Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
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.238. dated 19/11/23 Regarding NCMDR recall of K (Potassium) ELECTRODE for AU/DxC AU Beckman Coulter analyzers (AU480, AU680, AU5800 and DxC 700 AU) from (mfr: Beckman Coulter).

Copy to:

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

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

Circular No. 238/ 2023

05-05-1445 H
19 -11-2023

Recall of K (Potassium) ELECTRODE for AU/DxC AU Beckman Coulter analyzers (AU480, AU680, AU5800 and DxC 700 AU) from Beckman Coulter

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19764
Product	K (Potassium) ELECTRODE for AU/DxC AU Beckman Coulter analyzers (AU480, AU680, AU5800 and DxC 700 AU).
Description	IVD.
Manufacturer	Beckman Coulter.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Ref: MU919500 Lot: 22303.Serial No.:29540 – 29560, 29562 – 29671, 29673 – 29829, 29831 – 29929, 29931 – 29984,29986 – 30091, 30093 – 30192, Expiry Date: 2024-03-01
Reason	The K electrodes with the above listed lot number and serial numbers were filled with an incorrect inner liquid.
Action	1. If the S/N of the K electrodes is listed above: • Stop using the K electrode. • Dispose of the K electrode according to your laboratory protocol. • Replace the K electrode with one S/N that is not listed above. • Refer to the "Replace the Na, K, or CL Electrode" procedure in the instrument Instructions for Use (IFU). • Perform ISE calibration and QC according to the IFU, if you remove or replace an electrode. • Check the S/N on the box label of any K electrodes in your inventory, if the S/N of the K electrodes listed in the FSN, dispose of the K electrode according to your laboratory protocol. • No retrospective review of results is necessary 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: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

August 17, 2023

IMPORTANT PRODUCT NOTICE

K (Potassium) ELECTRODE for AU/DxC AU Beckman Coulter analyzers
(AU480, AU680, AU5800 and DxC 700 AU)

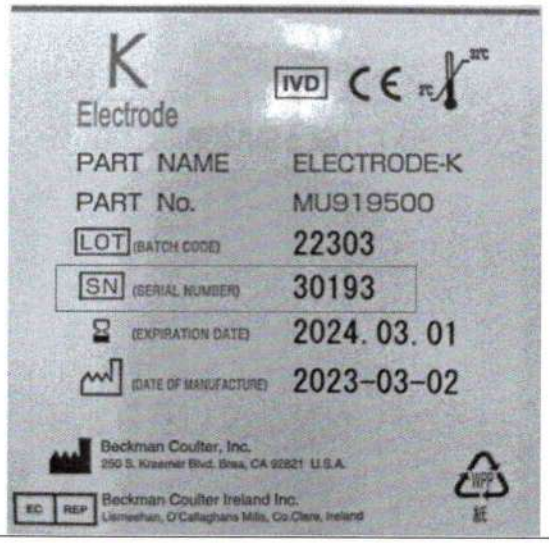
REF	LOT	Serial Number (S/N)	⌛
MU919500	22303	29540 – 29560 29562 – 29671 29673 – 29829 29831 – 29929 29931 – 29984 29986 – 30091 30093 – 30192	2024-03-01

Dear Beckman Coulter Customer,

Beckman Coulter is sending this letter regarding the K (Potassium) electrode REF MU919500 used for potassium testing on the ISE unit. Test results are not affected.

ISSUE:	• Beckman Coulter has determined that K electrodes with the lot number and serial numbers listed in the table above were filled with an incorrect inner liquid.
IMPACT:	• When a defective K electrode is used in the AU/DxC AU Beckman Coulter analyzers, calibration failures may occur resulting in the need to replace the electrode and repeat calibration and QC checks. • **There is no impact to patient results.** Patient results generated after calibration and QC have passed are accurate. • The worst-case health hazard in this case is that there is a possible delay in reporting patient results.
ACTION:	• Check the serial number (S/N) on the label of any K electrodes currently installed on your instruments: **Electrode Label**   ○ If the S/N of the K electrodes is listed above: ▪ Stop using the K electrode.

BECKMAN COULTER

	▪ Dispose of the K electrode according to your laboratory protocol. ▪ Replace the K electrode with one S/N that is not listed above. ▪ Refer to the "Replace the Na, K, or CL Electrode" procedure in the instrument Instructions for Use (IFU). ▪ Perform ISE calibration and QC according to the IFU, if you remove or replace an electrode. • Check the S/N on the box label of any K electrodes in your inventory: **Electrode Box Label**  ○ If the S/N of the K electrodes is listed above, dispose of the K electrode according to your laboratory protocol. • No retrospective review of results is necessary.
RESOLUTION:	• Beckman Coulter has discontinued shipment of the affected lot.

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 our Customer Support Center:

- From our website: http://www.beckmancoulter.com
- For customers in other geographies, contact your local Beckman Coulter Representative for replacement.

BECKMAN COULTER

We apologize for any inconvenience that this caused your laboratory.

Sincerely,

Alyssa Yarbrough
Director, Quality and Regulatory Affairs

Enclosure: Response Form