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**Baxter—ExactaMix 2400 Compounders: Device Accuracy May Be Affected By Incorrect User Setup and/or Manufacturing Problems with Valve Set [ECRI Exclusive Hazard Report]**

## Product Identifier(s)

[Capital Equipment]

| Product | Baxter Healthcare Corp<br>Model |
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| Compounders | ExactaMix 2400 |

## Manufacturer(s)

Baxter Healthcare Corp, One Baxter Pkwy, Deerfield, IL 60015, United States

## Problem

1. ExactaMix 2400 compounder accuracy may be affected by a user's incorrect device setup in the following ways:
    1. Incorrect use of the device (e.g., use of incorrect ingredient vial, use of incorrect syringe sizes)
    2. Incorrect setup may affect the compounder's pump function, and may result in incorrect ingredient volumes being introduced to the final admixture/parenteral nutrition (PN) bag.
3. ExactaMix 2400 compounder accuracy may also be affected by manufacturing problems with the valve set.
    1. Bater has identified the potential for problems with valve set ports 1 to 4, which is being addressed by a recent Baxter Urgent Medical Device Correction letter (Baxter FA-2022-024) (see ECRI Alert A39442).
    2. ECRI and ISMP have received reports from a healthcare facility indicating suspected leakage from other valve set ports beyond 1 to 4. Baxter's investigation into these additional reports is ongoing, and the root cause of the suspected problem is currently unknown.
    3. ECRI and ISMP have also received a report regarding a missing valve in the valve set (see Figure 1 below).
4. Incorrect device setup and/or manufacturing problems with the valve set can result in incorrectly compounded PN bags.
5. Identifying PN bags that have been incorrectly compounded may be difficult.
    1. The final weight measurement of the PN bag is unlikely to be sufficient to catch the discrepancies with some ingredients (e.g., micronutrients) because of the relatively small volumes used in comparison to the final admixture bag.
        1. According to Baxter: "*The ExactaMix compounder uses volumetric delivery, gravimetric verification, and automatic calibration to help ensure delivery accuracy. When used according to the Operator Manual, the compounder weighs only ingredient deliveries of 100 mL or more. The Operator Manual provides important information on activities during use that can impact the accuracy of the compounder.*"
    2. Most ingredients are also clear fluids.
    3. Infrequent need to replace ingredient source containers may also make it challenging to notice volume discrepancies (e.g., ingredient running out sooner than expected), which could indicate that PN bags were compounded incorrectly.
2. If administered to a patient, an incorrectly compounded PN bag may, in the worst case scenario, lead to patient harm. The risk of harm is the most significant with the neonatal population.

*Figure 1. ExactaMix valve set with missing valve 4*

**ECRI Recommendations:**

*Note: ECRI's recommendations are based upon ECRI's experience and our scientific team's opinions specific to this Alert, at the time that the recommendations are issued. These recommendations may differ from the manufacturer's recommendations, and your organization should consult with internal experts before implementing ECRI's recommendations*

1. Use the ExactaMix compounder only as outlined in the ExactaMix operator manual, including the following:
    1. Use only ingredient source containers as instructed:
        1. Per the operator manual, only BD 50 mL Luer syringes shall be used.
        2. Per the operator manual, only vials with a volume greater than 10 mL shall be used.
    3. According to the operator manual, "to maintain delivery accuracy, the valve set must be replaced after it has delivered 150 L of fluid or been installed for 24 hours, whichever comes first."
    4. Failure to adhere to the manufacturer outlined requirements will be off-label use of the device, which may affect the operation of the compounder, and may result in inaccuracies.
2. Review Baxter's letter regarding the problems with the ExactaMix valve set ports 1 through 4 (see ECRI Alert A39442). Conduct remediation actions as recommended by Baxter.
3. When replacing a valve set on the ExactaMix 2400, visually ensure that all valves are present.
4. Check ingredient source container levels periodically to determine if gross errors are present.
    1. Compounding reports provided by the machine may aid in identifying these discrepancies.
    2. Be extra vigilant with ingredient source container volumes as Baxter continues to investigate the single member site reports of leakage from ports beyond 1 to 4.
3. For ingredients that are high risk (e.g., micronutrients) or when compounding for patient populations that are specifically vulnerable (e.g., neonatal, pediatrics), consider manual addition of the ingredients with the highest risk of harm if involved in a dispensing error. Note that this may not be a practical option for most facilities, and manual compounding in itself can be a source for errors.
4. If you suspect that you are affected:
    1. Isolate any valve set that is suspected to have problems.
    2. Isolate any PN bags compounded with the potentially affected valve set because they may not contain accurate ingredient volumes. These may also aid in the investigation into the root cause of the failure.
    3. Report all suspected incidents to FDA, Baxter, ECRI, and ISMP. When reporting to Baxter, follow the instructions outline in the field action letter.
4. The Baxter medical affairs department is available as a training or informational resource by e-mail at medinfo@baxter.com.

