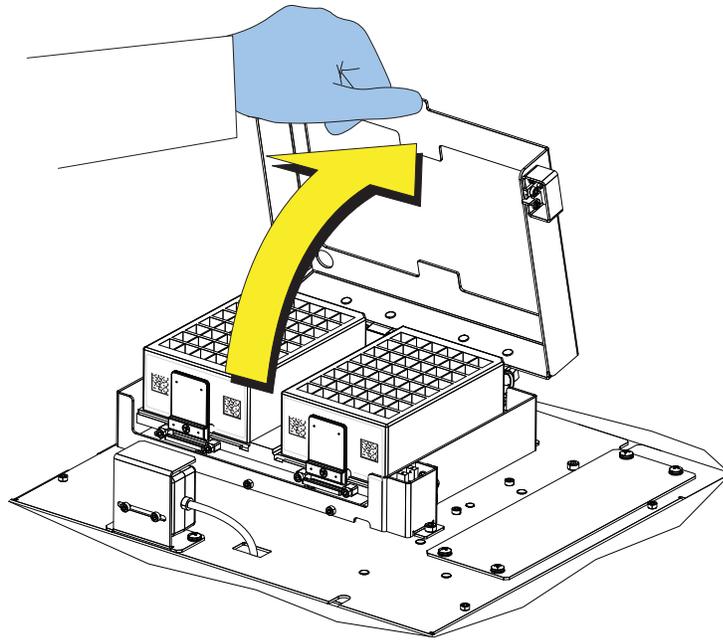
WARNING

Risk of biohazardous contamination. To avoid contamination when handling CellMek SPS carousels, cassettes, reaction plates, or reagent bottles, wear barrier protection including gloves, eye protection, and a laboratory coat.

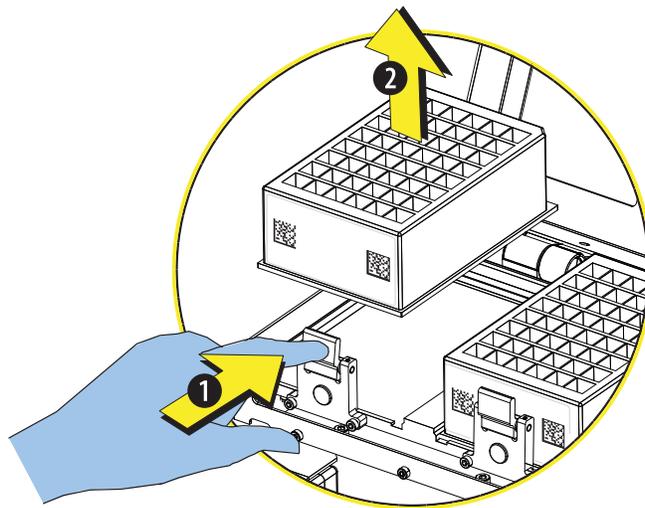
- 1 Open the front door.



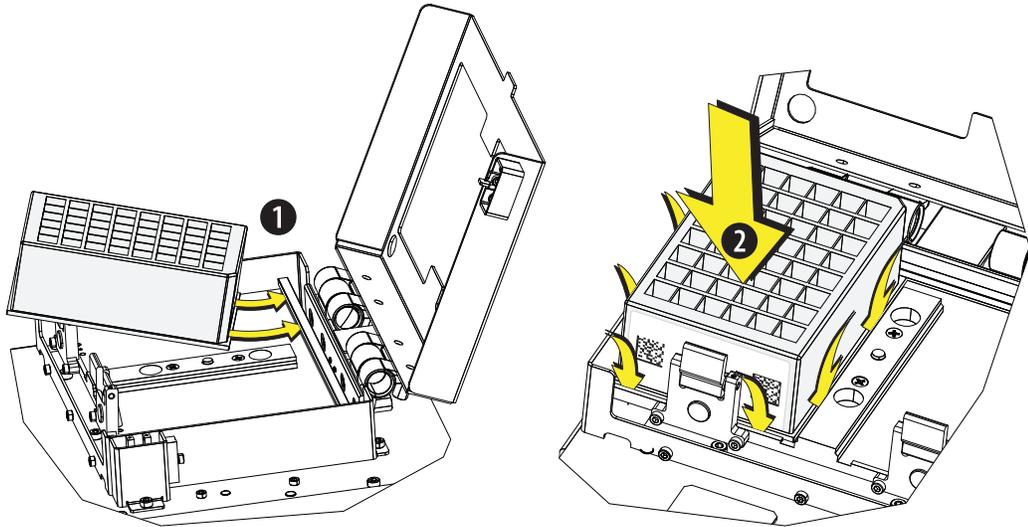
- 2 Open the lid on the Reaction Plate Module.



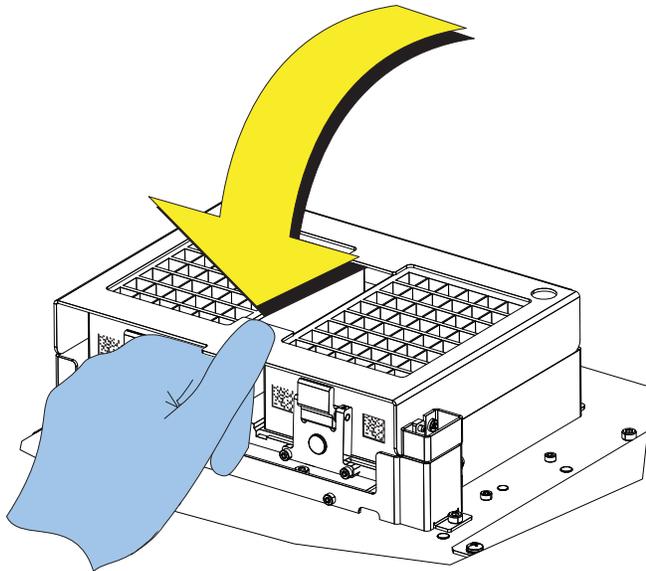
- 3 Push the lever forward and remove the used plate.



- 4** Insert the new plate on the module so that the barcode faces towards the front of the instrument. Ensure that the plate snaps into place.

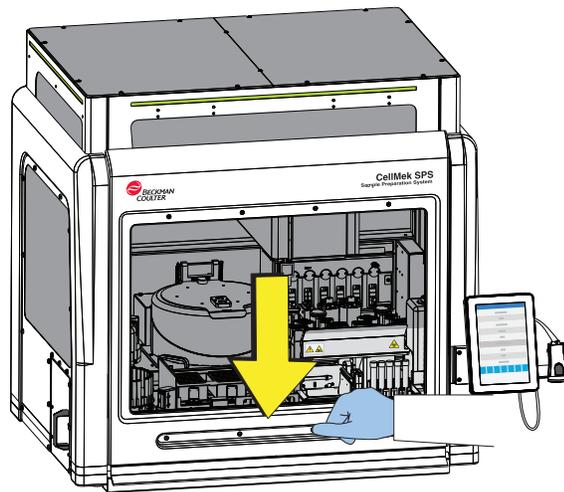


- 5** Close the lid on the Reaction Plate module.



- 6** Close the front door.

The system scans the plates when the instrument cover is closed.



- 7 To review that the plate is installed, go to **Status > Reaction Plate** and select the down arrow to expand the Reaction Plate to see the plates which are installed.

Replacing the Prep Reagents



WARNING

Risk of biohazardous contamination. To avoid contamination when handling CellMek SPS carousels, cassettes, reaction plates, or reagent bottles, wear barrier protection including gloves, eye protection, and a laboratory coat.

CAUTION

Risk of reporting erroneous results. To avoid problems with reagents or the system, always run an application-specific quality control check before testing with clinical samples.

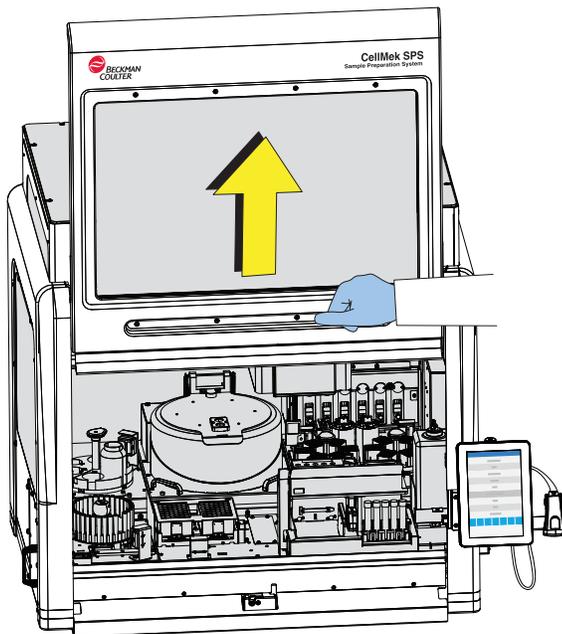
CAUTION

Risk of damage of instrument components. To avoid damage to the instrument components, remove prep reagent bottle cap prior to loading onto the system.

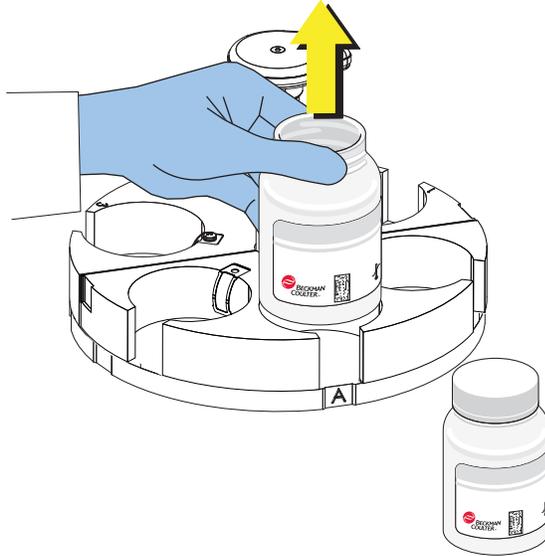
CAUTION

Risk of biohazardous contamination. Overfilling the Custom Defined prep reagent bottle may cause chemical spills. Ensure that the Custom Defined prep reagent bottle is not filled with more than 100 mL.

- 1 Open the front door.



- 2 Remove the empty Prep Reagents bottles from the carousel.



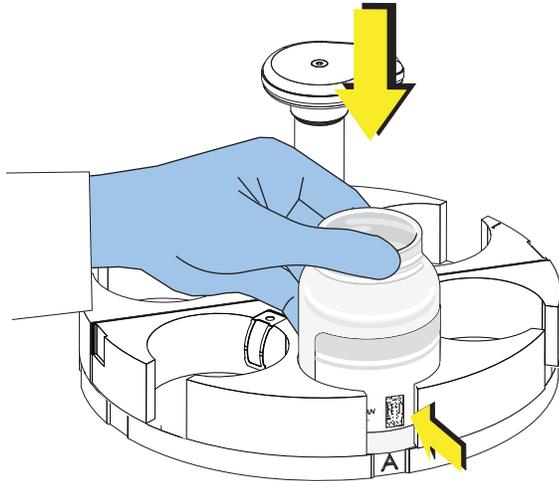
⚠ CAUTION

Risk of damage to instrument components. To avoid damage to the instrument components, remove the prep reagent bottle caps prior to loading onto the system.

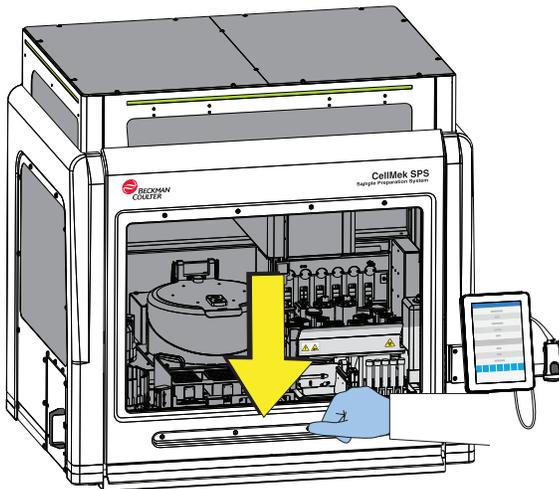
- 3 Remove the caps and foil wrapping on the new CellMek Prep Reagent bottles before loading.



- 4 Place the new bottles in the appropriate holders with the barcodes facing outwards.



- 5 Close the front door.



- 6 The instrument will scan the reagent barcodes and check for caps on prep reagent bottles.

NOTE Beckman Coulter prep reagents that are scanned will be listed as Unknown in the onboard reagents screen until a panel is imported that uses that reagent.

Replacing the Antibody Reagents



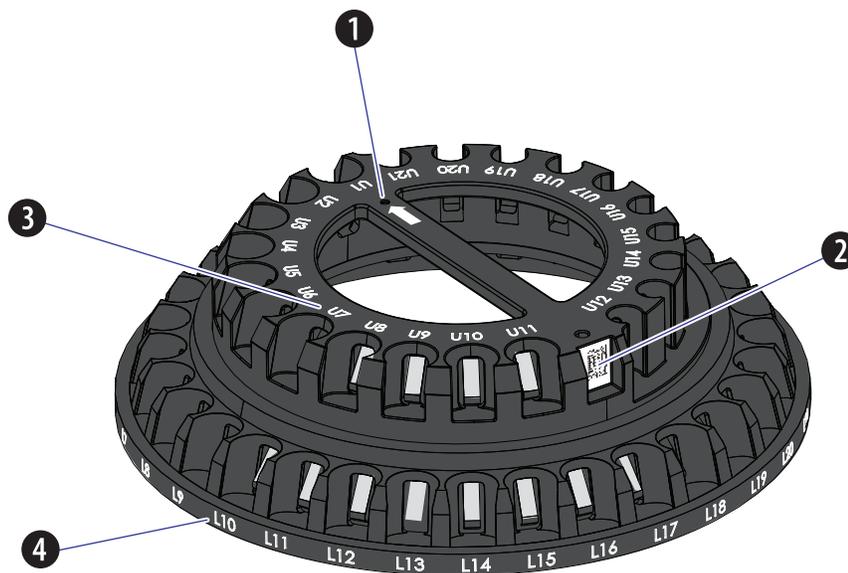
WARNING

Risk of biohazardous contamination. To avoid contamination when handling CellMek SPS carousels, cassettes, reaction plates, or reagent bottles, wear barrier protection including gloves, eye protection, and a laboratory coat.

CAUTION

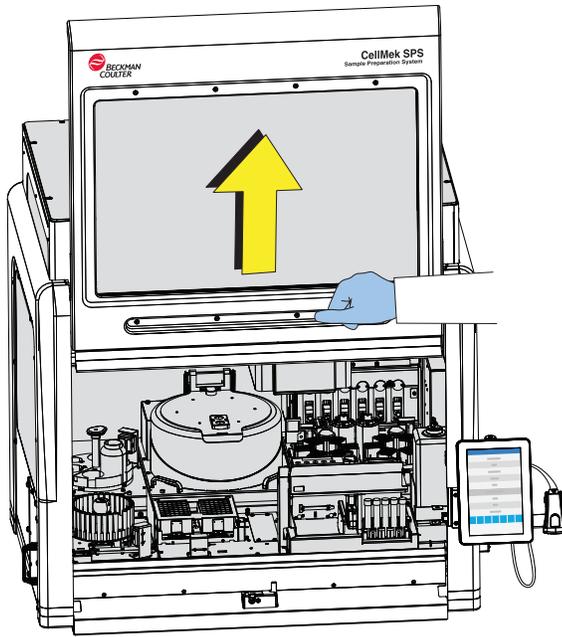
Risk of reporting erroneous results. To avoid problems with reagents or the system, always run an application-specific quality control check before testing with clinical samples.

Figure 9.1 Carousel for Antibody Reagents

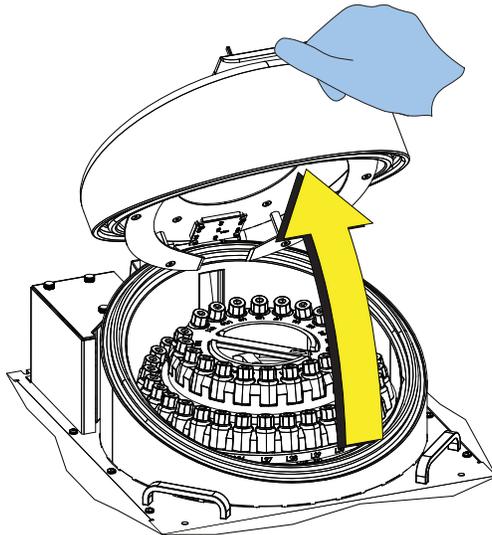


1. Alignment Hole
2. Carousel ID
3. Upper Deck Positions
4. Lower Deck Positions

- 1 Open the front door.



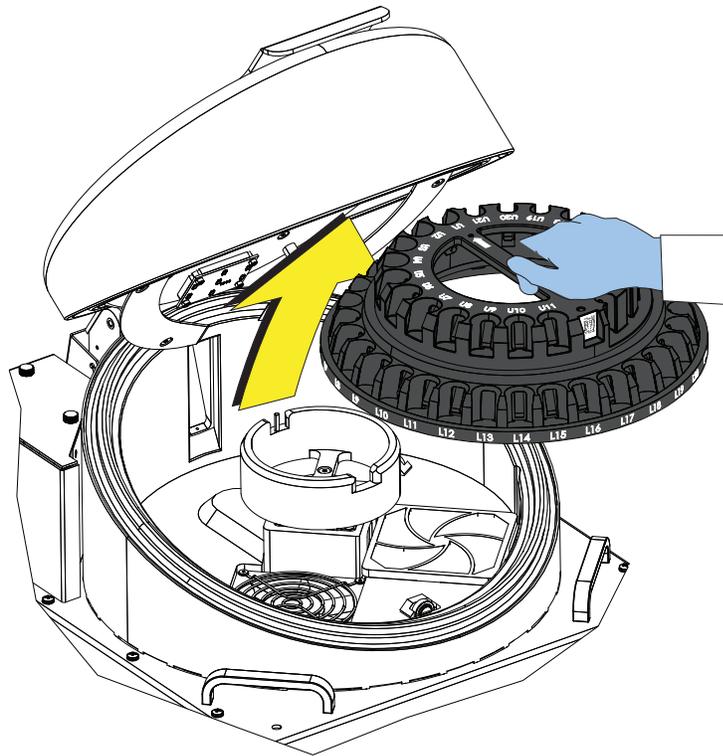
- 2 Open the Liquid Antibody Module cover.



⚠ WARNING

Risk of biohazardous contamination. Empty antibody vials should be considered as contaminated containers. Dispose of all empty Monoclonal Antibody vials in accordance with your local regulations and acceptable laboratory practices.

- 3 Remove the carousel from the instrument.



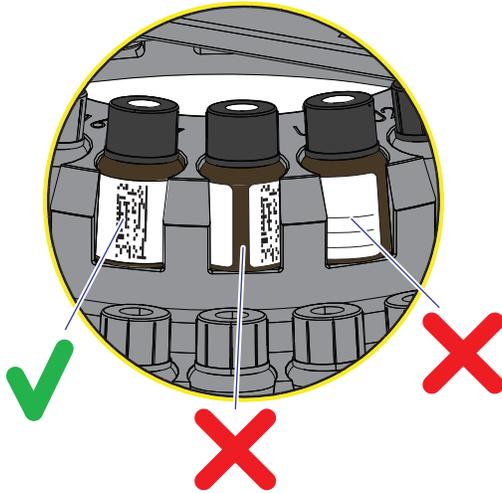
- 4 Remove any empty antibody vials.

⚠ CAUTION

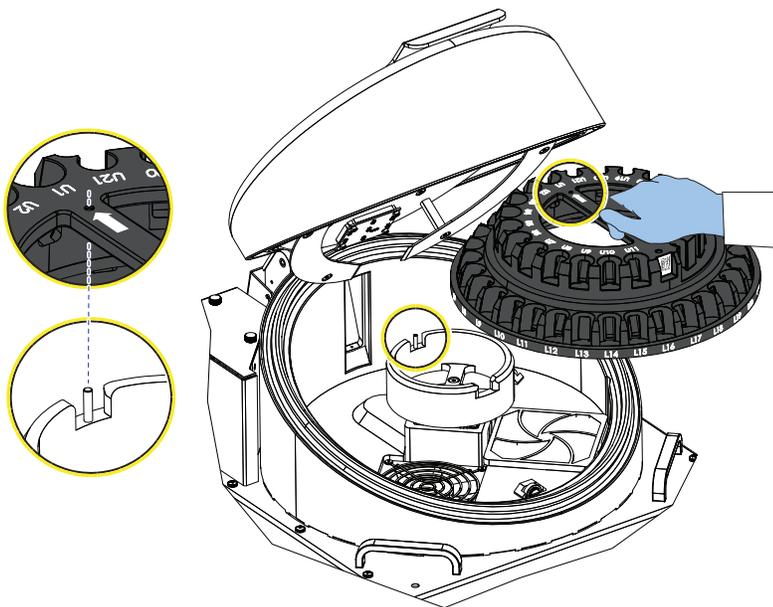
Risk of damage of instrument components. To avoid damage to the instrument components, replace original antibody vial cap with the pierceable cap prior to loading onto system.

- 5 For enrolling Custom Defined Reagents, follow [CHAPTER 6, Custom Defined Reagents](#). For Beckman Coulter reagents, proceed to the following step.

- 6 Place the new antibodies in any of the available positions on the carousel in the upper or lower deck and ensure they are properly aligned.

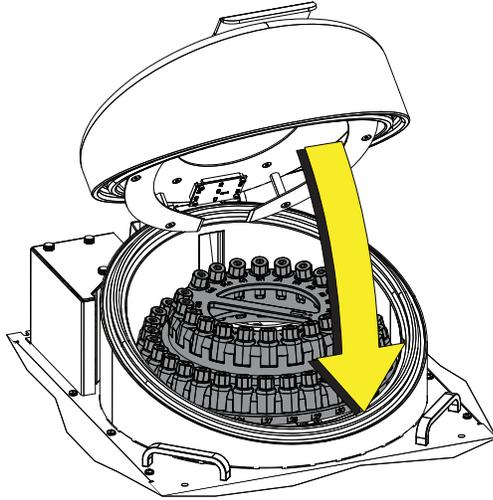


- 7 Place the carousel into the Liquid Antibody Module and ensure the slot aligns with the alignment pin.

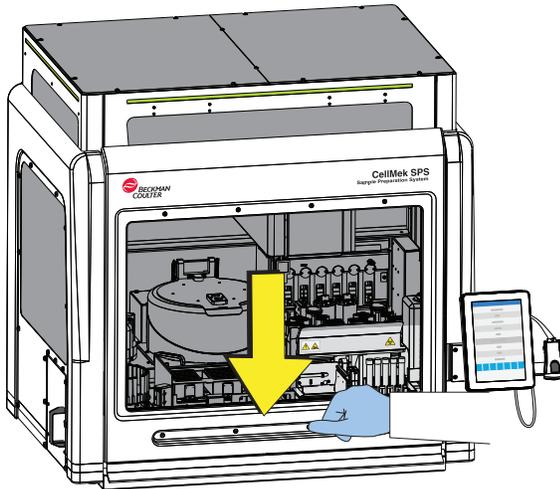


NOTE When loading the carousel into the instrument, align the arrow in the carousel with the pin in the hub, gently turn the carousel until it drops into position.

-
- 8 Close the Liquid Antibody Module cover.



-
- 9 Close the front door.



-
- 10 The instrument will scan the reagent barcodes.

NOTE Beckman Coulter Antibody Reagents that are scanned will show as Unknown until the panel is imported that uses that reagent.

-
- 11 The reagents are scanned and the Confirm Wash Buffer Fluid screen is opened. Specify what reagent is in the wash buffer bottle. Select **Confirm**.



- 12 Select **Check System** to prime the Cell Wash. This step is crucial if you plan to run samples that require the Cell Wash module. If you do not select **Check System**, the software will not allow you to run those samples.

Replacing the DURACartridge Reagents



WARNING

Risk of biohazardous contamination. To avoid contamination when handling CellMek SPS carousels, cassettes, reaction plates, or reagent bottles, wear barrier protection including gloves, eye protection, and a laboratory coat.

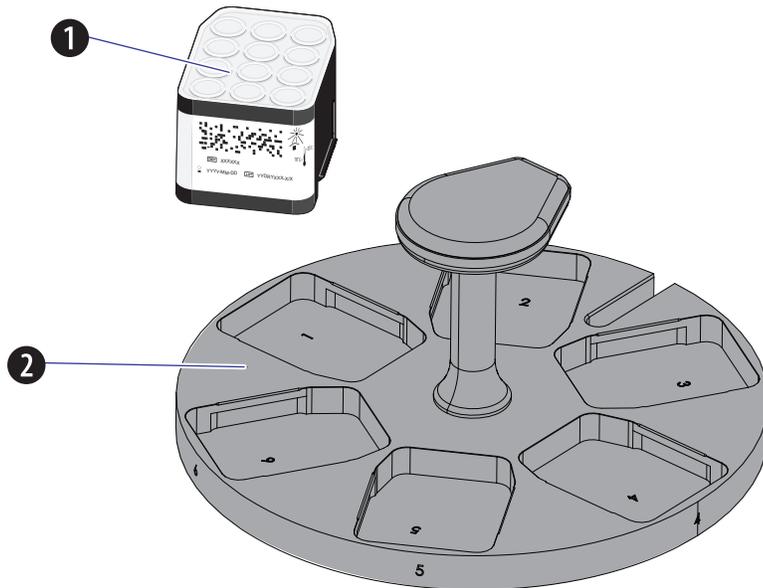
CAUTION

Risk of reporting erroneous results. To avoid problems with reagents or the system, always run an application-specific quality control check before testing with clinical samples.

CAUTION

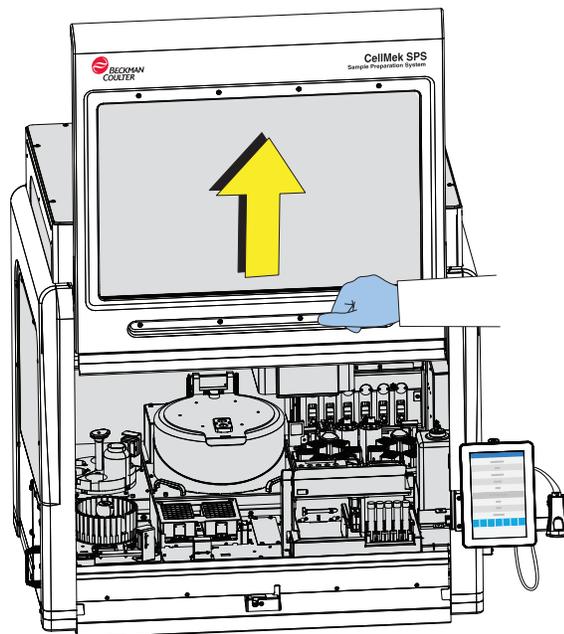
Risk of erroneous results. To avoid Dry Reagent deterioration, always store Dry Reagents cartridges, including the packaged product away, from light.

Figure 9.2 Carousel for DURACartridge Reagents

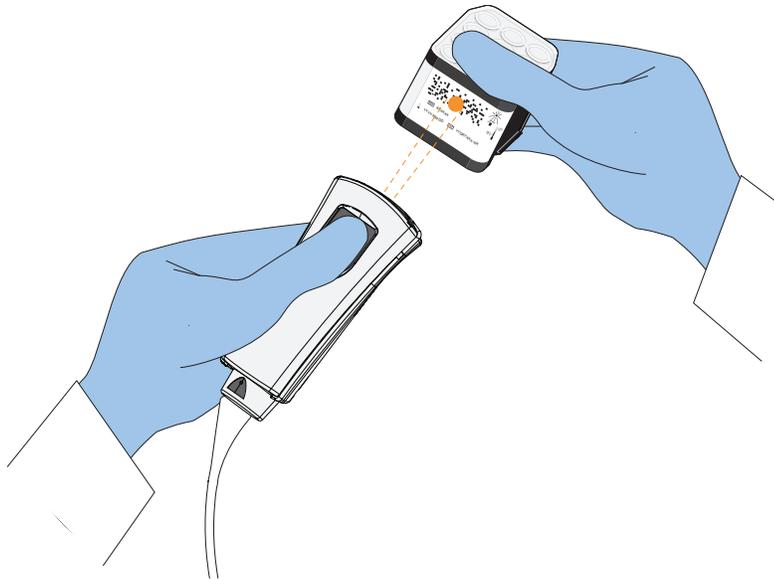


1. DURACartridge
2. Dry Reagent Carousel

1 Open the front door.

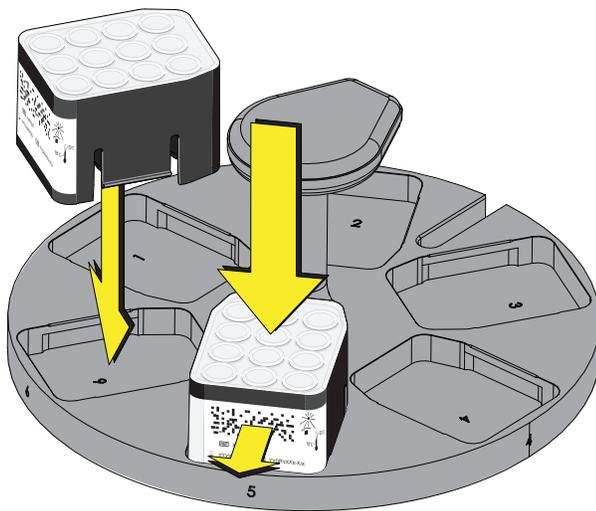


-
- 2 Scan the dry reagent barcode label.

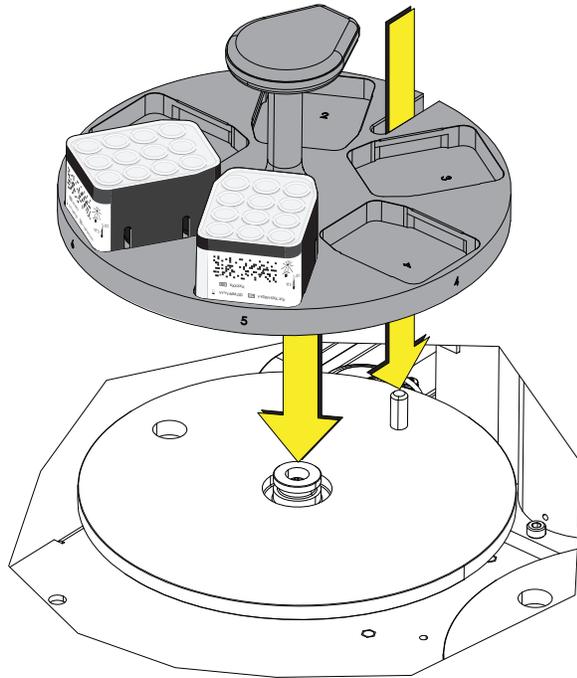


-
- 3 Select a reagent name on the software and select **Save**.

