



بنقدم بثقة  
Moving Forward  
with Confidence



To:  
**THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES**  
**Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)**  
**Director General of Engineering Affairs, MOH**  
**Director General of Royal Hospital**  
**Director General of Khoula Hospital**  
**Director General of Medical Supplies (MOH)**  
**Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)**  
**Hospital Director (Al Nahda Hospital)**  
**Hospital Director (Al Massara Hospital)**  
**The Head of Medical Services in SQU Hospital**  
**The Head of Medical Services in Royal Oman Police**  
**The Head of Medical Services in Ministry of Defence**  
**The Head of Medical Services in The Diwan**  
**The Head of Medical Services in The Sultan's Special Force**  
**The Head of Medical Services in Internal Security Services**  
**The Head of Medical Services in Petroleum Development of Oman**  
**The Head of Medical Services in LNG Oman**  
**ALL PRIVATE PHARMACIES & DRUG STORES**

After Compliments,

Please find attached our Circular No 65 dated 23/3/2025 Regarding SFDA Field Safety Corrective Action of Dxl 9000 Access Immunoassay Analyzer from (mfr: Beckman Coulter, Inc).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DSC
- Director of Pharmacovigilance & Drug Information Dept, DSC
- Director of Drug Control Department, DSC
- Director of Pharmaceutical Licensing Department, DSC
- Director of Central Quality Control Lab., DSC
- Supdt. of Central Drug Information



**DSC**  
مركز سلامة الدواء  
Drug Safety Center



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489

✉ @DSCPHO Email: dscpho@moh.gov.om



Circular No. 65 / 2025

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23 -09-1446 H  
23 -03-2025

**Field Safety Corrective Action of DxI 9000 Access Immunoassay Analyzer from Beckman Coulter, Inc.**

Source	SFDA- Saudi Food & Drug Authority. <a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/321">https://ade.sfda.gov.sa/Fsca/PublishDetails/321</a>
Product	DxI 9000 Access Immunoassay Analyzer.
Manufacturer	Beckman Coulter, Inc.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	REF: C11137 UDI: 15099590732103 SW 1.20.0 and below
Reason	This issue affects DxI 9000 analyzers that are run with the system software versions listed above and are connected to a host system (laboratory information system (LIS) or middleware). If a DxI 9000 analyzer has accumulated canceled QC test results that were not sent to the host system, the analyzer may lose communication with the host system. The lost connection cannot be restored by routine troubleshooting. Sample processing is affected when the DxI 9000 analyzer loses communication with the host system.
Action	1. To Prevent the Issue: Each time that the Cleaning Routine maintenance procedure is due, Beckman Coulter recommends that your laboratory perform the steps provided in Appendix A in the attachment before performing the Cleaning Routine. 2. If the Issue Occurs: If the DxI 9000 analyzer loses communication with the host system and does not generate an event message, perform the steps provided in Appendix A in the attachment to restore communication with the host system. If the DxI 9000 analyzer loses communication and generates an event message, follow the system event troubleshooting steps on the user interface to restore the LIS connection. If the troubleshooting steps do not resolve the event, perform the steps provided in Appendix A in the attachment to restore communication with the host system. Samples can be run on a different analyzer to prevent further delay to reporting patient results. 4. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: <a href="mailto:vigilance-md@moh.gov.om">vigilance-md@moh.gov.om</a>

Ph. Ibrahim Nasser Al Rashdi  
Director General



**DSC**  
مركز سلامة الدواء  
Drug Safety Center



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩  
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489  
☒ @DSCPHO Email: [dscpho@moh.gov.om](mailto:dscpho@moh.gov.om)

N+P





March 12, 2025

**URGENT FIELD SAFETY NOTICE**

Dxl 9000 Immunoassay Analyzer

REF	UDI**	
C11137	15099590732103	SW 1.20.0 and below

(SRN): US-MF-000010288

Attention Beckman Coulter Customer,

Beckman Coulter is initiating a field safety corrective action for the product listed above. This letter contains important information that needs your immediate attention.

