Urgent Field Safety Notice

Sharesource Claria

FA Number: FAV-2025-007

Manufacturer: Baxter Healthcare SA (CH-MF-000026124)

Type of Action: Correction

September 2025

Dear Dialysis Provider,

Problem Description

Vantive has issued a Correction due to a software defect that was identified within the **Sharesource Claria** application. Specifically, if a clinical user attempted to update a patient's program (prescription settings) while using multiple internet browser windows simultaneously, the changes were <u>not</u> updated on that patient's **Homechoice Claria** APD cycler located with the patient. **Vantive has since remotely deployed a fix to prevent this issue from happening if multiple internet browser windows are used to update a patient's program.**

Due to the urgency of this issue, clinics whose patients' programs were identified as being impacted by this issue were already directly contacted by Vantive and were provided specific instructions on how to mitigate this issue. Please note that Vantive will continue to be in touch with you to provide further information for those specific patient accounts.

Affected Product

Product Code	Description	Software Version
5CGM01	Sharesource Claria	8.13.4

Hazard Involved

Performing therapy using an outdated prescription may result in a patient receiving more therapy or less therapy than intended. There have been no reports of adverse events or serious injuries related to this issue.

Action to be taken by the user

- 1. The **Sharesource Claria** software fix has been deployed. However, Vantive will continue to be in touch with you regarding the next steps to correct those specific patient programs.
- Complete the enclosed customer reply form and return it to Vantive by either scanning and e-mailing it or sending it by post. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

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Further information and support

For general questions regarding this communication or any product issue you are experiencing, please contact your Vantive sales representative.

The local Ministry of Health (MOH) has been notified of this action.

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

Vantive Health GmbH

Attachment 1: Vantive Customer Reply Form