12th August 2024

URGENT: FIELD SAFETY NOTICE – BDB-24-5078

BD FACSDuet™ Sample Preparation Systems

REF: See Table 1 **Serial Numbers:** See Table 1

Type of Action: Field Work

Attention: Laboratory Managers, Risk Managers, Biomedical Personnel

This letter contains important information which requires your **immediate** attention.

Dear Customer,

BD is issuing a Field Safety Corrective Action for **BD FACSDuet™ Sample Preparation Systems**. According to our distribution records your organisation may have received the impacted product in Table 1.

Manufacturer's SRN: US-MF-000017797

Product Name	Product Code (REF)	Serial Number	UDI-DI
BD FACSDuet™ Sample Preparation System (Base)	662588	All serial numbers with BD FACSDuet™ software version 1.4.1	00382906625885
BD FACSDuet™ Premium Sample Preparation System	666339		00382906663399

Table 1: Impacted product

This notification is limited to the product codes / software version numbers listed in Table 1.

Description of the problem

Through a customer complaint investigation, BD identified a specimen volume bias issue with the BD FACSDuet™ Sample Preparation System when using software version 1.4.1.

When the Multidispense feature is enabled in the BD FACSDuet™ Sample Preparation System software, and the user is preparing a two-tube assay, the specimen volume dispensed into the first tube will be slightly higher than the specimen volume dispensed into the second tube. For assays, where absolute counts are calculated using BD Trucount™ Tubes, an increase in the volume may result in higher-than-expected absolute counts in the first tube compared to the second tube.

This issue will be observed when preparing the following assays on the BD FACSDuet™ Sample Preparation System:

1. BD Multitest™ IMK Kit with BD Trucount™ Tubes.

Note: If using the BD Multitest™ IMK Kit with BD Trucount™ Tubes, a QC message will appear on your report if the bias is outside the acceptable range per assay requirements.

2. BD Multitest™ 6-Color TBNK with BD Trucount™ Tubes only if consecutive replicates of two are run.

3. For all other quantitative assays utilizing BD Trucount™ Tubes in consecutive replicates of two, please follow your institution's procedures to determine if a review of reported results is necessary.

This issue does not affect assays that are determining percent positive, semi-quantitative information.

Clinical risk

Potential health consequences may be a delay in results, additional peripheral blood collection to repeat the flow cytometry testing and could potentially lead to a delay in patient therapy.

It is recommended that users do not use the specimen Multidispense functionality in BD FACSDuet™ Sample Preparation System with software v1.4.1. The Multidispense functionality should be disabled by the user. It is recommended that laboratories upgrade the BD FACSDuet™ Sample Preparation System to version 1.4.2 to correct the issue as soon as it is available. In the meantime, patient samples can be prepared using single dispense on the BD FACSDuet™ Sample Preparation System or manually.

To date there has been no adverse events worldwide related to this issue.

There is no requirement for customers to return any product to BD. These products can continue to be used in accordance with the guidance in this safety notice.

Clinical User Actions

1. Identify Software Version installed in BD FACSDuet™ Sample Preparation System at your site. Refer to Appendix 1

2. Cease use of the BD FACSDuet™ Sample Preparation System with software version 1.4.1. until the Multidispense feature has been disabled.

   If not already disabled, refer to Appendix 2 for instructions on how to disable the BD FACSDuet™ Sample Preparation System Multidispense feature.

BD Actions:

1. On return of the completed response form, BD will schedule a mandatory upgrade of your BD FACSDuet™ Sample Preparation System software to version 1.4.2.

2. A corrective and preventive action was initiated to confirm root cause and identify actions to prevent reoccurrence.

Customer Actions:

- Complete and return the Customer Response Form **even if you no longer have any of the impacted product remaining in your facility by 30th August 2024**.
- Circulate this notice to all those who need to be aware within your organisation or to any organisation where the potentially affected product has been transferred.
- If you experience any issues, please report as a complaint as per your normal process.

Contact reference person

If you have any questions or require assistance relating to this Field Safety Notice, please contact your local BD representative or the local BD office or e-mail flow.support@bd.com / +41 61 485 22 95.

We confirm that the appropriate regulatory agencies have been informed of these actions.

BD is committed to *Advancing the world of health*™. Our primary objectives are patient safety and user safety and providing you with quality products. We apologise for the inconvenience this situation may cause you and thank you in advance for helping BD to resolve this matter as quickly and effectively as possible.

Sincerely,

Kinga Stolinska
Director, Post Market Quality
EMEA Quality

Customer Response Form – BDB-24-5078
BD FACSDuet™ Sample Preparation Systems

REF: See Table 1 **Serial Numbers:** See Table 1

Return to **BDFieldActions@bd.com** as soon as possible or **no later than the 30th August 2024**

By signing below, you confirm this Field Safety notice has been read, understood and that all recommended actions have been implemented as required.

