Baxter

Field Safety Notice

12th November 2014

Dear Customer

Baxter Healthcare Corporation is sending this communication to inform you of additional and updated warnings and cautions being implemented in HomeChoice/HomeChoice PRO device product labeling. This notification is not due to any increase in complaints or adverse events associated with Baxter HomeChoice/HomeChoice PRO devices.

Affected Products	All HomeChoice Automated PD System and HomeChoice PRO Automated PD System devices Product Codes: 5C4474, R5C8320.
Problem Description	Baxter Healthcare Corporation is sending this communication to inform you of additional and updated warnings and cautions that are not in the Patient At-Home Guide (see Attachment 1).
Hazard Involved	The additional and updated warnings and cautions could have an impact on the safety of a patient or third party.
Action to be taken by customer/user	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. 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. Please complete the attached Customer Reply Form and return it to Baxter by either fax or scanned e-mail. Returning the Customer Reply Form promptly will prevent you from receiving repeat notices.
Further Information and support	• For clinical questions, contact your local Baxter Representative. • For general questions regarding this communication, please contact me at the number below.

- We apologise for any inconvenience this communication may cause you. The HPRA has been informed of this action.
- Please report any suspected adverse reactions to the HPRA via their website at www.hpra.ie
- Any suspected adverse reactions experienced with the use of these products may also be reported to Baxter Healthcare directly by calling 01-206-5500 or by email to qa_dublin@baxter.com.

We look forward to continuing to serve your dialysis needs and we thank you for your cooperation.

Yours Sincerely,

Ian Gavigan
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Enclosures: New Warnings and Cautions and Customer Reply Form

New Warnings and Cautions

HomeChoice is not intended to be a substitute for monitoring the patient's overall condition by a nephrologist. Use of the device without patient monitoring can lead to serious injury or death.

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 heart or lung 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 assistance in performing step 1, call Baxter Technical Assistance.
3. If you have ANY complaints or symptoms of IIPV including, but not limited to, those listed above, call your clinician immediately after performing step 1.
4. If you are unable to reach your dialysis center, clinician, or Baxter Technical Assistance, and you or the patient are experiencing symptoms of IIPV, call your National Emergency Number immediately or go to the nearest Hospital Emergency Room.

Ascites refers to the accumulation of fluid in the peritoneal cavity due to other medical conditions unrelated to your kidney disease. Peritoneal Dialysis patients with Ascites may have large volumes of fluid in their peritoneal cavity unrelated to their peritoneal dialysis solution. If you have Ascites, draining to empty may place you at an increased risk of low blood pressure.

Patients using the HomeChoice cycler with severe kidney failure and Ascites should be aware that the cycler will attempt to drain them to empty during Initial Drain. All subsequent cycle drains will be drain to empty with the exception of tidal night cycle drains which are based on programmed Tidal Volume % and tidal Total UF. The HomeChoice cycler allows you to pause any active Initial Drain, but does not allow you to bypass an active Initial Drain

unless you have reached a slow flow condition for a predetermined period of time. Cycle drains can be paused and bypassed.

Baxter recommends that clinicians closely monitor drain volumes of patients with Ascites who also use the HomeChoice cycler to treat their severe kidney failure.

Contact your clinician immediately if you have Ascites and observe the following:

- Your abdomen is more distended or tense than usual, or
- Drain volumes that exceed a pre-determined amount determined by your clinician.

⚠	Open the packaging of the disposable set by hand. To avoid injury or damage to the disposable set, do not use a knife, scissor, or other sharp object to open the packaging.
⚠	When removing the disposable set from the HomeChoice APD system, ensure all line clamps and drain bag clamps are closed to avoid solution or effluent leakage. Immediately clean up all fluid spills to prevent injury from slipping or falling.
⚠	The Emergency Disconnect requires the use of disconnect caps for the disposable set. If you do not have FlexiCap or OptiCap disconnect caps available, end your therapy and then restart your therapy using all new supplies (solution bags and disposable set). If you disconnect during therapy and do not reconnect using new supplies, there may be a possibility of contamination of your patient line, which may lead to peritonitis.
⚠	The power cables, modem cables, extension lines (if used) and fluid lines on the disposable set pose a strangulation hazard. Special care and close supervision is necessary when this product is used by, on or near children and patients unable to care for themselves.
⚠	There is a danger of fire if the lithium battery, located within the system cycler, is incorrectly replaced.
⚠	Tip protectors for disposable sets pose a choking hazard. Secure tip protectors appropriately and dispose promptly after use.
⚠	Extra caution should be used after administering subcutaneous insulin in preparation of APD therapy. A subsequent delay or interruption of therapy thereafter could lead to low blood glucose (sugar) levels. Adjust your insulin therapy as directed by your clinician.
⚠	Changing the PD solution concentrations of glucose or dextrose in patients receiving insulin may be associated with too high or too low of blood glucose (sugar) levels. Adjust your insulin therapy as directed by your clinician.
⚠	Close supervision is necessary when the cycler is used by, on or near children to prevent contamination of the fluid in case they bite the solution bag or disposable sets. Contamination of any portion of the fluid or fluid pathway could result in peritonitis.
⚠	Fluid lines and electrical cables pose a tripping hazard and may lead to injury. Exercise caution when moving near, or around electrical cables and fluid lines.
⚠	Injury can occur as a result of lifting the cycler or falling while attempting to move the cycler. Exercise caution under such conditions.
⚠	Caution must be taken if a single Pro Card is used with multiple HomeChoice PRO cyclers. Prescription changes manually entered on one HomeChoice PRO cycler will not be transferred back to a cycler that has previously used the same Pro Card. Prescription

changes that are desired to be permanent should be made using Clinical Application Software available to your physician or clinician. This caution does not apply when receiving a new cycler as part of a swap because your new cycler will not have previously been used with your Pro Card. This caution applies only to HomeChoice PRO cyclers described in HomeChoice and HomeChoice PRO APD System Patient At-Home Guide (07-19-64-016).

The use of wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, or walkie-talkies can affect the HomeChoice instrument and should be kept at least a distance of 3.3 m (10.8 ft) away from the HomeChoice instrument. A system alarm may occur if you use these devices within 3.3 m (10.8 ft) distance of your cycler.

Do not attempt to service or modify the cycler yourself. Doing so can result in personal injury or death. Return the product to Baxter for examination and repair if damage occurs. Contact Baxter Technical Assistance at the number listed in your Patient At-Home Guide.

Note – Acronyms used: IIPV – increased intraperitoneal volume (also known as overfill)
UF – ultrafiltration
PD – peritoneal dialysis
APD – automated peritoneal dialysis