Safety Communication

Urgent Device Correction of Hemodialysis Ultrafilter U9000 Manufactured by Baxter

Device/ Product Name:	Hemodialysis Ultrafilter U9000
Lot numbers/Serials:	Product Codes: 112062 Lot numbers: 6-1907-H-01 and higher
Manufacturer:	Baxter (Also known as **Gambro**)
Problem:	Saudi FDA would like to bring to your attention that Baxter Healthcare Corporation is issuing an Urgent Device Correction for the Ultrafilter U9000 lot number(s) listed above due to leaks during regular clinical use in conjunction with Artis/Evosys, AK98, and AK96 dialysis machines.
Recommendation/Actions:	1. If you have the affected devices mentioned above and haven't been contacted yet from the distributor, you should contact the Authorized representative listed below for corrective action. 2. Operators may continue to safely use affected units 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. 3. Baxter will reset the AK 96 & AK 98 vl monitor counters to the reduced maximum usage during the next scheduled preventive maintenance. No further action is needed for AK 98 v2 and Artis machines, as they have a leak detection sensor in place.

	4. Make sure to read and follow the instructions mention in the device correction letter. (Attached)
Devices/Products photo:	

Authorized Representative Details	**Company name:**	**Baxter AG**
	Contact Person:	**Ziad Awadallah**
	Phone:	**+966 557640902**
	Email:	ziad_awadallah@baxter.com

For further information, please **see the notification letter below or Click Here.**

Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.
Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)
North Ring Road - Al Nafal Unit (1)
Riyadh 13312 - 6288
Tel: +966 (11) 2038222 Ext: 2406, 2412
Fax: +966 (11) 2757245

For latest published Recalls/Alerts, please visit (NCMDR Website)

Sincerely,
NCMDR Team

Baxter

(SFDA Notification letter)

07th March, 2018

Subject: Field Safety Notice – Device Correction – Ultrafilter U9000 – External leakage

Product Name: U9000

Product Codes: 112062

Lot numbers: 6-1907-H-01 and higher

Dear NCMDR Team,

Baxter Healthcare Corporation is issuing an Urgent Device Correction for the Ultrafilter U9000 lot number(s) listed above due to leaks during regular clinical use in conjunction with Artis/Evosys, AK98, and AK96 dialysis machines. 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) states 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 occurrence of leaks, the IFU is being 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.

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. Baxter has received two (2) reports of serious injuries associated with this issue.

Baxter will reset the AK 96 & AK 98 v1 monitor counters to the reduced maximum usage during the next scheduled preventive maintenance. No further action is needed for AK 98 v2 and Artis machines, as they have a leak detection sensor in place.

Operators may continue to safely use affected units 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.

شركة باكستر أيه جي. المكتب العلمي س.ت: ١٠١٠٢٠٦٥٦٦ هاتف ٤٣٤٣٧٠٠ (٩٦٦١١)، فاكس٤٣٤٣٧٧٧ (٩٦٦١١)
ص.ب٢٤٦٩٦٨ الرياض١١٣١٢- المملكة العربية السعودية
Baxter AG Scientific (Rep) Office, C.R. 1010206566 Tel: 966 11 434 3700 Fax: 966 11 434 3777
P.O.Box 246968 Riyadh 11312, Saudi Arabia

Baxter

Our records indicate that 02 customers (Our distributors Arabian Medical Marketing Co. (Nawah Healthcare) and Med-Surg Supplies) have received this product in Saudi Arabia. For your information, please find attached the communication that is being sent to the customers.

Should you have any questions, please contact Ziad Awadallah at +966 11 4343 714.

[redacted]

ZIAD AWADALLAH
Senior CQA Officer Gulf, Baxter AG.
P.O. Box 246968 Riyadh 11312 Saudi Arabia
Phone : +966 11 4343 714/ Fax : +966 11 4343 777
E-mail : ziad_awadallah@baxter.com

Attachment 1: Draft Customer Letter (FA-2018-006).

Baxter

URGENT DEVICE CORRECTION

March XX, 2018 (to be adapted locally)

Dear Healthcare Provider (to be adapted locally):

Problem Description

Baxter Healthcare Corporation is issuing an Urgent Device Correction for the Ultrafilter U9000 lot numbers listed below due to leaks during regular clinical use in conjunction with Artis/Evosys, AK98, and AK96 dialysis machines. 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) states 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 occurrence of leaks, the IFU is being 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.

Affected Product

Product Code	Product Description	Lot Number	Expiration Dates
112062	Ultrafilter U9000	6-1907-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. Baxter has received two (2) reports of serious injuries associated with this issue.

Actions to be Taken by Customers

1. Operators may continue to safely use affected units 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.
2. Baxter will reset the AK 96 & AK 98 v1 monitor counters to the reduced maximum usage during the next scheduled preventive maintenance. No further action is needed for AK 98 v2 and Artis machines, as they have a leak detection sensor in place.
3. If you purchased this product directly from Baxter, complete the enclosed Baxter customer reply form and return it to Baxter by faxing it to *(insert local contact information)* or scanning and e-mailing it to *(insert local contact information)* or sending it by post to *(insert local contact information)*, **even if you do not have any inventory**. Returning the Baxter customer reply form promptly will prevent you from receiving repeat notices.

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4. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
5. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please notify your customers of this Urgent Medical Device Correction in accordance with your customary procedures.

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

Sincerely,

Name *(to be adapted locally)*
Title *(to be adapted locally)*
Medical Products *(to be adapted locally)*
Baxter Healthcare Corporation *(to be adapted locally)*

Baxter

Confirmation of receipt of communication

(DEVICE CORRECTION LETTER DATED XX (TO BE COMPLETED LOCALLY)

Ultrafilter U9000
Product code : 112062
Serial numbers : 6-1907-H-01 and higher

Please complete and return one copy of this form per facility either by fax (Fax :_____) or by e-mail (_____) as confirmation that you have received this notification.

A fax cover sheet is not required.

Facility Name and Address:	
Reply Confirmation Completed By: *(Please print name)*	
Title: *(Please print)*	
Email and/or Telephone Number (including Area Code):	

Signature/Date: REQUIRED FIELD	_____

We have received the above-mentioned letter, performed the actions outlined in the letter, and have disseminated the information / documentation to our staff, other services/facilities and customers, as applicable.