

## Urgent Field Safety Notice

### AK 98

**FA Number:** FAV-2024-006 Follow Up

**Manufacturer:** Gambro Lundia AB (SRN SE-MF-000018119)

**Type of Action:** Correction

October 2025

Dear Dialysis Provider:

This communication is a follow-up to the attached Correction notification you received from Vantive, formerly Baxter. Vantive issued the previous communication to inform patients about potential safety risks related to exposure to non-dioxin-like (NDL) polychlorinated biphenyl acids (PCBAs) and NDL polychlorinated biphenyls (PCBs) when using certain peritoneal and hemodialysis devices. This initial notice was based on publicly available information at that time. At that time Vantive was in the process of evaluating whether these same risks are present with the AK 98 hemodialysis machines (“AK 98”).

**Vantive now has a Toxicological Risk Assessment (TRA) with respect to the actual relative risks associated with the use of any AK 98 machines containing peroxide-cured silicone tubing components. These test results currently demonstrate that the presence of the peroxide-cured silicone tubing components is unlikely to pose a risk for patients with a body weight greater than 25kg, irrespective of the run-time of the machine (note: 25kg is the minimum patient weight indicated for AK 98). Accordingly, Vantive has determined that no corrections are needed for all devices currently with customers, and patients may continue to perform therapy with the current configuration of AK 98.**

### Affected Product

Product Code	Product Description	Serial Numbers
115244	AK 98, 230V, EFFICIENT	All serials lower than AK078305
115248	AK 98, 230V, BIO	All serials lower than AK078305
115249	AK 98, 115V, BIO	All serials lower than AK078305
115250	AK 98, 230V, SELF-CARE	All serials lower than AK078305
955403	AK 98 V2 230V	All serials lower than AK078305
955404	AK 98 V2 230V, SELF-CARE	All serials lower than AK078305
955406	AK 98 V2 115V, BIO VERSION	All serials lower than AK078305

955603	AK 98V3 230V BIO VERSION	All serials lower than AK078305
955604	AK 98V3 230V SELF-CARE	All serials lower than AK078305
955989	AK 98 AK98 V3RU	All serials lower than AK078305

### Hazard Involved

Vantive’s latest test results demonstrate that the presence of the peroxide-cured silicone tubing components in AK 98 is unlikely to pose a risk for patients with a body weight greater than 25kg, irrespective of the run-time of the machine. To date, Vantive has not received any complaints determined to be related to this issue.

### Actions to be Taken by Customers

1. No further action is necessary; all AK 98 machines, regardless of run-time, may continue to be used and no corrections are required.
2. Complete the enclosed customer reply form and return it to Vantive by either scanning and e-mailing it or sending it by post 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.
1. If you purchased this product from a distributor, please note that responding with the Vantive customer reply form is not applicable. If a response is requested by your distributor or wholesaler, please respond to them according to their instructions.
2. If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication to them.
3. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please notify your customers of this notification in accordance with your customary procedures.

### Further Information and Support

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

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 US Healthcare LLC

Enclosures: Vantive Customer Reply Form  
Dialysis Provider letter 2024  
Home Patient Letter