

Urgent Field Safety Notice

AK 98, AK 96

FA Number: FAV-2024-010

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

Type of Action: Correction

XX January 2025 (to be adapted)

Dear Dialysis Provider: (to be adapted)

Baxter Healthcare Corporation (Baxter) is issuing a Correction for the AK 95, AK 96 and AK 98 dialysis machines (to be adapted) with the self-care configuration listed below due to the potential for hemolysis caused by the arterial dialyzer line kinking from the position of the remote panel arm.

These machines have a remote panel, which is a movable screen that can be maneuvered towards the patient allowing for control of the self-care dialysis settings. If the remote panel and dialyzer arm are both mounted on the same side of the machine, it is possible for the remote panel to be positioned on top of the arterial line coming from the blood pump and entering the dialyzer. The interaction between the remote panel arm and bloodline could potentially induce a kink of the blood tubing that, if not visually noticed by the patient or operator, could result in hemolysis in the patient during administration of therapy. Kinking of the arterial line between the blood pump and the dialyzer is not systematically detectable by the AK 95, AK 96 and AK 98 (to be adapted) machine.

Affected Product (to be adapted)

Product Code	Product Description	Serial Numbers
110656	AK 96, 230 V, SELF CARE	All serials
114742	AK 96, 230V, SELF CARE P4	All serials
115250	AK 98 230V SELF-CARE	All serials
955404	AK 98 V2 230V SELF-CARE	All serials
955604	AK 98V3 230V SELF-CARE	All serials

Hazard Involved

Kinking of the blood line could lead to hemolysis which may be associated with life-threatening complications. There have been three reports of serious injury related to this issue.

Actions to be Taken by Customers

1. Confirm whether the remote panel is mounted on the same side as the dialyzer holder. Refer to Figures 1 and 2 below for an example of a machine with the remote panel mounted on the same and opposite side of the dialyzer holder.



Figure 1. Remote panel mounted on the **opposite** side as the dialyzer holder



Figure 2. Remote panel mounted on the **same** side as the dialyzer holder

- If you or your patients have machines where the remote panel is mounted on the **opposite** side as the dialyzer holder, the machine can continue to be used normally while ensuring that the blood tubing is free from kinks per normal dialysis practice.
- If you or your patients have machines where the remote panel is mounted on the **same** side as the dialyzer holder:

Please contact Baxter Renal Customer Care to provide the serial number of your machine(s) and arrange for the remote panel to be mounted on the other side of the device. Baxter Renal Customer Care can be reached at 800-525-2623, option 2, option 2, between the hours of 7:00 am and 5:00 pm Central Time, Monday through Friday. You will be receiving this correction from Baxter at no charge. The machine can continue to be used normally while ensuring that the blood tubing is free from kinks per normal dialysis practice. (to be adapted)

Please contact your home patients and provide them with a copy of the Home Hemodialysis Patient letter. Ensure that your home patients understand the issue and are aware of what to look for to prevent this issue during therapy. (to be adapted)

2. To minimize the risk of damage to the patient's blood cells, dialysis providers should check and/or instruct their patients to check that there are no kinks in the blood lines prior to start-up of the machine, and if the remote panel arm is moved. The machine may not be able to detect all flow and pressure conditions, which in combination with narrowed passages in the blood circuit, may lead to damage of the blood cells. Please refer to Figures 3, 4 and 5 below for examples of how the arterial line should appear normally and how it may become kinked between the dialyzer inlet and the blood pump based on the position of the remote panel arm.



Figure 3. Normal bloodline with no kink



Figure 4. Bloodline kink by remote panel



Figure 5. Bloodline kink by remote panel arm

3. Complete the enclosed customer reply form and return it to Baxter by either scanning and e-mailing it to (insert local contact information) or sending it by post to (insert local contact information), 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.
4. If you purchased this product from a distributor, please note that responding via the Baxter customer portal is not applicable. If a response is requested by your distributor or wholesaler, please respond to the supplier according to their instructions. (to be adapted)



5. If you distributed this product to other facilities or departments within your institution, please forward copy of this communication to them.
6. 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 Correction in accordance with your customary procedures and check the associated box on the customer portal. [\(to be adapted\)](#)

Further Information and Support

For general questions regarding this communication or any product issue you are experiencing, contact Baxter at [\(insert local contact information\)](#), between the hours of [\(insert local information\)](#).

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 [\(to be adapted locally\)](#)

Baxter Healthcare Corporation [\(to be adapted locally\)](#)

Enclosures: Baxter Customer Reply Form [\(to be adapted\)](#)

Home Hemodialysis Patient Letter [\(to be adapted\)](#)