<b>ISSUE:</b>	<ul style="list-style-type: none"> <li>This issue affects Dxl 9000 analyzers that are run with the system software versions listed above and are connected to a host system (laboratory information system (LIS) or middleware).</li> <li>If a Dxl 9000 analyzer has accumulated canceled QC test results that were not sent to the host system, the analyzer may lose communication with the host system. The lost connection cannot be restored by routine troubleshooting.</li> <li>Sample processing is affected when the Dxl 9000 analyzer loses communication with the host system.</li> </ul>
<b>IMPACT:</b>	<ul style="list-style-type: none"> <li>The Dxl 9000 analyzer responds in one of the following ways when it loses communication with the host system:                             <ul style="list-style-type: none"> <li><b>No event message is generated:</b> The analyzer may discharge sample tubes to the sample output area, or the samples may remain in the sample aspiration area. The analyzer cannot process additional tests using normal troubleshooting procedures.</li> <li><b>OR</b></li> <li><b>An event message is generated</b> that warns your laboratory that the LIS is Disconnected. The analyzer does not aspirate patient samples, but the sample tube is discharged to the sample output area.</li> </ul> </li> <li>Either response interrupts sample processing, which delays reporting patient test results and may subsequently delay patient treatment.</li> </ul>
<b>ACTION:</b>	<p><b>To Prevent the Issue:</b></p> <p>Each time that the Cleaning Routine maintenance procedure is due, Beckman Coulter recommends that your laboratory perform the steps provided in Appendix A before performing the Cleaning Routine.</p>

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FA-25027



	<p><b>If the Issue Occurs:</b></p> <ul style="list-style-type: none"> <li>• If the DxI 9000 analyzer loses communication with the host system and <b>does not generate an event message</b>, perform the steps provided in Appendix A to restore communication with the host system.</li> <li>• If the DxI 9000 analyzer loses communication and <b>generates an event message</b>, follow the system event troubleshooting steps on the user interface to restore the LIS connection. If the troubleshooting steps do not resolve the event, perform the steps provided in Appendix A to restore communication with the host system.</li> <li>• Samples can be run on a different analyzer to prevent further delay to reporting patient results.</li> <li>•</li> </ul>
<p><b>RESOLUTION:</b></p>	<ul style="list-style-type: none"> <li>• Beckman Coulter has identified the root cause of this issue and will implement the correction with a future software release.</li> <li>• Your Beckman Coulter service representative will contact you to schedule the software upgrade when available.</li> </ul>

The national competent authority has been informed of this field safety corrective action.

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product(s) listed above to another laboratory, please provide them a copy of this letter.

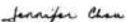
Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.


If you have any questions regarding this notice, please contact Customer Support Center:

From our website: <http://www.beckmancoulter.com>

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Signed by:  


 Signer Name: Jennifer Chau  
 Signing Reason: I approve this document  
 Signing Time: 12-Mar-2025 | 11:40:04 AM PDT  
 CC3CD3A8EA284A8CB13031EA135AA19D

Jennifer Chau  
 Vice President, QRA Hematology, UA, LS, CDSS & GQM

Enclosure: Response Form, Appendix A

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## **Mitigation Steps Outlined in Appendix A of the Field Action Letter**

### **Appendix A: FA-25027**

Follow the steps below to restore communication between the Dxl 9000 Immunoassay Analyzer and the host system.

1. Be sure that the analyzer is in the green running state but is not actively processing samples. Refer to the *Monitoring Sample Status* topic in the System Help or IFU for more information.
2. Select **Menu > System Configuration > LIS**.
3. In the LIS Protocol area, select **Disabled**.
4. Activate the draft configuration. Refer to *Activating a Draft Configuration* topic in the System Help or IFU for more information.
5. Restart the analyzer computer. Refer to the *Restarting the Analyzer Computer* procedure located in the System Help or IFU for more information.
6. Select **Menu > System Configuration > LIS**.
7. In the LIS Protocol area, select **CLSI LIS01-A/LIS02-A (ASTM)**.
8. Activate the draft configuration. Refer to *Activating a Draft Configuration* topic in the System Help or IFU for more information.
9. Send test results to the host system to confirm that communication has been restored.

If communication with the host system is not restored, contact your Beckman Coulter representative and schedule a service visit.