Baxter

MEDICAL DEVICE CORRECTION

September 27, 2018

Dear Healthcare Provider:

Problem Description

Baxter is communicating important safety information regarding the potential for AK 98 Hemodialysis Devices to generate excessive ultrafiltration (UF) in certain situations where treatment-related alarms occur, or where there is an ultrafilter leak. As discussed below, excessive UF may present hazards for sensitive patients, such as low-weight patients, for whom target UF values of zero or very low volumes are desired. **Due to the potential for excess fluid loss, when treating low-weight or other sensitive patients, weight loss should be monitored during treatment and the attached mitigating instructions should be followed (Refer to Attachment 1).**

Baxter is initiating a design improvement for all AK 98 devices to mitigate cases of excessive fluid loss in patients.

Excessive UF arising from Treatment-Related Alarms. Frequent arterial and venous pressure alarms and/or conductivity alarms, in combination with zero or low UF volume, may cause excessive removal of filtrate and lead to removal of extra fluid from the patient. The extra fluid loss is measured by the AK 98 device and displayed on the operator's screen.

Excessive UF arising from an Ultrafilter Leak. When there is an ultrafilter leak, the volume of fluid leaked represents the volume of the excessive UF being removed from the patient. This extra fluid loss is not displayed on the AK 98 operator's screen and is not accounted for by the device.

Affected Product (Singapore)

List of product code affected/ supplied in Singapore:

Product Code	Product family	Serial Numbers
955403	AK 98 V2 230V BIO VERSION	All
115248	AK 98, 230V, Bio	All

Affected Product (Globally)

Product Code	Product family	Serial Numbers
955406	AK 98 V2 115V BIO VERSION	All
955403	AK 98 V2 230V BIO VERSION	All
955404	AK 98 V2 230V SELF-CARE	All
955677	AK 98 V1 BIO CHINA ONLY 230V	All
115244	AK 98, 230V, Efficient	All
115248	AK 98, 230V, Bio	All
115249	AK 98, 115V, Bio	All
115250	AK 98, 230V, Self-Care	All
115251	AK 98 115V SELF-CARE	All

955106	2nd Hand AK 98 BIO	All
955407	AK 98 V2 115V, Bio Self-Care	All
955642	AK 98 (230V)	All
955643	AK 98 (115V Brazil)	All

Hazard Involved

Excessive ultrafiltration may lead to hypovolemia and subsequently hypotension, particularly in sensitive patients, such as low-weight patients. Depending on the amount of fluid removed, clinical symptoms may vary. There have been eight (8) reports of serious injury associated with this issue; all of which are related to patients with a low body weight.

Action to be Taken by Baxter

The AK 98 design will be improved to mitigate cases of excessive fluid loss in patients.

Actions to be Taken by Customers

1. When low-weight patients require use of the AK 98 device, frequently **supervise the patient's weight loss during treatments, and take the additional precautions described in Attachment 1.**

2. Baxter will improve the design of all AK 98 devices. Once the design upgrade is available, a local Baxter service representative will contact your facility to schedule the design upgrade.

3. If you are a dealer, wholesaler, or distributor/reseller that distributed any product to other facilities, please notify your customers of this device correction in accordance with your customary procedures.

4. Complete the enclosed customer reply form and return it to Baxter by scanning and e-mailing it to our sales representative. Returning the customer reply form promptly will prevent you from receiving repeat notices.

The Health Sciences Authority has been notified of this action. If you have questions regarding this communication or if you have any other questions, please call your Baxter Sales Representative or e-mail to Martin at [redacted].

Please kindly report any quality problems or any adverse events associated with the product to the following personnel:

- Please report Product Complaints to singapore_productcomplaint@baxter.com
- Please report Adverse Events to singapore_patientsafety@baxter.com

We sincerely apologize for any inconvenience this communication causes and thank you for your continued support. This field action will take additional measures to further ensure patient safety.

Sincerely,

[redacted]
Corynn Tan
Senior Manager, QA

Enclosure: Baxter Customer Reply Form,
Attachment 1: Precautions
cc Chairman Medical Board and Relevant Head of Departments

Attachment 1: Precautions

Treatment-Related Alarms	
Precautions during therapy set-up:	• Change the preset UF supervisory limit 2-28-0 to +/- 200 ml. • Do not prescribe/use dialysis fluid flows less than 500 ml/min. A lower dialysis fluid flow will only marginally affect the clearance when using smaller dialyzers like the Polyflux 2H or 6H dialyzers.
Other instructions during treatment:	• Supervise patient weight loss during treatment • Check the accumulated UF volume in the UF menu as there it is displayed with two decimals. • Avoid arterial and venous pressure alarms and/or conductivity alarms as much as possible and consider increasing the pressure windows. Alarms cause the device to pause, resulting in a temporary increase in pressure on the blood side of the filter and the movement of small volumes of filtrate to the fluid side. • Keep the concentrate connections clean and free from salt crystals. • When performing Single Needle therapy, decrease the venous pressure switching points to minimize the UF due to the high venous pressure.

Ultrafilter Leak	
General Precautions:	• Supervise patient weight loss during treatment • Add a check in the patient treatment record sheet to make sure the leakage detector tray is dry throughout therapy. • Do not exceed eight “CleanCart A” disinfections during a U 9000 ultrafilter lifetime.
Prior to connecting low-weight patient	• V2: Check that there is no fluid in the leakage detector tray. • V1: Check that there is no fluid beneath the ultrafilter. • If there is fluid, replace the ultrafilter. Ensure it is securely placed in the holder and perform a disinfection before using the machine. • After the disinfection, ensure the leakage detector tray (in V2 device)/area beneath the ultrafilter (in V1 device) is still dry.
In case of a fluid leakage alarm (V2) *or* fluid beneath the ultrafilter (V1)	• Discontinue the treatment immediately • Replace the ultrafilter and make sure it is securely placed in the holder • Perform a disinfection before using the machine again • *Note: Device alarm is not applicable to AK 98 V1 devices*

CUSTOMER REPLY FORM

Device Correction for AK 98

September 27, 2018

Affected Products:

Product Code	Product family	Serial Number
115248	AK 98, 230V, Bio	All
955403	AK 98 V2 230V BIO VERSION	All

Please complete and sign this form.
Email a scanned copy to [redacted] or fax it to **+65-6222 9927** as a confirmation that you have received this notification. A cover sheet is not required.

Please ensure that all below information is completed. Responding to this request will prevent unnecessary repeat notifications for this issue.

Please note that ***BAXTER CANNOT PROCESS UNSIGNED FORMS.***

Completed By: _____ **Title:** _____
Print Name

Phone Number: _____

Signature: _____ **Date:** _____/_____/_____

Your signature above indicates understanding of the contents of the attached letter, that you performed the actions outlined and disseminated this information, if applicable.