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 132 **dated** 25/9/2024 **Regarding SFDA Field Safety Notice of Automated Compounding Device Inlet from (mfr: Baxter Healthcare Corporation).**

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

Sultanate of Oman
Ministry of Health
Drug Safety Center
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سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

Circular No. 132 **/ 2024**

21 -03-1446 H
25 -09-2024

Field Safety Notice of Automated Compounding Device Inlet from Baxter Healthcare Corporation.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/97
Product	Automated Compounding Device Inlet.
Description	Disposable inlet.
Manufacturer	Baxter Healthcare Corporation.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Product Code: H938173 - H938174 - H938175 - H938176 Lot Numbers: All within expiry.
Reason	Particulate matter has been observed within the inlet primary packaging inlet components, including within the sterile fluid path tubing, before use. This issue only affects the disposable inlets and does not affect the ExactaMix or ExactaMix Pro compounder devices.
Action	1. Baxter is working to rectify the issue detected with the affected products. During this period, customers who do not observe particulate matter may continue to use the inlets as outlined in the 'Actions to be Taken by Customers' section in the attached letter. Customers should not use the disposable inlet if particulate matter is observed. The ExactaMix and ExactaMix Pro compounding devices can continue to be used with inlets where no particulate matter is observed. 2. Customers can order replacement ExactaMix inlets if particulate matter in the inlet is observed. 3. 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

Dr. Mohammed Hamdan Al Rubaie
Director General

سلطنة عمان - وزارة الصحة - مركز سلامة الدواء
SULTANATE OF OMAN - MINISTRY OF HEALTH
DRUG SAFETY CENTER

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

FA Number: FA-2024-050
Type of Action: Voluntary Field Safety Notice

September 2024

Dear Receiver:

Baxter Healthcare Corporation has received increased customer reports of particulate matter in the Automated Compounding Device Inlets (disposable inlet) listed below used with the **ExactaMix** and **ExactaMix Pro** compounders. Particulate matter has been observed within the inlet primary packaging inlet components, including within the sterile fluid path tubing, before use. This issue only affects the disposable inlets and does not affect the **ExactaMix** or **ExactaMix Pro** compounder devices.

Baxter is working expeditiously to rectify the issue detected with the affected product codes listed below, as only Baxter's disposable inlets are qualified for use with the **ExactaMix** and **ExactaMix Pro** compounders. During this period, customers who do not observe particulate matter may continue to use the inlets as outlined in the 'Actions to be Taken by Customers' section of this letter. Customers should not use the disposable inlet if particulate matter is observed. The **ExactaMix and ExactaMix Pro** compounding devices can continue to be used with inlets where no particulate matter is observed.

Customers can order replacement **ExactaMix** inlets if particulate matter in the inlet is observed, Baxter will send a follow-up notification.

Affected Product

Product Code	Product Description	Lot Numbers
H938173	Automated Compounding Device Inlet. Non-Vented, High-Volume Inlet	All within expiry
H938174	Automated Compounding Device Inlet. Vented, High-Volume Inlet	
H938175	Automated Compounding Device Inlet. Vented, Micro-Volume Inlet	
H938176	Automated Compounding Device Inlet. Syringe Inlet	

Hazard Involved

Particulate matter in the sterile fluid pathway may end up in the final admixture, if the priming cycle during compounder setup does not remove it into a discard bag. If the particulate matter is unnoticed and the infusion delivered, there is potential for serious or critical adverse health consequences if an in-line filter is not used during the infusion. If the particulate matter is noticed and the product discarded, a delay in parenteral nutrition therapy of up to 12 hours may result. To date, Baxter has **NOT** received any reports of patient injury related to this issue.

Actions to be Taken by Customers

1. Disseminate this information to anyone who may interact with the **ExactaMix and ExactaMix Pro** compounders and the products they produce (Pharmacy and Clinical Staff).

2. Pharmacy Staff: Inspect the inlets before use, including the inlet primary packaging, tubing, connectors, and spikes. Perform the inspection in accordance with the enclosed instructions.
    - If particulate matter is observed, do not use the inlet and contact Baxter Corporate Product Surveillance to report the complaint and to arrange for the safe return of the product for further investigation, see contact information below. Please have your Baxter 8-digit ship-to account number, product code, lot number, and quantity of product to be returned ready when contacting Baxter. The product code and lot number can be found on the individual product pouch and carton.
    - If no particulate matter is observed, the inlet can be used for compounding. Please ensure the inlet is primed before use according to the instructions provided in the *Priming and Verifying* section of the **ExactaMix** and **ExactaMix Pro** compounder Operator's Manual.

3. Pharmacy and Clinical Staff: After compounding, visually inspect the finished solution in the patient bag for precipitates and particulates per the *Fulfilling the Order* section in the **ExactaMix** and **ExactaMix Pro** compounder Operator's Manual.

4. Use a minimum of 1.2 micron in-line filter during product administration. The American Society for Parenteral and Enteral Nutrition (ASPEN) recommends using a 1.2 microns in-line filter for administration of total nutrient admixtures (TNAs), dextrose-amino acid admixtures, and lipid injectable emulsion. If you are already using in-line filtration per ASPEN recommendation, no additional action is necessary.

5. Please follow the steps outlined above, including inspection processes and the use of in-line filtration.

6. Complete the enclosed customer reply form and return it to Baxter by scanning and e-mailing it to Bandar_Alosaimi@baxter.com , even if you don't have any inventory. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

7. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

8. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please notify your customers of this action in accordance with your customary procedures.

Further Information

For general questions regarding this communication or any product issue you are experiencing, contact Baxter at Bandar_Alosaimi@Baxter.com.

We apologize for any inconvenience this may cause you and your staff.

Sincerely,

Name Bandar Alosaimi
Title Regional Quality Assurance Lead

Signature: 

Email: bandar_alosaimi@baxter.com

Enclosure: **Baxter Customer Reply Form**
Automated Compounding Device Inlets Inlet Visual Inspection Instructions