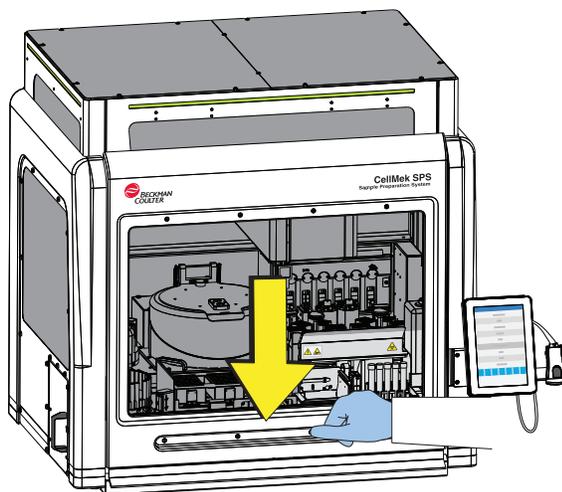
-
- 4 Insert the DURACartridge reagents in the Dry Reagent Carousel.



- 5 Place the carousel into the Dry Reagent Carousel Hub ensuring the slot aligns with the alignment pin.



- 6 Close the front door.



- 7 The reagents are scanned and the Confirm Wash Buffer Fluid screen is opened, specify what reagent is in the wash buffer bottle.

- 8 Select **Confirm** and screen will close.



- 9 Select **Check System** to prime the Cell Wash. This step is crucial if you plan to run samples that require the Cell Wash module. If you do not select **Check System**, the software will not allow you to run those samples.

Replacing the IsoFlow Sheath Solution Cubitainer



WARNING

Risk of biohazardous contamination. To avoid contamination when handling CellMek SPS carousels, cassettes, reaction plates, or reagent bottles, wear barrier protection including gloves, eye protection, and a laboratory coat.

CAUTION

Risk of losing in-process samples if IsoFlow Sheath Solution is replaced during sample processing. Only replace the IsoFlow Sheath Solution when the system is in the Ready or Not Ready state.

Use this procedure when the following message appears:

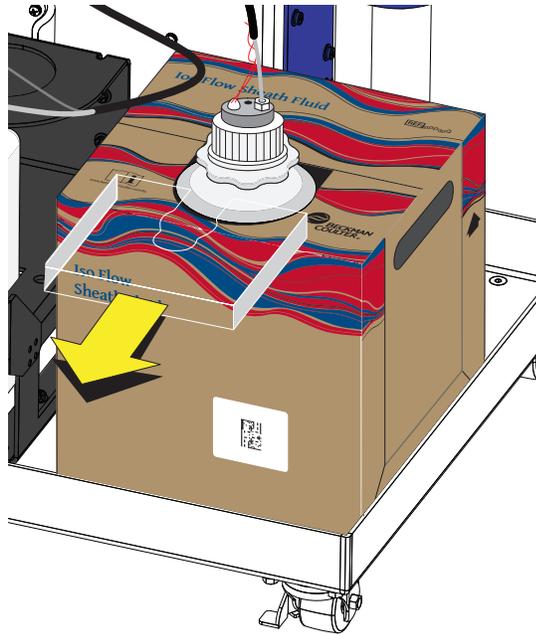
Diluent is empty. Ensure system is not in processing state, change the diluent container, scan the barcode, and press the Check System button on the status bar. Contact service representative if problem continues.

- 1 Allow all loaded samples to complete processing and do not load any new samples in the system.

CAUTION

Misleading results could occur if you contaminate the sheath fluid. Be careful not to contaminate the sheath fluid. Do not let your fingers, paper towels, or other objects touch the pickup tube assembly.

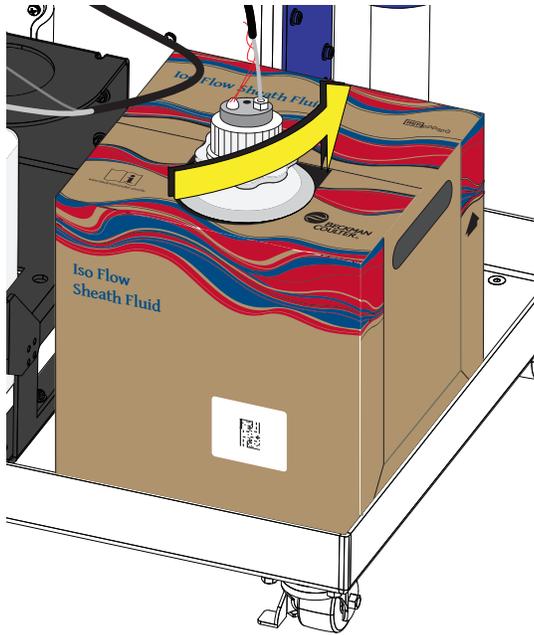
- 2 Remove the support collar from the external sheath fluid container and set aside.



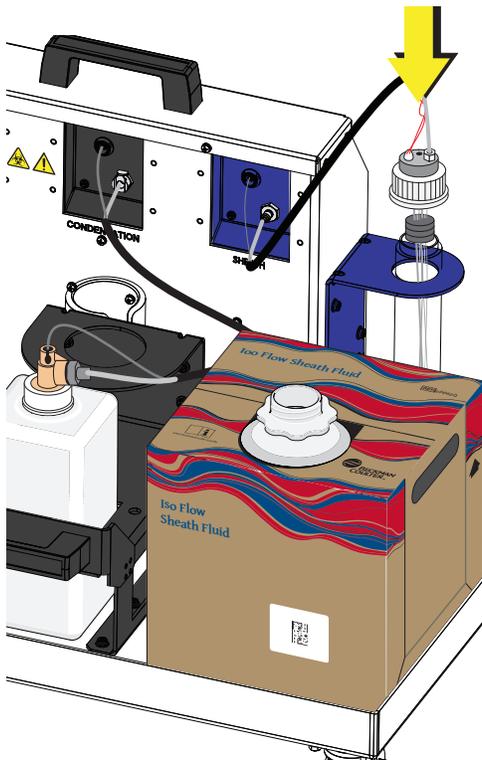
Replacement Procedures

Replacing the IsoFlow Sheath Solution Cubitainer

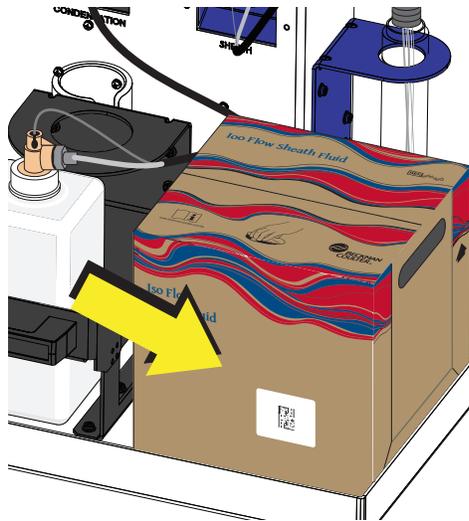
- 3 Unscrew the IsoFlow Sheath cap.



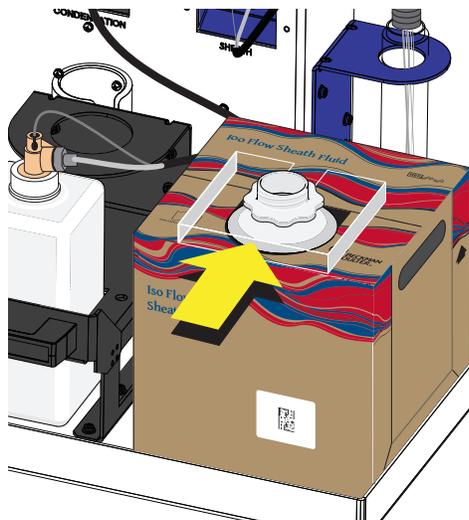
- 4 Transfer the IsoFlow sheath fluid pickup tube from the empty sheath fluid container into the sheath fluid pickup tube holder.



- 5 Replace empty sheath container from the cart with a new one.



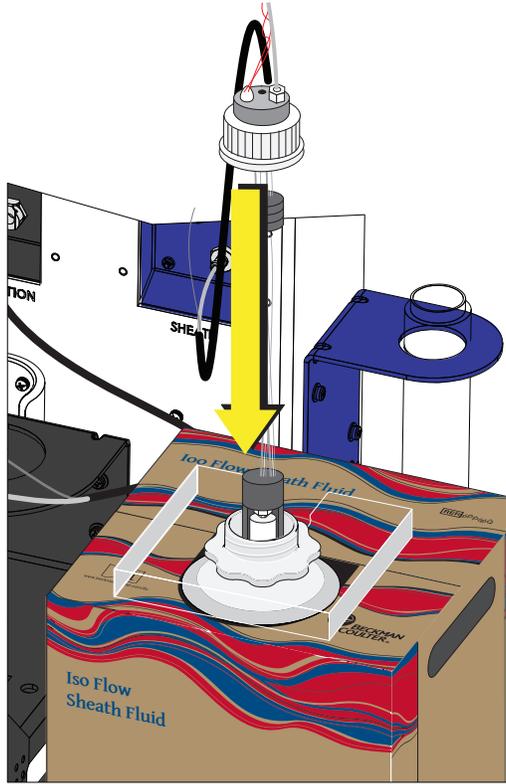
- 6 Remove any cardboard cutouts from the new sheath fluid container.
- 7 Remove the cap and seal from the new sheath fluid container. Ensure that you have completely removed the foil seal.
- 8 Install the support collar.



Replacement Procedures

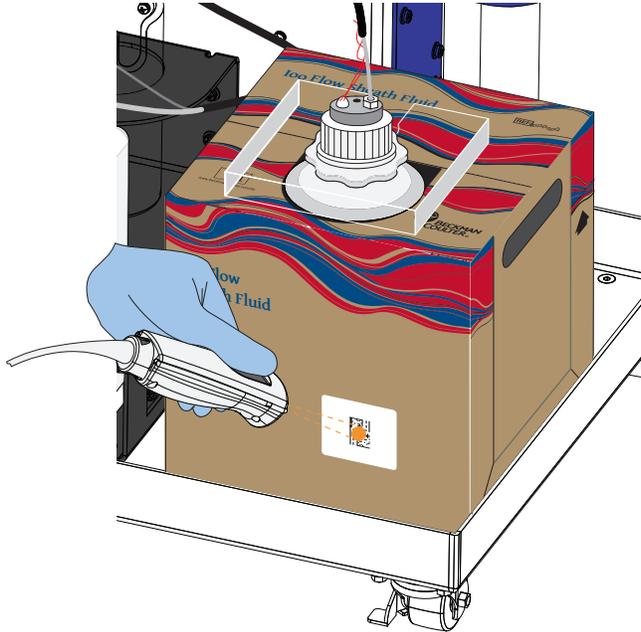
Replacing the IsoFlow Sheath Solution Cubitainer

- 9 Lift the pickup tube assembly straight up and out of the sheath holder and carefully insert the pickup tube assembly straight into the new sheath fluid container.



- 10 Tighten the cap.
- 11 Put the cap from the new container onto the old container and dispose of the container properly.

-
- 12** Scan the sheath container with the handheld barcode reader in any screen other than the **Load Specimen** screen.



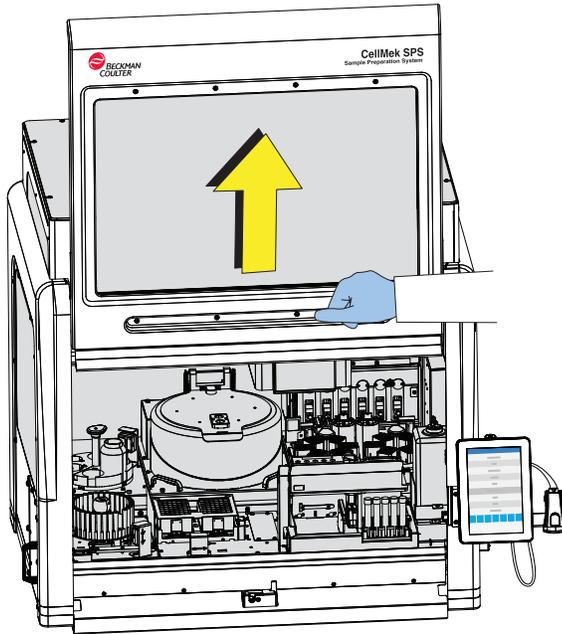
-
- 13** Select **Save** on the Diluent enrollment screen.

-
- 14** Verify that the tubes are not crimped or pinched after the IsoFlow Sheath Solution cubitainer replacement. If necessary, readjust the tubing or containers to prevent tubing damage. If you see tubing damage, [contact us](#).

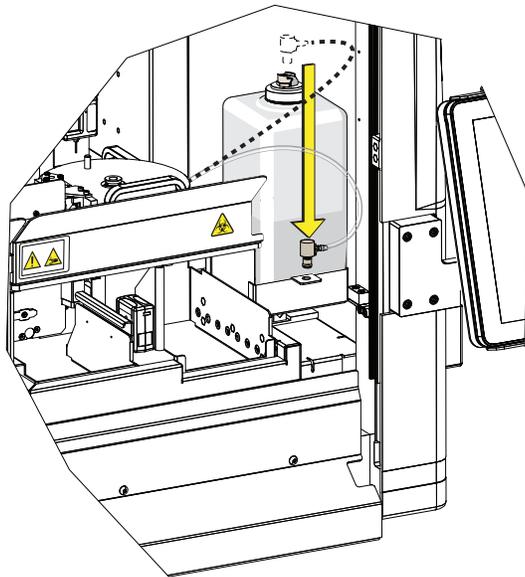
-
- 15** Select  **Check System** from the status bar to prime the fluid lines with the new IsoFlow Sheath.

Replacing the Wash Buffer in the Cell Wash Fluid Bottle

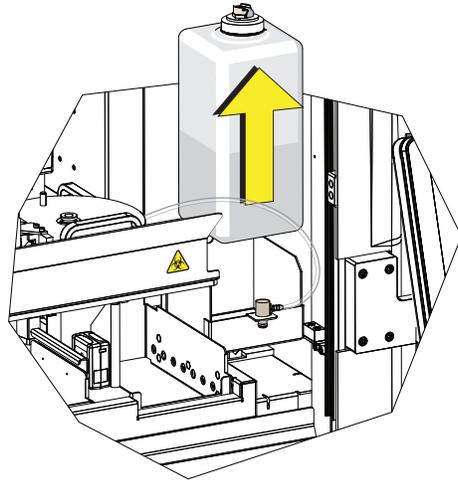
- 1 Open the front door.



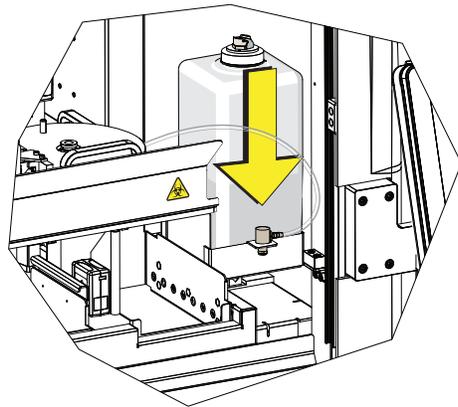
- 2 Unsnap the tubing connector from the cap of the cell wash fluid container and place it into the connector holder.



-
- 3 Remove the current cell wash fluid container from the system.



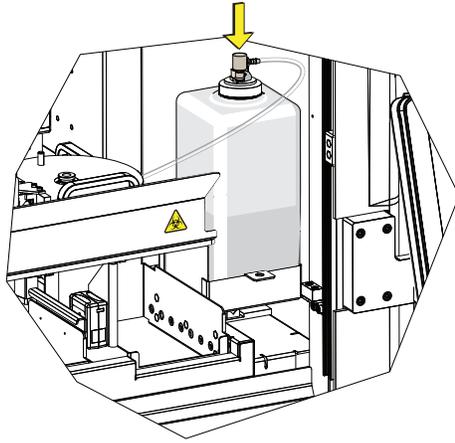
-
- 4 Load a new cell wash fluid container filled with the wash buffer.



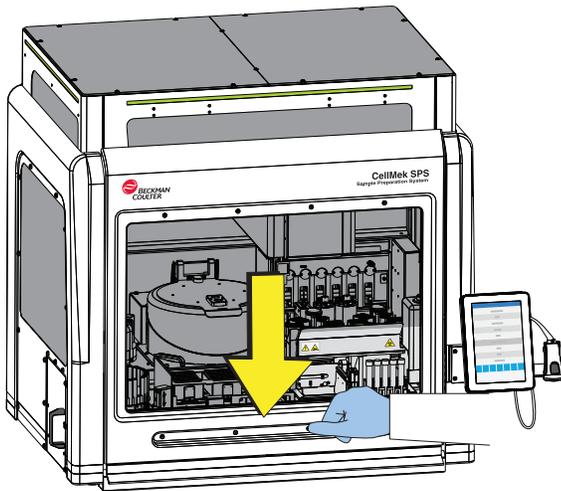
Replacement Procedures

Replacing the Wash Buffer in the Cell Wash Fluid Bottle

- 5 Attach the tubing connector to the cap of the new cell wash fluid container.



- 6 Close the front door.



- 7 Select the Wash Buffer Type, the Lot Number, and the Expiration Date.

- 8 If you loaded a new Wash Buffer, the **Check System** button will appear in the status bar.

IMPORTANT If the Wash Buffer is not primed, the panels that require Cell Wash will not run.



- 9 Select **Check System** from the status bar to prime the fluid lines with the new Wash Buffer.

Replacing the Waste Container



CAUTION

Risk of losing in-process samples if the waste container becomes full during sample processing. Ensure that the waste container is emptied daily.

WARNING

Risk of possible biohazardous contamination. Wear the appropriate protective attire and avoid contact with the waste container contents. Always dispose of waste in accordance to all applicable local regulations.

WARNING

Risk of personal injury or contamination if you have skin contact with the waste container, its contents, or its associated tubing. The waste container and its associated tubing can contain residual biological material and must be handled with care. Clean up spills immediately. Dispose of the contents of the waste container in accordance with your local regulations and acceptable laboratory procedures.

CAUTION

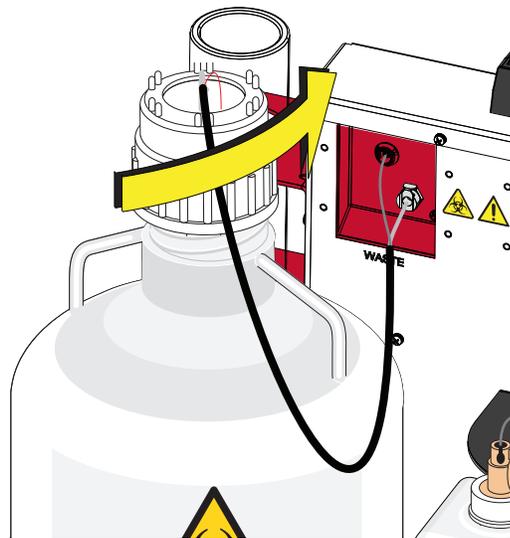
Risk of losing in-process samples if waste container is disconnected while processing samples. Only replace the waste container when the system is in the Ready or Not Ready state.

Use this procedure daily or when the following message appears:

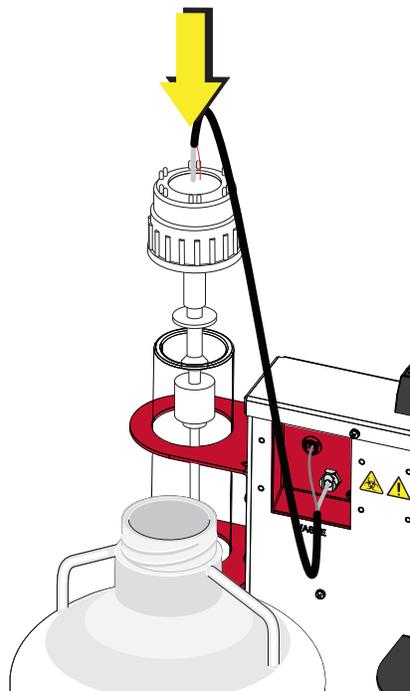
Waste container full. Ensure system is not in processing state, empty the waste container, and press the Check System button on the status bar. Contact service representative if problem continues.

- 1 Allow all loaded samples to complete processing and do not load any new samples in the system.

- 2 Remove the waste cap by twisting counterclockwise.



- 3 Transfer the waste cap to the holding cylinder on the supply cart.



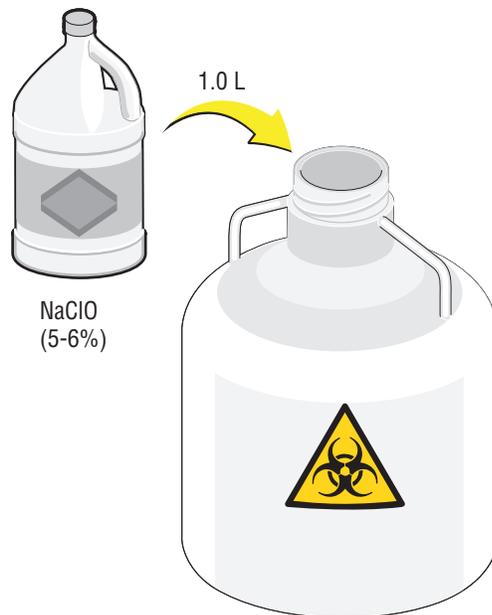
- 4 Empty the waste container according to your laboratory's procedures and local regulations.

NOTE Take proper precautions to avoid spills if you are emptying the waste container into a sink, drain, or larger container. When moving the waste container to dispose of its contents, be sure the provided spare cap is secure to avoid spills.

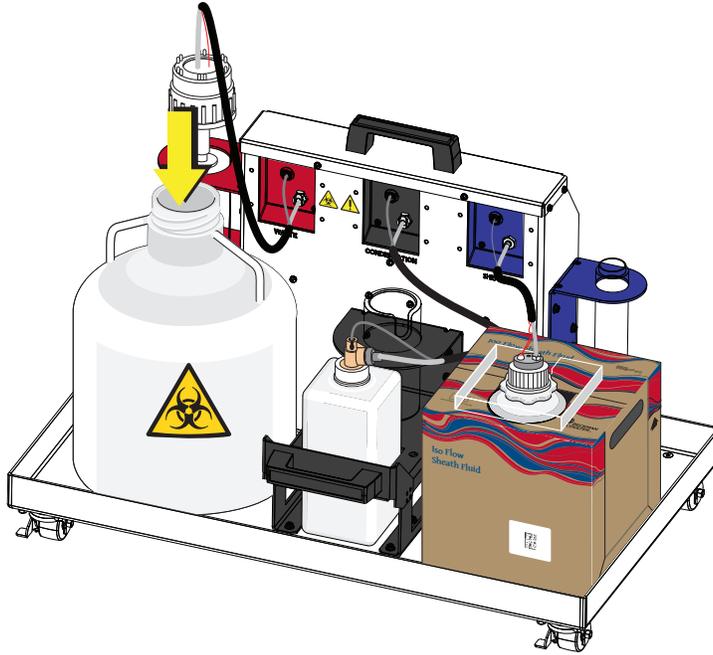
CAUTION

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.

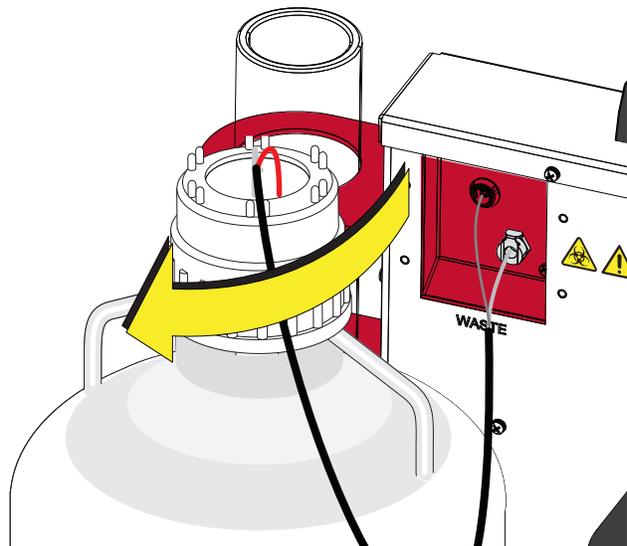
- 5 Put about 1.0 L of high-quality, fragrance-free, gel-free bleach (1) (5 to 6% solution of sodium hypochlorite - available chlorine) in the 15-L waste container to cover the bottom of the container.



- 6 Transfer the waste cap back to the waste container.



- 7 Tighten the waste cap.



- 8 If replacing the IsoFlow Sheath Solution cubitainer and waste container at the same time, proceed to [Replacing the IsoFlow Sheath Solution Cubitainer](#).

-
- 9  Select **Check System** on the status bar to clear the waste full status.
-

Replacing the Condensate Container

WARNING

Risk of spill, if the condensate container is not changed when prompted by the software. To reduce workflow interruptions, it is recommended that you empty the condensate container daily.

CAUTION

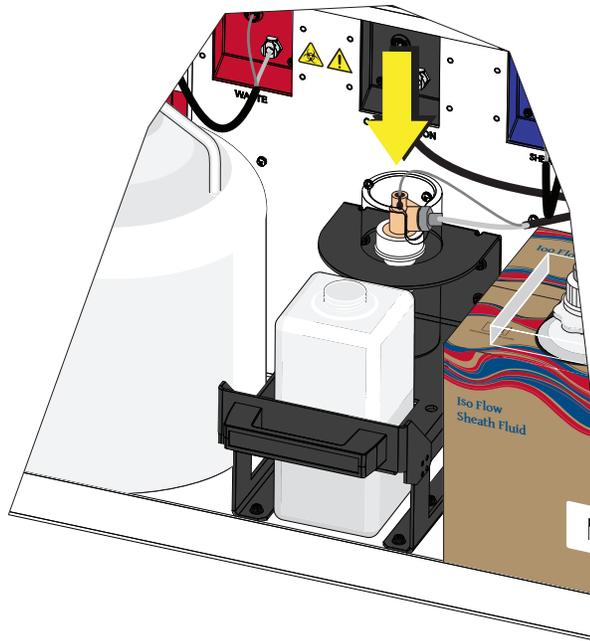
Risk of reagent spoilage; the onboard refrigerator turns off when condensate container becomes full. It is recommended that you empty the condensate container daily.

Use this procedures when the following message appears:

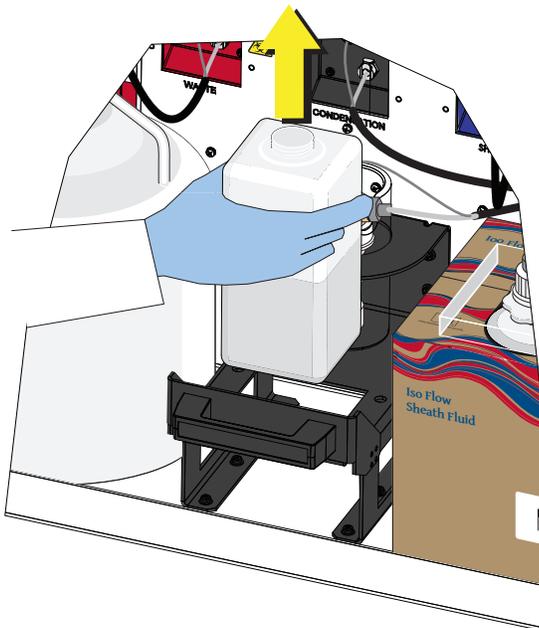
Condensate container full. Empty the condensate container.

- 1 Allow all loaded samples to complete processing and do not load any new samples in the system.

- 2 Remove the condensate cap by twisting counterclockwise and place in the holding cylinder.

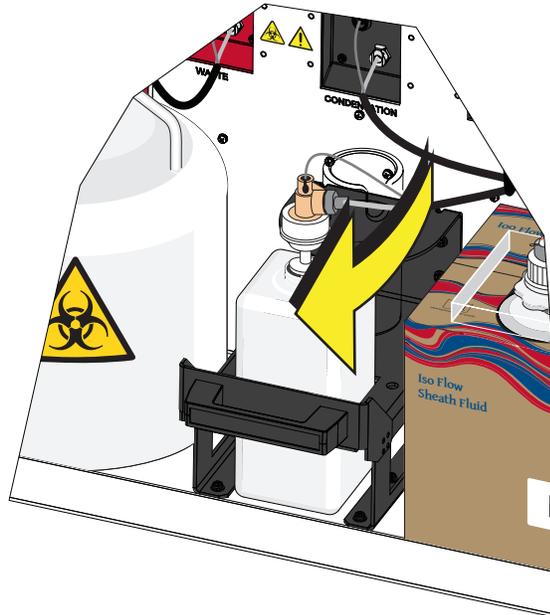


- 3 Unload the full condensate container from the Supply Cart.



- 4 Empty the contents and place back on the supply cart. Empty the condensate container according to your laboratory's procedures and local regulations.

- 5 Place emptied condensate container back into the supply cart and replace the cap turning clockwise until it is tight.



Replacing the Probes

The probes should be replaced if they are visibly worn or bent. A probe tubing tool and a mandrel tool are required to perform this procedure.



CAUTION

Risk of probe crash. Do not replace the probe tip without first running the probe replacement method. The method creates an air gap to reduce fluid spill and also frames each probe tip. [Contact us](#) if a probe is bent. A bent probe should NOT be replaced with the method described below.

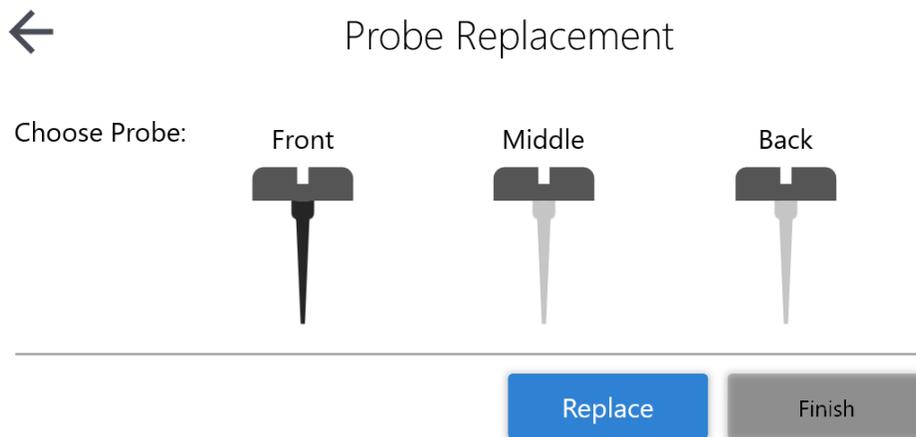
WARNING

Risk of biohazardous exposure when replacing probes. To prevent possible injury or biohazardous exposure, always wear proper laboratory attire, including gloves, a laboratory coat, eye wear, and a face shield.

