WARNING

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

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

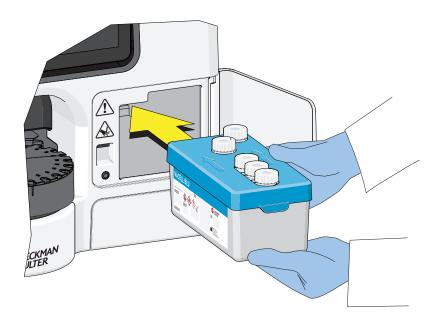
Remove empty Reagent Pack



E-4

E-5

Insert new Reagent Pack.



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Close the reagent door and select **\(\right\)**.





7 Confirm Reagent information and select 2



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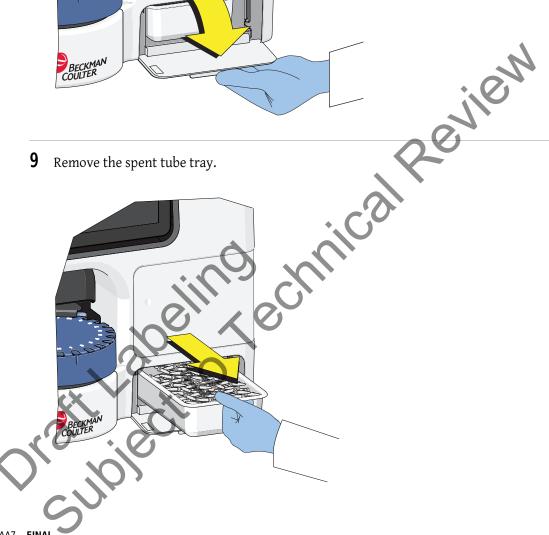
• WARNING

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

Open the spent tube tray door.



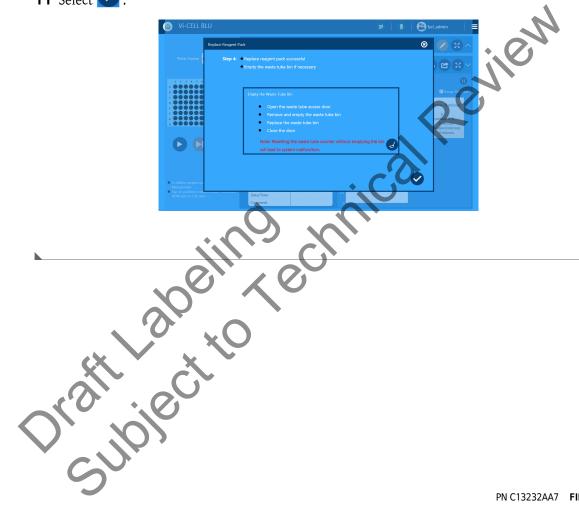
Remove the spent tube tray.



10 Empty the spent tube tray.



11 Select .



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Prime the Instrument

1 Select and Prime.



2 When priming is complete, select **3** to exit the screen.

Decontaminate





Green Screens need to be replaced throughout

1 Select and Decontaminate.Colin asks if we could recommend this be done weekly

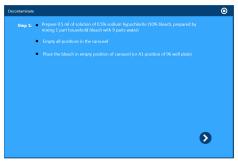


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Risk of chemical injury from bleach. To avoid contact with the bleach, use barrier protection, including protective eyewear, gloves, and suitable laboratory attire. Refer to the Safety Data Sheet for details about chemical exposure before using the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

Prepare a bleach solution and select



3 Decontaminate the rest of the instrument and tap **\leftur**.



The instrument will perform a flush cycle.



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5 The instrument will Prime the fluid lines.

Decontaminate with Vaporized Hydrogen Peroxide

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

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



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

MARNING

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

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! CAUTION

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

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

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∴ CAUTION

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

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

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E-14

Abbreviations

IEEE — Institute of Electrical and Electronics Engineers

PN — part number

RoHS — Restriction of Use of Hazardous Substances

X — times

WEEE — Waste Electrical and Electronic Equipment Directive

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Vi-CELL BLU Cell Viability Analyzer, Instructions for Use

PN C13232

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