Baxter

(SFDA Notification letter – FA-2016-058)

URGENT DEVICE CORRECTION

December 13th, 2016

At the kind attention of: National Center for Medical Device reporting
Medical Devices Sector - SFDA
Kingdom of Saudi Arabia
Tel.: (+966) (1) 2759222
Fax: (+966)(1)2757245
E-mail: ncmdr.md@sfda.gov.sa

Subject: Field Safety Notice – Urgent Device correction

Central Water Plant – Insufficient crimping of main pump causing overheated cables

Product Name: Central Water Plant (CWP) Reverse Osmosis Units

Product Codes: 106278, 102695, 100340, 100976, 100975, 103310, 100474 and 102036.

Serial Numbers: As per attached list.

Dear NCMDR Team,

Baxter AG is issuing a device correction for specific models of the Central Water Plant (CWP) Reverse Osmosis Units in order to correct the insufficient crimping of the cables within the main pump. The issue was identified as a result of one customer complaint received for the presence of smoke in the water treatment room due to the overheating of the pump in the CWP. As part of Baxter's investigation, based on pictures provided from the event, the most likely cause of the thermal event was due to the crimp of the cables for the main pump being insufficient. The affected units were distributed between May 01st , 2007 and November 30th , 2016.

The CWP device is designed to be used as a dialysis accessory device to obtain purified water by using reverse osmosis as the purification method. Potential hazards and harms arising from this issue are inhalation of smoke, interruption/delay of therapy/no therapy, and burn injury. There have been no reports of injury associated with these issues.

Baxter is organizing the replacement of the Central Water Plant pump components that are impacted by the issue described here-above. Meanwhile, Baxter is asking its Customers to ensure that all panels of the CWP are in place in order to minimize any potential side effects of thermal events.

Our records indicate that 01 customer (Our distributor Arabian Medical Marketing Co. (Nawah Healthcare)) has 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.

Yours Sincerely,

[redacted]

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-2016-058).

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Attachment 1: Draft Customer Letter

URGENT DEVICE CORRECTION

November DD, 2016 *(to be adapted locally)*

Dear Dialysis Provider: *(to be adapted locally),*

Problem Description

Baxter Healthcare Corporation *(to be adapted locally)* is issuing a device correction for specific models of the Central Water Plant (CWP) Reverse Osmosis Units in order to correct the insufficient crimping of the cables within the main pump. The issue was identified as a result of one customer complaint received for the presence of smoke in the water treatment room due to the overheating of the pump in the CWP. As part of Baxter's investigation, based on pictures provided from the event, the most likely cause of the thermal event was due to the crimp of the cables for the main pump being insufficient. The affected units were distributed between *Month Day, Year and Month Day, Year*. *(To be adapted locally)*

Affected Product *(to be adapted locally)*

Product family	Product Code	Product model	Serial Numbers
CWP 100	Refer to Attachment 2		
CWP 60			

Hazard Involved

The CWP device is designed to be used as a dialysis accessory device to obtain purified water by using reverse osmosis as the purification method. Potential hazards and harms arising from this issue are inhalation of smoke, interruption/delay of therapy/no therapy, and burn injury. There have been no reports of injury associated with these issues.

Action to be taken by the Customer/User

Baxter is kindly asking to take the following actions:

1. Contact your local Baxter Service representative to arrange for replacement of the affected component. The Baxter service representative will work with your facility to determine the replacement plan and schedule the replacement for your facility. Meanwhile, Baxter is asking you to ensure that all panels of the CWP are in place in order to minimize any potential side effects of thermal events.

2. Complete the enclosed customer reply form, and return it to Baxter by either 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)*. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

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

4. 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 support *(to be adapted locally)*

For general questions regarding this communication, contact Baxter at *(insert local contact information)*, between the hours of *(insert local information)*.

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

The Local MOH *(to be adapted locally)* has been informed about this action. *(To be removed if not applicable)*

Sincerely,

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

Attachment 1: Customer Reply Form
Attachment 2: Table of Affected Machines

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Attachment 1: Customer Reply Form
URGENT DEVICE CORRECTION LETTER DATED *XX (TO BE COMPLETED LOCALLY)*

Product name: Central Water Plant (CWP) Reverse Osmosis Units

Models: 100 and 60 series models *(To be adapted locally)*

Product codes: *(To be adapted locally)*

Please complete and return one copy of this form per facility either by fax (_____) or by e-mail (_____) as confirmation that you have received this notification. A fax cover sheet is not required. ***(Can be adapted locally)***

Customer Confirmation

☐ We confirm that that we have have received the above mentioned letter, understood its content, performed actions outlines, and have disseminated this information to our staff, other services and facilities.

☐ We confirm that we have received the above mentioned letter, understood its content, performed actions outlines and have disseminated this information to our Customers ***(To be adapted locally - for Distributor)***

<table>
<tr><td>Facility Name and Address:
(Please Print)</td><td></td></tr>
<tr><td>Product code, Serial Number and Distribution Date of Machine(s) – Refer to a signed attachment if too many machines have to be listed.</td><td>
<table>
<tr><th>Product Code</th><th>Serial Number(s)</th><th>Distribution Date</th></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Reply Confirmation Completed By:
(Please Print Name and Title)</td><td>Print Name:_____

Title: _____</td></tr>
<tr><td>Email and/or Telephone Number (Including Area Code):</td><td></td></tr>
<tr><td>Signature/Date:
REQUIRED FIELD</td><td>_____/____/_____</td></tr>
</table>

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Attachment 2: Table of Affected Machines

Product Code	Product Family	Product Name	Serial Numbers
100340	CWP 100	CWP, WRO103H 208V 60Hz	1000425, 1000608, 1000755, 1000756
100474	CWP 100	CWP, WRO104H 208V 60Hz	1000778, 1000779, 1000797, 1000798, 1000804, 1000860, 1000863, 1000867, 1000868, 1000833, 1000861, 1000873, 1000874, 1000882, 1000883, 1000834, 1000862
100975	CWP 100	CWP, WRO101H 208V 60Hz	1000707
100976	CWP 100	CWP, WRO103S 208V 60Hz	1000609, 1000759, 1000760
102036	CWP 100	CWP, WRO104S 208V 60Hz	1000780, 1000781, 1000799, 1000800, 1000805, 1000869, 1000870, 1000871, 1000872, 1000835, 1000836, 1000886, 1000887, 1000888, 1000889, 1000884, 1000885
102695	CWP 60	CWP, WRO62 3X220V 60Hz	4017
103310	CWP 100	CWP, WRO101S 208V 60Hz	1000708
106278	CWP 100	CWP, WRO103H(P) 3x220V 60Hz	4015, 4016