Baxter

IMPORTANT PRODUCT INFORMATION

2 August 2017

Dear Stela,

Affected Product

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

Problem Description

Baxter Healthcare Corporation has been made aware that users may not be following the instructions in the Operator's Manual and incorrectly opening disposable set packaging while setting up their Peritoneal Dialysis (PD) therapy, damaging the cassettes for the HomeChoice or HomeChoice PRO cyclers.

The HomeChoice cycler operator's manual specifically warns the operator to open the disposable set packaging by hand and not use tools that may damage the cassette sheeting. Please do not use knives, scissors, clamp accessories, or other objects to open the disposable set packaging. If damaged cassettes are used, the cyclers may not consistently detect very small holes/cuts in the sheeting of the cassette in the patient valve region (see Figure 1), and the cycler may deliver air into the patient.

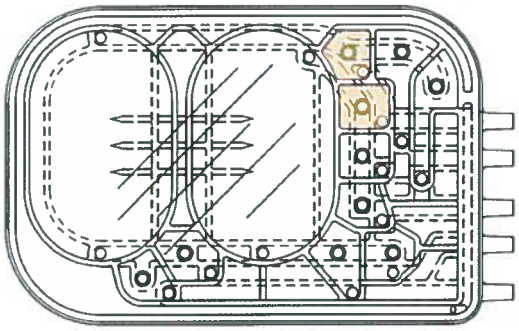

Figure 1: Picture of Patient Valve Region (highlighted yellow) of the Disposable Cassette.

An indicator that you may have a hole in your cassette sheeting is the flow of fluid out of the connector at the end of the patient line following the prime phase of PD therapy. A hole in the cassette sheeting could lead to delivery of air to the peritoneal cavity.

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Hazard Involved

If the user does not follow existing instructions in the operator's manual while opening the disposable set packaging, it is possible for the patient valve portion of the cassette sheeting to be damaged and the damage to go undetected by the cycler and the user. If this occurs, delivery of air into the patient line at a rate of 10 to 30 mL/min may result during the fill or dwell phase of a Peritoneal Dialysis (PD) therapy. A resulting pneumoperitoneum (air in the peritoneal cavity), if clinically significant, would present as pain and, with increased intraperitoneal pressure from significant volume of air, there is potential for serious adverse health consequences.

Actions taken by Baxter to avoid reoccurrence of the issue

Baxter is updating the HomeChoice Patient-At-Home-Guide labeling to include the additional risk information described in this letter. Below is an excerpt of the updated labeling:

- ***NOTE:*** *Fluid flow out of the connector at the end of the patient line when only the heater bag is on the heater pan and when the patient line or extension line is correctly positioned in the organizer may indicate a hole in the cassette sheeting and could lead to delivery of non-sterile air to your peritoneal cavity.*

End therapy. Return the disposable set to Baxter by calling Baxter Technical Assistance at the number located in Numbers to Call for Assistance on page 1-1. Restart your therapy using all new supplies (solution bags and disposable set).

Action to be taken by the user

Baxter is kindly asking that you take the following actions:

1. As stated in the Patient-At-Home-Guide, open the packaging of the disposable set by hand. Do not use a knife, scissor, or other sharp object to open the packaging.

2. Be aware that flow of fluid out of the connector at the end of the patient line after the prime phase of PD therapy is a visual indication of the potential for air delivery due to an undetected hole over the patient valve area in the cassette sheeting. Baxter will be updating the labeling to include this observation.

3. Complete the enclosed customer reply form, and return it to Baxter by e-mailing it to monika_lichniak@baxter.com. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

4. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

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5. 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 Monika Lichniak monika_lichniak@baxter.com

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

Sincerely,

Monika Lichniak
CQA Specialist
Baxter Healthcare Corporation

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CUSTOMER REPLY FORM

(IMPORTANT PRODUCT INFORMATION LETTER DATED 2 AUGUST 2017

HOMECHOICE PRO, HOMECHOICE CLARIA

***Product code:** R5C8320*

***Serial Number**: All*

Please complete and return one copy of this form per facility by e-mail monika_lichniak@baxter.com as confirmation that you have received this notification.
A fax cover sheet is not required.

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

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

☐ We have received the above mentioned letter and have disseminated this information to customers

Signature/Date: REQUIRED FIELD	_____

Your signature above indicates understanding of the contents of the attached letter, that you performed the actions outlined and disseminated this information, if applicable.