1 Ensure the instrument is in the **Ready** or **Not Ready** state.

2 Select **Maintenance** > **Probe Replacement** .

3 Select the probe you want to replace such as Front, Middle, or Back.



NOTE Only one probe can be replaced at a time.

4 Select **Replace** . The instrument status changes to **Processing** state. The instrument cleans the probes before you replace them.

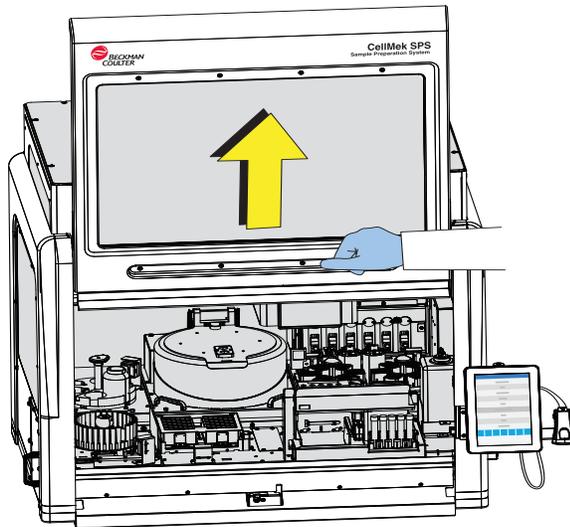
The status changes from **Processing** to **Replacing Probes**.

Once the probe cleaning is complete, the instrument automatically moves the probe selected for replacement in the down position and the other two will be in the up position.

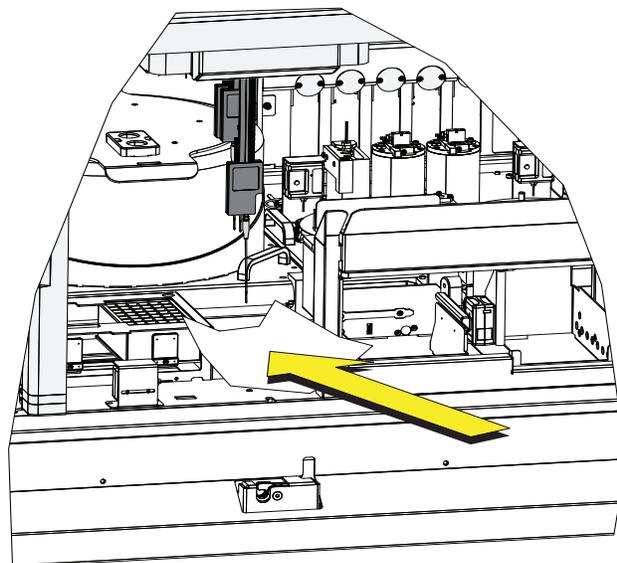
⚠ WARNING

Risk of biohazardous exposure. To prevent possible injury or biohazardous exposure, always wear proper laboratory attire, including gloves, a laboratory coat, eye protection, and a face shield.

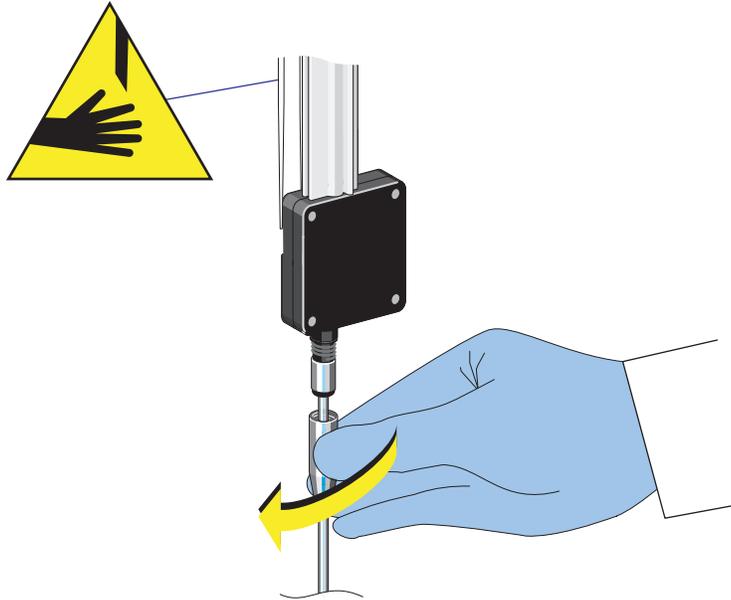
- 5 Open the front door.



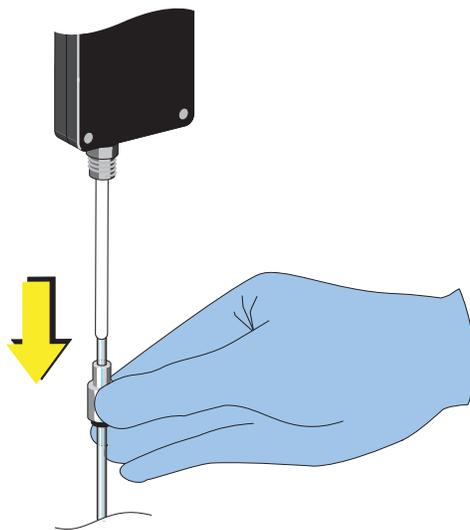
- 6 Place a paper towel below where the probe is located to capture any droplets.



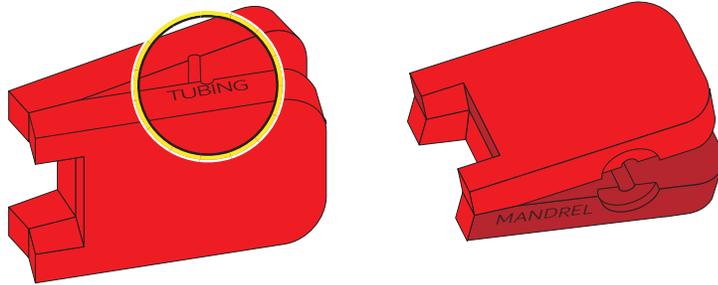
-
- 7 Remove the probe tip collar by turning in the direction shown.



-
- 8 Gently pull the probe tip down out of the probe holder to expose the probe tubing.

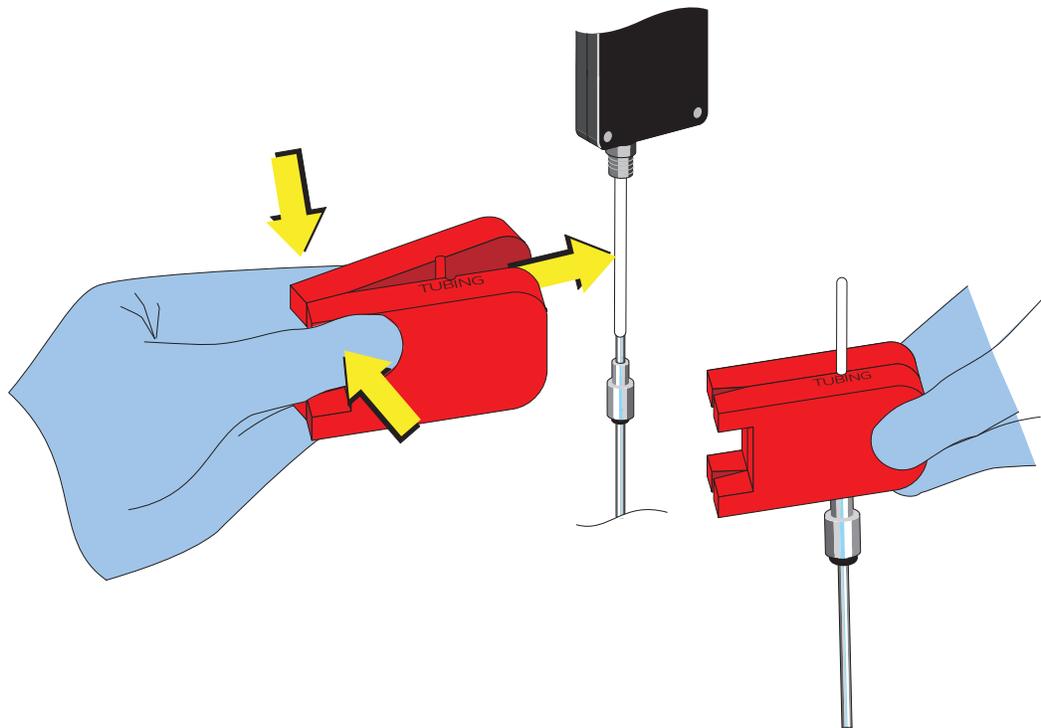


9 Obtain tubing tool and orient TUBING side up.

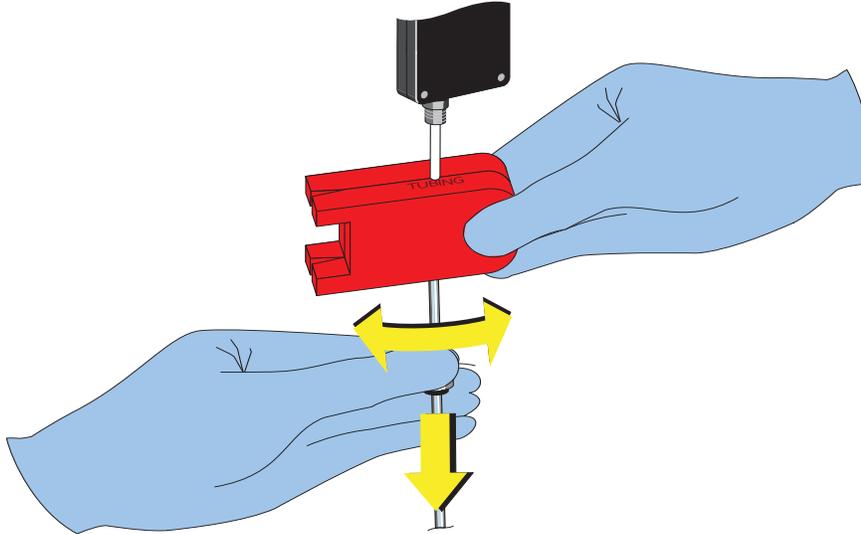


IMPORTANT Ensure the side of the tool labeled “MANDREL” faces down toward the probe and is flush with the end of the tubing. The side of the tool labeled “TUBING” should face up toward the probe tubing.

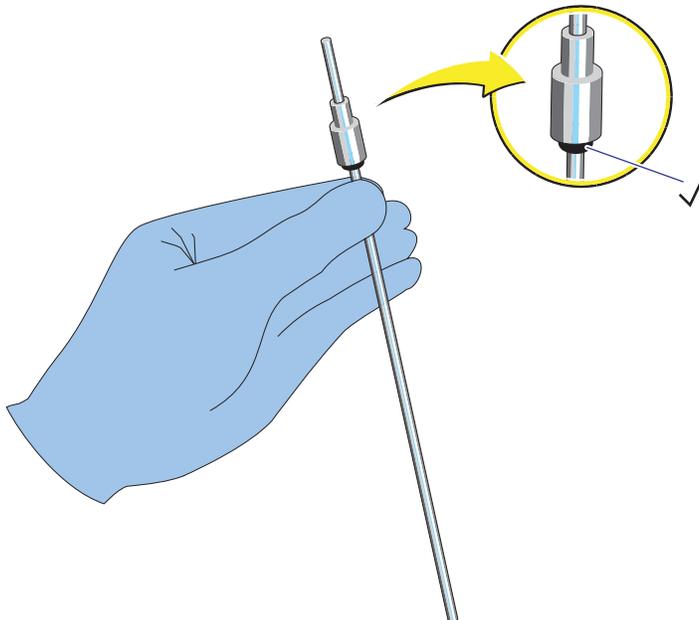
10 Install tubing tool onto tubing.



- 11** Remove the MANDREL tool to free both hands, then hold the neck of the probe and gently twist out of the tubing, and put the probe in a safe place.

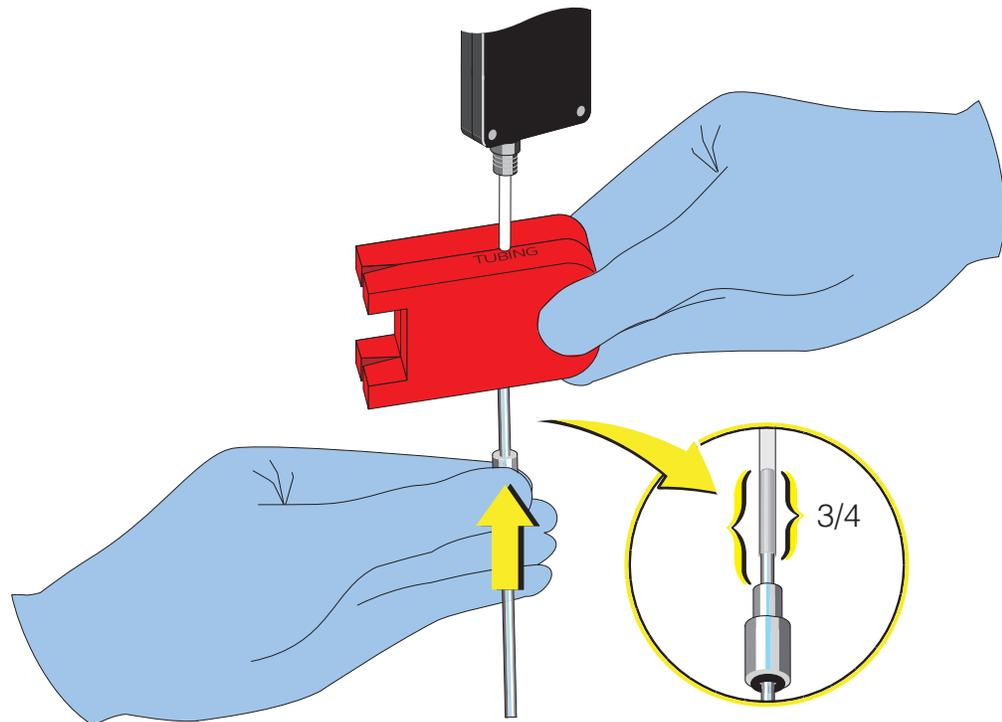


- 12** Install the new O-ring onto the new probe.



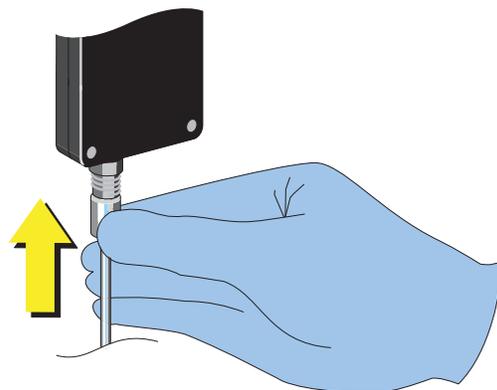
IMPORTANT The sleeve for the probe needs to be inserted at least 3/4 of the way through.

13 Insert the new probe into the end of the tubing using the MANDREL side of the tool as a guide.

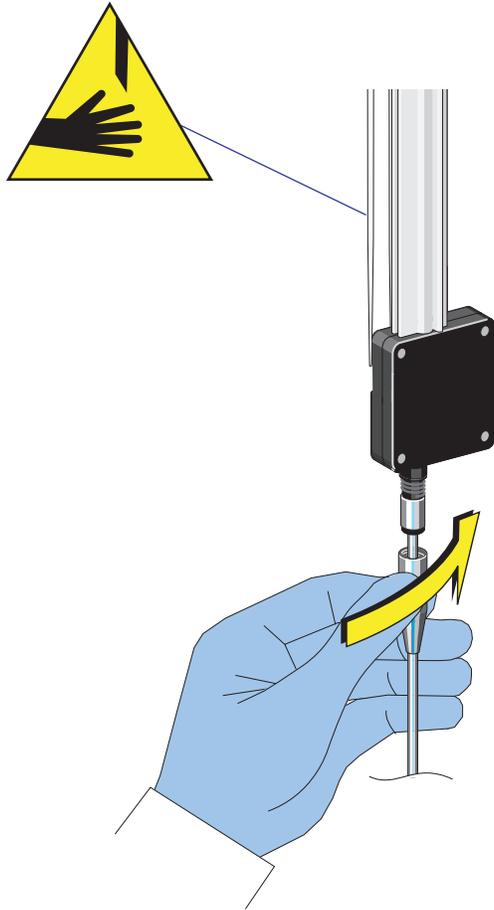


NOTE Verify that the probe is inserted into the tubing at least 3/4 of the way through.

14 Gently push the probe back up into the tip interface until the probe is flush with the interface.

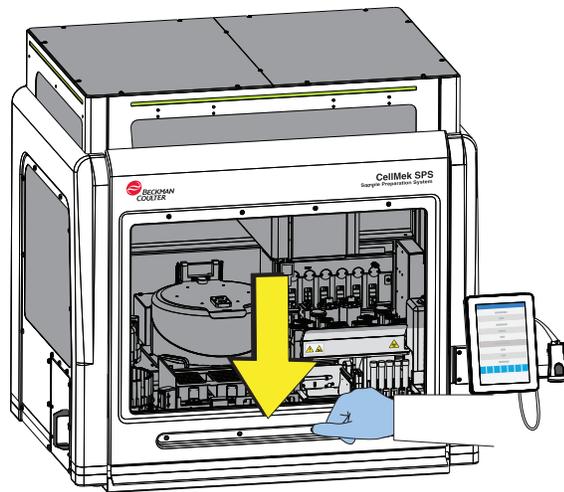


-
- 15** Slide the probe tip collar onto the probe and turn in the direction as shown below until fully hand tightened.



-
- 16** Dispose the paper towel and old probe in a sanctioned biological waste container according to local regulations.

17 Close the front door.



18 Repeat steps 3 to 17 to replace any additional probes.

19 Once all necessary probes are replaced, select **Finish**.

The system cleans and aligns the probes and returns the instrument state to **Ready**.

Overview

- Use the CellMek Panel Designer software to define sample preparation panels. These panels are then transferred to the instrument through a USB drive and used to prepare samples for your applications on the CellMek SPS.
- The minimum system requirements are: Operating System: Windows 10 version 1709 or higher; Architecture: x86, x64; Minimum HD Space: 50 MB.
- You must import the panels onto the CellMek SPS before you can process samples.
- Before defining a panel, you must define any custom or DURACartridge reagents to be used by the panel. This includes reconstitution information.
- To define the panel definition, you need to include the information that the CellMek SPS uses to process samples, such as:
 - Number of daughter tubes in the panel
 - Number of wash cycles and reconstitution volume
 - Sample size dispensed into the daughter tube
 - Reagents used by the panel
 - Reagents and volumes dispensed per daughter tube
- After defining the panels, load them from the computer and then download them into the CellMek SPS using a USB drive. The files are saved into a folder called CellMek.
- Once the panels are downloaded into the CellMek SPS, you only need to use the Panel Designer software again if you need to define new panels or modify existing panels.

Installing the CellMek Panel Designer Software

IMPORTANT The CellMek Panel Designer software must be installed on a laboratory PC. It will not install on the CellMek SPS touchscreen tablet. Internet access is necessary to download and install the CellMek Panel Designer software.

Installation Procedure Prerequisites

- 1 Windows 10 version 1709 (build 16299) or later. To check the version of Windows:
 - a. Open **Settings**.
 - b. Select **System**.
 - c. Select **About**.
 - d. The version is displayed in the Windows specifications section.

IMPORTANT User with administrator rights is required to enable **Sideload apps**.

- 2 Sideload apps is enabled. Sideload apps allows for installing Windows apps outside of the Windows Store for Windows 10 versions prior to 20H2 (October 2020 update). For Windows version 20H2 and newer this prerequisite is not required. To check and/or set Sideload apps:
 - a. Open **Settings**.
 - b. Select **Update & Security**.
 - c. Select **For developers**.
 - d. Under **Use developer features**, select the **Sideload apps** option.
 - e. Select **Yes** to confirm the risks involved running an app outside the Windows Store.

Installing CellMek Panel Designer Software

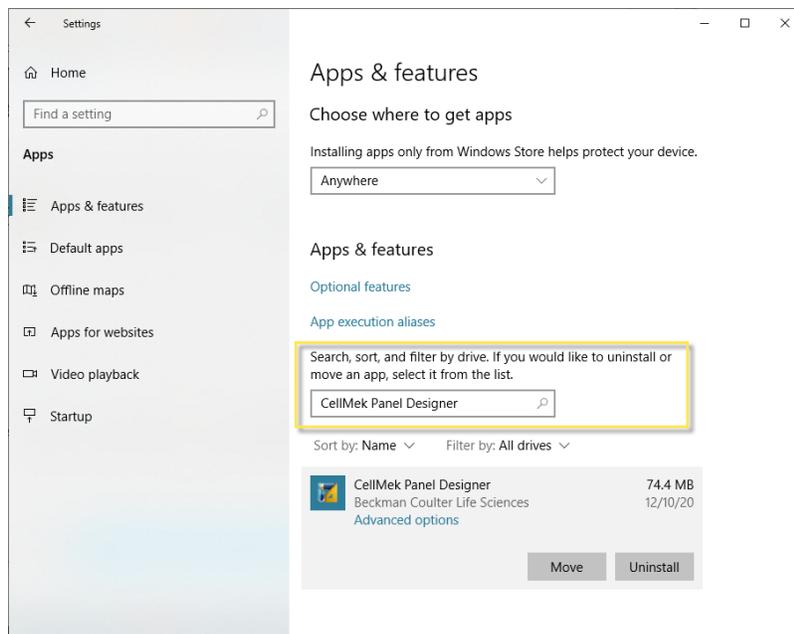
- 1 Insert the CellMek Panel Designer installation USB drive into a USB port on the computer.
- 2 Open Windows File Explorer and select the CellMek Panel Designer installation USB drive from **This PC** to open the drive.
- 3 Double-click on the CellMek Panel Designer installer executable file (CellMekPanelDesignerInstaller_x.x.x.exe where x.x.x.x is the version number, example CellMekPanelDesignerInstaller_1.1.87.0) on the USB drive.

NOTE The software will not install on the CellMek SPS instrument computer.
- 4 The CellMek Panel Designer software will open and have two options: Install vx.x.x.x (where x.x.x.x is the version number, example “Install v1.1.87.0”) and exit.
- 5 Select the **Install** button to display the End User License Agreement page.
- 6 Select **Accept** to accept the End User License Agreement terms and continue the installation.
- 7 The installing screen displays while the CellMek Panel Designer is being installed.
- 8 The Installer displays *CellMek Panel Designer Installed Successfully* when the installation is complete.
- 9 Select **Exit** to close the CellMek Panel Designer installer.

- 10 A CellMek Panel Designer shortcut will be created in the Windows Start menu. Open the Windows Start menu and select this shortcut to launch the software.

Uninstalling CellMek Panel Designer Software

- 1 Select **Start > Settings > Apps > Apps & features**.
- 2 Select **CellMek Panel Designer**.



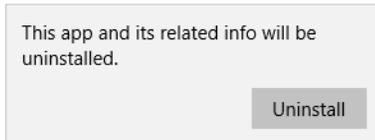
3 Select **Uninstall**.



NOTE CellMek Panel Designer software does not support the **Move** feature. If you select the **Move** button, a message box will pop up to prevent moving the application to a different location. See below.



4 A confirmation message appears: This app and its related info will be uninstalled. Select **Uninstall** and Windows will begin uninstalling the CellMek Panel Designer software.



CellMek Panel Designer Software Screen

The CellMek Panel Designer software ([Figure A.1](#)) displays all the basic processes necessary to design a CellMek SPS panel. The software menu options and icons are always displayed and accessible from any other software window. For details, see [Table A.1](#).

Figure A.1 Panel Designer Software Screen

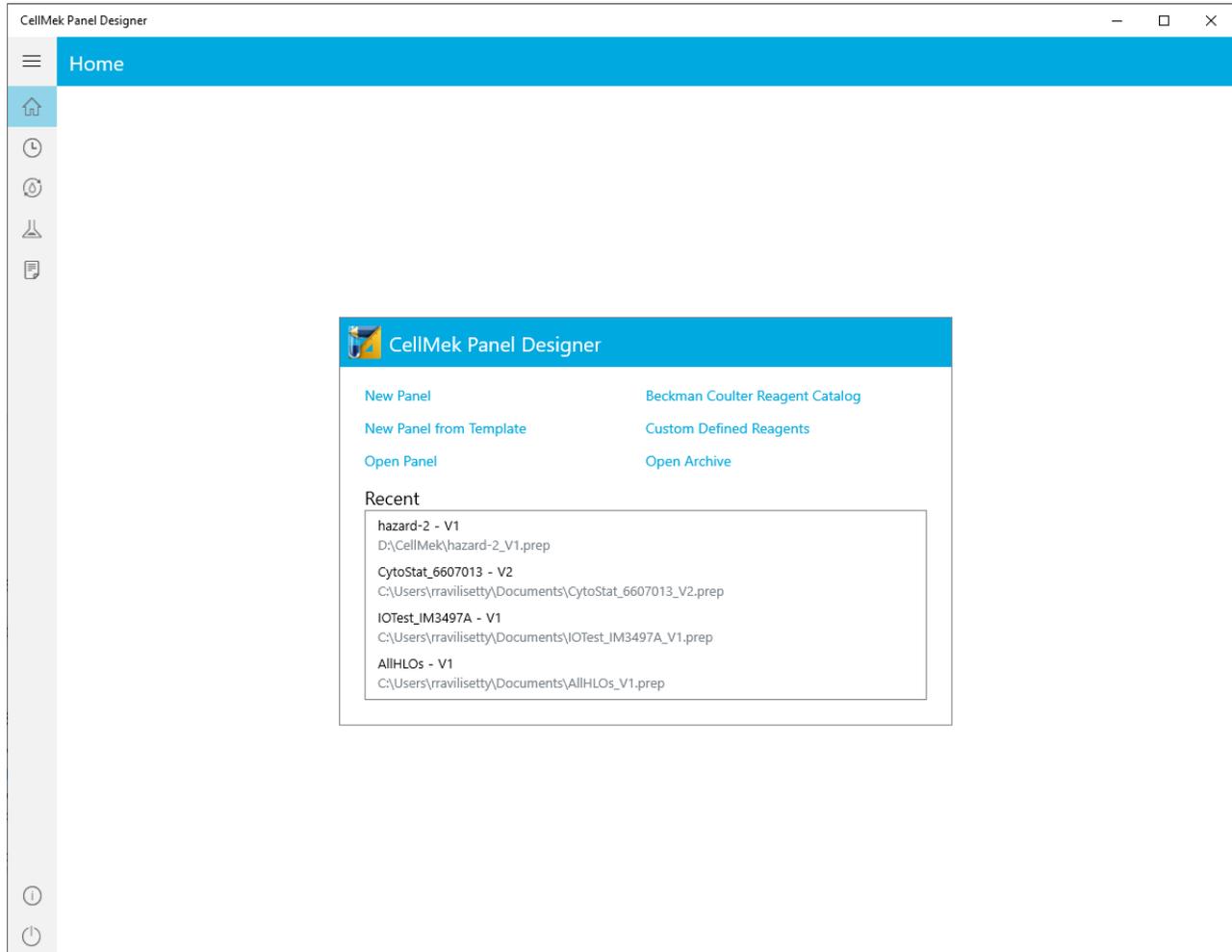


Table A.1 CellMek Panel Designer Software Definitions

Item	Description
	Use to go back to the Home screen.
	Use to access recent activities.
	Use to access the panel menu.
	Use to access the reagent catalog or custom defined reagents.
	Use to open archived runs and audit trails from the instrument software.

Table A.1 CellMek Panel Designer Software Definitions (*Continued*)

Item	Description
	Use to access more information on software version and legal notices.
	Use to exit the Panel Designer Software.

Updating the Reagent Catalog

1 Select  to access the reagent catalog update.

2 Select **Beckman Coulter Reagent Catalog**.

3 Select  to update the catalog.

NOTE Once the update is complete, a message *The reagent catalog is up to date.* appears.

Creating a Custom Defined Panel

For more information, refer to [CHAPTER 2, Liquid Antibody Module](#) and [CHAPTER 2, Prep Reagents Module](#) for the supported reagent containers.

Creating Custom Defined Reagents

1 Select  to access the custom defined reagents.

2 Select **Custom Defined Reagents**.

- 3 Select **Liquid Antibody Reagent, Stain Reagent, Dry Antibody Cartridge, or Lyse and Prep Reagent.**

Custom Defined Reagents

Liquid Antibody Reagent Stain Reagent Dry Antibody Cartridge Lyse and Prep Reagent

+ Add Reagent

<input type="checkbox"/>	Reagent Name	Comments
--------------------------	--------------	----------

- 4 Select **Add Reagent.**

- 5 Enter the Reagent Name and Comments (if needed).

- 6 Select **OK.**

- 7 Repeat steps 3 - 6 until you have completed adding all your custom defined reagents.

Custom Defined Reagents Export and Import

Custom Defined Reagents Export/Import feature has been added to the CellMek Panel Designer which can be used to backup or transfer the Custom Defined Reagents to another computer. The **Import Custom Defined Reagents** and **Export all Custom Defined Reagents** options have been added to the Reagents menu.

Exporting your Custom Defined Reagents

- 1 Select  on the left menu.
- 2 Select **Export all Custom Defined Reagents.**
- 3 Choose a file name and select the **Save** button on the **Save As** dialog.

Importing your Custom Defined Reagents from a Custom Defined Reagents Export File

- 1 Select  on the left menu.

- 2 Select **Import Custom Defined Reagents**.
- 3 Choose the Custom Defined Reagents export file and select **Open** in the Open dialog.

