

Sundhedsstyrelsen  
Axel Heides Gade 1  
2300 København S  
Medicinsk Udstyr

20-Sep-2013

**Field Safety Notice - INFUSOR, FOLFUSOR and INTERMATE Portable Elastomeric Infusion Systems**

**Product codes:**

**2C1071KJP, 2C1073KJP, 2C1075KJP, 2C1080KJP, 2C1082KJP, 2C1087KP, 2C1008KP, 2C1009KP, 2C1156KP, 2C1063KP, 2C4700K, 2C4702K, 2C4711K, 2C4705K, 2C4063K, 2C1976KJ, 2C1154KP, 2C1155KP, 2C9960KP, 2C9961KP, 2C1811K, 2C1712K, 2C1732K, 2C1734K, 2C1714K, S2C1715, 2C1720K, 2C1722K, 2C1742K 2C1724K, 2C1064K**

**Lot numbers:** All

Baxter Healthcare Corporation is issuing an important safety information regarding the INFUSOR, FOLFUSOR, and INTERMATE portable elastomeric infusion systems.

Baxter has received complaints for infusion flow rates greater than intended for the above referenced portable elastomeric infusion systems. In many cases, the complaint details an overinfusion of medication that are the result of uses inconsistent with the Instructions for Use.

Delivery of medication at an infusion rate faster than intended may lead to toxicity and changes to efficacy that require medical intervention.

Baxter is requesting that healthcare providers continue to follow the device Instructions for Use which explains the factors that may impact resulting flow rate.

Our records indicate that 40 customers have received the products in our country. You will find attached, for your information, the letter that is being sent to those customers.

If you have any questions please contact Baxter at 4816 6400.

Sincerely,  
Baxter A/S



Aase Bendtsen  
Regulatory Affairs Assistant  
T 4816 6423