



**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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- If you are a distributor, wholesaler or if you provide this product to any other department/facility, please make sure to cascade this information as appropriate.
- Complete the attached Customer Reply Form and return to Baxter by emailing or faxing to the number provided on the form. Returning the Customer Reply Form promptly will prevent you from receiving repeat notices.
- The addendum will be added to the User Manual by end of Q3 2014.

We apologize for any inconvenience this may cause you and your staff. Should you have any technical questions related to this, please contact Baxter Technical Services on 01635201902.

Any adverse reactions or quality problems experienced with the use of these products may be reported using one of the following options:

Reporting product quality complaints:

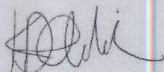
- Call 01604 704 603
- Fax to: 01604 704688
- Email to: uk_shs_qad@baxter.com

Reporting adverse events with drugs:

- Call 01635 206 360
- Faxing to: 01635 206 281
- Email to: vigilanceuk@baxter.com

The MHRA has been informed about this action.

Sincerely,



Karen Wilson
Renal Marketing Manager
Baxter Healthcare Ltd.
Newbury, Compton- RG20 7QW

Attachment 1: Warning Statement
Attachment 2: Customer Reply Form

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ATTACHMENT 1

Warning

Some patients are uniquely vulnerable to excess retention of fluid in the peritoneal cavity that may be related to the dialysis therapy. These patients include neonates, infants and small children, and any patient with significant heart or lung disease.

- Due to their small size, neonates, infants and small children may display severe symptoms with the retention of small amounts of fluid in the peritoneal cavity.
- Any patient with significant heart or lung disease, regardless of age, may also show severe symptoms with seemingly small amounts of fluid retention in the peritoneal cavity.

Symptoms that should alert the patient or caregiver that excess fluid may have accumulated may be specific for the patient's age and developmental level, as described below:

- Neonate/Infant: General signs of distress (e.g., fussiness, crying), paleness or bluish skin color, difficulty breathing, refusal to eat, bloated abdomen or persistent vomiting.
- Small child: Complaints of feeling full, report of pain in abdomen, persistent crying, difficulty breathing, refusal to eat, bloated abdomen or persistent vomiting.
- Patients with cardiovascular or pulmonary disease: Difficulty breathing, shoulder and/or chest pain, paleness or bluish skin color.

If IIPV is suspected, please do the following:

1. Press STOP immediately, then press [Down Arrow] and initiate a Manual Drain. Drain the fluid completely from your abdomen.
2. For only technical assistance in performing step 1, call the Baxter Customer Service Line which is available 24 hours a day, 7 days a week at 01635201902.
3. If you have ANY clinical queries or symptoms of IIPV including, but not limited to, those listed above, call your nephrologist/renal healthcare provider immediately.