

**Urgent Field Safety
Notice**

14th January 2016

Dear Peritoneal Dialysis Provider,

Affected Product All HomeChoice Automated PD System and HomeChoice PRO Automated PD System devices

Product Code	Description
R5C8320	HomeChoice PRO Automated PD Cycler, 230V

Actions taken by Baxter Baxter Healthcare Corporation is updating the HomeChoice Patient At-Home Guide Addendum to include a discussion of the expected operating sounds associated with all HomeChoice and HomeChoice PRO devices. The new labeling will address the following:

The HomeChoice cycler utilizes an air (pneumatic) pump; some sounds related to the operation of this pump are expected as part of normal operation of the HomeChoice cycler. There will be sounds like humming, swishing, clicking, and venting (air being released) that are normal for the operation of the cycler. In certain portions of the therapy, the sound level is expected to increase which is also part of normal operation. If there is a significant change in the sound level or a new, previously unheard sound when using the HomeChoice cycler, please contact your doctor and/or nurse or Baxter Technical Services.

Your peritoneal dialysis (PD) patients who receive product directly from Baxter are also receiving a letter with this information.

Action to be taken by the user

Baxter is kindly asking that you take the following actions:

- Please keep this letter with your Patient At-Home Guide.
- Complete the enclosed customer reply form, and return it to Baxter by either faxing it to 01 206 5577 or scanning and e-mailing it to qa_dublin@baxter.com even if you don't have any inventory. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.
- Please forward a copy of this letter to other facilities or departments within



your institutions to ensure that those locations are aware of this action.

- If you are a dealer, wholesaler, or distributor/reseller that distributed any product to other facilities, please notify your customers of this communication in accordance with your customary procedures.

Further information and support For general questions regarding this communication, contact Baxter at 01 206 5500, between the hours of 9am – 5pm

We apologize for any inconvenience this may cause you and your staff.

Yours Sincerely,

Ian Gavigan
Head of CQA UK/Ireland
Baxter Healthcare Ltd.
Deansgrange Business Park
Blackrock
Co. Dublin
Ph: 01 2065500

Attachment 1: Customer Reply form



CUSTOMER REPLY FORM

IMPORTANT PRODUCT INFORMATION LETTER DATED 14TH JANUARY 2016

HOMECHOICE/HOMECHOICE PRO AUTOMATED PD SYSTEM

Product code: R5C8320

Batch/Serial Number: All

Please complete and return one copy of this form per facility either by fax (Fax :01 206 5577) or by e-mail (qa_dublin@baxter.com) as confirmation that you have received this notification.

A fax cover sheet is not required.

Facility Name and Address: <i>(Please Print)</i>	
Reply Confirmation Completed By: <i>(Please Print Name)</i>	
Title: <i>(Please Print)</i>	
Email and/or Telephone Number <i>(Including Area Code):</i>	

We have received the above mentioned letter and have disseminated this information to our staff, other services and facilities.

Signature/Date: REQUIRED FIELD	<hr/>
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