Urgent Field Safety Notice

HOMECHOICE AUTOMATED PD SET WITH CASSETTE AND 4-PRONG LUERS
FAV-2026-007
Manufacturer: Baxter Healthcare SA (SRN: CH-MF-000026124)
Type of Action: Recall

June 26, 2026

Dear Peritoneal Dialysis Patient:

Vantive is issuing a Medical Device Recall for certain lots of HomeChoice Sets with 4-prong Cassettes listed below due to an issue associated with an increase of reports of alarms while using the HomeChoice cycler. The most frequent alarms, "Check Lines & Bags" and "Reload the Set 156", may occur and repeated alarms could prevent the HomeChoice system from initiating the therapy cycle.

Vantive has determined that this issue is caused only by specific cassettes from lots listed in the table below.

While Vantive is actively working on correcting this issue, you may continue to perform therapy using the HomeChoice Sets in your inventory by following the steps in the Actions to be Taken section.

Affected Product:

Product Code	Product Description	Lot Number
R5C4479	HOMECHOICE AUTOMATED PD SET WITH CASSETTE AND 4-PRONG LUERS	25L07T019

Hazard Involved

This issue could lead to a delay or interruption of therapy. In addition, it may potentially lead to touch contamination of the sterile fluid path due to failure of following aseptic technique as stipulated in the Patient Guide as a result of having to repeatedly change sets. Vantive has received one report of serious patient injury potentially related to this issue.

Actions to be Taken by Patients

Follow the steps below before setting up the cycler **for each therapy** to determine if the HomeChoice Set can be used.

1. Check if the HomeChoice set lot number is listed on the attached Affected Product Table. The lot number can be found on the product over-pouch. If the lot number **is NOT listed on the Affected Product Table**, continue to use the set for therapy.

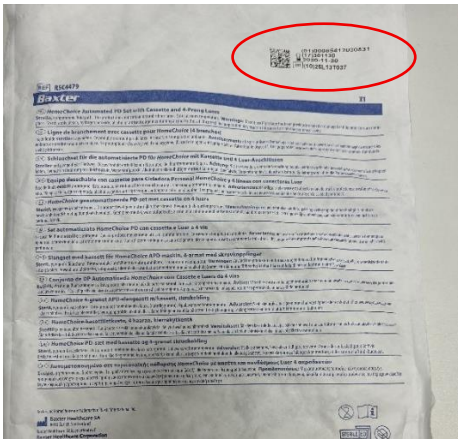

Fig 1: HomeChoice Set Over-pouch

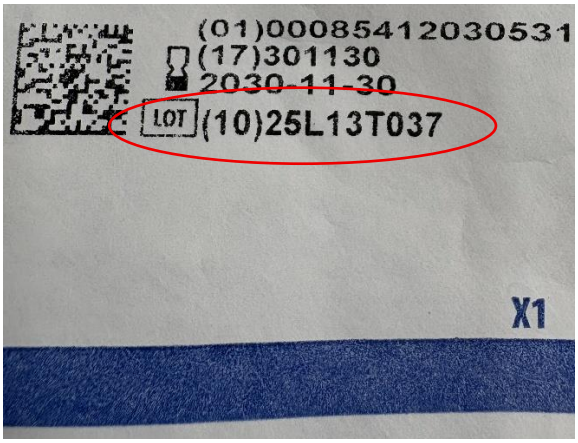

Fig 2: Lot number on Over-pouch

2. If the lot number **IS listed on the Affected Product Table**, open the set over-pouch. Hold the cassette against a dark background. Check if the cassette is stamped with M5, as shown in the images below, (see the red circle):

Fig 3: Set with cassette

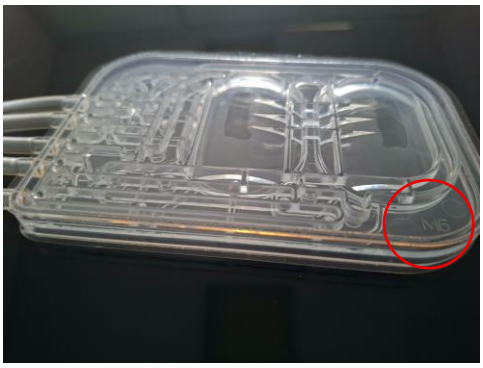

Fig 4: "M5" identifier on the cassette

Fig 5: Close up of M5 identifier

3. If the cassette is stamped with M5, please discard the HomeChoice set and obtain another one.
4. If the cassette is stamped with an identifier other than M5, continue to use the set for therapy.
5. If you received this communication directly from Vantive, please acknowledge receipt of this letter by completing Vantive Home Patient Reply Form. Returning the Home Patient 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, please contact Vantive Customer Care helpline 017-7229837 or your Vantive sales representative. Vantive Customer Care is available 24 hours a day, seven days a week.

The Medical Device Authority (MDA) has been notified of this action. Any product quality complaints or adverse events experienced with the use of these products may be reported via contacting Vantive Product Surveillance by navigating to the Product Feedback Portal at https://productfeedback.vantive.com.

We apologize for any inconvenience this may cause you and appreciate your attention to this matter.

Sincerely,

Electronically signed by: Wensze Sharon Ding
Reason: I have reviewed this document
Date: Jul 23, 2026 16:32:46 GMT+8

Sharon Ding
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Enclosures: Vantive Customer Reply Form