Urgent Field Safety Notice

Sharesource Adequest
FA Number: FAV-2025-006
Manufacturer: Baxter Healthcare SA (CH-MF-000026124)
Type of Action: Correction

XX July 2025 (to be adapted locally)

Dear Sir/Madam (to be adapted locally),

Problem Description

Sharesource Adequest is a web-based Peritoneal Dialysis (PD) kinetic modeling application that will calculate, report, and predict the adequacy of PD prescriptions for individual patients using both Continuous Ambulatory PD (CAPD) and Automated PD (APD).

Vantive has identified the following errors in Sharesource Adequest software version 2.10.1:
When the clinic's units are set to mmol/L, the value for Urine Creatinine that was input by the clinician on the 24 Hour Collection page was converted to 0 when proceeding to the review screen. No other input values were incorrectly converted.

The incorrect value for Urine Creatinine was used within Sharesource Adequest's calculations, which resulted in the following calculated values on the 24 Hour Collection report to be incorrect:

- Total Creatinine Clearance (CCL)
- Residual CCL
- Estimated Glomerular Filtration Rate (GFR)
- Creatinine Generation Rate

Furthermore, because regimens models are dependent upon the 24 Hour Collection results, any regimen models that were generated using the affected 24 Hour Collection record were also impacted. All predicted values in the regimen model could contain incorrect values due to this issue, but the largest difference would been seen in the following values:

- Regimen: Predicted Values Weekly – Dialysate CCL
- Residual Weekly – CCL
- Total – CCL

On June 7, 2025, Vantive deployed the fix as software version 2.10.2. While the fix will ensure any future Urine Creatinine values that are entered are correctly stored, any affected 24 Hour Collection records created during the period between defect introduction (31-May-2025) and defect fix deployment (07-Jun-2025) will continue

to contain the incorrect value for Urine Creatinine until the clinician corrects the record.
The incorrect calculated values on the 24 Hour Collection and Regimen Summary report that were caused by this defect (listed above) are primarily related to the patient's residual creatinine clearance. If the clinician didn't detect the erroneously changed value, they may have interpreted the data incorrectly to indicate that the patient has a lower creatinine clearance than they do.

Affected Product

Product Code	Description	Software Version	UDI
5CGM20	Sharesource Adequest	2.10.1	00085412547404

Hazard Involved

This issue could lead the clinician to adjust the patient's prescription by increasing the dialysis dose which could result in excessive therapy. Excessive therapy may cause the removal of more fluid and solutes than is necessary. There were no reports of serious injury associated with this issue.

Action to be taken by the user

Vantive is kindly asking that you take the following actions:

1. Customers may continue to safely use the Sharesource Adequest software. The software defect has been fixed and no new records will be impacted.

2. Please contact your Vantive clinical specialist (to be adapted locally) for assistance in identifying the patient records at your facility that need to be corrected.

3. Please correct the 24 Hour Collections for the affected patient records by following these steps:

    1. Check if any Regimens were created using a 24 Hour Collection from May 31, 2025 through June 7, 2025. If yes, manually record the regimen so you can create it again once the 24 Hour Collection has been fixed as Sharesource Adequest will delete any Regimens, including Preferred Regimens, if there are any changes to the associated 24-Hour collection used in modeling that Regimen.
    2. Locate the 24 Hour Collections to be fixed (any 24 Hour Collection created from May 31, 2025 through June 7, 2025) and click on the date of the 24 Hour Collection to amend.
    3. From the 24 Hour Collection details screen, scroll down to the "Lab Data" section and click the "Edit Lab Data" button.
    4. A reminder notification (any associated regimens with this 24 Hour Collection will be deleted) will pop-up, be sure you have completed Step 1 and click "OK" to continue

5. Scroll down to the “Urine” section, in the Creatinine (mmol/L) field, enter the correct value, Click “Review”, check your data entered and then Click “Calculate”. The 24 Hour Collection is now corrected and you can proceed with modeling regimens using this 24 Hour Collection.

4. Complete the enclosed customer reply form and return it to Vantive by either scanning and e-mailing it to (insert local contact information) or sending it by post to (insert local contact information). Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

Further information and support (to be adapted locally)	For general questions regarding this communication or any product issue you are experiencing, please contact your Vantive sales representative. (to be adapted locally)

The local Ministry of Health (MOH) has been notified of this action. (to be adapted locally)

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

Name (to be adapted locally)
Title (to be adapted locally)
Vantive Health GmbH (to be adapted locally)

Attachment 1: Vantive Customer Reply Form