**Background:**

- ECRI and ISMP have received reports from a member facility of suspected leak(s) beyond ports 1 to 4.
    - The member's self-testing indicated that some ingredients ran out prematurely, which could indicate that some PN may have been compounded incorrectly.
    - These reports were shared with Baxter. Baxter was not able to replicate leaking from ports beyond 1 to 4 with the valve set samples returned from the member facility. A leak from port 2 was replicated, according to Baxter. The source of the member facility's concern is still under investigation by Baxter.
- ECRI and ISMP have received a report from another member facility regarding a missing valve (shown in Figure 1 above), which caused leakage. ExactaMix valve sets have been the subject of an Urgent Medical Device Correction letter from Baxter regarding ports 1 to 4. The manufacturer has provided advice to users regarding this matter (see ECRI Alert A39442 and the Baxter Urgent Medical Device Correction letter FA-2022-024).
- Once Baxter has implemented corrective actions to resolve this problem, a follow-up notification will be sent to customers to provide additional instructions.

**Manufacturer's Corrective Action/Recommendations:**

1. Contact Baxter by telephone at 888-608-9898, 8 a.m. to 7 p.m. Eastern Time, Monday through Friday, to schedule an appointment for a device correction that will add new compounder configurations. You will require setup of new compounder configurations that omit the use of ports 1-4, and only use ports 5-24 for the ingredients on your compounder. During the device correction period, a maximum of 20 ingredients will be able to be pumped via the compounder.
2. Customers may continue compounding with affected valve sets during the device correction period, including any valve sets that were set aside by customers pending Baxter's investigation of this leak issue, provided those valve sets have remained in their original unopened packages, were stored in accordance with the instructions for use, and are not expired.

    1. Baxter recommends that customers observe the pumping process to monitor for leaks.
    2. Leaks have been reported on ports 1 and 2 when in the closed position, where standard EXACTAMIX configurations have lipids (white opaque colored) and multi-vitamin (yellow colored) ingredients. Additionally, port 3 is also designated for multi-vitamin ingredients.
    3. Baxter recommends customers observe the pumping process to ensure they do not see unintended white or yellow discolored solution pumping through the valve set tubing into the final container.
    4. If unintended transfer of solutions from ports 1-4 are noted during the compounding process, the user should abort the compounding process, discard the final container, replace the valve set, and report it to Baxter Product Surveillance.
    5. Depending on the ingredients on ports 1-4 and the respective volumes, customers may be able to add these ingredients as manual additions.
    6. Consideration needs to be made for the type of ingredient to ensure there is no risk of precipitation based on the sequence of those additions.
    7. Customers should continue to follow their institutional policy and procedures for compounding. The use of a 1.2-micron filter is a recommended best practice by ASPEN when administering all parenteral nutrition formulations.
8. DO NOT attempt to add new compounder configurations on your own due to the complexity of the process and potential patient safety concerns if not done correctly. Serious injuries may result to patients due to incorrect, excessive, or insufficient product in the compounded bag if configured incorrectly.
9. Once Baxter has implemented corrective actions to resolve the valve set leak issue, a follow-up notification will be sent to customers to provide additional instructions.
10. Baxter states that the ExactaMix compounder must be used according to the operator manual.

## UMDNS Term(s)

Intravenous Solution Compounders [17459]

## Geographic Region(s)

(Impact in specific regions has not been identified or ruled out at the time of this posting), Worldwide

## Suggested Distribution

Clinical/Biomedical Engineering, Nursing, Risk Management/Continuous Quality Improvement, Home Care, Pharmacy, IV Therapy, Materials Management

## Comment

- This alert is a living document and may be updated when ECRI receives additional information.