

Urgent Field Safety Notice

27th July 2017

Dear Sir/Madam,

Affected Product

Product Code	Product Description	Serial Number
5C4474	HomeChoice Automated PD Cyclers, 230V	ALL
R5C8320	HomeChoice PRO Automated PD Cyclers, 230V	ALL
5C6M00	HomeChoice Claria APD System, 230V	ALL
5C6M10	HomeChoice Claria APD System, 115V/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.

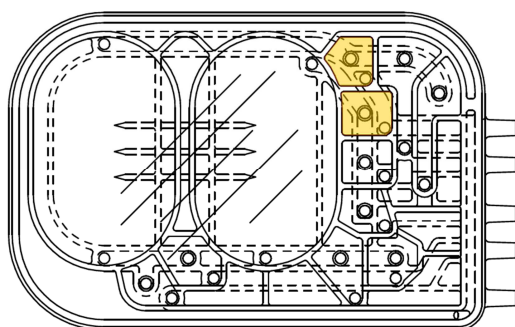


Figure 1: Picture of Patient Valve Region (highlighted yellow) of the Disposable Cassette.



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 your peritoneal cavity.

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 cyclor 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 (see Attachment). 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).

Further information and support

For general questions regarding this communication, contact your local Baxter Representative.

We apologise for any inconvenience this may cause you.

The HPRA has been informed about this notice.



Sincerely,

A handwritten signature in blue ink, reading "N. Farrelly", is enclosed in a light gray rectangular box.

Niamh Farrelly
CQA Team Lead
Baxter Healthcare
Unit 7 Deansgrange Business Park
Blackrock
Co. Dublin.

Attachment: Patient At-Home Guide - New Instructions for Use