

DEVICE CORRECTION

March XX, 2018

Dear Hemodialysis Patient:

**Problem
Description**

Baxter Healthcare Corporation is issuing a Device Correction for the Ultrafilter U9000 lot numbers listed below due to leaks during regular clinical use. The leaks are caused by cracks near the header cap due to the stress of repeated disinfection cycles over the lifetime of the product. The current Instructions For Use (IFU) state the Ultrafilter has a maximum lifetime usage of 90 days, or 150 heat disinfection cycles, with a maximum of 8 sodium carbonate and 12 sodium hypochlorite disinfection cycles. In order to reduce the patient risk associated with the occurrence of leaks, the IFU will be updated to reduce the maximum lifetime usage to 60 days, or 100 heat disinfection cycles, with a maximum of 8 sodium carbonate and 12 sodium hypochlorite disinfection cycles when the Ultrafilter is used in conjunction with AK96 and AK98 v1 dialysis machines. The maximum lifetime usage instructions will remain unchanged for Ultrafilter use in conjunction with AK 98 v2 and Artis/Evosys machines, as they have a leak detection sensor in place.

**Affected
Product
(Singapore)**

Product Code	Product Description	Lot Number	Expiration Dates
114604	Ultrafilter U9000 APAC	6-1801-H-01 and higher	All non-expired product

**Affected
Product
(Globally)**

List of product codes affected globally:

Product Code	Product Description	Lot Number	Expiration Dates
112062	Ultrafilter U9000	6-1907-H-01 and higher	All non-expired product
114604	Ultrafilter U9000 APAC	6-1801-H-01 and higher	All non-expired product

**Hazard
Involved**

An undetected leaking Ultrafilter U9000 could lead to excessive fluid removal during dialysis and subsequently, hypovolemia. Depending on the amount of fluid removed, the patient may experience serious adverse health consequences. The AK98 v2 and Artis machines have a leak detector sensor that will trigger an alarm as a result of a leaking Ultrafilter. Therefore, the occurrence of excess fluid removal in patients using these machines is unlikely. **Baxter has not received any reports of complaint or adverse events or patient injury associated with this issue from the impacted lots in Singapore.**

**Actions to be
Taken by
Customers**

1. Patients may continue to safely use affected units with AK96 and AK98 v1 dialysis machines according to the new maximum lifetime usage criteria of 60 days, or 100 heat disinfection cycles, with a maximum of 8 sodium carbonate and 12 sodium hypochlorite disinfection cycles. If Ultrafilters currently in use with

AK96 and AK98 v1 machines have exceeded any of the new maximum lifetime usage criteria, it is recommended the filter be changed.

2. Baxter will reset the AK 96 & AK 98 v1 monitor counters to the reduced maximum usage during the next scheduled preventive maintenance.
3. Complete the enclosed Baxter customer reply form and return it to Baxter by scanning and e-mailing it to our sales representative or Lily Yip at lily_yip@baxter.com. Returning the Baxter 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 Lily Yip at lily_yip@baxter.com.

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,

Corynn Tan
Senior Manager, QA

cc: Chairman Medical Board and relevant Head of Departments

Enclosure: Baxter Customer Reply Form

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March XX, 2018

Dear Healthcare Provider:

**Problem
Description**

Baxter Healthcare Corporation is issuing a Device Correction for the Ultrafilter U9000 lot numbers listed below due to leaks during regular clinical use. The leaks are caused by cracks near the header cap due to the stress of repeated disinfection cycles over the lifetime of the product. The current Instructions For Use (IFU) state the Ultrafilter has a maximum lifetime usage of 90 days, or 150 heat disinfection cycles, with a maximum of 8 sodium carbonate and 12 sodium hypochlorite disinfection cycles. In order to reduce the patient risk associated with the occurrence of leaks, the IFU will be updated to reduce the maximum lifetime usage to 60 days, or 100 heat disinfection cycles, with a maximum of 8 sodium carbonate and 12 sodium hypochlorite disinfection cycles when the Ultrafilter is used in conjunction with AK96 and AK98 v1 dialysis machines. The maximum lifetime usage instructions will remain unchanged for Ultrafilter use in conjunction with AK 98 v2 and Artis/Evosys machines, as they have a leak detection sensor in place.

**Affected
Product
(Singapore)**

List of product code affected/ supplied in Singapore:

Product Code	Product Description	Lot Number	Expiration Dates
114604	Ultrafilter U9000 APAC	6-1801-H-01 and higher	All non-expired product

**Affected
Product
(Globally)**

List of product codes affected globally:

Product Code	Product Description	Lot Number	Expiration Dates
112062	Ultrafilter U9000	6-1907-H-01 and higher	All non-expired product
114604	Ultrafilter U9000 APAC	6-1801-H-01 and higher	All non-expired product

**Hazard
Involved**

A leaking Ultrafilter U9000 could lead to excessive fluid removal during dialysis and subsequently, hypovolemia. Depending on the amount of fluid removed, the patient may experience serious adverse health consequences. The AK98 v2 and Artis machines have a leak detector sensor that will trigger an alarm as a result of a leaking Ultrafilter. Therefore, the occurrence of excess fluid removal in patients using these machines is unlikely. **Baxter has not received any reports of complaint or adverse events or patient injury associated with this issue from the impacted lots in Singapore.**

**Actions to be
Taken by
Customers**

1. Operators may continue to safely use affected units with AK96 and AK98 v1 dialysis machines according to the new maximum lifetime usage criteria of 60 days, or 100 heat disinfection cycles, with a maximum of 8 sodium carbonate and 12 sodium hypochlorite disinfection cycles. If Ultrafilters currently in use with AK96 and AK98 v1 machines have exceeded any of the new maximum lifetime usage criteria, it is recommended the filter be changed.

2. Baxter will reset the AK 96 & AK 98 v1 monitor counters to the reduced maximum usage during the next scheduled preventive maintenance.
3. If you purchased this product directly from Baxter or distributor (DKSH), complete the enclosed Baxter customer reply form and return it to Baxter by scanning and e-mailing it to our sales representative, **even if you do not have any inventory**. Returning the Baxter customer reply form promptly will prevent you from receiving repeat notices.
4. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

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 Lily Yip at lily_yip@baxter.com.

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,

Corynn Tan
Senior Manager, QA

cc: Chairman Medical Board and relevant Head of Departments

Enclosure: Baxter Customer Reply Form