Creating Panels

Creating a New Panel

- 1 Select  to create a panel.
 - 2 Select **New Panel**.
 - 3 Enter Panel Name.
 - 4 Under the Specimen Section, select the checkbox if you **Want to wash specimen for all tubes**.
 - 5 Enter the number of Wash Cycles from 1-5.
NOTE This step only applies if the Wash specimen for all tubes is checked.
 - 6 Enter the volume 25 μ L - 400 μ L of the specimen.
NOTE You can enter the value or set the volume based on WBC.
- IMPORTANT** Sample and Specimen reports can be viewed using the Panel Designer Software or can be exported as html files for printing. See [Sample of the Sample Report](#) and [Sample of the Specimen Report](#) for the information contained in the reports.
- 7 If you choose to **Set Volume Based on WBC**, you will see the following display.
 - a. Enter the upper limit (1,000 - 150,000 μ L).
 - b. Select **Process Specimen** if you choose process the specimen with WBC values in that range. If **Process Specimen** is selected, enter the volume (25 - 400 μ L).
 - c. Select + to add additional range rows to the table and repeat Steps a-d.
 - d. Select the checkbox to **Dilute specimen**, and enter the volume of final diluted specimen.

Figure A.2 Set Volume Based on WBC

Specimen

Wash specimen for all tubes

Wash Cycles: 2

Volume (μl): Set Volume Based on WBC

	Lower Limit (Cells/μl)	Condition	Upper Limit (Cells/μl)	Volume (μl)	Process Specimen
+	1000	WBC <=	1000	100	<input checked="" type="checkbox"/>
	1000	< WBC			<input type="checkbox"/>

Dilute specimen to obtain [] μl per tube

- 8 Select the Tube 1 box or box defined by the tube name and following screen will be displayed.

Figure A.3 Tube 1 Instructions

Tube 1 Status: Error Tube Fill: -- μl X

Wash specimen once

Dilute final sample to obtain at least [] μl per tube

+ Add Reagents

- a. Select the checkbox to **Wash the specimen once**.

NOTE The checkbox **Wash specimen once** is automatically selected when **Wash specimen for all tubes** is selected in Specimen section. This is dependent on the number of Wash Cycles.

NOTE The specimen wash occurs in the beginning of the assay washes whole blood.

- b. Select the checkbox to **Dilute the final sample to obtain at least X μL per tube**. The maximum value of X is 2300 μL. Enter the amount in the box.

NOTE This step occurs after all reagents are added/incubated and before sample is transferred to output tubes.

NOTE If this checkbox is selected, the sample is diluted with IsoFlow Sheath Fluid.

- c. Select **Add Reagents**.

d. Select **Stain and Antibody**, **Lyse and Prep**, or **Prep Kit**.

Lyse and Prep Well Fill: 2170 µl (94.35 %)

1x IO Test... 1x IO Test + 0.25% Fix Volume (µl): 2000

+ Add Reagent

Incubation (minutes): Min: 10 Max: 15

Wash Sample: 1 Wash Cycle Resuspend to 500 µl using Wash Buffer

+ Add Reagents

1) For **Stain and Antibody** and **Lyse and Prep**:

- Enter the Volume (µL) between 3 - 100 µL (Stain and Antibody)
- Enter the Volume (µL) between 3 - 2000 µL (Lyse and Prep)

IMPORTANT Incubation Max time must be greater than or equal to the minimum incubation time plus 2 minutes.

- Enter the minimum incubation time in Min field which cannot exceed 58 minutes.
- Select the Wash Sample: No Wash, Spin Only, and 1 - 5 Wash Cycles.

No Wash
Spin Only
1 Wash Cycle
2 Wash Cycles
3 Wash Cycles
4 Wash Cycles
5 Wash Cycles

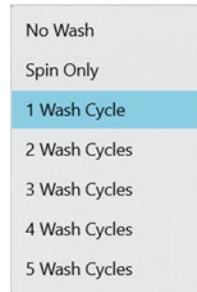
- To add a max incubation time: Add another Reagent block or select a Wash Sample Option, the Max incubation time box will appear. Max incubation time cannot exceed 60 minutes.

NOTE A max incubation time field will appear if a Cell Wash option was selected, another reagent block is added, or dilute sample is selected.

2) For the **Prep Kit**:

- Enter the Reagent Name.

- Select the Wash Sample: No Wash, Spin Only, and 1 - 5 Wash Cycles.



NOTE If Wash Sample option is other than NO Wash and Spin Only, Resuspend to X μL using Wash Buffer option is displayed.

If selected, the washed sample is resuspend in the Cell Wash with wash buffer, to up to 1500 μL before being transferred to a new in reaction plate.

9 Select  to Check Panel and/or select  to check for errors.

10 Select  to save the panel.

11 Repeat steps 8 - 10 until you added all the tubes required for this panel, by closing the current tube, and selecting **Add Tube** button on the main panel page.

IMPORTANT The panel must be saved in a folder title **CellMek** in the root of the USB drive.
The errors in the panel **MUST** be resolved for the panel to be imported to the CellMek SPS.

12 Select  to move the panel to a USB drive to import into the CellMek SPS. For more information on importing panels, see [CHAPTER 4, Importing Panels](#).

Creating a New Panel from Template

1 Select  to create a panel.

2 Select **New Panel from Template**.

3 Locate the file and select **Open**.

-
- 4 Enter New Panel Name.
-
- 5 Follow instructions on Creating Panels, see [Creating Panels](#) to make changes to the template.
NOTE Panel version will start at 1 when saved.
-

Opening Panel from Template

-
- 1 Select  to create a panel.
-
- 2 Select **Open Panel**.
-
- 3 Locate an existing panel to use as a template when creating the new panel and select **Open**.
NOTE Panel version will increase by 1 when saved.
-

Load the Panel

For information on importing the panels created, see [CHAPTER 4, Importing Panels](#).

Viewing CellMek Archives

-
- 1 Select  .
-
- 2 Select **Open Archive**.
-
- 3 Locate the file and select **Open**.
NOTE Archive files (Runs and/or Audit Trail) can be generated in CellMek SPS software using Archive and Backup option. See [CHAPTER 6, Archive and Backup](#).
-
- 4 Select **Export** to save the Sample Report, Specimen Report or Audit Trail Report and to Print the reports.

Sample Reports contain the following information: Report Generated Time, Sample ID, Instrument Serial Number, Instrument Name, Software Version, Cassette Type and ID, Cassette Tube Location, Specimen ID, Cell Concentration Index and Source, Specimen Flags and Notifications, Panel Name and Version, Specimen Volume, Panel Flags and Notifications, Reaction Plate IDs and Well Locations, Reagent Names, Reagent Part and Lot Numbers, Reagent Vial IDs, Reagent Expiration Dates, Reagent Volume, Reagent QC Status, Consumables, User, and Comment. See [Figure A.4](#) as an example.

Figure A.4 Sample of the Sample Report

The screenshot shows the 'CellMek Panel Designer' application window. The title bar indicates the file path: 'D:\CellMek\112233_20210301_20210308_20210308111618.wfsa'. The interface includes a navigation menu on the left with icons for home, clock, refresh, and print. The main content area has tabs for 'Sample', 'Specimen', and 'Audit Trail'. Below the tabs, there is a 'Sample ID' input field containing '\$N89352297538' and buttons for 'Query' and 'Export'. The report content is as follows:

Sample ID \$N89352297538
Report Generated Time: 8 Mar 2021 11:16:44 AM

System Information

Instrument Serial Number:	112233
Instrument Name:	My112233
Software Version:	1.0.0.0

Specimen

Cassette Type:	A
Cassette ID:	00001
Cassette Tube Location:	1
Specimen ID:	A12345678
Cell Concentration Index:	N/A
Cell Concentration Index Source:	N/A
Flags:	N/A
Notifications:	N/A

Panel

Panel Name:	1CDRAb1
Panel Version:	1
Specimen Volume (µl):	100
Flags:	N/A
Notifications:	N/A

Sample

Tube Name:	Tube 1
Tube Location:	1
Status:	Prepared
Time:	8 Mar 2021 11:16:01 AM
Flags:	N/A

Specimen Reports contain the following information: Report Generated Time, Specimen ID, Instrument Serial Number, Instrument Name, Software Version, Specimen Status and Time, Cassette Type and ID, Cassette Tube Location, Cell Concentration Index and Source, Specimen Flags and Notifications, Panel Name and Version, Specimen Volume, Panel Flags and Notifications, Tube Name and Location, Sample ID, Tube Status and Time, Tube Flags and Notifications, Reaction Plate IDs and Well Locations, Reagent Names, Reagent Part and Lot Numbers, Reagent Vial IDs, Reagent Expiration Dates, Reagent Volume, Reagent QC Status, Consumables, User, and Comment. See [Figure A.5](#) as an example.

Figure A.5 Sample of the Specimen Report

The screenshot shows the CellMek Panel Designer interface. At the top, the file path is `D:\CellMek\112233_20210301_20210308_20210308111618.wfsa`. The main window displays a specimen report for ID **A12345678**, generated on 8 Mar 2021 at 11:16:37 AM. The report is organized into four sections:

- System Information:**
 - Instrument Serial Number: 112233
 - Instrument Name: My112233
 - Software Version: 1.0.0.0
- Specimen:**
 - Status: Completed
 - Time: 8 Mar 2021 11:16:01 AM
 - Cassette Type: A
 - Cassette ID: 00001
 - Cassette Tube Location: 1
 - Cell Concentration Index: N/A
 - Cell Concentration Index Source: N/A
 - Flags: N/A
 - Notifications: N/A
- 1CDRab1:**
 - Panel Version: 1
 - Specimen Volume (µl): 100
 - Status: Completed
 - Time: 8 Mar 2021 11:16:01 AM
 - Flags: N/A
 - Notifications: N/A
- Tube 1:**
 - Tube Location: 1
 - Sample ID: SN89352297538
 - Status: Prepared

Audit Trail Reports contain the following information: Report Generated Time, Time Period, Instrument Serial Number, Operation, User, Time, and Records. See [Figure A.6](#) as an example.

Figure A.6 Sample of the Audit Trail Reports

The screenshot shows the CellMek Panel Designer interface. The title bar reads "CellMek Panel Designer" and the address bar shows "D:\CellMek\112233_20210301_20210308_20210308111618.wfsa". The main menu includes "Sample", "Specimen", and "Audit Trail". The "Audit Trail" section is active, showing a "Time Period" filter set to "All" and an "Instrument" dropdown set to "112233". There are "Query" and "Export" buttons. The main content area displays the "Audit Trail" report, generated on 8 Mar 2021 at 11:17:05 AM. It includes a "Time Period" section with start and end times, and a "Records" table with columns for Serial Number, Operation, User, Time, and Record.

Serial Number	Operation	User	Time	Record
112233	Setup	Service	1 Mar 2021 3:24:58 PM	Instrument Serial number updated: Serial number: 112233, Nickname: 112233
112233	Setup	Service	1 Mar 2021 3:24:59 PM	Instrument nickname updated: Serial number: 112233, Nickname: M112233
112233	Setup	Service	1 Mar 2021 3:25:00 PM	Instrument nickname updated: Serial number: 112233, Nickname: My112233
112233	External Resources	System	1 Mar 2021 3:25:41 PM	Waste tank full.
112233	User	Service	1 Mar 2021 3:26:29 PM	User signed in successfully: Service.

Archive Advanced Search

The CellMek Panel Designer now has an Advanced Search for finding specimens or samples in a CellMek Archive file. The advanced search allows you to find records by date, instrument serial number, panel name, consumable type, reagent name, reagent lot, reagent vial, reaction plate ID, and/or reaction plate well.

Performing an Advanced Search in an Archive File

- 1 Create an Archive file from the CellMek SPS Instrument, refer to [CHAPTER 6, Archive and Backup](#).
- 2 Open the CellMek Panel Designer software.
- 3 Select  on the left menu and select **Open Archive** or select the Open Archive link on the home screen.

-
- 4 Choose the archived file to search and select the **Open** button in the Open dialog.

 - 5 The Archive screen will be displayed with the **Advanced Search** option. Select **Advanced Search**.

 - 6 The screen displays all the fields that can be used to search the archive file. Enter values in only the fields that the records in the archive are to be filtered by. Records are not filtered by any field that is left blank.

 - 7 Select **Report Type**. The Report Type specifies which report will be generated for the results, refer to [Sample of the Sample Report](#) and [Sample of the Specimen Report](#).

 - 8 Select **Export**.
 - a. Choose the filename and location for the results and select **Save** in the Save As dialog box.
 - b. A report for each record from the archive that meet the criteria entered in the screen is created and added to the file specified in the Save As dialog box.
 - c. Unzip the exported file to find and view the reports.
-

Instrument Software Interface

The instrument software screen (Figure B.1) displays all the basic processes necessary to operate the CellMek SPS. The instrument status bar and the instrument software screen buttons are permanently located and accessible from any other software window. For details, see Table B.1.

Figure B.1 Instrument Software Screen

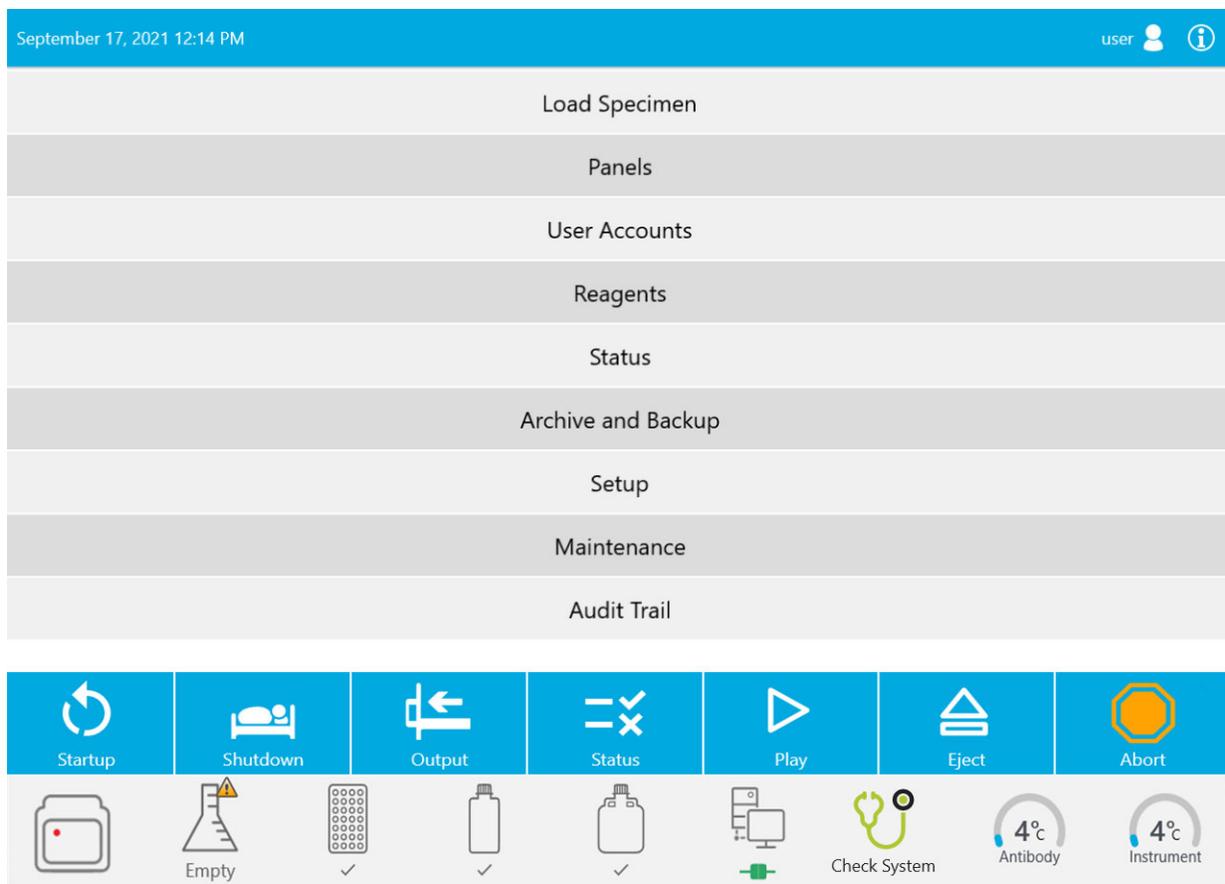


Table B.1 Main Screen: Definitions

Item	Description
	Use to access user menu.
	Use to find Information about the version of the software and legal notices.

Table B.1 Main Screen: Definitions (*Continued*)

Item	Description
	Use to display the errors or warnings on the instrument.
Load Specimen	Use to load the specimens.
Panels	Use to access the panels.
User Accounts	Use to access user accounts.
Reagents	Use to access reagent list and reagent settings.
Status	Use to access the status screen. The Status Screen provides information on scheduled tasks, samples prepared in the last 48 hours, output carousel, onboard reagents, pending requests, and hardware. NOTE This is the same information as the  button.
Archive and Backup	Use to archive and backup systems.
Setup	Use to setup instrument info, alerts, external worklist, specimen barcode symbology, and LIS.
Maintenance	Use to access the maintenance features of the instrument.
Audit Trail	Use to access the Audit Trail.
	Startup - Use to perform the system startup and get the system ready to prepare sample.
	Shutdown - Use to perform a system shutdown to clean the instrument.
	Output - Use to open output drawer and create worklists. This also indicates if the drawer is open.
	Use to access the status screen. The Status Screen provides information on scheduled tasks, samples prepared in the last 48 hours, output carousel, onboard reagents, pending requests, and hardware.
	Play - Use to start the Specimen Transport Module.

Table B.1 Main Screen: Definitions (*Continued*)

Item	Description
	Pause - Use to pause the Specimen Transport Module.
	Eject - Use to eject the cassettes in the input buffer.
	Use to abort the sample preparation.
	Displays instrument and main door status. Selecting this icon displays Status > Hardware tab (unless Status is already displayed).
	Shows Empty if any reagent vial is empty. Shows Low if any reagent vial is below their warning level. Selecting this icon displays Status > Onboard Consumables tab (unless Status is already displayed).
	Shows Empty if no wells are available. Shows Low if there are less than 10 wells remaining. Selecting this icon displays Status > Onboard Consumables tab (unless Status is already displayed).
	Shows Full when Condensate bottle is full.
	Shows full when waste is full. Shows Low if there is less than 2.5 L of remaining space.
	Selecting this icon displays Setup > LIS tab (unless Setup is already displayed).
	Visible when there is a system error.
	Temperature inside the antibody module.
	Temperature of the Instrument.

Preparing the Site

This section details the required site preparation prior to the installation of the instrument and components. Pay careful attention to the specifications and requirements described in this manual. Accurate and timely preparation allows the Beckman Coulter Field Service Engineer to unpack and install the instrument and components efficiently upon arrival.

Site Preparation

NOTE Consult local fire codes to determine required ceiling height and other requirements for your location.

Appropriate site preparation includes making sure that:

- System specification requirements are met when the instrument is installed. See [System Specifications](#).
- Adequate workspace is set up for the instrument and automation controller. See [Work Area Minimum Dimensions](#).
- Aisle and door widths are sufficient to allow the instrument to be moved from the receiving area to the final work area. See Door and Aisle Clearances under [Work Area Minimum Dimensions](#).
- The bench holding the system meets the minimum dimensions and supports the total installed weight of the instrument and any peripheral equipment. The bench must also be level and stable so that normal operations of the instrument do not cause the bench to shift, jerk, or sway.
- Electrical supply and power quality are adequate for operation. See [Instrument Electrical Requirements](#).

System Specifications

For more information on System Specifications, see [CHAPTER 1, System Specifications](#).

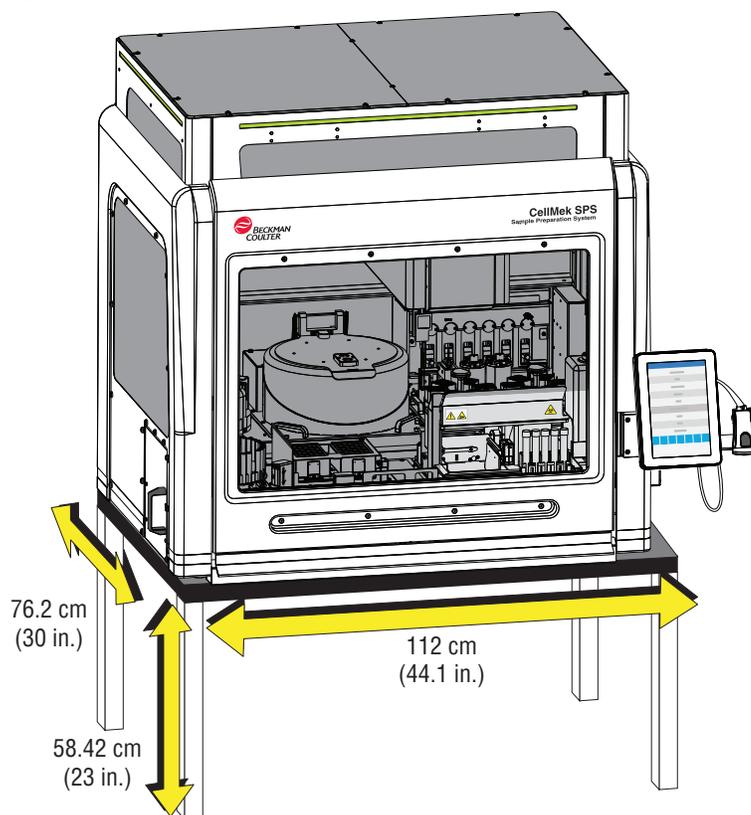
Work Area Minimum Dimensions

Bench Dimensions for Instrument



Risk of serious injury. To avoid serious injury, [contact us](#) to remove or transfer the CellMek SPS from its lab bench.

Figure C.1 CellMek SPS Instrument Minimum Bench Size



Minimum bench necessary for instrument (see [CHAPTER 1, Space and Table Requirements for Instrument](#))

Use [CHAPTER 1, Space and Table Requirements for Instrument](#) to determine:

- Minimum dimensions required for the system work area.

- Location for the automation controller and stand near the instrument bench.

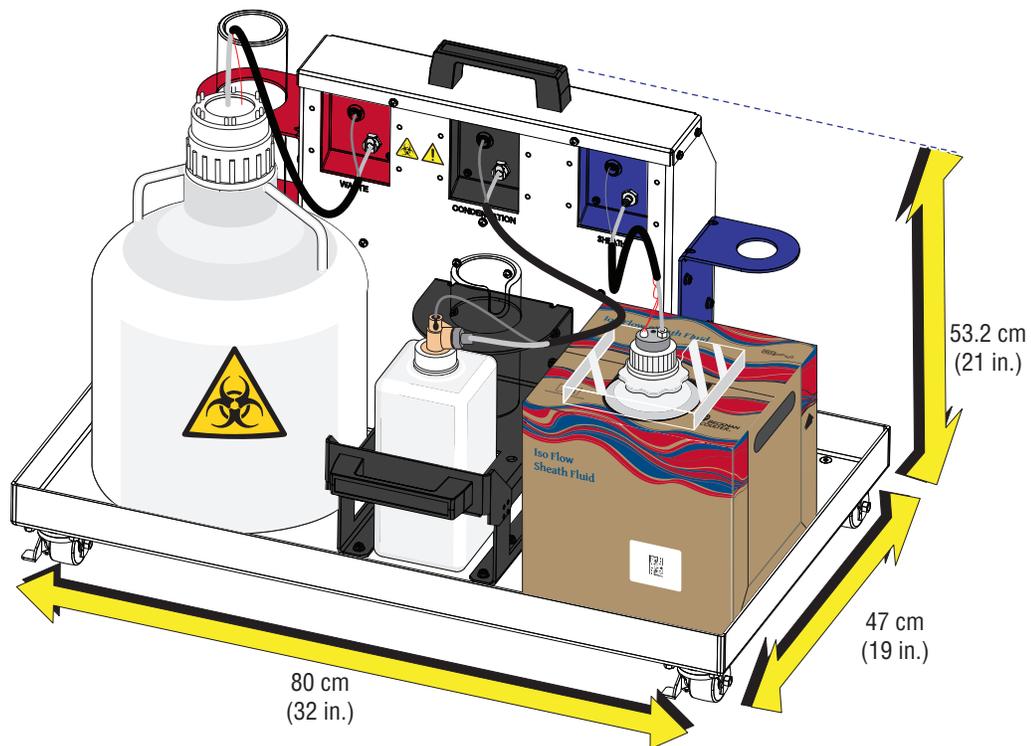
NOTE The dimensions for the lab bench do not include space for the reagent cart. Refer to [CHAPTER 1, Space and Table Requirements for Instrument](#).

Supply Cart Dimensions

CAUTION

Risk of possible operator injury. A minimum of two people is necessary to lift or carry the supply cart. The CellMek Supply Cart weighs up to 14 kg (31 lbs) excluding reagents.

Figure C.2 Supply Cart Dimensions

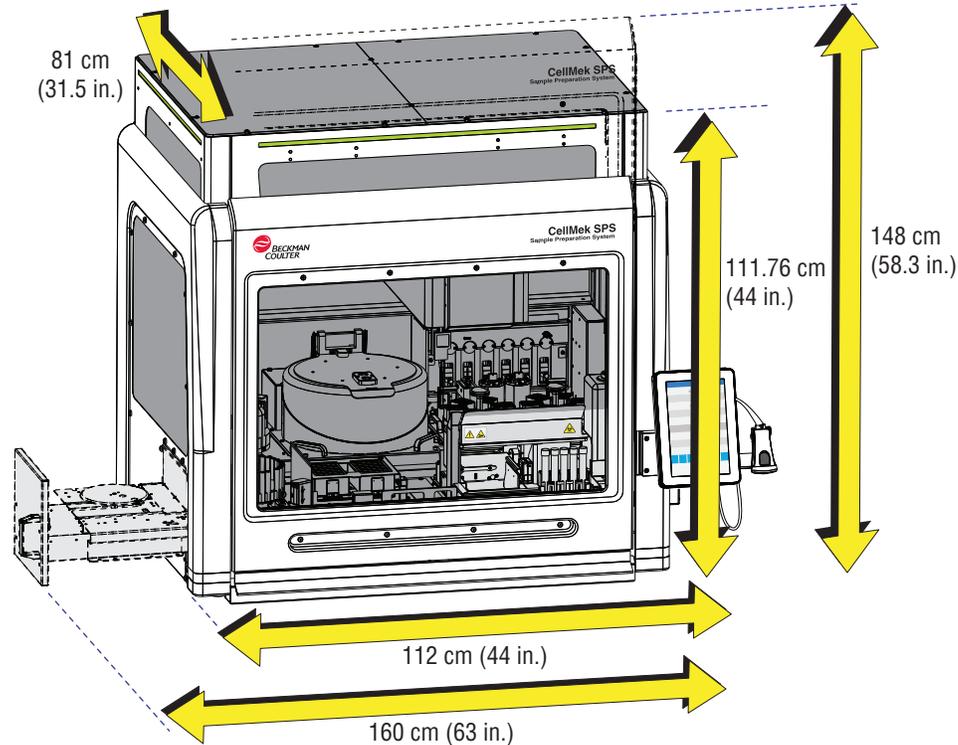


Space Requirements

The work space must allow enough space to operate the instrument with the door raised and the Output Drawer fully open. The maximum height of the instrument with the door raised is approximately 148 cm. The maximum width of the instrument with the Output Drawer fully open

and including the touchscreen display is approximately 160 cm. Also, ensure that there is approximately 25 cm on either side of the instrument for serviceability. See [Figure C.3](#).

Figure C.3 Maximum Dimensions of the Instrument With the Door Raised



Lifting or Carrying System Components



Risk of possible operator injury. A minimum of two people are necessary to lift or carry the instrument. The CellMek SPS weighs up to 187 kg (412 lbs).

CellMek SPS component weights are listed in [Table 1.2](#).

Electrical Requirements

Instrument Electrical Requirements

Make sure the proper electrical supply dedicated solely to the instrument is available at the bench where instrument will be positioned. [Table C.1](#) defines the electrical requirements.

Table C.1 Electrical Components and Requirements

Electrical Component	Electrical Requirements
Base Unit	100 – 240VAC @ 10 amps

NOTE All AC devices are at 50/60 Hz.

NOTE Connecting the instrument to an uninterruptible power source (UPS) is recommended to prevent unexpected power failures.

System Connections

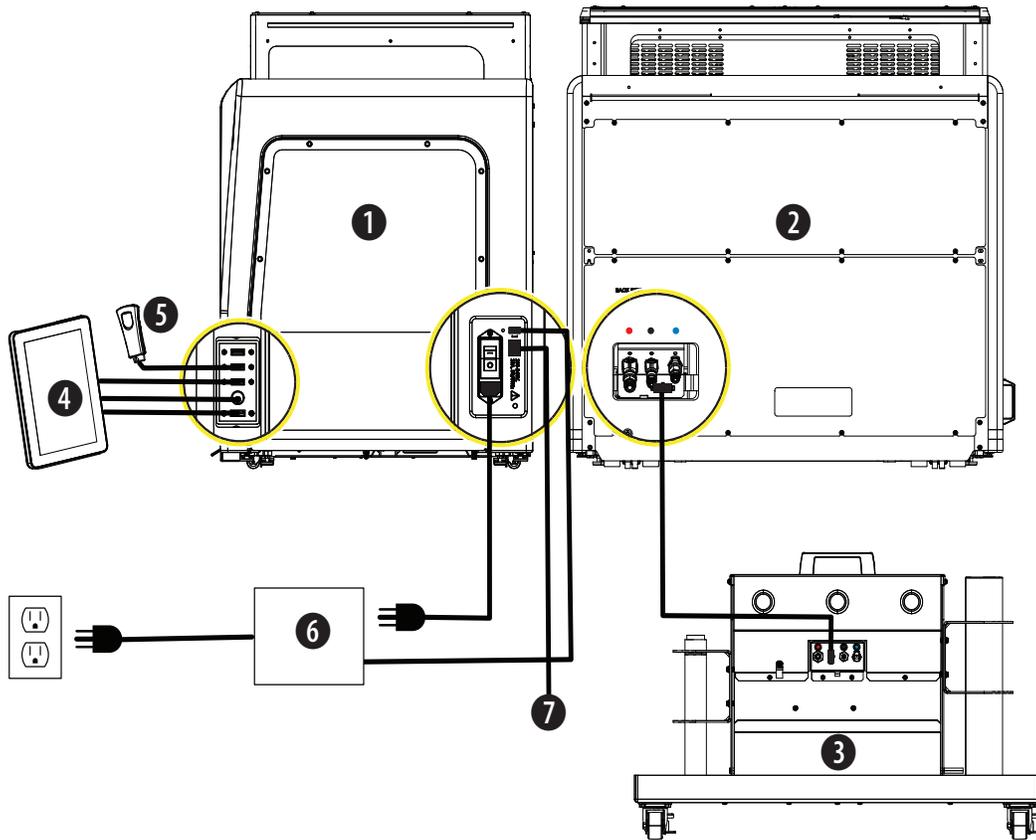
Power and Signal Cable Connections



Risk of personal injury if instrument cover is removed or a door is left open due to possible exposure to high voltages, and/or moving parts. Never operate the instrument without a cover or with a door opened.

