Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

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 98 **dated** 19/5/2025 **Regarding SFDA Recall of AU480 and AU680 Clinical Chemistry Analyzers 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

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سلطنة عُمان
وزارة الصحة
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Circular No. 98 / 2025

21 -11-1446 H
19 -05-2025

Recall AU480 and AU680 Clinical Chemistry Analyzers from Beckman Coulter Inc.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/365
Product	AU480 and AU680 Clinical Chemistry Analyzers.
Manufacturer	Beckman Coulter Inc.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Please refer to the attachment for the affected REF and Serial Numbers.
Reason	It has been identified by Beckman Coulter that using MU993400 sample probes with lot numbers from 178713114 to 179433670 on AU480 and AU680 clinical chemistry analyzers. There is a probability of false low test results due to sample dispensing issues in the affected products.
Action	1. Please refer to "ACTION" in the attachment. 2. 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: vigilance-md@moh.gov.om

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

April 23, 2025

URGENT MEDICAL DEVICE RECALL

AU480 and AU680 Clinical Chemistry Analyzers

Analyzer	REF	Serial Numbers
AU480	B11810, B12183, B80091, B96692, B96693, C02654, C02655, C02845, C41919, C41920, N3659700, N3659800, N3659900, N3660000, N3660100, N3660200, N3660300, N3660400, N3660500, N3660600, N3660800, N3912400, N3912500, N3150700, N3151000, N3151300, N3151400, N3151500, N3151600, N3151900	From 10155 to 2025021482
AU680	B12185, B12186, B12187, B12188, B96694, B96695, B96696, C02656, C02657, N3147700, N3662000, N3662100, N3662200, N3662700, N3663000, N3910200, N3910400, N3910500, N3910600, N3910800, N3910900, N3911200, N3911700, N3911900, N3147100, N3147200, N3147300, N3147400, N3147600, N3148100, N3149400, N3149800	From 10436 to 2022087656

Attention Beckman Coulter Customer,

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

ISSUE:	• Beckman Coulter has identified that using MU993400 sample probes with lot numbers from 178713114 to 179433670 on AU480 and AU680 clinical chemistry analyzers. There is remote probability of false low test results due to sample dispensing issues. 
IMPACT:	• There is a remote possibility that affected sample probes may cause false low results for assays with sample volume between 1.0 - 2.0 uL (Max. 34% error at 1.0 uL and 7% error at 1.6 uL sample dispensing volume).

Beckman Coulter, Inc.
250 S. Kreamer Boulevard
Brea, CA 92821, USA

Telephone: (800) 854-3633
Internet:
www.beckmancoulter.com

FA-001346

BECKMAN COULTER

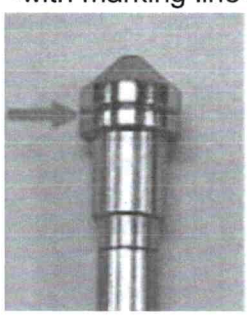
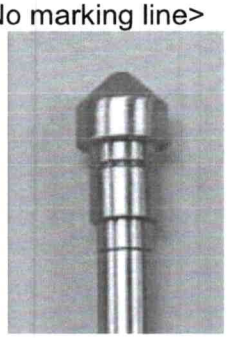
	• In a worst case scenario, there is a remote possibility of delayed recognition or treatment.
ACTION:	• Check the analyzers, which meet the condition below, as they may include a defective sample probe. ○ Analyzers whose Serial No. is from 2023070718 to 2025021482. ○ Analyzers whose sample probe has been replaced since July 1, 2023. • For analyzers that meet either of the above criteria, remove the sample probe from the instrument in accordance with IFU Section 6, Maintenance / As needed Maintenance/Replace a Sample or Reagent Probe. And then, check the groove on the head of the removed sample probe. (see Fig.-1) ● If it has "a marking line", please continue to use. ● If it does not have "a marking line", please replace the sample probe with a probe not included in the impacted sample probe LOT numbers. Fig.-1  Good sample probe <with marking line>  Defective sample probe <No marking line>  • Analyzers that do not fall into the above condition can be used as is. • Please check your stock of sample probes as follows: ○ Check the outer box label of your sample probes. ○ If you have MU993400 sample probes with LOT numbers from 178713114 to 179433670, please dispose of the impacted probe to ensure it is not used and contact your BEC representative for a replacement (see Fig.-2). Note: Also check the sample probes included in the maintenance kits for AU480 (PN: B66751) and AU680 (PN: B66752) (see Fig.-3). Contact your BEC representative for a replacement if impacted probes are identified.

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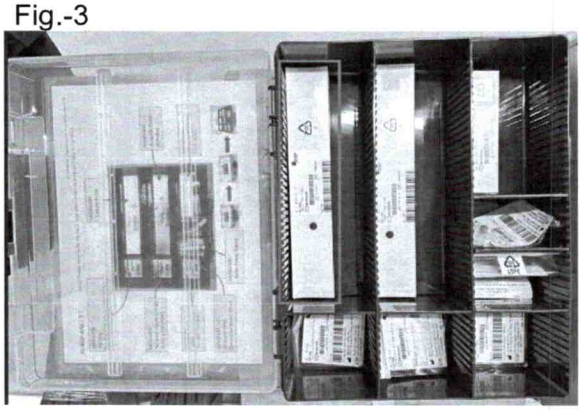
	Fig.-2  Fig.-3  • If all the results of the actions above show only defective sample probes on your analyzers and in stock, stop measuring the assay items which sample volume is 2.0 uL or less and contact your BEC representative for a replacement. • Beckman Coulter recommends that customers who have replaced probes on your analyzers per this letter should share the content of this letter with your laboratory and/or medical director to assess if a retrospective review of the patient results is needed.
RESOLUTION:	• Beckman Coulter has discontinued shipment of the affected lots of sample probes. • New lots numbers of sample probes are not affected.

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.

So that we are assured you have received this important communication, please respond within 10 days in one of the following ways:

- Electronically, if you received this communication via email.
- Manually, complete and return the enclosed Response Form.

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

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

- For customers in the United States, if you need replacement product:
  - Complete the attached "Replacement Order Form" and email to askbeckman@beckman.com or fax to (866) 294-7850 OR
  - Call Client Services at (800) 526-3821

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Signed by:
Jennifer Chau
Signer Name: Jennifer Chau
Signing Reason: I approve this document
Signing Time: 23-Apr-2025 | 9:22:12 AM PDT
CC3CD3A8EA284A8CB13031EA135AA19D

Jennifer Chau
Vice President, U.S. Quality Operations

Enclosure: Response Form
Replacement Order Form