Baxter

Urgent Field Safety Notice

17th September 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 (An indication of a low-weight patient is a patient **under 25 kg**), 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

Product Code	Product family	Serial Numbers
115248	AK 98, 230V, Bio	All
955403	AK 98 V2 230V BIO VERSION	All
955404	AK 98 V2 230V SELF-CARE	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.

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. Complete the enclosed customer reply form, and return it to Baxter by either faxing it to 01 206 5577 or scanning and e-mailing it to QA_Dublin@baxter.com

or sending it by post to Quality Department, Baxter Healthcare, Unit 7 Deansgrange Business Park, Blackrock, Dublin. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

4. If you have patients using the affected product in the home setting that may be impacted by this communication, please contact them regarding the information contained in this communication.

5. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

Further information and support

For general questions regarding this communication, contact your local Baxter Representative.

We apologise for any inconvenience this may cause you and your staff. Baxter is committed to ensuring our products and services consistently meet the highest standards of quality and safety for our patients and healthcare providers.

The HPRA has been informed about this action.

Sincerely,

Niamh Farrelly
CQA Manager
Baxter Healthcare
Unit 7 Deansgrange Business Park
Blackrock
Co. Dublin

Enclosure: Baxter Customer Reply Form
Attachment 1: Precautions