Figure C.4 shows the inter-unit connections of the power and signal cables.

Figure C.4 Overview of Power and Signal Cables Connections



- 1. Instrument (Right Side)
- 2. Instrument (Rear)
- 3. Supply Cart (Rear)
- 4. Touchscreen

- 5. Handheld Barcode Scanner
- 6. UPS
- 7. Ethernet

Fluidic and Pneumatic Tubing

Figure C.5 shows the fluidic and pneumatic signal cables inter-unit connections.



WARNING

Risk of biohazardous contamination. Do not disconnect the tubing from the back of the instrument or the supply cart. If you need to disconnect the tubing in order to move the instrument, [contact us](#).

Figure C.5 Reagent, and Waste Interconnectors

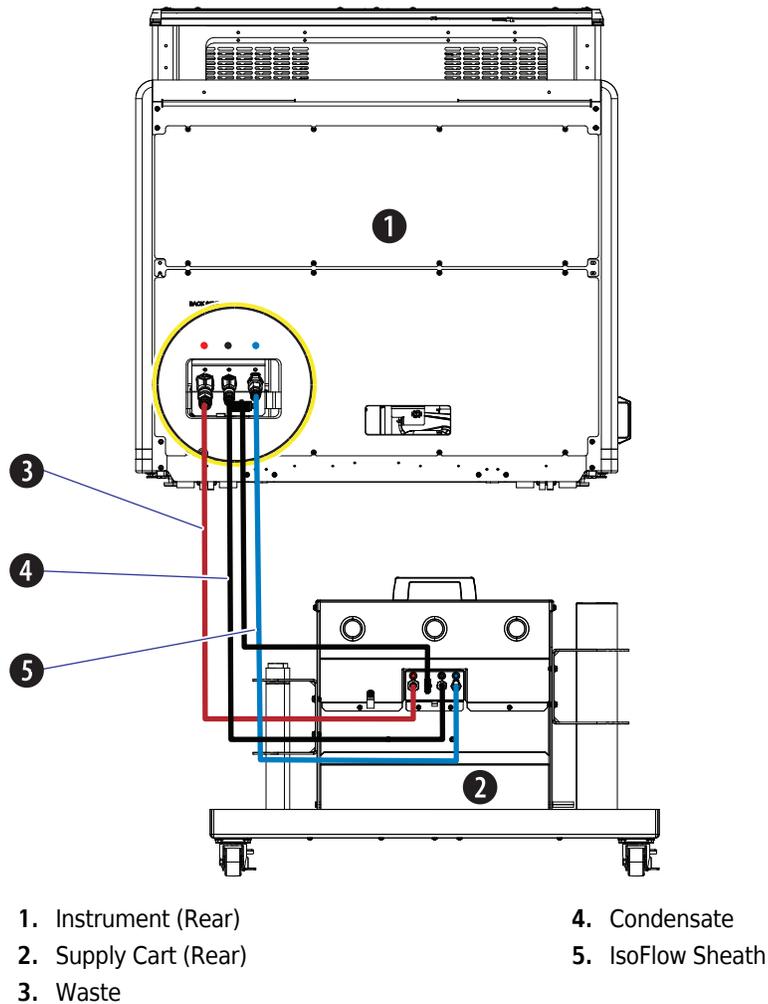


Figure C.6 Sheath Fluid Connections

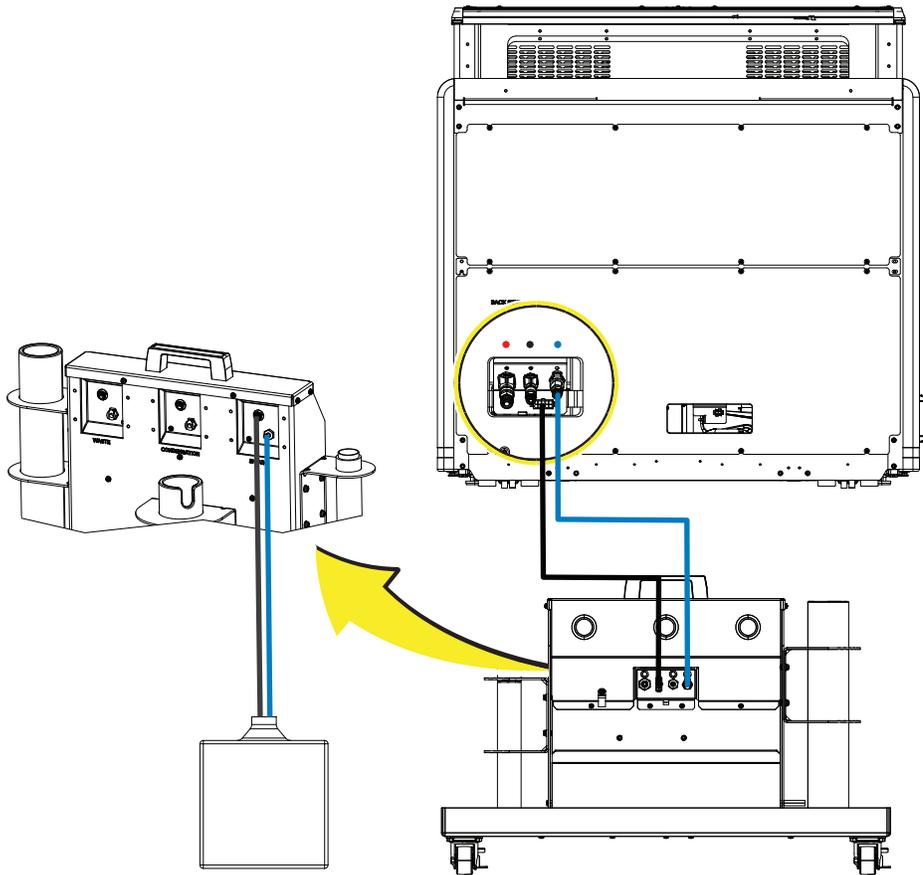


Figure C.7 Waste Connections

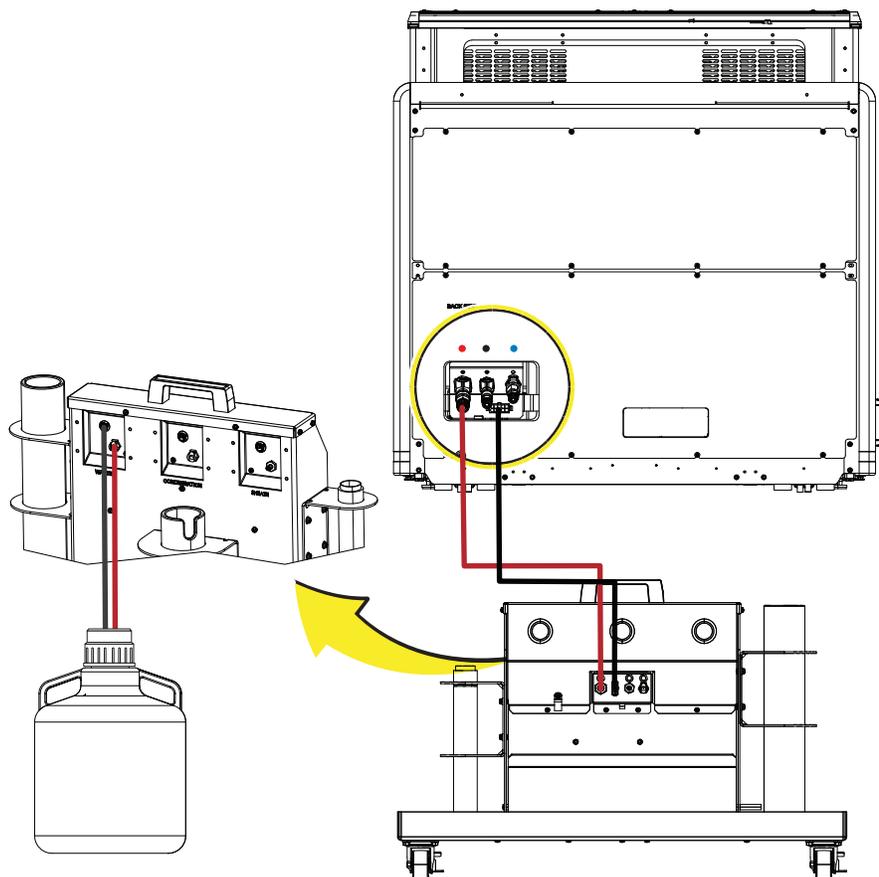
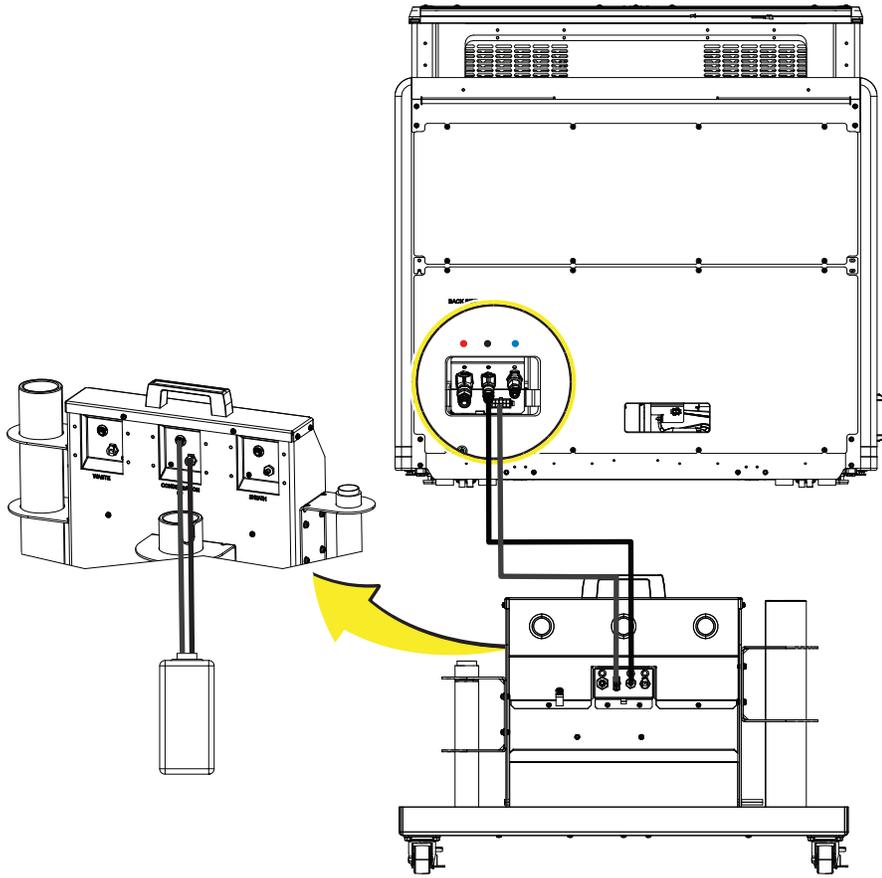
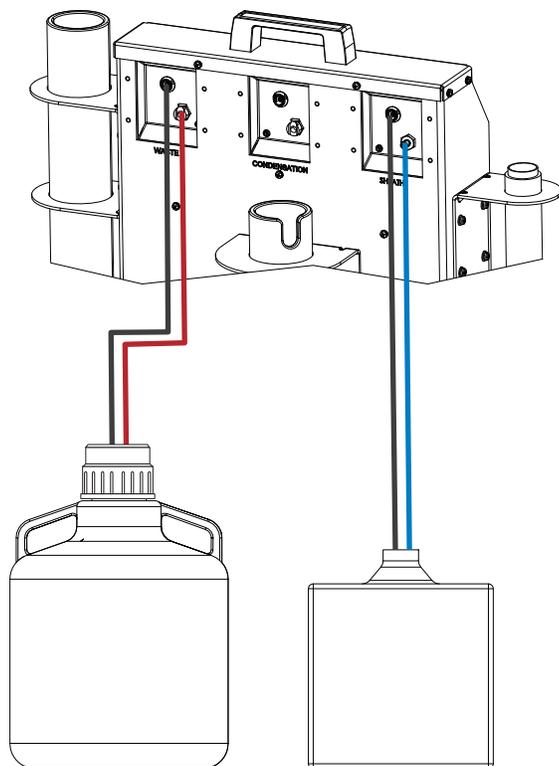


Figure C.8 Condensate Connections



Supply Cart

Figure C.9 Sheath and Waste Connections on the Supply Cart



Specimen Collection Tube Specifications

⚠ CAUTION

Risk of clog or biological fluid spills if the recommended number of pierces are exceeded. Specimen tubes can be pierced a maximum of eight (8) times with the following exceptions:

- Sarstedt Monovette tubes can be pierced a maximum of five (5) times.
- Beckman Coulter ClearLLab Control Cells Normal and Abnormal tubes can be pierced a maximum of five (5) times. Wipe specimen droplets from the stoppers if tubes will be re-processed in the CellMek SPS.

Beckman Coulter does not recommend the use of one tube in preference to another nor guarantee the acceptability of the sample tube to produce quality results. Specimen tubes not included in this table should be validated by the user for use with the CellMek SPS.

Table D.1 Tube List for CellMek SPS

Manufacturer	Part Number	Dimensions (mm)	AntiCoag	CellMek SPS Dead Volume (µL)
Cassette Type A				
Becton Dickinson	367861	13x75	EDTA	750
	367856			
	367841			
	367842			
	367871	13x75	Sodium Heparin	750
	367884	13x75	Lithium Heparin	
	366703	13x75	None	
	367835	13x75	EDTA	900
	367844			
	367863	13x100	EDTA	850
366450	950			
Covidien	8881311446	13 x 75	EDTA	900

Tube List

Specimen Collection Tube Specifications

Table D.1 Tube List for CellMek SPS

Manufacturer	Part Number	Dimensions (mm)	AntiCoag	CellMek SPS Dead Volume (µL)
Beckman Coulter ClearLLab Control Cells Normal and ClearLLab Control Cells Abnormal	B90002 B90003	12 x 76	N/A	750
Cassette Type A+				
	366643 366457	16x100	EDTA	1500
Covidien	8881311743			
Cassette Type B				
Sarstedt	04.1917.001	13x75	EDTA	750
	04.1917.100			
	04.1931.001	13x90		
	04.1931.100			
	05.1167.001	11x66		
	05.1167.100			
	04.1901.001	13x65		
	04.1901.100			
Cassette D				
Beckman Coulter IMMUNO-TROL and IMMUNO-TROL Low Control Cells	6607077 6607098	13x64	N/A	750
Covidien	8881311149	10.25 x 50	EDTA	600
CAUTION				
Processing panels that use more than 400 µL of specimen volume with the Covidien 10.25 x 50 tube, this tube type may lead to volumes that do not meet the accuracy specifications, see CHAPTER 1, Performance Characteristics . It is recommended to only run panels that use less than 400 µL with this tube type to achieve accurate transfers.				
Cassette E				
Sarstedt	01.1605.001	15x92	EDTA	1300
	01.1605.100			

Barcode Specifications

Specimen Tube 1-Dimensional Barcode Specifications

 **CAUTION**

Use of barcodes is an extremely accurate and effective method of positive patient identification. Certain features, such as checksum digits, maximize accuracy in linear (1-dimensional) barcodes such as Codabar, Code 39 and Interleaved 2-of-5 labels. In one study, the use of checksum digits detected 97% of misread errors.

Use checksums to provide protection against occasional misread errors caused by problems such as damaged or misapplied labels. If you must use barcodes without checksums, Beckman Coulter recommends that you verify each barcode reading to assure correct patient identification.

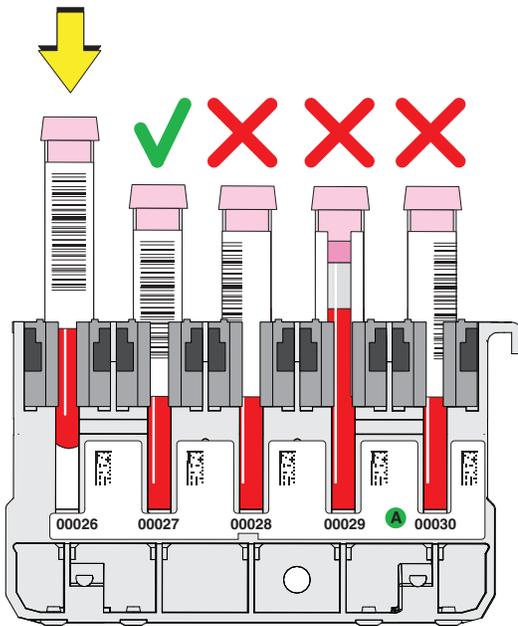
NOTE Code 128 has an inherent checksum; if using this symbology, checksum does not require enabling.

Beckman Coulter instruments use four linear (1-dimensional) barcode symbologies (types) to identify specimens:

- Code 128
- Code 39
- Codabar
- Interleaved 2-of-5.

The barcode reader senses the difference between enabled barcode symbologies.

The barcode label must be placed a minimum of 10 mm (.4 in.) from the bottom of the tube.



Label Size and Thickness

The length of the label must be less than 29 mm (1.14 in.). The label includes the barcode symbol and a minimum quiet zone of 3.5 mm (0.14 in.) at each end of the symbol. See [Figure E.1](#).

Figure E.1 Barcode Label Specifications



- 1 Quiet zones 3.5 mm (0.14 in.) minimum
- 2 Barcode symbol height 33 mm (1.30 in.) minimum
- 3 Barcode label length 29 mm (1.14 in.) maximum

Symbol Dimensions

The height of the barcode symbol must be 19.05 mm (0.75 in.) minimum.

See [Table E.2](#).

Label and Print Quality

All barcode symbols must agree with the American Identification Manufacturer's (AIM) Uniform Symbology Specification.¹

All barcode symbols must be printed at print quality class "B" or better as defined by the American National Standards Institute (ANSI).³ Several factors affect print quality:

- Labels must be clean, not yellowed, and used before the expiration date.
- Print the barcode symbol on material that has a matte finish. Use a background diffuse reflectance of 80% or more for maximum contrast.
- The labels must not have defects such as spots, lines, missing sections, cuts, folds, or density problems.
- The bars in the barcode symbol must be well-defined. Edges must be constant (not irregular), so the bars and spaces have the correct widths for the barcode symbology used.

Barcode Error Rate

The quality of the barcode symbol and the label is important for accurate reading. To get the highest possible accuracy only use labels that meet all the specifications described for labels and symbols. Deviations from these specifications make the barcode more difficult to read and allow for a possible increase in the error rate.

The symbology and the configurable parameters that the laboratory selects have an effect on the error rate. Certain features of the symbologies and the selections made by the laboratory have an important effect on the accuracy of the barcode reading system. In general:

- Code 128 and Code 39 are more accurate and have lower error rates than Codabar or Interleaved 2-of-5.
- CLSI recommends Code 128 because of its accuracy, compact form, and self-checking capabilities.¹
- A checksum greatly increases accuracy. Use a checksum with Interleaved 2-of-5 and Codabar because they are less accurate symbologies.
- Select the fixed length option, if available, because it is more accurate than the variable length option.
- To keep label and printing flaws to a minimum, use a narrow element of more than 0.25 mm (0.010 in.).

Beckman Coulter recommends the use of:

- **Code 128**
- **Checksum for all other symbologies**
- **Fixed length code symbols**
- **Narrow bar sizes of 0.25 mm (0.010 in.) minimum.**

Linear Barcode Symbologies

Within the given specifications, the reader and the optional handheld barcode reader automatically distinguish the following barcodes:

Table E.1 Specimen Tube Barcode Symbologies

Barcode Type	Description
Code 128 (also known as USD-6)	<ul style="list-style-type: none"> • Variable length • Alphanumerics; 107-character set • Self-checking • Continuous code; intercharacter space is part of code structure for higher density of code per square inch; compact bar code • Code 128 is recommended by the Clinical and Laboratory Standards Institute (CLSI) for its accuracy, compact form, and self-checking capabilities³
Code 39 (also known as 3-of-9 and USD-3)	<ul style="list-style-type: none"> • Variable length • Checksum Available (Beckman Coulter recommends to use checksum) • Discrete code; white spaces are not part of this code
Interleaved 2-of-5 (also known as I2 of 5, USD-1, and USD-1.25)	<ul style="list-style-type: none"> • Numerics only • Checksum Available (Beckman Coulter recommends to use checksum) • Lower density of code per square inch; longer label • Requires an even number of digits to be encoded, a leading "0" must be added if the number count is odd • Fixed only when Checksum is OFF.
Codabar (also known as USD-4 and NW7)	<ul style="list-style-type: none"> • Variable length • Has specific start and stop characters which lead to improvement in readability • Checksum Available (Beckman Coulter recommends to use checksum) • Lower density of code per square inch; longer bar code

Barcode Labels

A barcode consists of black lines (bars) and white lines (spaces), which are called elements.

There are narrow elements (NE) and wide elements (WE). The barcode symbology determines their arrangement.

 **CAUTION**

Sample misidentification can occur from the use of incorrect, poor quality, damaged, dirty or improperly placed barcode labels. Follow the specifications in this section to create your barcode labels to prevent incorrect sample identification.

Table E.2 Code-Related Specifications

Code	Interleaved 2-of-5*	Codabar*	Code 39*	Code 128*
Narrow element (NE) width	0.010 in. \pm 0.001			
Wide element/narrow element ratio (WE/NE)	3:1	N/A	3:1	N/A
Intercharacter gap	No	0.010 in. minimum	_NE	No
Data digits	14**	1 to 10**	1 to 7**	2 to 16

* See ISO/IEC 16388 for detailed specification.

** Includes checksum character

Specimen Tube 2-Dimensional Barcode Specifications



CellMek SPS supports the Aztec, Datamatrix, and QR Code 2-dimensional barcode types for specimen identification of the primary tube.

Table E.3 2D Specimen Barcodes Recommended Settings

Symbology	Example	Minimum Size of Modules	Level of Correction	White Space Required Around Symbol
Aztec		.33 mm (.013 inches) 4 dots if printer resolution = 12 dpm (300 dpi) or 8 dots if printer resolution = 24 dpm (600 dpi)	23%	None
Datamatrix Square			Not applicable	.33 mm (.013 inches)
Datamatrix Rectangle			Not applicable	.33 mm (.013 inches)
QR Code			Error Correction Level 2	1.32 mm (.052 inches)



CellMek SPS supports specimen IDs with up to 26 characters which may consist of numbers, letters, and special characters. The following special characters are not allowed (* < > \ / ? | : , [] ' ") within the specimen ID.

- Barcode printer settings may affect the ability to print special characters. If your specimen ID includes special characters, validate your printed barcodes to ensure that any characters were printed correctly.
- The QR Code and Aztec barcode types allow you to increase the error correction capability resulting in higher read rates. However, increasing the error correction results in larger

symbols that may not fit in the area of the tube exposed outside of the cassette. If you don't use 26 characters to encode your specimen ID, you may set larger error correction settings as long as the resulting barcode fits in the exposed area of the tube.

- The readability of the 2-dimensional barcode will be impacted by the curvature of the specimen tube, the barcode printer quality, and the label quality. Validate your specimen barcodes for readability before using in the CellMek SPS.
- With some Sarstedt specimen tubes, there is insufficient specimen tubes area exposed outside of the cassette to fit a square barcode. For those tubes, the only viable specimen 2D barcode is the Datamatrix rectangular type.
 - In the picture below, the tube on the right is a Sarstedt tube where the square barcode is being blocked by the cassette. If this occurs, use the rectangular Datamatrix barcode type (shown on the left) to encode the Specimen ID.



- **Pipe Delimiter:** When the Output Mode is set to Barcode Assigned, the system will accept specimen barcodes with pipe symbols (|) which are normally not allowed. If two pipe symbols are found within the specimen barcode, the system will use only the characters to the left of the first pipe symbol for the Specimen ID. This feature allows you to use the same 2D barcode format for the specimen tubes as for the output tubes.

Output Tube Barcode Specifications

The quality of the barcode symbol and the label is important for accurate reading. For high accuracy, use labels that meet all of the specifications.

The CellMek SPS requires all output tubes to have a 1-dimensional barcode that uniquely identifies the tube. In addition to this tube identification barcode, a 2-dimensional specimen information barcode is required when the output tube mode is set to **Barcode Assigned**. Refer to [CHAPTER 6, Setup](#) for instructions on setting up the output tube mode.

Tubes that are pre-barcoded with 1-dimensional tube identification barcodes are available from Beckman Coulter. Alternatively, you can follow the instructions in this section to print your own tube identification labels and attach them to third-party tubes.

IMPORTANT If you are not using the output tubes provided by Beckman Coulter, you should validate your output tubes for proper functioning in the CellMek SPS and your flow cytometer.

To create the 2-dimensional specimen information barcode required in Barcode Assigned mode, you have two options:

1. Print 2-Dimensional Specimen Information Labels and attach them to tubes with pre-attached Output Tube Identification 1-Dimensional Barcode Labels, or
2. Print labels containing both the 2-dimensional specimen information barcode and the 1-dimensional tube identifier and attach them to the third-party tubes.



Output Tube Identification 1-Dimensional Barcode Label

CellMek SPS uses only the Code 128, Code Set B symbology for output tubes.

Figure E.2 Output Tube Identification Barcode Label

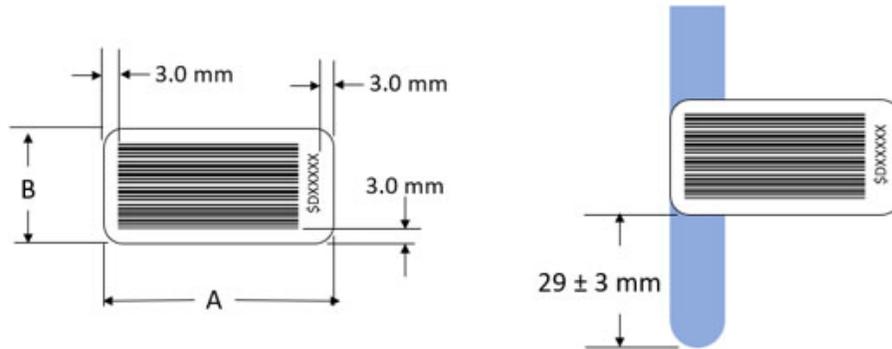


Table E.4 Output Tube Barcode Symbol

Description	Details
Label Dimensions	A - 50 mm or 2.0 inch B - 25 mm or 1.0 inch
Minimum Print Resolution	12 dpm (dots per millimeter) or 300 dpi (dots per inch)
Narrow Bar Width	.1693 mm or .0067 inch NOTE Depending on the printer model, the Narrow Bar Width may also be expressed in the number of dots. It must be 2 dots for a 12 dpm (300 dpi) printer or 4 dots for a 24 dpm (600 dpi) printer.
Color	Black ink on white background.

Table E.4 Output Tube Barcode Symbol

Description	Details
Encoded Data Sequence	<ul style="list-style-type: none"> • 7 alphanumeric characters • First two characters must be "\$Z" (\$Z is used when barcodes are printed by the user. In the pre-labeled Beckman Coulter tubes the codes are \$N or \$D). • Letters can only be uppercase. • The last five characters must form a unique alphanumeric code. <p>NOTE CellMek SPS remembers all the output tube identification codes used in the past and will not accept duplicates.</p> <ul style="list-style-type: none"> • Recommended incrementation sequence for last 5 characters: <ul style="list-style-type: none"> — Start with 10000 — Increment from 0 to Z starting from the right-most digit — Example: 10001,10002, ...,10009, 1000A, ...,1000Z, 10010, 10011, 10012, ...,10019, 1001A, ...,1001Z — Sequence ends with ZZZZZ (>50 million unique IDs)
Print Quality	Print quality is an important factor that affects the ability of barcode readers to scan your barcodes. Test your labels on the CellMek SPS and the flow cytometer to confirm they are read successfully. You may need to adjust your printer setup parameters such as print speed and darkness to optimize label quality.
Human Readable Information	Print the human readable text of the sample tube ID barcode to help you visually identify the tube.

Output Tube Labels for Barcode Assigned Mode

CAUTION

Risk of sample misidentification if the output sample tube's 2D barcode information (Specimen_ID, Panel_Code, Tube_Number) does not match the human readable information printed on the tube label. Laboratory barcode printer templates should be validated for concordance between the barcoded and the human-readable content.

CellMek SPS uses 12 x 36 Datamatrix symbology for output tubes options below.

You have two options for labeling your output tubes when using Barcode Assigned Mode:

Option 1

Print 2-Dimensional Specimen Information Labels and attach them to the tubes with pre-attached Output Tube Identification 1-Dimensional Barcode Labels.

Figure E.3 Output Tube for Barcode Assigned Mode (2D Barcode)

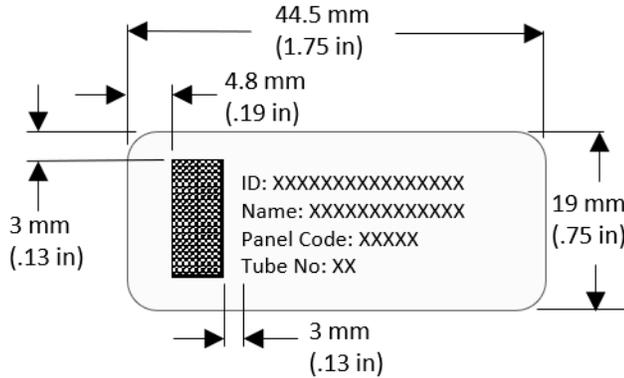
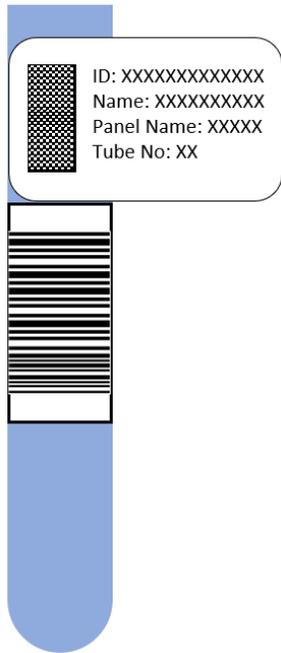


Table E.5 Output Tube Barcode Symbol

Description	Details
Minimum Print Resolution	300 dpi (dots per inch)
Module Size	<ul style="list-style-type: none"> • 8 dots if printing 600 dpi (dots per inch) • 4 dots if printing 300 dpi (dots per inch)
2D Barcode Content: Specimen_ID\Panel_Code\Tube_Number	<ul style="list-style-type: none"> • The 2D Barcode must contain the following fields (ID, Name, Panel Name, and Tube No.). Refer to Figure E.3 for more information. • The fields must be separated by a pipe symbol “ ”. • Specimen_ID must match the specimen ID that is scanned from the specimen (primary) tube. • Panel_Code is a 1 to 5-character alphanumeric code that uniquely identifies each panel. Refer to CHAPTER 4, Importing Panels. • Tube_Number is a 1 or 2-digit number representing the tube order in the panel. For example, in a four-tube panel, the second tube will have Tube_Number = 2.
Human Readable Information	You can enter human readable information to help you visually identify the tube. The space remaining in the label after including the 2D barcode can be used for this information. At minimum, the Specimen_ID, Panel_Code, and Tube_Number should be included to help you place the tubes in the correct order in the output carousel.

