



**PRODUCT NOTIFICATION**  
**BDB-25-5181**  
**BD FACSLyric™ Flow Cytometer**  
**Power Supplier Failures**

02 December 2024,

Dear Customer,

CC: Chairman Medical Board and relevant head of department

**Type of Field Action:**

Field Work (Service at Customer / Repair depot / Correction)

**Affected Product**

Product Name	Catalog Number	UDI-DI	Serial Number
BD FACSLyric™ Flow Cytometer	662875	00382906628756	Please see URL link for impacted device serial numbers: <a href="https://bdx.my.site.com/CC360/s/impactedproducts?rn=BD-25-5181%20GLOBAL">https://bdx.my.site.com/CC360/s/impactedproducts?rn=BD-25-5181 GLOBAL</a>
BD FACSLyric™ Flow Cytometer	662876	00382906628763	
BD FACSLyric™ Flow Cytometer	662877	00382906628770	
BD FACSLyric™ Flow Cytometer	662878	00382906628787	
BD FACSLyric™ Flow Cytometer	663518	00382906635181	
BD FACSLyric™ Flow Cytometer	651164	00382906511645	
BD FACSLyric™ Flow Cytometer	651165	00382906511652	
BD FACSLyric™ Flow Cytometer	654587	00382906545879	
BD FACSLyric™ Flow Cytometer	659180	00382906591807	
BD FACSLyric™ Flow Cytometer	663029	00382906630292	
BD FACSLyric™ Flow Cytometer	662381	N/A	
BD FACSLyric™ Flow Cytometer	662382	N/A	
BD FACSLyric™ Flow Cytometer	662383	N/A	
BD FACSVerse™ Flow Cytometer	651154	N/A	
BD FACSVerse™ Flow Cytometer	651155	N/A	

**Description of the Problem:**

BD has identified through complaints an increase in field failures / replacements of the power supply module on BD FACSLyric™ and BD FACSVerse™ Flow Cytometer. The capacitor on the power supply can split which has the potential for the instruments to fail to power on and / or stay on.

**Clinical Risk Statement:**

The hazardous situation caused by the potential power supply failure in BD FACSLyric™ Flow Cytometer may have direct impact on the patient biospecimen testing capabilities of the clinical laboratory and/or delay to provide the testing results.



There may be additional risks to the laboratory staff that might include potential inhalation of fumes from a split capacitor in the power supply unit which could lead to shortness of breath or coughing if failure occurs during laboratory working hours.

In addition, the patient may be asked to return for additional biospecimen collection procedure and risks associated with the procedure (bruising, pain, bleeding, etc.).

Since no results would be generated due to power failure, no review of results would be required. Take appropriate action as deemed necessary.

**Complaint & Adverse Event Statement:**

To date, there have been no adverse events worldwide reported related to this issue.

**Actions for Clinical Users**

The health care team will manage the patient risks according to their institutional policies and procedures.

**Action Taken by BD:**

BD has identified the root cause and is taking action to prevent recurrence of this product issue.

**Action To be Taken by BD:**

BD Field Service Engineers will replace the power supply module of affected BD FACSLytic™ and BD FACSVerser™ Flow Cytometer.

**Please Take the Following Actions:**

- 1) Ensure the contents of this notification are read and understood.
- 2) Share and post this notification within your facility network to ensure awareness.
- 3) Complete and return the attached Customer Response Form and return it to your distributor / BD contact noted on the form so that BD may acknowledge your receipt of this notification.
- 4) Please provide a contact name and email address in the Customer Response Form for BD to coordinate the service visit.
- 5) Please contact your distributor / BD representative if you require assistance with this process.
- 6) Report any adverse health consequences experienced with the use of these products to BD.



2 International Business Park Road  
The Strategy #08-08  
Singapore 609930  
Registration No. 201114149N  
[bd.com](http://bd.com)

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Yours Sincerely,

Signed by:  
*Karena Han*

 Signer Name: Karena Han  
Signing Reason: I approve this document  
Signing Time: 02-Dec-2024 | 7:05:02 AM GMT  
992DAF448F77410697FB3524C491D633

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Karena Han  
Quality Manager, Southeast Asia



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**CUSTOMER RESPONSE FORM**  
**BDB-25-5181**  
**BD FACSLyric™ Flow Cytometer**  
**Power Supplier Failures**

Please fill in the information below so that we may acknowledge your receipt of this notification. Complete and return the completed form to **SEA\_Quality** [SEA\\_Quality@bd.com](mailto:SEA_Quality@bd.com) / **distributor / local BD representative** by **30 December 2024**.

Please tick as appropriate.

I have read and understood the attached notice and will share this notice with all the users within my facility.

**Please assist BD by confirming the person to be contacted for service visit in below:**

<b>Contact Name:</b>	
<b>Title:</b>	
<b>Phone Number:</b>	
<b>Email Address:</b>	

**Response Form Completed By:**

<b>Name:</b>	
<b>Title:</b>	
<b>Signature:</b>	
<b>Date:</b>	
<b>Facility / Address / Telephone Number:</b>	