

Baxter Healthcare Pty Ltd
A.B.N. 43 000 392 781
Postal Address:
P.O. Box 88 Toongabbie,
N.S.W. Australia, 2146
1 Baxter Drive, Old Toongabbie
N.S.W. Australia, 2146

www.baxterhealthcare.com.au
Telephone: 02 9646 1111
Fax: 02 9646 1123

Baxter

March 15, 2010

Safety Alert

Customer

Dear

RE: HomeChoice Automated PD System and HomeChoice PRO Automated PD System

Product Code: R5C8320

Baxter Healthcare is sending you this Safety Alert letter to help reduce or eliminate overfill, also referred to as Increased Intraperitoneal Volume (IIPV). This is caused when patients override warning messages on the HomeChoice / HomeChoice PRO cyclers. IIPV can result in serious injury or death from conditions including, but not limited to, hydrothorax, heart failure, pulmonary edema or pericardial effusion. In the USA, Baxter has received complaints of IIPV, which resulted from patient use errors and/or prescription errors.

Description of IIPV

Overfilling or not draining enough fluid can result in excess fluid in the abdomen. While some patients may not have any symptoms, the most common symptoms of IIPV (overfill) include:

- Feeling full, bloated, or overfull
- Abdominal pain or discomfort
- Expanded or tense abdomen
- Vomiting or spitting-up
- Difficulties feeding
- Localised swelling around the PD catheter exit site, belly button, groin region, or genital area
- Leakage of fluid from the PD catheter exit site
- Difficulty breathing
- A child complaining of a "funny feeling" in the abdomen
- A child crying
- Unexpected increase in blood pressure

Additional care should be taken to monitor patients who are not able to communicate IIPV symptoms to their caregiver during treatment, such as small children or infants.

BRISBANE
Tel: (07) 3273 7300
Fax: (07) 3273 7332

MELBOURNE
Tel: (03) 9359 3000
Fax: (03) 9351 1691

ADELAIDE
Tel: (08) 8347 3773
Fax: (08) 8347 4822

PERTH
Tel: (08) 9455 7028
Fax: (08) 9455 7516

Baxter, HOMECHOICE AND HOMECHOICE PRO are registered trademarks of Baxter International, Inc. 2009-077-RN

Baxter

How IIPV Occurs

IIPV is a condition that occurs when there is more fluid in the abdomen than was prescribed. This condition is sometimes called "overflow." Baxter has received reports of IIPV associated with patient use error or prescription error when using either the HomeChoice Automated PD System or HomeChoice PRO Automated PD System.

IIPV can occur if the prescription parameters are not programmed appropriately. It is important that clinicians consider these parameters when setting new patient prescriptions. It is also important for clinicians to consider whether current patient prescriptions need to be revised. Baxter may contact you if, during the course of complaint investigations, we determine that patient prescriptions are potentially contributing to IIPV.

The following prescription parameters can influence the risk of IIPV:

- Fill Parameters such as Fill Volume, Day Fill Volume, Night Fill Volume, Last Fill Volume
- Drain Parameters such as I-Drain Alarm, Minimum Drain Volume %, Last Manual Drain, UF Target, Tidal Volume %, Total UF, Tidal Full Drains
- Low Fill Mode Only such as I-Drain Time, Minimum Drain Time, Negative UF Limit %

Actions to Take

Clinicians must carefully program patient fill volumes to prevent IIPV situations. Clinicians must also program drain alarms and ultrafiltration percentage to ensure patients are draining sufficiently. Insufficient draining could lead to an IIPV situation during their subsequent cycle or accumulation of ultrafiltration volume within the peritoneal cavity.

Note: It is essential that you and your staff inform all patients of this potential risk and ensure that they appropriately use the Home Choice devices and understand how to use the manual drain option.

IF YOU SUSPECT YOUR PATIENT HAS IIPV, PLEASE TELL YOUR PATIENT OR PATIENT CAREGIVER TO DO THE FOLLOWING:

- 1.) Press STOP immediately, then press ▽ and initiate a Manual Drain. The Manual Drain procedure is located in the HomeChoice manual.
- 2.) Once the fluid is completely drained from the abdomen, call your nephrologist.
- 3.) Call your nephrologist immediately if you have ANY complaints or symptoms of IIPV including those listed above.
- 4.) For assistance in performing the above steps, contact your Baxter clinical sales specialist.
- 5.) If you are unable to reach your dialysis center, nephrologists, or the Baxter Clinical Sales Specialist, and the patient is experiencing symptoms of IIPV, go to the nearest Emergency Room.