Label Placement for Option 1

Apply the specimen information label to be flush with the upper edge of the pre-applied label in the output sample tube.



OPTION 2

Apply one label containing both the sample specimen information and the unique output tube ID to a third-party output tube.

Figure E.4 2-Dimensional Barcode Portion of the Label

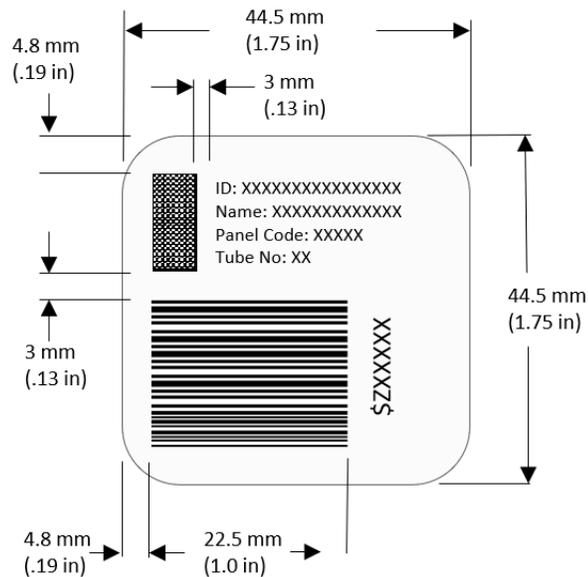
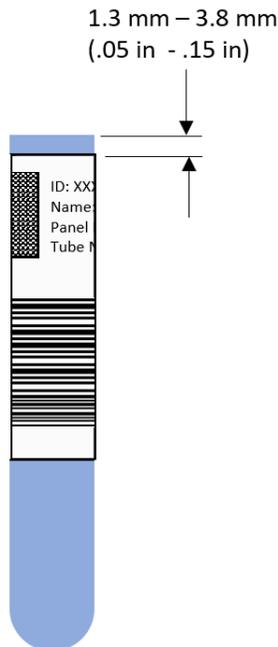


Table E.6 Output Tube Barcode Symbol

Description	Details
Minimum Print Resolution	300 dpi (dots per inch)
Module Size	<ul style="list-style-type: none"> • 8 dots if printing 600 dpi (dots per inch) • 4 dots if printing 300 dpi (dots per inch)
2D Barcode Content: Specimen_ID\Panel_Code\Tube_Number	<ul style="list-style-type: none"> • The 2D Barcode must contain the fields shown in Figure E.4. • The fields must be separated by a pipe symbol “ ”. • Specimen_ID must match the specimen ID that is scanned from the specimen (primary) tube. • Panel_Code is a 1 to 5-character alphanumeric code that uniquely identifies each panel. Refer to CHAPTER 4, Importing Panels. • Tube_Number is a 2-digit number representing the tube order in the panel. For example, in a four-tube panel, the second tube will have Tube_Number = 2.
Human Readable Information	You can enter human readable information to help you visually identify the tube. The space remaining in the label after including the 2D barcode can be used for this information. At minimum, the Specimen_ID, Panel_Code, and Tube_Number should be included to help you place the tubes in the correct order in the output carousel.

For the 1-Dimensional Barcode portion of the label, refer [Output Tube Identification 1-Dimensional Barcode Label](#).

Label Placement for Option 2



Consumables and Accessories

Consumables and Accessories

The following [Table F.1](#) is a list of consumables and accessories that are provided with the instrument and are orderable. To order consumables and accessories, [contact us](#).

 **CAUTION**

Risk of erroneous results. Use only reagents and well plates provided by Beckman Coulter for use with the CellMek SPS.

Table F.1 Orderable Consumables and Accessories

Item	Quantity
Cell Wash Fluid Bottle - Wash Buffer, 2 L	3 each
Cell Wash Fluid Bottle - DI Water, 2 L	2 each
Cell Wash Fluid Bottle - Bleach Water, 2 L	2 each
Reaction Plate - 48 well with barcode	25 each
Waste Container, 15 L	1 each
Condensate Bottle, 2 L	1 each
IsoFlow Sheath Fluid (IVD), 10 L	1 each
Custom Defined Reagent Barcode Labels - Primary	8 sheets
Custom Defined Reagent Barcode Labels - Secondary	8 sheets
CytoSTAT Vials Pierceable Caps - blue	50 each
IOTest Vials Pierceable Caps - yellow	100 each
IOTest Type Antibody and Stain Reagent Vials	187 each
Output Tubes - barcodes	250 each
Prep Reagent Bottles, 125 mL	36 each
Probe non-piercing	1 each
Probe piercing	1 each
Mandrel - Probe Replacement	1 each
Cubitainer Support Neck	1 each
Dry Reagents Carousel	2 each
Output Tube Carousel	2 each
Antibody Vial Carousel - 43 IOTest and 10 CytoSTAT	1 each
Prep Reagent Carousel	1 each
Carousel Number Label Sheet	2 sheets

Table F.1 Orderable Consumables and Accessories (*Continued*)

Item	Quantity
Prep reagent adapter P01 - Custom, Versalyse, and Optilyse C	2 adaptors
Prep reagent adapter P02- Immunoprep	2 adaptors
Prep reagent adapter P03 - Perfix-NC	2 adaptors
Type A cassette, see APPENDIX D, Tube List for CellMek SPS	1 box 10 cassettes
Type A+ cassette, see APPENDIX D, Tube List for CellMek SPS	3 cassettes
Type B cassette, see APPENDIX D, Tube List for CellMek SPS	1 box of 5 cassettes
Type D cassette, see APPENDIX D, Tube List for CellMek SPS	1 box of 5 cassettes
Type E cassette, see APPENDIX D, Tube List for CellMek SPS	3 cassettes
Specimen Cassette Barcode Labels for each cassette type	Sheets of labels

Good Practices for Cyber Security

The following procedures are the only validated and approved recommendations for cyber privacy and security. Contact your IT professional for assistance.

 **CAUTION**

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

- 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 join the system to a domain and apply domain policies which alter the default configuration.
- Ensure that all external devices are free from viruses before connecting.
- You alter the system in a manner other than the approved changes outlined below.

 **CAUTION**

Risk of software failure. To avoid software failure, only install operating system updates supplied and approved by Beckman Coulter.

 **CAUTION**

Risk of unauthorized access and modification. To avoid unauthorized access and modification, enable all product security features and install all approved operating system updates.

 **CAUTION**

Risk of CellMek workstation sending unencrypted data to the LIS, LIS Middleware or any network printer. Ensure adequate network protection mechanism are in place to avoid unauthorized access to transmitted data.

IMPORTANT BitLocker is the only approved disk encryption method.

- Your Windows 10 system is equipped with BitLocker. Use BitLocker disk encryption software to prevent unauthorized access to your hard drive, refer to [BitLocker Keys](#). For instructions on BitLocker Encryption or BitLocker Decryption, see [BitLocker Encryption](#) or [BitLocker Decryption](#).

- Direct TCP/IP network connections with the workstation are only supported on systems with all security features available and active.
- Before connecting to an external device such as a hard drive, USB, verify that it does not have a virus or malware.
- Auto-run is disabled on your system to prevent the automatic launching of an application on external media. Leave auto-run disabled on the system.
- Close all unnecessary applications while operating the CellMek software.
- Ensure all Beckman Coulter approved operating system security updates are installed once validated and approved.
- Beckman Coulter supports continuous network connectivity on Windows 10 systems.
- Changes below require exiting Kiosk mode and logging in with Administrator Level Windows access.

Exiting Kiosk Mode



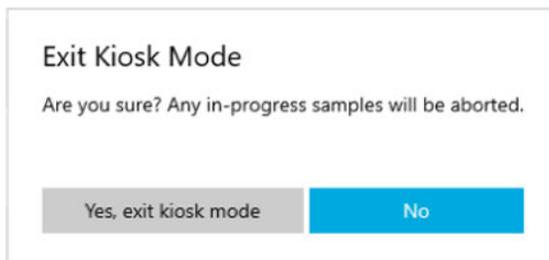
Risk of erroneous results due to reagent spoilage. The liquid antibody refrigerator will shut off after several hours if the CellMek SPS software is not running. To avoid reagent spoilage, ensure that the CellMek SPS software is running after restarting the computer. You can know that the CellMek SPS software is running if the log in screen is displayed and the system says Not Ready.

IMPORTANT Operate the system in Kiosk mode (as Windows users CellMekKiosk) unless a procedure requires exiting kiosk mode into the CellMekUser Windows login. Do not configure the system for domain authentication.

Exiting the Kiosk Mode (when applicable)

1 Login to the CellMek SPS software as a user with Exit Kiosk permission.

2 Select **Exit Kiosk Mode** from the user menu  and the following message displays.



- 3 Select the **CellMekUser** in the lower left corner of the login screen.



- 4 Enter the password configured for the CellMekUser in **Changing Your Windows Password** section in [CHAPTER 6, Software Setup](#) or use the default password *cellmekuser*.

NOTE If the login is not completed within 45 seconds, the system may return to Kiosk mode.

Returning to Kiosk Mode

IMPORTANT Operate the system in Kiosk mode (as Windows users CellMekKiosk) unless a procedure requires exiting kiosk mode into the CellMekUser Windows login. Do not configure the system for domain authentication.

Returning to Kiosk Mode (after exiting)

- 1 Select , then select  with the username, and then select **Signout**.

- 2 Select the **CellMekKiosk** in the lower left of the login screen.



- 3 Enter the password configured for CellMekKiosk, see [Changing Your Windows Password](#) or use the default password *cellmekkiosk* if password has not been altered.

Drive Encryption

The BitLocker drive encryption is XTS-AES 256-bit.

BitLocker Keys

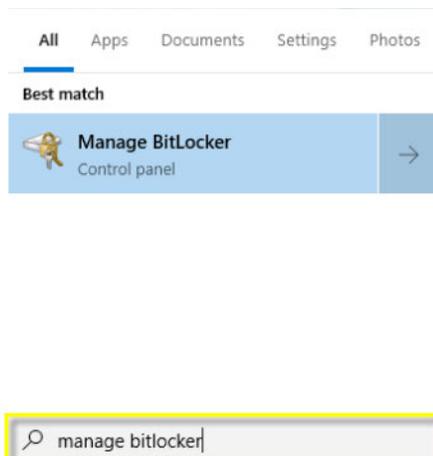


Risk of data loss. Store your BitLocker key in a safe place. For instructions on saving your BitLocker key, refer to the [Backing Up Your Recovery Key](#) section. If you lose your BitLocker Key, you will lose access to your entire hard drive including all of your data. Beckman Coulter is not responsible for security keys and will not be able to recover your data from the hard drive. Work with your IT department in creating and storing the keys in a safe place.

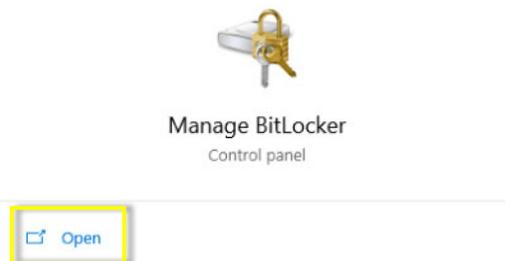
BitLocker Encryption

Enabling BitLocker (C Drive)

- 1 Exit Kiosk Mode, see [Exiting Kiosk Mode](#).
- 2 Type **Manage BitLocker** from the Windows search bar to locate the **Manage BitLocker Control Panel**.

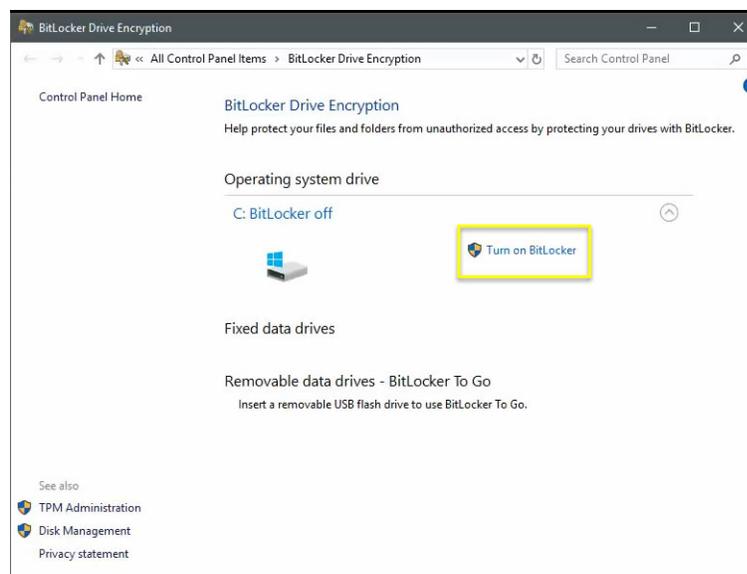


3 Select **Open** on the **Manage BitLocker Control Panel**.

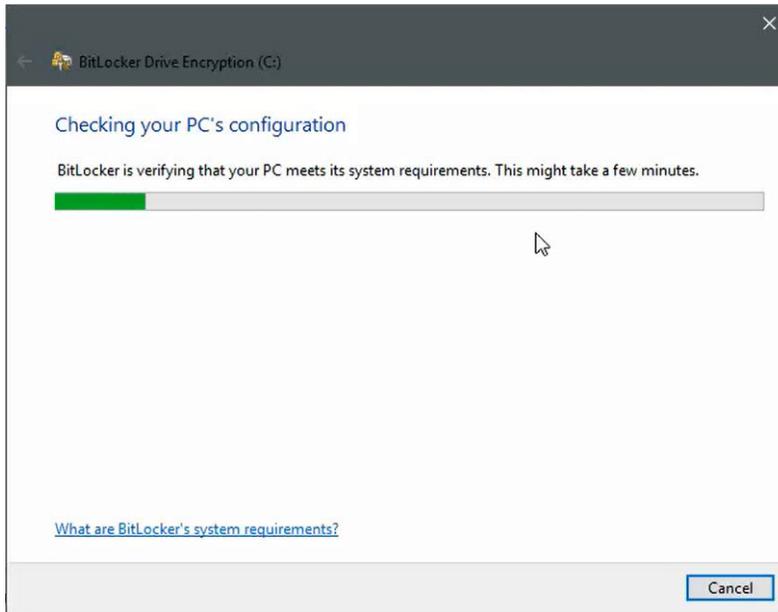


NOTE If you encrypted an external drive, enter a BitLocker password.

4 Select **Turn on BitLocker** from the Control Panel screen.

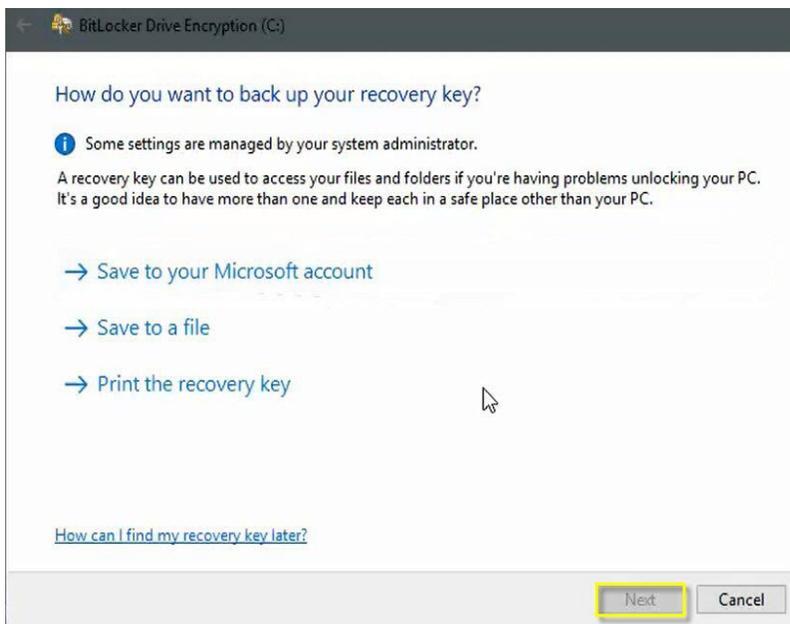


5 BitLocker will verify your PC meets the requirements.

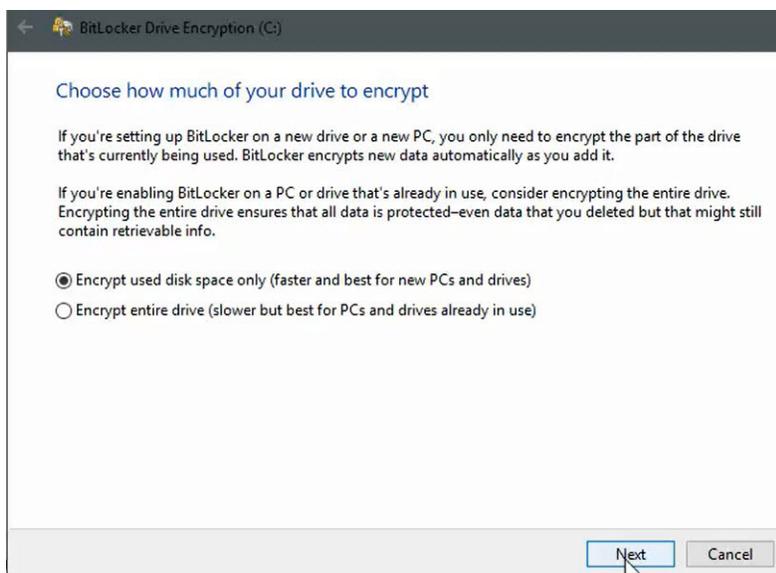


IMPORTANT The Back Up Your Recovery Key to your Microsoft Account is not supported at this time.

6 Select either **Save to a File**, or **Print the Recovery Key** to back up your recovery key then select **Next**. For instructions on backing up your recovery key, refer to [Backing Up Your Recovery Key](#).

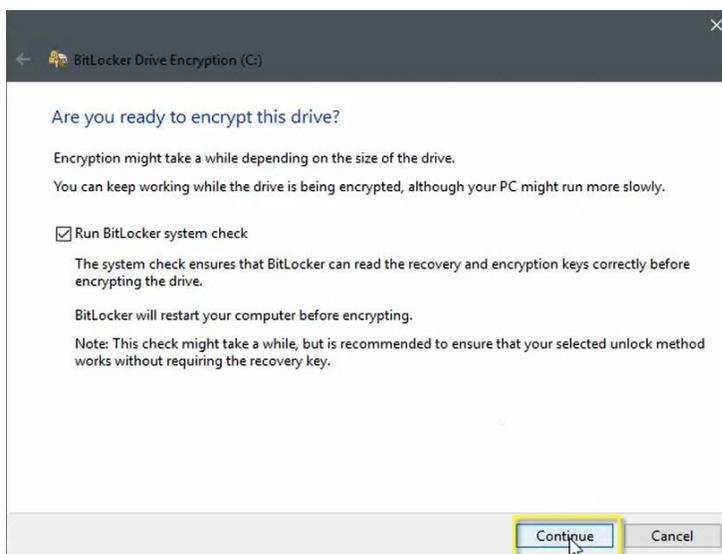


- 7 Select “*Encrypt used disk space only (faster and best for new PCs and drives)*”, then select **Next**.



IMPORTANT The system check will ensure that BitLocker can read the recovery and encryption keys correctly before encrypting the drive. This check may take some time, but it is recommended to ensure that your selected unlock method works without requiring the recovery key.

- 8 Select “*Run BitLocker system check*” checkbox, then select **Continue**.



NOTE BitLocker will restart your computer before encrypting.

- 9 Select **Restart now** to begin the BitLocker System Check.

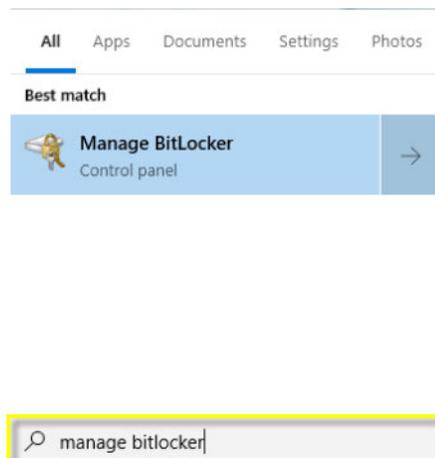


NOTE If you encrypted to an external drive, you will not be prompted to restart.

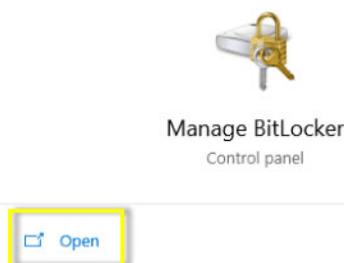
- 10 Enter your User Name and Password and follow the on-screen prompts.

NOTE After logging in you may see a Window that says **Encrypting in Progress**.

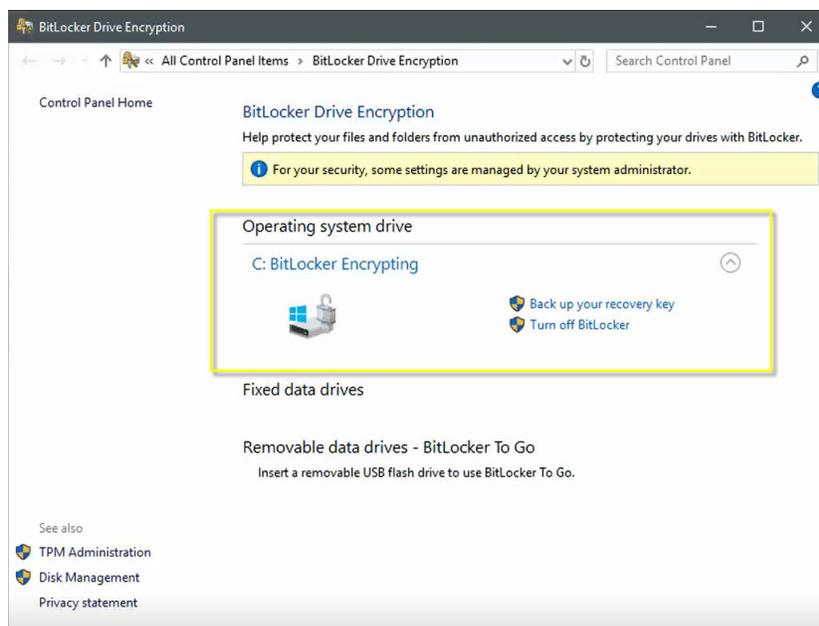
- 11 Type **Manage BitLocker** from the Windows search bar to locate the **Manage BitLocker Control Panel**.



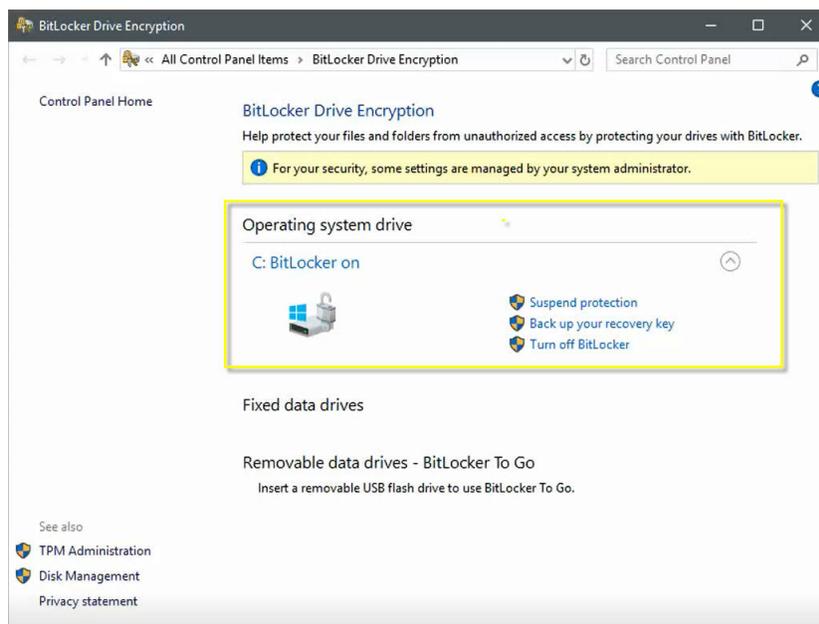
- 12 Select **Open** on the **Manage BitLocker Control Panel**.



13 Under Operating System Drive, you will see the BitLocker is Encrypting the drive.



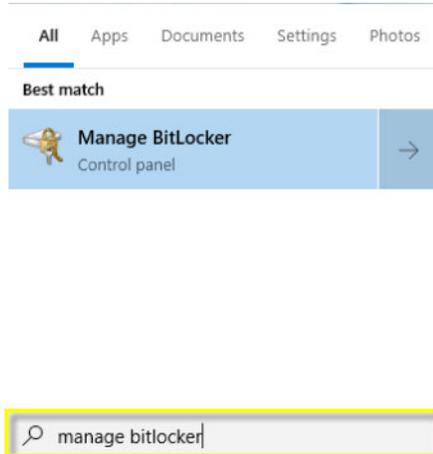
14 Once the BitLocker has encrypted the drive, the BitLocker will be on.



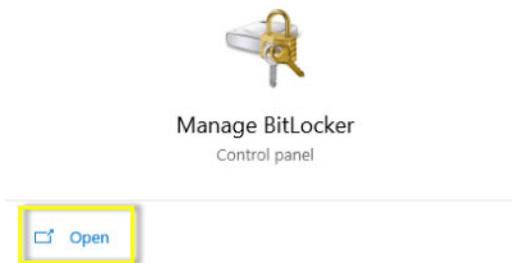
Enabling BitLocker (Removable Media)

1 Exit Kiosk Mode, see [Exiting Kiosk Mode](#).

- 2 Type **Manage BitLocker** from the Windows search bar to locate the **Manage BitLocker Control Panel**.

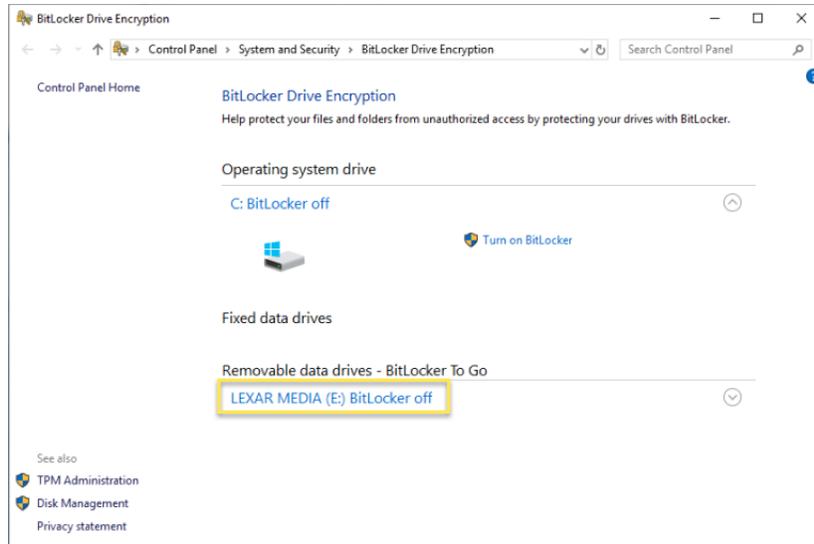


- 3 Select **Open** on the **Manage BitLocker Control Panel**.

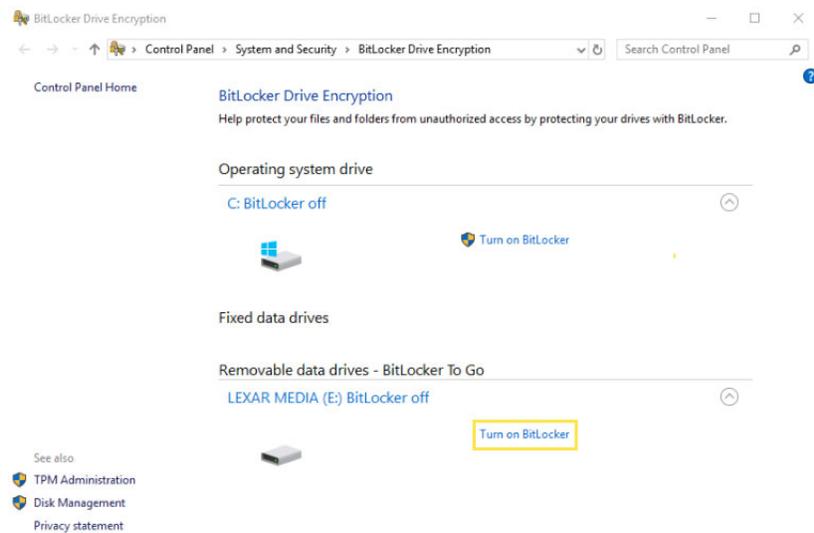


NOTE If you encrypted an external drive, enter a BitLocker password.

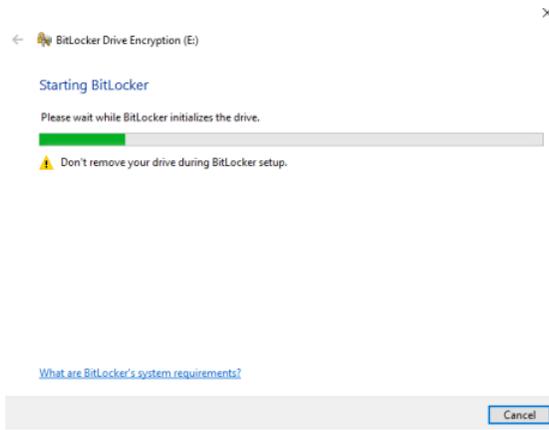
4 Choose removable drive.



