Baxter

Urgent Field Safety Notice

28th October 2016

Dear Customer,

Problem Description

Baxter Healthcare Corporation is issuing a voluntary Urgent Device Correction for AK 98 dialysis machines due to two software issues.

I. The machine could become stuck in a fluid by-pass state if the operator confirms the air detector alarm during priming. In a fluid bypass state, the fluid path bypasses the dialyzer and no Ultrafiltration (UF) or diffusion occurs, leading to an absence of treatment.
II. The Ultrafiltration Supervision (UFS) may be put in an idle (non-functional) state, if the functional check of the blood module is delayed and is completed after the functional check of the fluid module.

Affected Product

Product Code	Product Description	Software Version	Serial Number
115248	AK 98, 230V Bio	SW 1.1.0 and earlier versions	10644

Hazard Involved

I. When the machine gets stuck in a bypass state, this could result in a patient not being able to have the prescribed therapy.

II. When the UFS is in a nonfunctional state, the machine may not be able to detect deviations in ultrafiltration during treatment. This could lead to hypovolemia or hypervolemia.

There have been no reports of injury associated with these issues.

Actions taken by Baxter to avoid reoccurrence of the issue

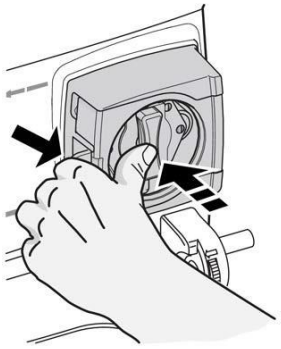
Baxter has developed a new software version for the AK 98 dialysis machine that addresses the two issues described above. This upgraded software will be released on October 31, 2016. Until your software is updated, please follow the instructions detailed below.

A Baxter Service Representative will contact you to arrange the upgrade of your software version once the update to the software is released.

Additional Information to the Operator of the AK 98 device

To ensure the machine does not get stuck in a bypass state or have the UFS in a nonfunctional state, please follow below instructions:

1. Make sure that the blood pump door is closed during the Function Check i.e. before “Green Fluid Path” is reached



2. Wait to put on the blood lines and the dialyzer on the machine until the machine has reached Green Fluid Path.

Action to be taken by the user

Baxter is kindly asking to take the following actions:

1. 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 Ltd., 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.

2. Please forward a copy of this letter as appropriate to ensure that all users are aware of this communication.

3. If you are a dealer, wholesaler, or distributor/reseller distributing this product to other facilities, please notify your customers of this communication in accordance with your procedures.

Further information and

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

support

We apologise for any inconvenience this may cause you and your staff.

The HPRA has been informed about this action.

Sincerely,

Ian Gavigan
Head of CQA UK/Ireland
Baxter Healthcare Ltd.
Deansgrange Business Park
Blackrock
Co. Dublin
Ph: 01 2065500

Attachment: Customer Reply Form

Baxter

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DEVICE CORRECTION LETTER DATED 28TH OCTOBER 2016

Product name: **AK 98**

Models: AK 98, 230V, Bio

Product codes: 115248

Please complete and return one copy of this form per facility either by fax 01 206 5577 or by e-mail QA_Dublin@baxter.com as confirmation that you have received this notification.

A fax cover sheet is not required.

Customer Confirmation

We confirm that that we have have received the above mentioned letter and have disseminated this information to our staff, other services and facilities.

We confirm that we have received the above mentioned letter and have disseminated this information to customers/Home Patients.

Facility Name and Address: *(Please Print)*	
Product code and Serial Number of Machine	
Reply Confirmation Completed By: *(Please Print Name)*	
Title: *(Please Print)*	
Email and/or Telephone Number (Including Area Code):	
Signature/Date: ***REQUIRED FIELD***	_____/____/_____