



**IMPORTANT
PRODUCT
INFORMATION**

March 2014

Subject: Field Safety Notice – IIPV new warning labeling

Dear Peritoneal Dialysis Health Care Provider:

Baxter Healthcare is sending this communication to inform you of an additional Warning being implemented in HomeChoice/HomeChoice PRO device product labeling related to patients more vulnerable to unintended Increased Intraperitoneal Volume (IIPV), also known as overfill. See Attachment 1 for the additional Warning. IIPV is an inherent risk of Peritoneal Dialysis (PD) therapy. This notification is not due to any increase in complaints or adverse events associated with IIPV and Baxter HomeChoice/HomeChoice PRO devices.

Affected Products	All HomeChoice Automated PD System and HomeChoice PRO Automated PD System Product Codes: 5C4474, R5C8320
Problem Description	Specific populations using Peritoneal Dialysis therapy including neonates, infants, small children and any patient with significant heart or lung disease are more vulnerable to the negative effects of excessive retention of fluid in the peritoneal cavity that may be related to their dialysis therapy. The additional Warning identifies symptoms related to unintended IIPV that may result in these specific populations and provides specific instructions for the patient to follow if IIPV is suspected.
Hazard Involved	Increased Intraperitoneal Volume (IIPV) is a condition with an unintended excess of fluid in the peritoneal cavity that may become symptomatic, especially in high risk populations (neonates, infants, small children and any patient with significant heart and/or lung disease). Overfilling with dialysate (IIPV) or not draining enough fluid during PD therapy can result in excess fluid in the abdomen accompanied by patient symptoms.
Action to be taken by customer/user	<ul style="list-style-type: none">• Please keep a copy of this warning letter and the attachment 1 with your Homechoice manual.• Please make sure that your home patients receive a copy of this warning letter.

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