

URGENT DEVICE CORRECTION

November 22, 2016

Dear Dialysis Provider / Home Patient:

Problem Description Baxter Healthcare Corporation is issuing a voluntary Urgent Device Correction for AK98 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 (non-functional) idle state, if the functional check of the blood module is delayed and is completed after the functional check of the fluid module.

The software version for the AK98 dialysis machine will be updated and the new software will be released on October 31, 2016 to address these issues. Until your software is updated, please follow the instructions detailed below.

Affected Product

Product Code	Product Description	Software Version	Serials
115244	AK 98, 230V, Efficient	SW 1.1.0 and earlier versions	All
115248	AK 98, 230V Bio	SW 1.1.0 and earlier versions	All
115249	AK 98, 115V, Bio	SW 1.1.0 and earlier versions	All
115250	AK 98, 230V, Self-Care	SW 1.1.0 and earlier versions	All
115251	AK 98, 115V, Self-Care	SW 1.1.0 and earlier versions	All
955403	AK 98, 230V Bio, v2	SW 2.0.0	All

Note: *There is no impacted machine with the software version mentioned supply to Singapore market.*

Hazard Involved

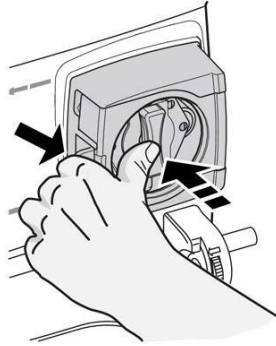
- I. When the machine gets stuck in a bypass state, this could result in a patient not being able to have prescribed therapy.
- II. When the UFS is in a nonfunctional state, the machine may not be able to detect deviations in ultrafiltration during treatment. This could lead to hypovolemia or hypervolemia.

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

**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.



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

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

Sincerely,

Amy McKernan
Director, Quality
Baxter Healthcare Corporation

Enclosure: Baxter Customer Reply Form

Cc: Director of Nursing