Account/Organisation Name:	
Department *(if applicable)*:	
Address:	
Postcode:	**City:**
Contact Name:	
Job Title:	
Contact Telephone Number:	**Contact E-mail Address:**
Signature:	**Date:**

This form must be returned to BD before this action can be considered closed for your account.

Please confirm **ONE** of the following options:

☐ I have one or more affected product(s) within my organisation.

Please provide a contact name of a representative from your organisation who will be the point of contact to organise product remediation, if different from above:

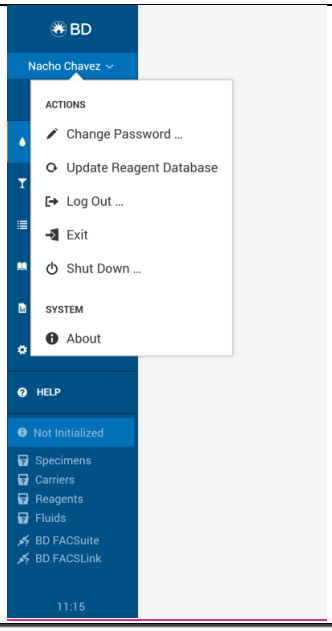
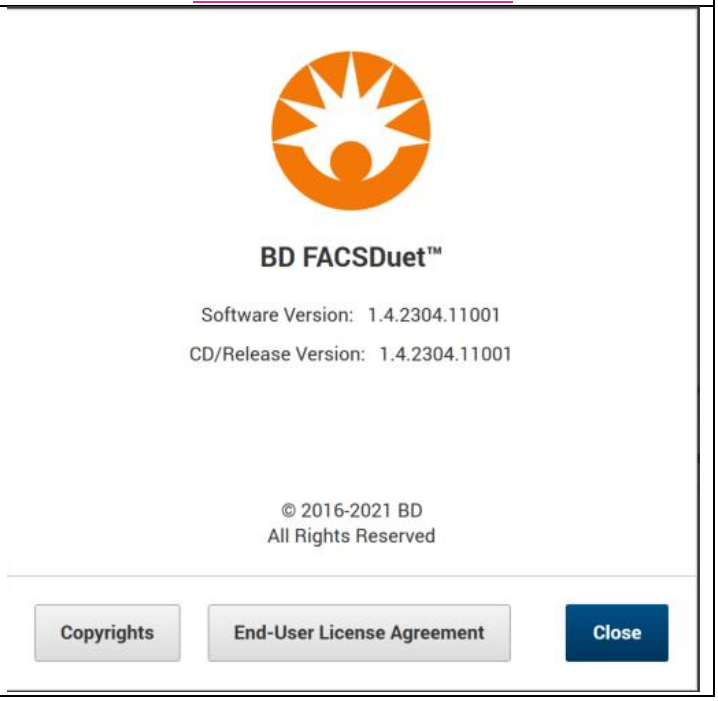
Name:	*Telephone No:*	*Email:*	*No. of Impacted product:*

OR

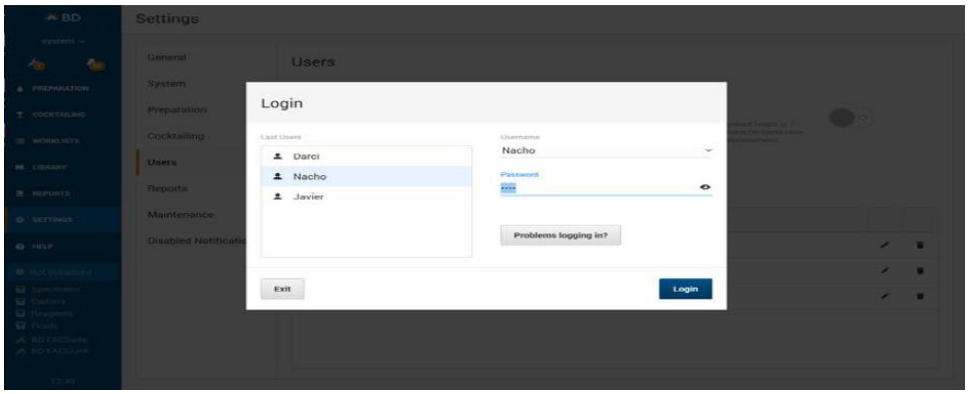
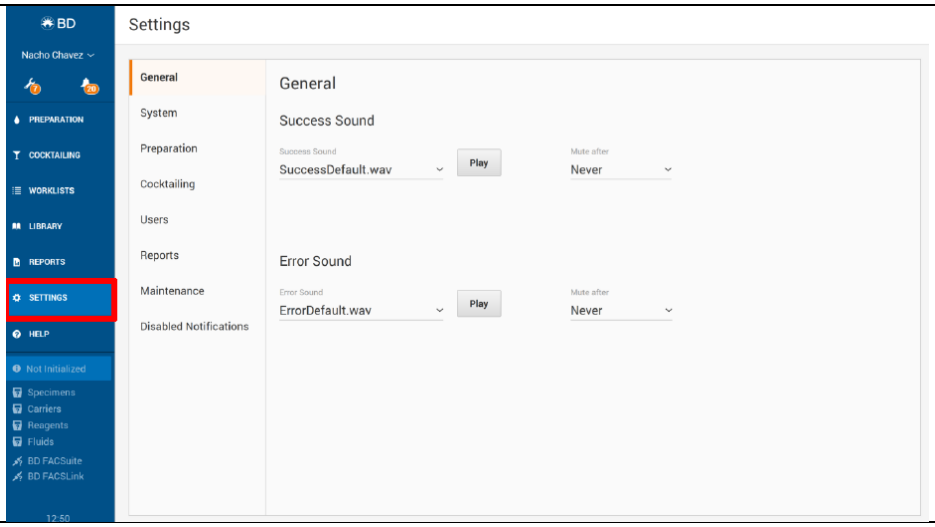
☐ I confirm that our facility **does not have any** of the affected product listed in this Field Safety Notice.

