

## Urgent Field Safety Notice

14<sup>th</sup> June 2017

Dear Sir/Madam,

### Affected Product

Product Code	Description
5CGM01	CLARIA SHARESOURCE PLATFORM

### Problem Description

Over the weekend of May 27, 2017, a planned maintenance of the Sharesource application resulted in three unintended effects:

First, a revision of the Patient Consent was sent from Sharesource to Homechoice Claria cyclers, while there was no revision to the patient consent content. However, after Homechoice Claria power up and receipt of the revision, patient has to reconfirm for data sharing (the cycler initiates the workflow described in steps 1 through 3 of Section 7.3.2 of the Homechoice Claria Patient At-Home Guide (071972003B1) to confirm an update). The two steps in the sequence to confirm an updated patient consent are 1) confirm the patient name (e.g. Are You Mary Smith?), and 2) select choice of patient consent (e.g. Share: Clinic & Baxter See User Manual).

If the user presses STOP at the display to confirm the patient name (indicating the name displayed is not theirs), the remainder of the sequence is not executed. As a result, the Homechoice Claria cycler believes it has an unverified Patient Activation Code, while keeping the previous prescription. In this situation, the patient is asked to enter their Patient Activation Code after each power on, and the Clinic is unable to access the patient's treatment data.

Second, clinicians saw incorrect message "Not for Human Use" on the Sharesource website.

Finally, some reviewed treatment history was not visible; those treatments were no longer marked as "reviewed".

### Hazard Involved

There is no safety risk associated with those issues.

### Actions taken by Baxter to avoid reoccurrence of the issue

Actions have been taken to resolve issues encountered between HomeChoice Claria and Sharesource since the Sharesource maintenance on May 27, 2017:

- Internal communication was sent to Technical Support team for resolving technical requests or complaints associated to Patient Consent issue.

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- Sharesource team removed the incorrect “Not for human use” message from the web page on May 30, 2017.
- The reviewed treatment history was recovered and restored within the Sharesource database on June 2, 2017.

Baxter is committed to helping resolve the issues this has caused and is working to prevent such issues in future Sharesource outages.

**Action to be taken by the user**



If your patients are asked to enter their Patient Activation Code each day or have their data not transmitting to Sharesource, they may not have completed the patient consent confirmation process. Some of these patients have not connected their Homechoice Claria to Sharesource, and others have their Homechoice cyler in the state described above. For cyclers that have not yet connected to Sharesource since May 27, the patient will be prompted to submit their consent prior to treatment when the Claria first reconnects to Sharesource.

Baxter is contacting you to remind your patients to correctly confirm their consent option and to provide options to resolve issues for patients that have their Homechoice Claria in the undesired state described.

For patients being prompted for the Patient Activation code each day, one option can be performed by the operator (patient) of the Claria cyler, and the other may be performed at the clinic through Sharesource.

**1. Homechoice Claria Operator Work-Around – Reset Patient Activation Code**

You can assist the Claria cyler operator in recovering from this undesired state by walking them through the following steps to reset their Patient Activation Code. These steps are also documented in the Homechoice Claria Patient At Home Guide (071972003B1).

- 1) Power On the Device
- 2) At the ENTER ACTIVATION CODE, press STOP.
- 3) Upon seeing “PRESS GO TO START”, following Homechoice Claria Patient At Home Guide, Section 10.4 to RESET ACTIVATION CODE.
  - a. Press  until you see RESET ACTIVATION CODE
  - b. Press  to remove the current Patient Activation Code from the system’s memory.
- 4) Power cyler the Claria Off then On
- 5) The operator must follow the Homechoice Claria prompts to enter Activation Code. (reference Homechoice Claria APD System Patient At-Home Guide, section 7.3.1 to ENTER ACTIVATION CODE.)
- 6) The operator must follow the Homechoice Claria prompts to

confirm the configuration settings (reference Homechoice Claria APD System Patient At-Home Guide, section 7.3.2 to CONFIRM CONFIGURATION)

## **2. Clinic Work-Around – Edit and Save Patient’s Prescription**

Clinician can recover from the undesired state by following steps documented in the Sharesource Connectivity Platform User Guide for Use with the Homechoice Claria APD System (071973157A1) to edit the patient’s prescription. The Homechoice Claria operator (patient) will need to respond to prompts on their cycle after the edits in Sharesource. These instructions are also provided below.

Clinic User:

- 1) Log in to Sharesource as a Clinic user with Homechoice Claria Device Manager Role.
- 2) Navigate in Sharesource to Edit Patient Settings for the desired patient by following Section 7.7.2, Viewing or Editing Patient Settings, clicking on “Edit” option.
- 3) It is not necessary to make any changes to patient settings.
- 4) Review and Submit the Patient Settings with no modifications by following Section 7.7.2 Steps 5 through 8.  
Note: “Modified Date” and “Modified By” Columns will now display the current date and clinical user for Patient Settings.

Homechoice Claria Operator (At Home Patient):

- 5) After the update to Patient Settings have been submitted, power on the Homechoice Claria Device.
- 6) Patient will be prompted to ENTER ACTIVATION CODE. The operator must follow the Homechoice Claria prompts to enter Activation Code. (reference Homechoice Claria APD System Patient At-Home Guide, section 7.3.1 to ENTER ACTIVATION CODE.)
- 7) The operator must follow the Homechoice Claria prompts to confirm the configuration settings (reference Homechoice Claria APD System Patient At-Home Guide, section 7.3.2 to CONFIRM CONFIGURATION)

Patients that followed the steps outlined in the Homechoice Claria APD System Patient At-Home Guide to submit a consent option do not need to take any action.

Baxter is kindly asking you to take the following actions:

- 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. Returning the customer reply form promptly will

confirm your receipt of this notification and prevent you from receiving repeat notices.

**Further  
information  
and support**

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

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

The HPRA has been informed about this notice.

Yours Sincerely,



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Attachment 1: Customer Reply Form