HomeChoice Labeling and Software Changes

Baxter is developing changes to the HomeChoice / HomeChoice PRO product labeling and software to reduce the potential incidence of IIPV due to patient use errors or prescription errors. Labeling refers to the instructions for use of the device, such as the Patient At-Home Guide. Software refers to the firmware, or embedded software, in the device itself. Baxter will notify you when these changes are available and arrange for your cyclers to be upgraded.

BRISBANE
Tel: (07) 3279 7300
Fax: (07) 3273 1232

MELBOURNE
Tel: (03) 9389 3000
Fax: (03) 9381 1651

ADSLAIDE
Tel: (08) 8347 2773
Fax: (08) 8347 4822

PERTH
Tel: (08) 9455 7036
Fax: (08) 9455 7515

Baxter

Attached to this letter is information on IIPV. This attachment contains Patient guidance and Clinician Guidance. Please read the attachment and share this important information with your home patients. The attachment includes:

- A definition of IIPV, the related symptoms, and guidance on how to address IIPV should it occur.
- Warnings and cautions about IIPV.
- Programming instructions for the HomeChoice / HomeChoice PRO cyclers to improve clinicians' understanding of how programming the device relates to IIPV. New details have been added to specifically address Low-Fill Mode.
- Tables have been included with recommendations for the Initial drain (I-drain) alarm settings, recommendations for maximum Fill Volume based on patient's weight, and targets for Tidal Therapy ultrafiltration levels.

Adverse reaction reporting

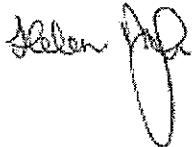
Any adverse reactions experienced with the use of this product, and/or quality problems should be reported to Baxter Customer Service on 1300 789 646 during the hours of 8:00 am – 5:00 pm.

Please complete the enclosed reply form and fax it to Baxter at the number provided on the form. The completed reply form will acknowledge receipt of this letter and will prevent you from receiving repeat notices.

If you have any questions about this issue, please contact your local Clinical Sales Specialist. We apologise for any inconvenience you may experience as a result of this notification.

This action is being undertaken following consultation with the Therapeutic Goods Administration.

Sincerely,



Helen Morrison
Quality Assurance

Clinical Sales Specialist

NSW	Phone Number	VIC	Phone Number
Andrew Bertram	0412 847333	Catherine Blackmore	0409 409477
Margaret Connell	0409 005015	Sheela Bowling	0418 612957
Christine Hunt	0400 600 793		
Bienvenido Roman	0417 555160		
Andrew Reid	0410 221154		
		SA	
QLD	0458 555260	Susan Owen	0419 219076
Brian Graham	0418 885044		
Maxine Liles	0429 300001	WA	
Angela Read		Sandra Handy	0400 600 324

BRISBANE
Tel: (07) 3273 7300
Fax: (07) 3273 7332

MELBOURNE
Tel: (03) 9569 3000
Fax: (03) 9351 1691

ADELAIDE
Tel: (08) 8347 1773
Fax: (08) 8347 4822

PERTH
Tel: (08) 9455 7088
Fax: (08) 9455 7515



HomeChoice Automated PD System and HomeChoice PRO Automated PD System

Product Code: R5C8320

CUSTOMER REPLY FORM

Safety Alert

March 15, 2010

Please complete and return this form to the FAX number listed below as confirmation that you have received this notification. A fax cover sheet is not required.

Attention: Helen Morrison

Fax: 02 9848 1023

Facility Name and Address:	
Reply Completed By: (Signature/Date)	
Name: (Please Print Name)	
Title: (Please Print)	
Telephone Number: (Including Area Code)	

Check all that apply:

I have read, understand, and disseminated the content of the letter.

All home patients connected with this hospital have been contacted to inform them of this potential risk and ensure that they appropriately use the Home Choice devices and understand how to use the manual drain option.

The HomeChoice Automated PD System or HomeChoice PRO Automated PD System is no longer used.

Signature/Date: REQUIRED FIELD	
--	--

PLEASE ENSURE THE REPLY FORMS CONTAIN YOUR NAME, TITLE, SIGNATURE AND DATE IN THE ABOVE FIELDS.

RESPONDING TO THIS REQUEST WILL PREVENT THE RECEIPT OF UNNECESSARY REPEAT NOTIFICATIONS CONCERNING THIS ISSUE.