Baxter

(SFDA Notification Letter)

Important Product Information

January 14th, 2016

Subject: Field Safety Notice – Important Product Information – Noisy HomeChoice

Product Name: HomeChoice/HomeChoice PRO Automated PD device

Product Codes: 5C8310, and R5C8320.

Lot numbers: All

Dear NCMDR Team,

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.

No auditory damage is expected from the level of noise generated by the HomeChoice, even in case of "Noisy device". The expected outcome for a noise issue is the notification to the clinician / technical service. If the noise is identified as undesirable, the HomeChoice will be swapped. In this case, an interruption in the therapy is unlikely as the unit continues to operate and remain capable of delivering therapy. For the patients who elect not to continue with therapy, a swap may result in a delay of therapy of less than 48 hours and mild overload and/or electrolyte imbalance may result. However, during HomeChoice training, patients are instructed to be able to perform manual therapy at home in case of device swap situation when the unit is not functional.

In conclusion, while this issue may temporarily impact the patient's quality of life (temporary discomfort), permanent injury is not expected. As worst case scenario, for the general population, missing therapies may result in mild fluid overloaded and/or electrolyte imbalance. This outcome is considered a Minor severity or Transient Adverse Health consequences.

Baxter AG
Müllerenstrasse 3, Volketswil
Postfach CH-8604, Switzerland

Baxter AG Scientific Office
PO Box 64332, Dubai, UAE
Tel +971.4.4298100

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Our records indicate that 01 customer (our distributor Arabian Healthcare Supply Co.) have received this product in Saudi Arabia.

Baxter Healthcare Corporation is planning to send an important product information communication to customers to inform them about the new labeling statement.

Should you have any questions, please contact Ziad Awadallah at +966 11 4343 714.

Yours Sincerely,

14th Jan. 2016

ZIAD AWADALLAH
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Attachment 1: Customer Letter

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Postfach CH-8604, Switzerland

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Attachment 1: Customer Letter

IMPORTANT PRODUCT INFORMATION

January DD, 2016 *(to be adapted locally)*

Dear Peritoneal Dialysis Provider, Peritoneal Dialysis Patient *(to be adapted locally),*

Affected Product *(to be adapted locally)*

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

Product Code	Description
5C4471	HomeChoice Automated PD Cycler, 115V
5C4471R	HomeChoice Automated PD Cycler, 115V, Serviced
5C8310	HomeChoice PRO Automated PD Cycler, 115V
5C8310R	HomeChoice PRO Automated PD Cycler, 115V, Serviced
5C4474	HomeChoice Automated PD Cycler, 230V
R5C8320	HomeChoice PRO Automated PD Cycler, 230V
T5C4441	HomeChoice (Yume) Automated PD Cycler, 100V
T5C8300	HomeChoice PRO (Yume Plus) Automated PD Cycler, 100V

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:

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Your peritoneal dialysis (PD) patients who receive product directly from Baxter also are receiving a letter with this information *(to be kept if communication done directly to patients),*

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Action to be taken by the user	Baxter is kindly asking that you take the following actions: 1. Please keep this letter with your Patient At-Home Guide. 2. Complete the enclosed customer reply form, and return it to Baxter by either faxing it to *(insert local contact information)* or scanning and e-mailing it to *(insert local contact information)* or sending it by post to *(insert local contact information),* 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. 3. 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. 4. 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 *(to be adapted locally)*	For general questions regarding this communication, contact Baxter at *(insert local contact information)*, between the hours of *(insert local information)*.

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

Sincerely,

Name *(to be adapted locally)*
Title *(to be adapted locally)*
Medical Products *(to be adapted locally)*
Baxter Healthcare Corporation *(to be adapted locally)*

Attachment 1: Customer Reply form

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CUSTOMER REPLY FORM

IMPORTANT PRODUCT INFORMATION LETTER DATED XXXXXX *(TO BE COMPLETED LOCALLY)*

HOMECHOICE/HOMECHOICE PRO AUTOMATED PD SYSTEM

Product code: _____ *(to be completed locally)*

Batch/Serial Number: _____ *(to be completed locally)*

Please complete and return one copy of this form per facility either by fax (Fax :_____) or by e-mail (_____) as confirmation that you have received this notification.

A fax cover sheet is not required.

(Can be adapted locally)

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/Home Patients. ***(to be adapted locally)***

Signature/Date: REQUIRED FIELD	_____