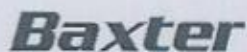


**Safety  
Alert**  
(to be adapted  
locally)

April XX, 2014 (to be adapted locally)

Dear Director of Pharmacy (to be adapted locally)

<b>Issue Description</b>	Baxter Corporation (to be adapted locally) is providing you with important safety information regarding the SV0.5 INFUSOR and FOLFusor system (to be adapted locally and list below to be adapted locally). Baxter has continued to investigate complaints for over-infusion and wants to make you aware that the direction insert states that infusion rates may be up to 10% greater than the nominal (labeled) infusion rate of 0.5mL/hr. Even though this variation of the flow rate is described in the direction insert, recent review of flow rate testing indicates that infusion rates may be higher and could result in a 15% greater than nominal (labeled) infusion rate.
<b>Product Codes</b>	2C4700K FOLFusor SV 0.5ml/h system D2C4700K FOLFusor SV 0.5 ml/h system 2C1700KP INFUSOR SV 0.5ml/h system
<b>Hazard Involved</b>	Delivery of medication at a faster rate than intended may lead to toxicity and changes to efficacy that require medical intervention.
<b>Action to be taken by healthcare providers</b>	Follow the device Instructions for Use which explain the following factors that may impact resulting flow rate, noting that the labeling discrepancy as noted above, combined with all other use factors, can contribute to infusion rates in excess of 30% greater than the nominal (labeled) flow-rate. (to be adapted locally) <ol style="list-style-type: none"><li>1. The choice of medication: Refer to the drug manufacturer's package insert for drug reconstitution/dilution and storage procedures.</li><li>2. Instructions for calculating the correct fill volumes, including the potential for increase in flow rate, which may result from a fill volume below the stated nominal (labeled) fill volume.</li><li>3. Temperature change, as flow rate will decrease approximately 2.3% per 1°C decrease in temperature and will increase approximately 2.3% per 1°C increase in temperature.</li><li>4. Choice of the diluents (5% Dextrose vs. 0.9% Sodium Chloride) e.g., a ~10% increase in nominal flow rate may result when 0.9% Sodium Chloride is used.</li></ol>



5. Nominal flow rate of the INFUSOR is realized when the Elastomeric Reservoir and the Distal End Luer Lock are positioned at the same height. Flow rate will decrease ~0.5% for every inch the Elastomeric Reservoir is positioned below the distal end luer lock and increase ~0.5% for every inch the elastomeric reservoir is positioned above the distal end luer lock.
6. Length, diameter, and location of catheter.

Baxter is investigating options to bring the flow rate into alignment with current labeling. Short term, Baxter will be adding the Safety Alert letter to each customer shipment or carton of product.

Baxter is requesting that you take the following actions in response to this notification:

**Action to be taken in response to this notification**

1. Acknowledge your receipt of this Safety Alert notification by completing the attached Customer Reply Form (Attachment 1) and return it to Baxter by either faxing it to XX (to be adapted locally) or scanning and e-mailing it to (to be adapted locally). Returning the Customer Reply Form promptly will prevent you from receiving repeat notifications.
2. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them to ensure that they are aware of this notice. (to be adapted locally)
3. If you are a dealer, wholesaler, or distributor/reseller that distributed any product to other facilities, please notify your customers of this action. (to be adapted locally)

**Further information and support**

If you have questions regarding this communication, please call... (to be adapted locally)

Any adverse reactions or quality problems experienced with the use of these products must be reported through your local Baxter Sales Representative (to be adapted locally)

The local MOH (to be adapted locally) has been notified of this action. (to be adapted/removed locally)

Sincerely,

Name (to be adapted locally)  
Title (to be adapted locally)  
Medical Products (to be adapted locally)  
Baxter Healthcare (to be adapted locally)

Attachment 1: Customer Reply Form