

April 19, 2022

EXACTAMIX Valve Set Extended Use

Dear Healthcare Professional,

We understand there are currently supply constraints for the ExactaMix valve sets (ExactaMix 1200 Valve Set H938792 and ExactaMix 2400 Valve Set H938724) that are driving healthcare providers to consider conservation measures when compounding with the ExactaMix Automated Compounder. The information in this letter is intended to help inform healthcare professionals of the clinical and technical considerations with respect to the extended use of the ExactaMix valve set beyond 24 hours or after the delivery of >150 L of fluid. Baxter has not validated extended use of the valve sets for longer than 24 hours, or delivery of >150 L of fluid, therefore, Baxter does not recommend the use of the valve sets outside of the Operator Manual.

Per the ExactaMix Operator Manual, in order 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.¹ The ExactaMix compounder will warn the user when the 150 L volume transfer limit has been reached, and any admixture bags made past the warning will require an override by the user. All orders that have an associated override by the user will be captured in the MixCheck report.

The following information should be considered if the valve sets are used outside of the Operator Manual recommendations due to conservation initiatives resulting from supply constraints:

- The accuracy of compounding is dependent on multiple factors such as pump mechanism, durability of the valve set components, ingredient flow factors, and device performance.
- Different components of the valve set (tubing, pump segment, valve) have not been tested beyond 24 hours, or >150 L of pumped fluid, to further evaluate the effects of extended wear.
- Overuse of the pump segment can cause changes to the durability of the tubing resulting in variability of pump accuracy. It can also lead to the breakdown of the external and/ or internal surfaces of the tubing which can further result in particles inside the admixture container.
- Baxter has not performed studies to assess the impact of prolonged exposure of ingredients (e.g. dextrose, lipids) sitting idle in the valve core from both a microbial perspective as well as ability to maintain general mechanical function over extended periods of time beyond 24 hours. While we realize steps can be implemented to mitigate certain solutions remaining in the tube set from the valve to the final admixture container, the individual ingredients connected to the valve by the inlets will continue to expose the valve core to the ingredient.

A literature search was conducted to identify any pertinent information to further assist you with your clinical decision. The below referenced article was the only information found to be relevant to the extended use of the valve set.

Chappuy L, Charroin C, Vetele F, et al. Study of physicochemical and bacteriological impact of an assembly weekly from the BAXA® Exacta-Mix 2400 on parenteral nutrition pouches: *French Pharmaceutical Annals*. 2014; Vol 72: pgs. 22-27. <https://doi.org/10.1016/j.pharma.2013.07.003>.

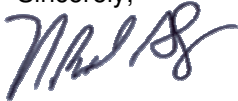
It should be noted that there are limitations associated with the above referenced article. The study evaluated 10 parenteral nutrition admixtures each day (n=60) however did not report the total amount of fluid delivered over the study period. Admixture stability was assessed only by visual inspection and did

not include microscopic analysis. No testing was performed on the components of the device to assess the impact of extended use beyond the delivery of 150 L of fluid.

Use of the ExactaMix Valve Set beyond the Operator Manual should only be determined by an experienced pharmacist after careful consideration of the facility specific practices in combination with the limitations and risks outlined above.

We apologize for the inconvenience you are experiencing due to the shortage. Should you have further questions or concerns please contact Medinfo@baxter.com and someone from Medical Affairs will follow up with you directly.

Sincerely,



Brad Glazer, PharmD
VP, Medical Affairs Americas
Worldwide Medical
Baxter Healthcare Corporation

This letter is intended to provide pertinent data to assist you in forming your own conclusions and is not to be considered as medical advice. The information contained in this letter is applicable to products approved or cleared in the United States of America, unless specifically noted. Baxter does not advocate the use of its products outside of approved labeling. Please refer to Instructions for Use or Prescribing Information. This letter and the information within are provided as a service to Baxter customers and are not intended to be reproduced without the prior written permission of Baxter Healthcare Corporation.

Reference:

1. Operator Manual for the Baxter ExactaMix 2400 Compounder. 53007410 Rev C.