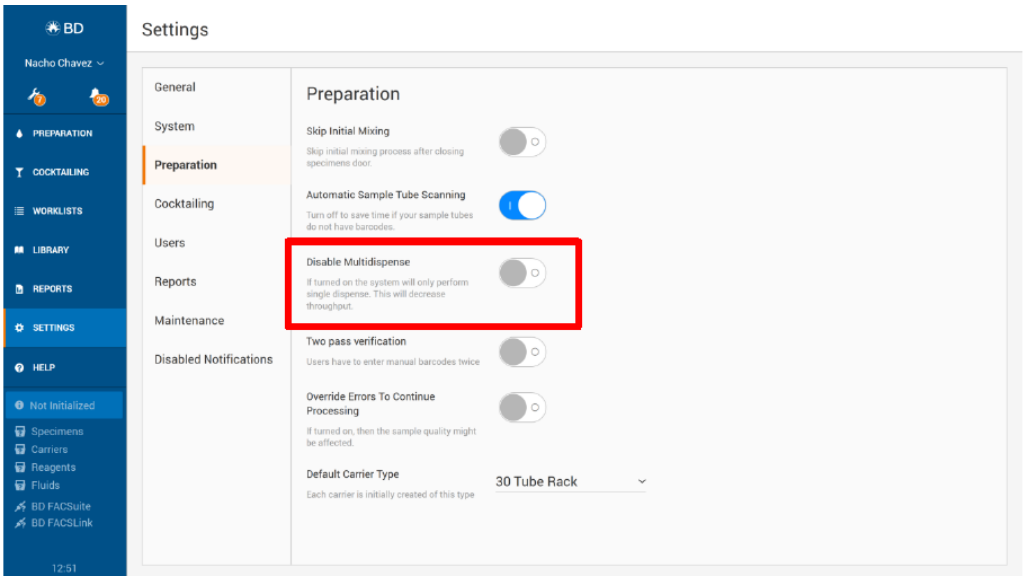
All product that is not available for remediation will be considered as dispositioned at your location and therefore physically unavailable unless otherwise specified

Appendix 1 - Instructions for Identifying the Software Version Number

Step 1: Login into the FACSDuet software **as an Administrator**. **Step 2:** Click on the log in name to enable the pulldown menu. **Step 3:** Scroll down the pulldown menu and select "**About"**.	
Step 4: The **"About"** window will now appear. The software version number can be found on the left-hand side of the window, directly below the BD symbol and the instrument name	

Appendix 2 - Instructions for disabling Multidispense in software version 1.4.1 of the BD FACSDuet™ Sample Preparation System

Step 1: Login into the BD FACSDuet™ software **as an Administrator**. Disabling Multidispense in one Administrator account disables the features for all users and Administrators.	
Step 2: Once Logged in, select **"Settings"**	

Step 3: Select “**Preparation**”. There you will see the toggle button for “Disable Multidispense”. If the button is on the left-hand side of the toggle, the toggle is gray and you see a ”O” symbol, then Multidispense is on.	
Step 4: Click on the toggle button to slide the button to the right. The entire toggle button should now appear blue, and you will see a ”I” symbol on the button. Multidispense is now OFF.