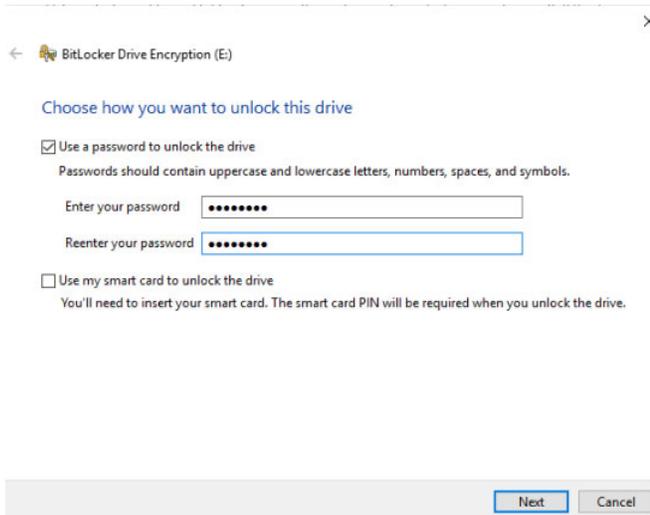
5 Select **Turn on BitLocker** from the Control Panel screen.



6 BitLocker will verify your PC meets the requirements.

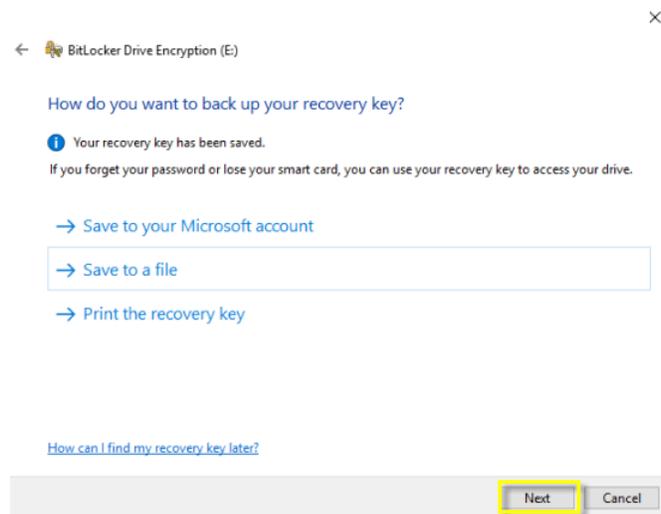


7 Select **Use a password to unlock the drive** or **Use my smart card to unlock the drive**.

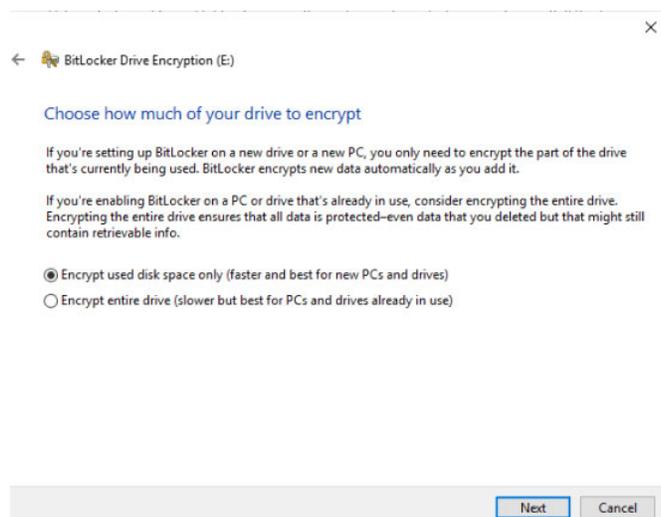


IMPORTANT The Back Up Your Recovery Key to your Microsoft Account is not supported at this time.

- 8 Select either **Save to a File**, or **Print the Recovery Key** to back up your recovery key then select **Next**. For instructions on backing up your recovery key, refer to [Backing Up Your Recovery Key](#).

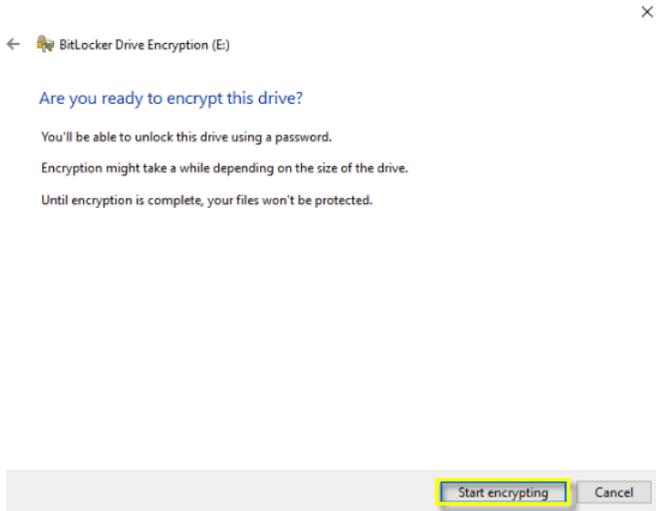


- 9 Select "Encrypt used disk space only (faster and best for new PCs and drives)", then select **Next**.



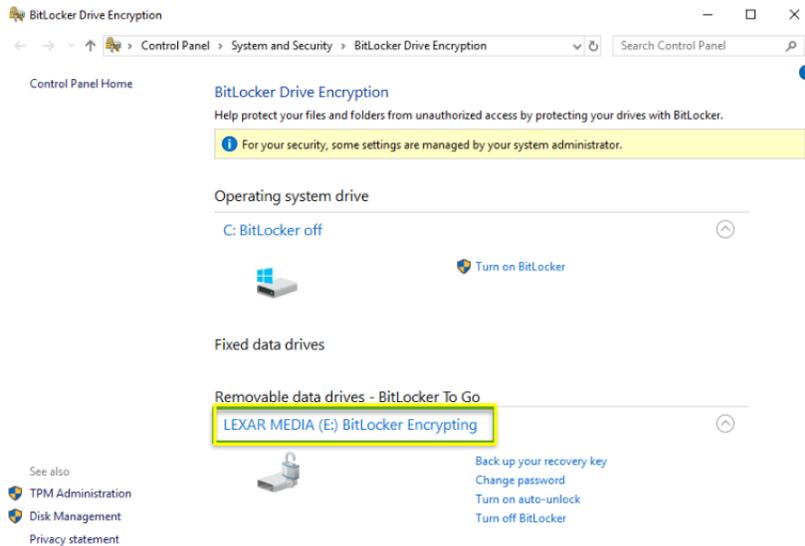
IMPORTANT The system check will ensure that BitLocker can read the recovery and encryption keys correctly before encrypting the drive. This check may take some time, but it is recommended to ensure that your selected unlock method works without requiring the recovery key.

10 Select **Start encrypting**.

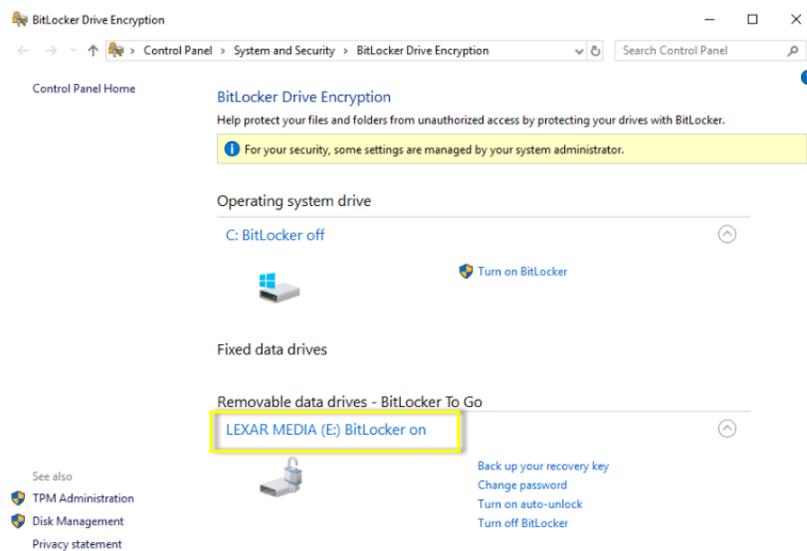


NOTE BitLocker will restart your computer before encrypting.

a. Under Operating System Drive, you will see the BitLocker is Encrypting the drive



- b. Once the BitLocker has encrypted the drive, the BitLocker will be on.



- c. The final message shows that the Encryption of E drive is complete.



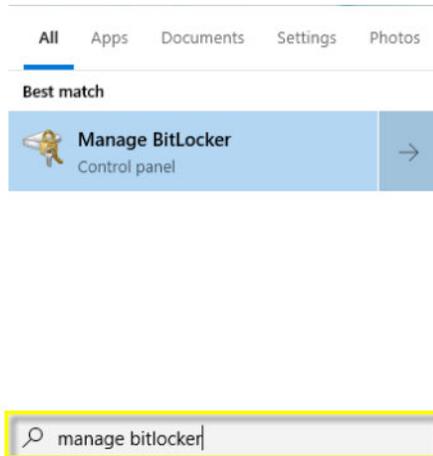
Backing Up Your Recovery Key

IMPORTANT The Back Up Your Recovery Key to your Microsoft Account is not supported at this time.

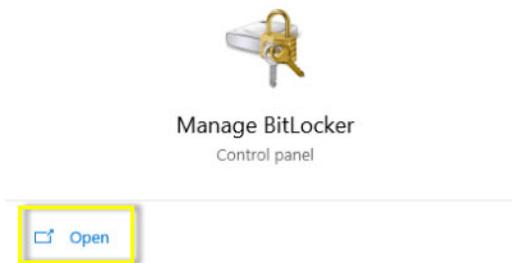
Backing up your recovery key to a file

- 1 Exit Kiosk Mode, see [Exiting Kiosk Mode](#).

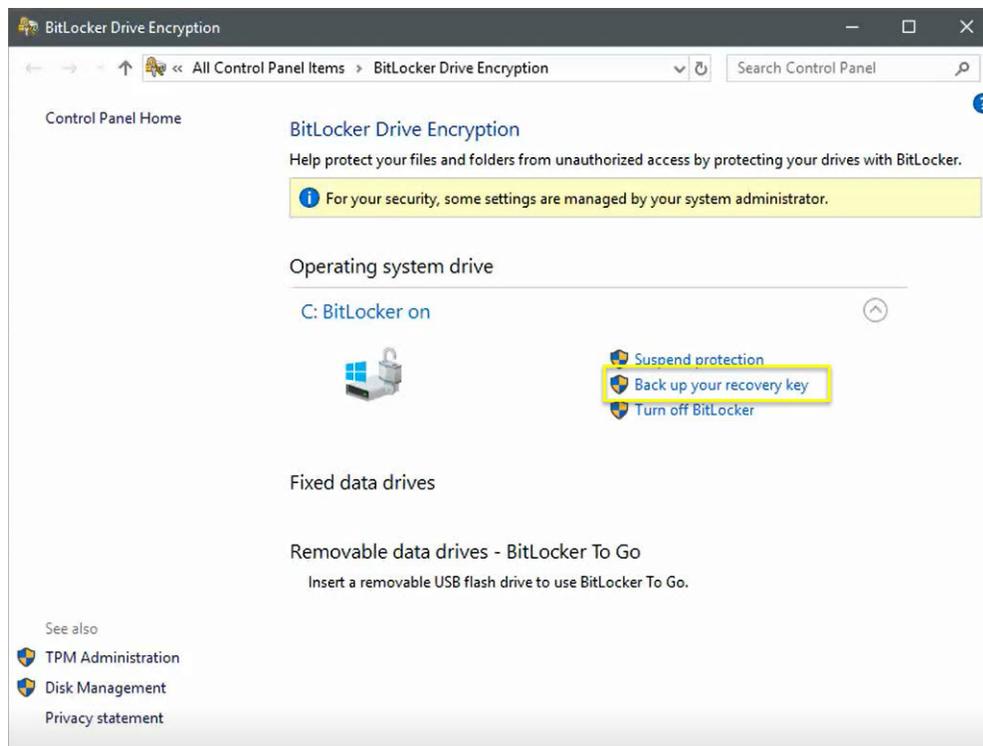
- 2 Type **Manage BitLocker** from the Windows search bar to locate the **Manage BitLocker Control Panel**, see below.



- 3 Select **Open** on the **Manage BitLocker Control Panel**.

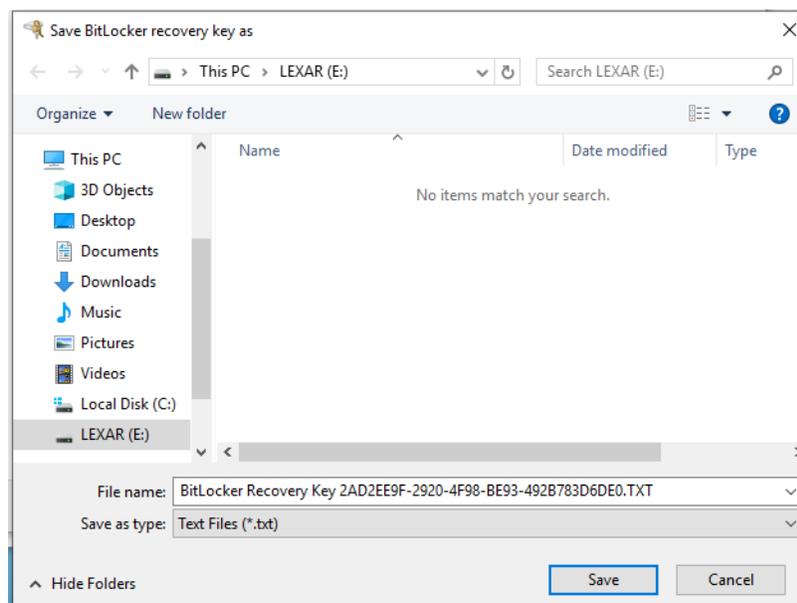


4 Select “Backup your recovery key”.



IMPORTANT The Recovery Key can only be saved to a USB or external drive. You cannot save to a location on your PC.

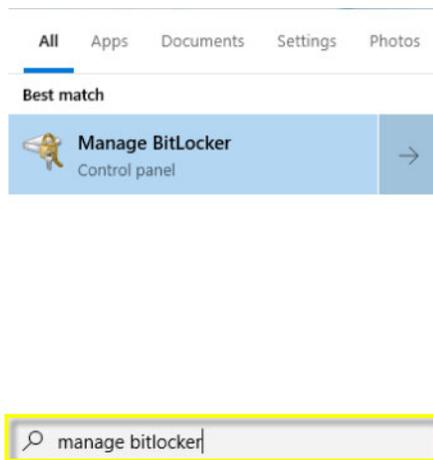
5 Select “Save to a file” and the **Save BitLocker recovery key as** screen appears.



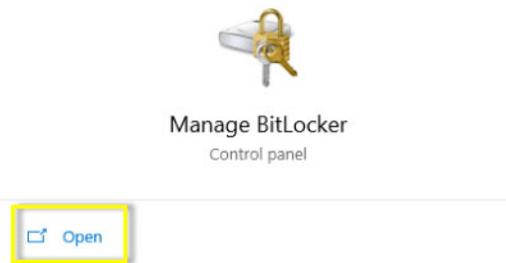
-
- 6 Select **Save** then select **Finish**.
-

Backing up your recovery key in PDF form

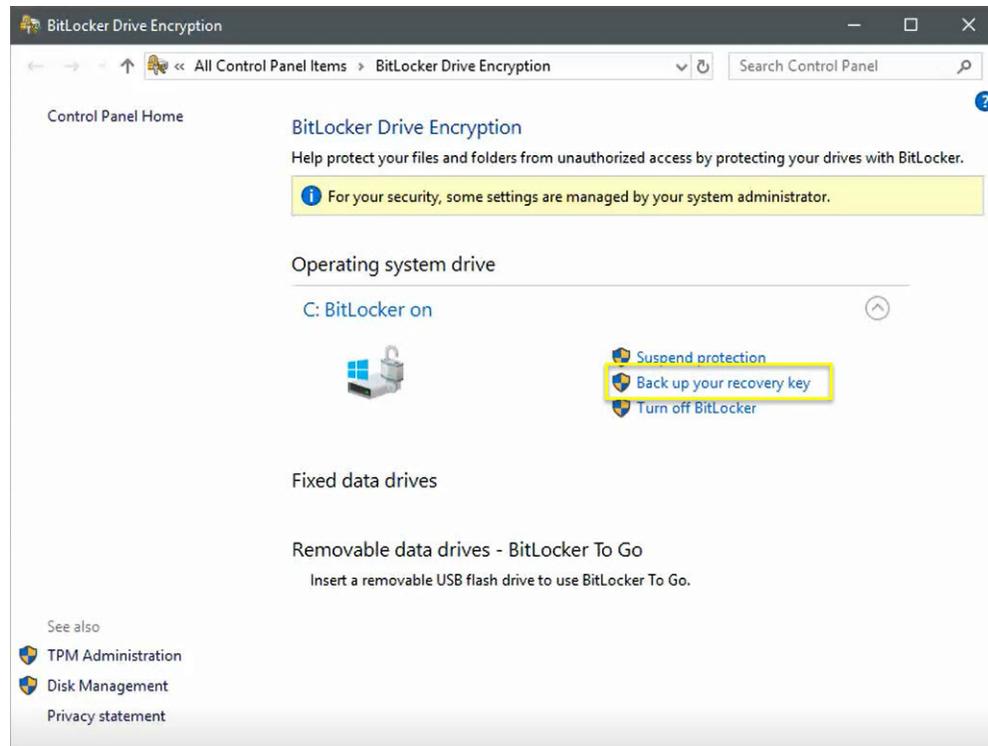
- 1 Exit Kiosk Mode, see [Exiting Kiosk Mode](#).
-
- 2 Type **Manage BitLocker** from the Windows search bar to locate the **Manage BitLocker Control Panel**.



-
- 3 Select **Open** on the **Manage BitLocker Control Panel**.



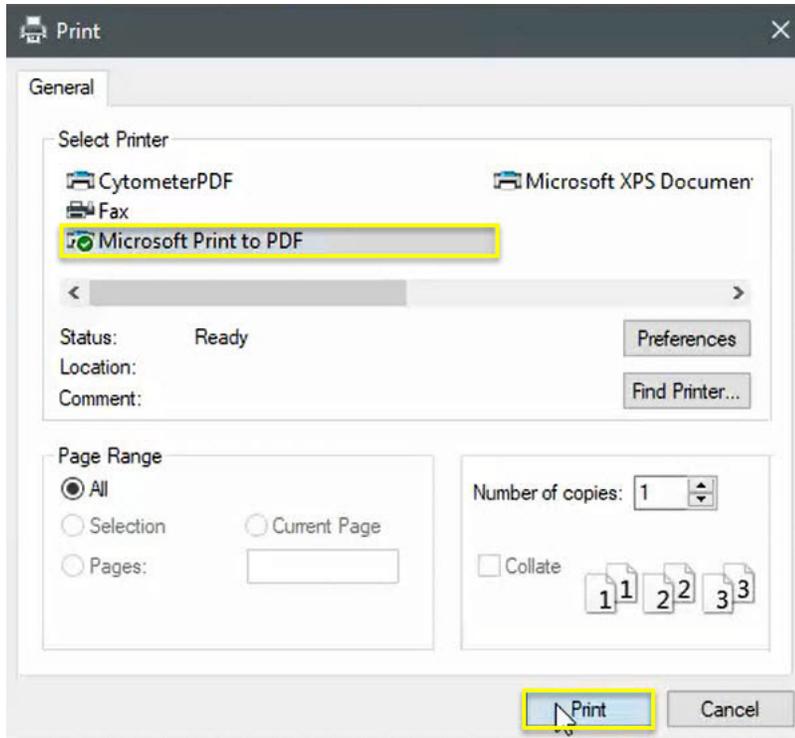
4 Select “*Backup your recovery key*”.



5 Select “*Print the recovery key*”, then select Next.

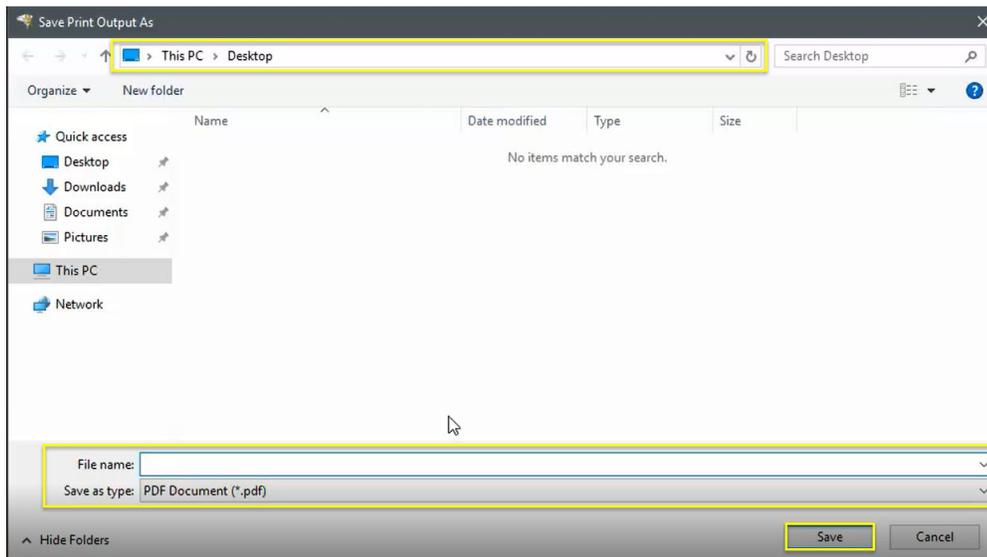
NOTE If you do not have a printer installed, the software may ask you to install a printer. Otherwise, you may use the Microsoft Print to PDF as shown in the following step.

- 6 Select “Microsoft Print to PDF”, then select **Print**.



IMPORTANT Save the PDF to external media or a network drive.

- 7 Select the location that you want the file saved. In the File name, type **BitLocker Key** and in the Save as type, ensure that it is listed as .pdf. Then select **Save** and **Finish**.



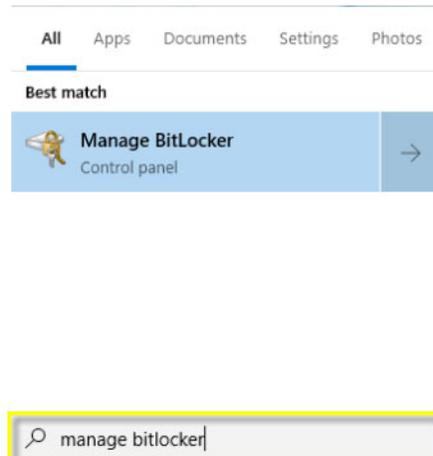
BitLocker Decryption

IMPORTANT Turning off the BitLocker feature will decrypt all the data on the drive. Decrypting your operating system means that you have removed BitLocker from your system. The BitLocker key will change each time BitLocker is re-enabled. Only the latest BitLocker key will work. Previous BitLocker keys will be invalid and will not unlock the system. Please note this is a time-consuming process. However, you can also suspend BitLocker instead of decrypting the drive, see [Suspending BitLocker Drive Encryption](#).

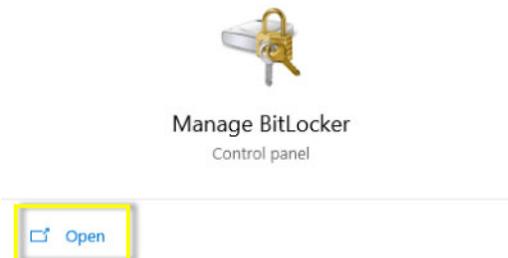
Turning off BitLocker (Removable Media)

1 Exit Kiosk Mode, see [Exiting Kiosk Mode](#).

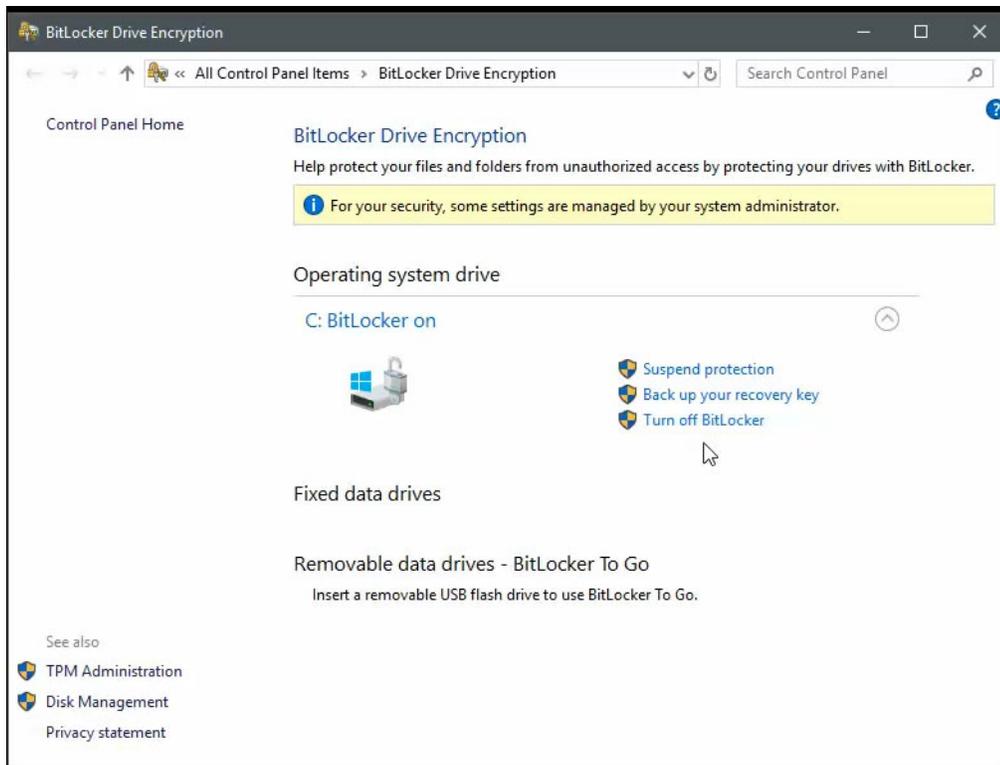
2 Type **Manage BitLocker** from the Windows search bar to locate the **Manage BitLocker Control Panel**.



3 Select **Open** on the **Manage BitLocker Control Panel**.



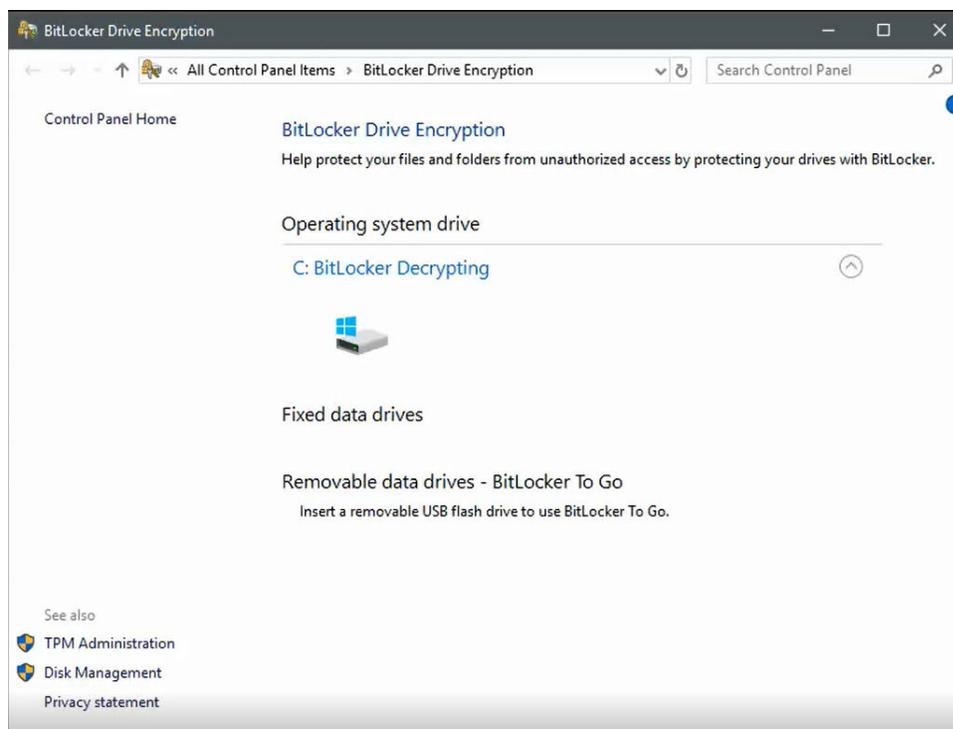
4 Select **Turn off BitLocker**.



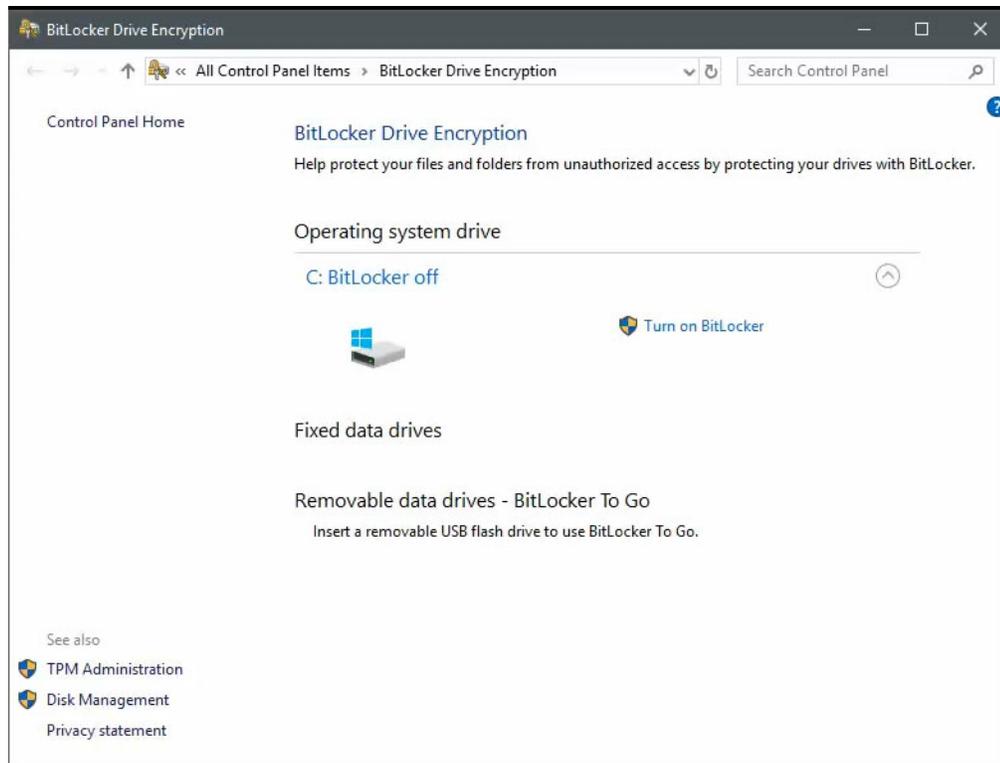
5 A message will appear *“Your drive will be decrypted. This might take a long time, but you can keep using your PC during the decryption process.”*. Select **Turn Off BitLocker**.



