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 40 **dated** 21/2/2023 **Regarding NCMDR Field Safety Corrective Action of FreeStyle Libre 2 Sensors from (mfr: Abbott).**

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

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Circular No. 40/ 2023

30-07-1444 H
21-02-2023

Field Safety Corrective Action of FreeStyle Libre 2 Sensors from Abbott.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=18438
Product	FreeStyle Libre 2 Sensors.
Description	Glucose Monitoring System Sensor.
Manufacturer	Abbott.
Local agent	Ibn Sina Pharmacy.
The affected products	Lot: 6913207.
Reason	May provide erroneously high glucose readings.
Action	1. - If your patient is currently using the FreeStyle Libre 2 system and wearing an affected sensor, please instruct them to immediately discontinue use. - Please communicate this issue to any patients whom you have supplied FreeStyle Libre 2 sensors from lot 6913207 - You or your patients will be sent replacements for any affected sensor(s), including a mailing kit to return any affected sensor(s). - While waiting for a replacement Sensor, your patients can continue to use sensors that are not affected and can use the built-in blood glucose meter in the FreeStyle Libre 2 reader to check glucose at any time. 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

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Abbott

February 01, 2023

Urgent Field Safety Notice

Product: FreeStyle Libre® 2 Sensors
Reference: ADC FA1004-2023
Communication from Manufacturer

Dear Health Care Professional,

Abbott is initiating a voluntary recall of certain FreeStyle Libre 2® sensors from lot 6913207. No other Abbott diabetes products are affected.

Problem / Issue

- Abbott has recently identified that certain FreeStyle Libre® 2 sensors from lot **6913207** may provide erroneously high glucose readings. For example, your patients' sensor glucose reading may be high and out of their target range while their actual glucose levels may be below or within target range.

Potential Harms

- If undetected, erroneously high glucose readings can pose a potential health risk for people living with diabetes.
- Erroneously high glucose readings can lead to incorrect treatment decisions, such as taking insulin when not required.

Actions for You and Your Patients

- To determine if you or your patients' current sensor or any unused sensors are affected, please visit www.FreeStyleConfirm.com and enter the sensor serial number.
- If your patient is currently using the FreeStyle Libre® 2 system and wearing an affected sensor, please instruct them to immediately discontinue use.
- Please communicate this issue to any patients whom you have supplied FreeStyle Libre® 2 sensors from lot **6913207** by forwarding the attached letter.
- You or your patients will be sent replacements for any affected sensor(s), including a mailing kit to return any affected sensor(s) to us.
- While waiting for a replacement Sensor, your patients can continue to use sensors that are not affected and can use the built-in blood glucose meter in the FreeStyle Libre® 2 reader to check glucose at any time.

We sincerely apologize for any inconvenience this has caused.

We are notifying Saudi Food and Drug Authority, and we are implementing additional measures to address this issue.

If you have any further questions or would like to report a device fault, please call your Abbott Diabetes Care sale representative or Abbott Customer Service at 8001180055

Sincerely,

Abbott, Diabetes Care