6 The BitLocker Drive Encryption screen will be displayed.



7 After the decryption has completed, the following screen will be displayed.



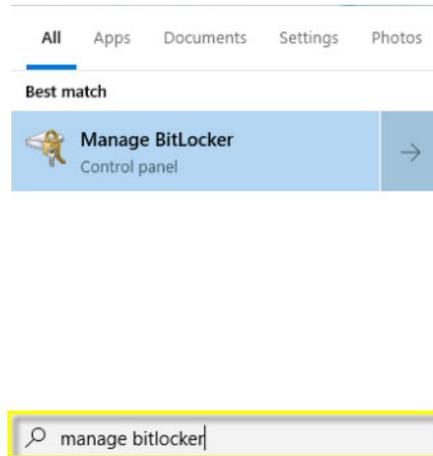
Suspending BitLocker Drive Encryption

IMPORTANT Suspending BitLocker Drive Encryption is a temporary method for removing BitLocker protection without decrypting the Windows drive. Use Suspend BitLocker if you need to update the BIOS firmware or Windows bootloader/startup files that requires access to the drive in a pre-boot environment. This will help prevent BitLocker from locking the drive and may avoid a lengthy decryption process.

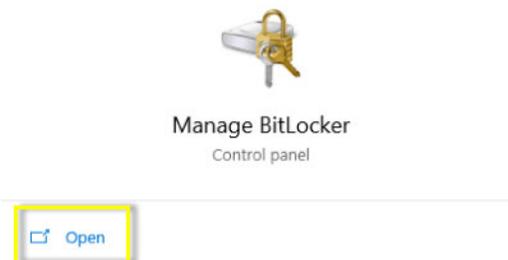
Suspending BitLocker

1 Exit Kiosk Mode, see [Exiting Kiosk Mode](#).

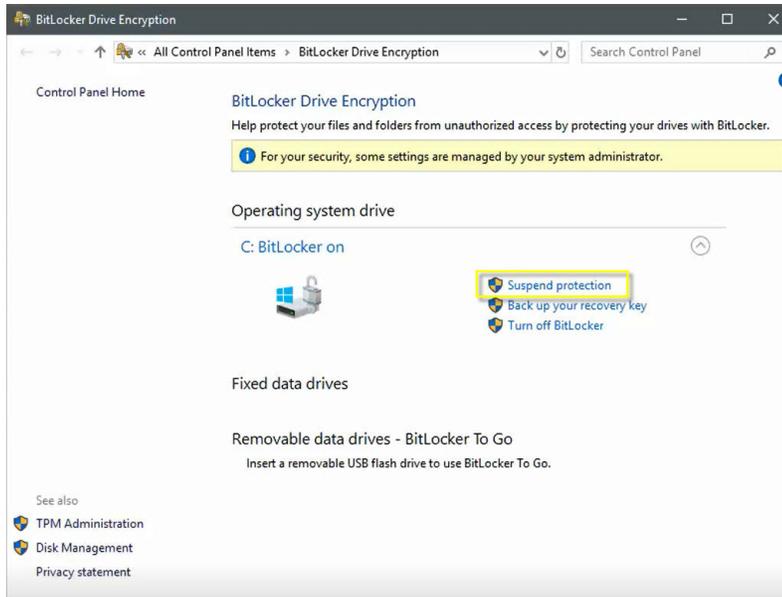
- 2 Type **Manage BitLocker** from the Windows search bar to locate the **Manage BitLocker Control Panel**.



- 3 Select **Open** on the **Manage BitLocker Control Panel**.



4 Select Suspend Protection.

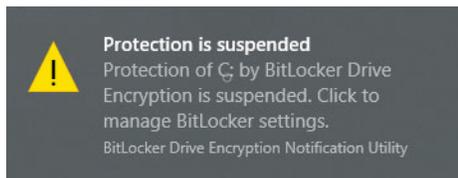


IMPORTANT If you choose to suspend BitLocker, your data will not be protected.

5 A confirmation message will be displayed, “Do you want to suspend BitLocker protection?”.



If you want to proceed, select **Yes** and the following notification message will be display.



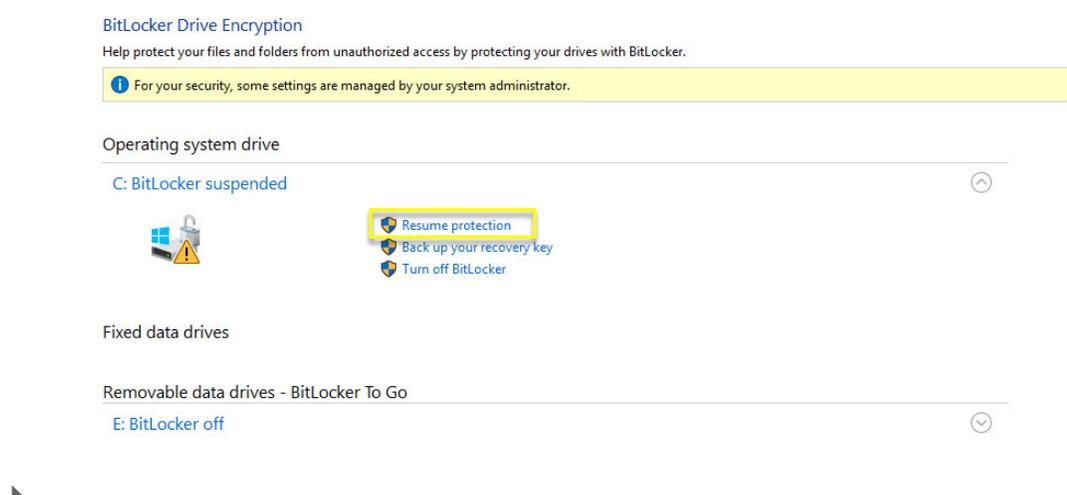
If you do not want to proceed, select **No**.

NOTE There are certain situations where you may want to suspend BitLocker such as updating your PC's firmware, hardware, or operating system. If you forget to resume BitLocker after these updates are completed, BitLocker will resume automatically the next time you restart your PC.

Restarting BitLocker Protection

1 Exit Kiosk Mode, see [Exiting Kiosk Mode](#).

2 Select **Resume Protection**.



Recovering using your BitLocker Key

There may be situations where the BitLocker Key is requested from your computer, such as:

- Your drive is placed onto another computer
- Computer requests your recovery key, it may be due to one of the following but is not limited to:
 - Hardware changes
 - Firmware changes
 - Other Windows updates
 - System Restore

BitLocker Recovery

- 1 BitLocker Recovery window will be displayed upon powering on your system.



- 2 Enter your key from your saved text file or printed copy, then select **Enter**.



- 3 Windows may reboot your computer.
-

Using BitLocker Encrypted Media in Kiosk Mode

IMPORTANT This procedure must be used after each reboot.

- 1 Exit Kiosk mode, see [Exiting Kiosk Mode](#) and Login as CellMekUser.

- 2 Attach BitLocker encrypted external drive.

- 3 Enter the BitLocker password when prompted.

- 4 Return to Kiosk Mode, see [Returning to Kiosk Mode](#).

- 5 Repeat Steps 1 - 4 after each reboot to enable access to BitLocker encrypted drive.

Encryption of the Database



Risk of data loss. Databases in Windows 10 are encrypted. Refer to [CHAPTER 6, Restoring Database](#).

The database is AES-CBC 256-bit encrypted at the bit level.

Password Security

CellMek SPS software enforces 90-day password expiration and the complexity requirements below. Reuse of the previous 10 passwords is prohibited.

- Blanks passwords are not allowed.
- Password must be a minimum of 10 characters or greater.
- Password must contain the following:
 - One upper case alpha character;
 - One lower case alpha character;
 - One numeric value; Base 10 digits (0 through 9)
 - A special character (i.et., !, @, #, \$, %, ^, &)

Windows does not enforce any password requirements. Users should change the windows password every 90 days or less and adhere to the password complexity requirements above.

Changing Your Windows Password

For CellMekUser:

- 1 Exit Kiosk Mode, see [Exiting Kiosk Mode](#).
- 2 Select **(Ctrl) + (Alt) + (Delete)** and select change password.
- 3 Enter old password and new password twice. The default password is cellmekuser.

For CellMekKiosk:

- 1 Exit Kiosk Mode, see [Exiting Kiosk Mode](#).
- 2 Select the windows icon and type netplwiz and select netplwiz.
- 3 Uncheck **Users Must Enter a username and password to use this computer**.
- 4 Select **CellMekKiosk**.
- 5 Select **Reset Password**.
- 6 Check **Users Must Enter a username and password to use this computer** and select OK.
- 7 Enter the username and the new password for **CellMekKiosk**.
- 8 Logoff **CellMekUser** to login to the Kiosk Mode.

Application Control

Application control is a computer administration practice used to prevent unauthorized programs from running. This ensures that the system is configured to only run authorized software defined in the application control and anything else is prevented from running. Application control is preferable to traditional Anti-virus solutions as it is less hardware resource intense, and it does not need any updates to protect the product against future vulnerabilities.

IMPORTANT Beckman Coulter will not alter the application control to permit installation of any software not listed below.

The following executables and installers can be installed:

- CellMek SPS software
- Microsoft Operating Systems updates downloaded from Beckman Coulter RSU Portal
- BeckmanConnect

The control will prevent the following:

- Installing any software other than the ones stated above.

Error Messages

[Table G.2](#) lists the messages, with their cause and what to do about them. These are the messages produced by the system.

Table G.1 Application Control Error Messages

Message	Probable Cause	Recommended Action
Windows cannot access the specified device, path, or file. You may not have the appropriate permissions to access the item.	<ul style="list-style-type: none">• Insufficient rights to access the device, path, or file.• Blocked by application control.	<ol style="list-style-type: none">1. Ensure you have sufficient rights.2. If problem persists, Contact us for additional assistance.
System does not run or install a program not on allowed software list.	<ul style="list-style-type: none">• User attempted to run or install an unvalidated/unauthorized program.• Blocked by application control.	<ol style="list-style-type: none">1. Do not install unvalidated/unauthorized programs.

Operating System Updates

IMPORTANT Before installing the operating system update, ensure you have a recent backup of the instrument database, refer to [CHAPTER 6, Backing Up Data](#) and [Restoring Database](#), and the current BitLocker key, refer [Backing Up Your Recovery Key](#).

WARNING

Risk of software incompatibility. Only operating system updates posted to the Beckman Coulter website should be installed on the instrument controller PC. Installation of operating system updates from other sources has been disabled.

Install the update on one instrument and verify functionality before installing on other instruments.

Creating a Restore Point

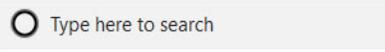
A restore point is used to remove all software installations and operating system changes that occurred after it was created. If installing an update on your PC causes any loss of functionality, the restore point may be used to place the system back into the operable state present before the update installation. In all cases, a system restore with any restore point would not cause loss of any data on the system. Refer to [Recovering from Failed Operating System Updates](#).

CAUTION

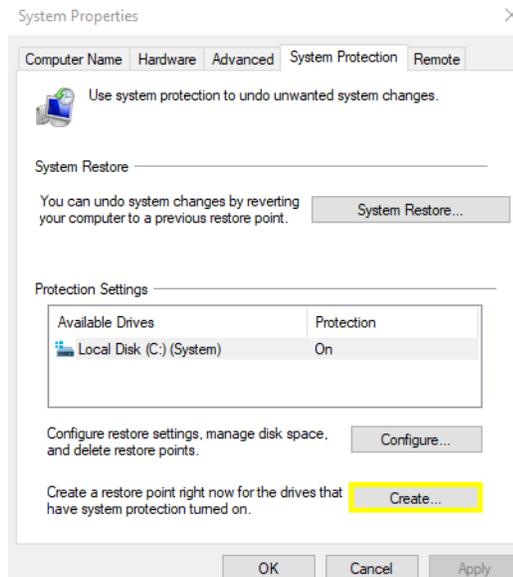
Risk of unexpected software modification. To ensure a system recovery point is available that is indicative of the most recent software configuration, the user should create a system restore point immediately prior to running the operating system update installer. Otherwise, a user would need to utilize the most recent automatically created restore point which may be up to 72 hours old and not include all recent software modifications.

Creating a Restore Point

1 Exit Kiosk Mode, see [Exiting Kiosk Mode](#).

2 In the Start Menu  Type here to search, type **Restore** and select **Create a Restore Point**.

3 Select **Create**.



4 Type a name for the restore point and select **Create**.



5 Wait for the restore point creation to complete and then select **Close**.

6 Close the System Properties window by selecting **OK**.

Downloading Operating System Updates

In order to download and install operating system updates, you will need to access the Beckman Coulter website at www.beckmancoulter.com from a computer.

Downloading Operating System Updates

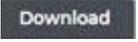
- 1 If performing this procedure on the CellMek tablet, exit Kiosk mode and then go to www.beckmancoulter.com.

- 2 Using the menu bar in the upper right-hand corner of the screen, hover over **Login**, then scroll down to select **Software Downloads**.

- 3 To search by product:
 - a. Select **Research & Discovery** from the Market Segment drop-down menu.
 - b. Select **Clinical Flow Cytometry** from the Product Line drop-down menu.
 - c. Select **Instruments** from the Product Series drop-down menu.
 - d. Select **CellMek SPS** from the Product drop-down menu.

- 4 Select **Search**.

IMPORTANT Print out the Release Notes for each update as they will not be available when the next update is released. The Component Name section of the release notes identifies the Microsoft updates that are included in the download. This information may be requested by your IT team and will be needed to recover from a failed update.

- 5 Each operating system update is cumulative and only the most recent validated set of updates will be available for download. Select the first file in the results to view the release notes and then select .
 - a. If downloading the installer from Internet Explorer on the CellMek controller PC, select **Save** when prompted.
 - b. You may see a file security warning. Do not make any selection.

NOTE If the installer is downloaded with another browser, the required actions to save the file may vary.

If more than one update is listed in the search results, select, and repeat this step for each update.

If the operating system updates cannot be downloaded directly to the instrument controller PC, transfer the downloaded files through a virus free external media or secured network drive to the instrument controller PC.

Downloading Your CellMek SPS Manuals

In order to download your CellMek manuals, you will need to access the Beckman website at www.beckman.com/techdocs.

Downloading CellMek Manuals

- 1 If performing this procedure on the CellMek tablet, exit Kiosk mode and then go to www.beckman.com/techdocs.

 - 2 Enter **CellMek SPS** or the part number of the instrument in the search dialog box and select **(Enter)** to locate the available documents.

 - 3 Select the **Technical Documents** tab.

 - 4 To narrow your results use the panel to the left of your results search:
 - a. Select **Document Type** and select **Instrument IFU**.
 - b. Select **TechDoc Language** and select your IFU language.
-

Notification Options

To receive notification when a new operating system update is validated and available for download, you must sign up for an account on www.beckmancoulter.com and follow the procedure for setting up subscriptions.

Signing Up for Product Notifications

- 1 If performing this procedure on the CellMek tablet, exit Kiosk mode and then go to www.beckmancoulter.com.

- 2 Using the menu bar in the upper right-hand corner of the screen, hover over **Login**, then scroll down to select **My Technical Document**.

- 3 To search for your product:
 - a. Select the **Document Language** consistent with your IFU language.
 - b. Select **Research & Discovery** from the Market Segment drop-down menu.
 - c. Select **Clinical Flow Cytometry** from the Product Line drop-down menu.
 - d. Select **Instruments** from the Product Series drop-down menu.
 - e. Select **CellMek SPS** from the Product drop-down menu.

4 Select **Search**.

5 Select the product to turn notifications on.

If you do not sign up for product notifications, you will have to check periodically for newly released operating system updates, see [Downloading Operating System Updates](#).

Installing the Operating System Updates on the Instrument Controller PC



Risk of software incompatibility. Beckman Coulter only supports operating system updates on unmodified systems. Application of domain policies or other system configuration changes may impact compatibility.

IMPORTANT If more than one update is available for your product, install the updates in the order indicated by the sequence number as outlined in the file naming convention below. Downloads with different sequence numbers contain different Microsoft updates. A sequence revision number higher than 0 indicates an update for previously released installer.

RSU - <operating system>-<product name>-<Year><Month>_<Sequence #>_<Sequence Revision #>

Example: RSU-W10-CellMek-2020May_1_0

Installing Operating System Updates

1 Exit Kiosk mode, see [Exiting Kiosk Mode](#).

2 Ensure you have a recent backup of the instrument database, refer to [CHAPTER 6, Backing Up Data](#) and [Restoring Database](#), and the current BitLocker key, refer to [Backing Up Your Recovery Key](#). Ensure the backups are saved to an encrypted external media or secured network drive.

3 Login to Windows as a user with Administrator access.

4 Close all programs and save open files.

IMPORTANT If you downloaded the installer from Internet Explorer on the CellMek controller PC or external media, the files may be accessed by searching for File Explorer.

- 5 Open the first operating system update file (For example: RSU-W10-CellMek-2020May_1_0) on the Instrument Controller PC by pressing and hold on the RSU file to view the menu and select **Run As Administrator**. If the Microsoft Windows Defender SmartScreen prompt appears, select **More Info** and then select **Run Anyway** to launch the installer, see [Figure G.1](#). Select **Yes** on the User Account Control prompt, see [Figure G.2](#). The installation process may take several minutes, see [Figure G.3](#).

Figure G.1 Microsoft Windows Defender SmartScreen



Figure G.2 User Account Control

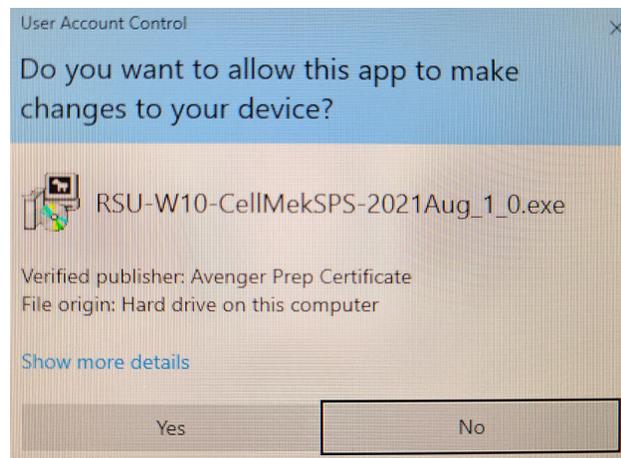
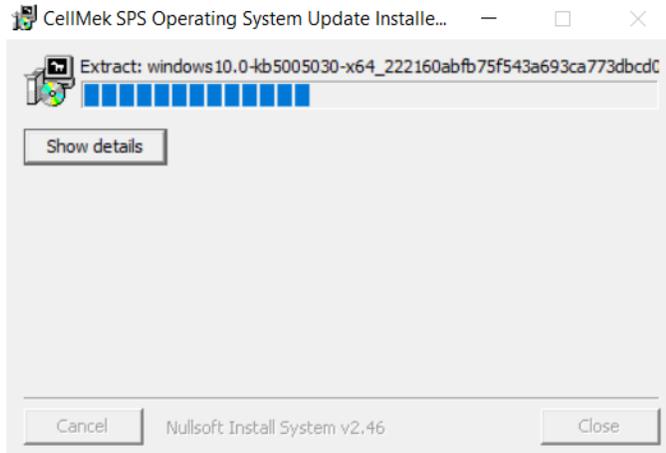


Figure G.3 Operating System Update Setup Installation



NOTE The operating system update installer will automatically detect and install only the necessary updates.

- 6 Once the operating system update setup has completed, select **OK** to restart the system and complete the update process. See [Figure G.4](#) and [Figure G.5](#).

Figure G.4 Operating System Update Setup Successfully Installed

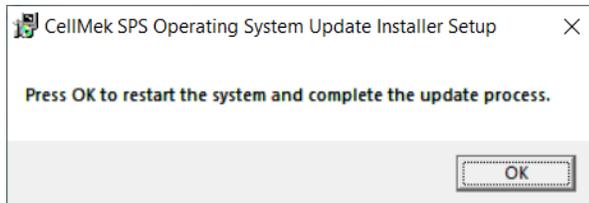
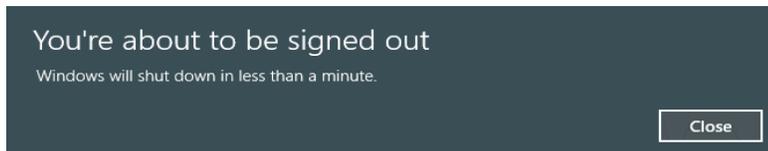
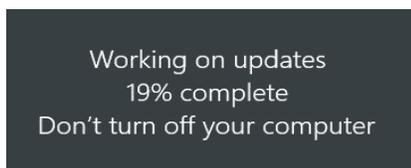


Figure G.5 Windows Shutdown



- 7 Wait while the system completes the installation of the operating system updates. This process may take several minutes and will return you to the Windows login screen.



-
- 8** Install any additional downloaded operating system updates (sequence numbers above 1) by repeating steps 5 to 7.
-
- 9** Verify functionality of instrument software. If functionality is impaired, see [Recovering from Failed Operating System Updates](#).
-
- 10** Repeat Steps 2 through 9 for installing operating system updates on other CellMek systems.
-

Error Messages

[Table G.2](#) lists the messages, with their cause and what to do about them. These are the messages produced by the system.

Table G.2 Operating System Update Error Messages

Message	Probable Cause	Recommended Action
Extract: error writing to file.	Hard disk does not have sufficient space to extract the installation files.	<ol style="list-style-type: none"> 1. Empty the recycle bin. 2. Free up disk space on the C drive by removing files. 3. Retry operating system update installation.
Application software not found. This update may only be installed on a valid system.	Update installer is being run on a PC that does not have CellMek SPS software installed.	<ol style="list-style-type: none"> 1. Ensure the update utility is only run on a CellMek SPS PC with the CellMek SPS software installed. 2. Contact us for additional assistance.
All updates included in this download package have been previously installed.	All updates included have been previously installed.	<ol style="list-style-type: none"> 1. Ensure you have the latest updates, refer to the instructions provided in Downloading Operating System Updates. 2. No further action is necessary.
One or more updates failed to install, please contact BEC support.	Update installer was not able to install one or more updates.	<ol style="list-style-type: none"> 1. If C drive has less than 20 GB of space available, free up disk space by moving files to external media. 2. Run the update installer again. 3. Contact us for additional assistance.
This update is not compatible with the installed operating system.	Update installer is being run on a CellMek SPS PC Controller PC with an operating system incompatible with the update.	<ol style="list-style-type: none"> 1. Ensure you have the correct update, refer to the instructions provided in Downloading Operating System Updates. 2. Contact us for additional assistance.

Table G.2 Operating System Update Error Messages (*Continued*)

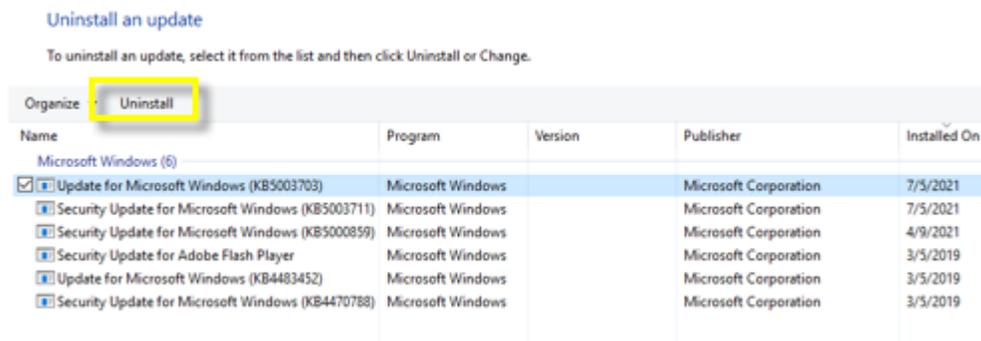
Message	Probable Cause	Recommended Action
Administrator rights required!	Windows user running the update installer does not have administrator permissions in Windows.	<ol style="list-style-type: none"> 1. Login as windows administrator. 2. Run the installer as administrator again.
System software is running. Please close the software and try again.	CellMek SPS software is open.	<ol style="list-style-type: none"> 1. Close the CellMek SPS software. 2. Run the update installer again. 3. Contact us for additional assistance.

Recovering from Failed Operating System Updates

These steps below should only be followed if the instrument software or operating system functionality is impaired after an operating system update was applied.

Recovering Failed Operating System Updates:

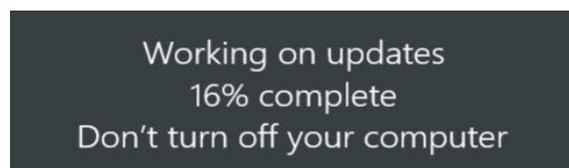
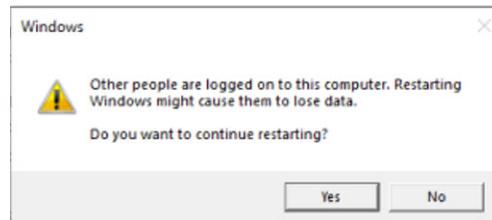
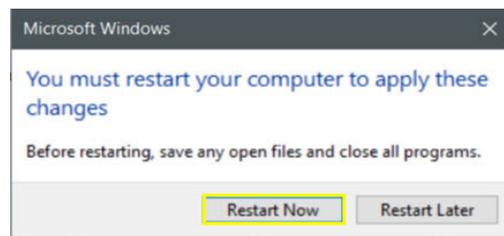
- 1 Exit Kiosk Mode, see [Exiting Kiosk Mode](#) and login as CellMek SPS user. Do not turn your workstation off.
- 2 Select search and enter **View Update** and select **View your Update History**.
- 3 Select **Uninstall Updates**.
- 4 Highlight the update listed under Microsoft Windows that matches the cumulative security update KB number in the release notes and select **Uninstall**. Refer to Component Name section of the Release Notes, see Step 5, [Downloading Operating System Updates](#).



- 5 Select **Yes** when prompted to verify the uninstall. This process may take several minutes to complete.



- 6 When prompted to restart, select **Restart Now**.



- 7 Verify Microsoft update has been removed by repeating steps 1 and 2. Verify the KB selected in Step 3 is no longer listed.

- 8 Power on the instrument and verify restored software functionality.
 - a. If software functionality has been restored, continue using your instrument without the update installed.
 - b. If software functionality has not been restored.

[Contact us](#) for troubleshooting the update incompatibility.

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Abbreviations

µm — micrometer

µL — microliter

A — ampere

ADC — Analog to Digital Converter

Admin — System Administrator

AS — Authoring Software

CDR — Custom Defined Reagents

COM — Serial communications port on the computer

CSV — comma separated value file format readable by Microsoft Excel

CWM — cell wash module

dba — A-weighted decibel

Hrs — hours

ID — Identification

IFU — Instructions for Use (manual)

L — liter

LIS — Laboratory Information System

mL — milliliter

MSDS — Material Safety Data Sheet

PDF — Portable Data Format file from Adobe Systems, Inc.

QC — Quality Control

RT — room temperature

SDS — Safety Data Sheet

STM — Specimen Transport Module

UPM — Uninterruptible Power Manager

USB — Universal Serial Bus

USPTO — US Patent and Trademark Office

V — volts

Vac — volts alternating current

WBC — white blood count

Glossary

CellMek SPS — System that consists of a fully integrated equipped with an autoloader and on-board sample preparation, a Supply Cart, and an tablet.

Carousel — A circular holder for reagents or tubes.

Cassette — A type of holder for specimen tubes.

CellMek Panel Definition Software — The CellMek Panel Designer software is used to define sample preparation panels.

Cleaning agent — A fluid used to flush sample from tubing and minimize protein buildup.

Control — A substance used to routinely monitor the performance of an analytical process that has the characteristic being measured [For example: Whole blood controls].

Cytometer — The system component that analyzes the sample.

Defaults — Original settings for the instrument. You can change them to customize the settings for your laboratory.

Front door — Main door on the front of the instrument. Opening this door allows you to access the instrument including replacing reagents.

Instrument Controls and indicators — Instrument controls are the mechanisms you use to communicate with the instrument. Indicators are the mechanisms the instrument uses to communicate with you.

Laboratory Information System (LIS) — Software that can receive and store patient orders, patient and specimen draw information, patient results for a laboratory.

Monoclonal Antibody — Antibodies produced by a single cell or its identical progeny, specific for a given antigen.

Notification — System warning indicating that results from a sample preparation are questionable, or low/empty reagent vials.

Panel — Sample preparation workflow created by the user for one input sample that can produce multiple output tubes. A panel includes one or more tubes (protocols).

Reagent — Substance used to prepare samples.

Sample — A patient specimen that has gone through the preparation process and is ready for analysis by the Flow Cytometer. Depending on the application, one Specimen may result in multiple samples.

Sample Prep — The preparation of the whole blood or other specimen sample types with the monoclonal antibodies and lyse reagents, to allow for analysis of the populations of interest by the analyzer or flow cytometer.

Scroll bar — The area on the right of a pop-up window. The bar's arrows let you move (scroll) the window's content up or down so that you can see other parts of it.

Select — To position the mouse cursor on an item, and then press and release a mouse button or tapping on the screen to choose that item.

Specimen ID — Identification assigned to a specimen tube.

Sheath fluid — A balanced electrolyte solution.

Specimen — The suspension of cells being presented to the instrument for sample preparation. The term specimen will be used even after a specimen aliquot has been washed (i.e. “wash specimen”) but will not be used after the specimen aliquot has been mixed with other reagents, at which point it will be referred to as a sample.

Supply Cart — The system component that provides diluent to the system, and collects waste from the system.

Symbology — A set of rules for encoding and decoding information contained in a barcode symbol. Examples of symbologies include Interleave 2 of 5 (with checksum), Code 39 Regular (with and without checksum; default is with checksum), and Code 128 (Code A, Code B, and Code C).

Uninterruptible Power Manager — A power conditioner and battery backup for the CellMek system.

Touchscreen — The system component that runs the software that controls the instrument. It displays sample results and other information.

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Beckman Coulter, Inc.

End-User License Agreements

CellMek Panel Designer Software

IMPORTANT Read this End-User License Agreement

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Related Documents

**CellMek SPS Sample Preparation Instrument
Instructions for Use**

PN C48507

CellMek SPS Host Transmission

PN C48508

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