Baxter

MEDICAL DEVICE CORRECTION

November 29, 2018

Dear Dialysis Provider:

Problem Description

Baxter Healthcare will be implementing design improvements in the CWP 800 (Central Water Plant) systems and Clinic Panels in order to make them compliant with the International Electrotechnical Commission (IEC) standards. The affected units were distributed between Jan 2018 and Mar 2018.

Affected Product

Product Code	Product Name	Serial Number
115642	CWP 800 RO2 220-240V/ 380-415V 50Hz	[redacted]
115645	CWP 800 HW 220-240V/ 380-415V 50Hz	[redacted]

Do note: There are other identifiers and/or lots affected globally but not supply in Singapore. Kindly verify with Baxter if in doubt.

Hazard Involved

This issue does not have the potential to lead to adverse health consequences and there have been no associated adverse events reported.

Actions to be Taken by Customers

1. Operators may continue to safely use CWP 800 systems per the instructions in the Operator's Manual until the devices are corrected.
2. A local Baxter service representative will contact your facility to determine the correction plan and timeline for the devices at your site. Your facility will be receiving these corrections from Baxter at no charge.
3. Kindly complete the enclosed Baxter Customer Reply Form and return it to Baxter by e-mailing it to Baxter Representative. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.
4. If other facilities or departments within your institution utilize this product, please forward a copy of this communication to them.

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The Health Sciences Authority (HSA) 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.

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,

[redacted]

Corynn Tan
Senior Manager, QA

Enclosure: Customer Reply Form
cc Chairman Medical Board and Relevant Head of Departments

CUSTOMER REPLY FORM

Medical Device Correction

Central Water Plant 800 (CWP) Reverse Osmosis Units and Clinic Panels

November 29, 2018

FA-2018-053

Product Code	Product Name	Serial Number
115642	CWP 800 RO2 220-240V/ 380-415V 50Hz	[redacted]
115645	CWP 800 HW 220-240V/ 380-415V 50Hz	[redacted]

Please complete and sign this form.
Email a scanned copy to [redacted] as a confirmation that you have received this notification. A cover sheet is not required.

Please complete this reply form even if there is no remaining inventory at your facility. Ensure that all fields below are completed. Responding to this request will prevent unnecessary repeat notifications for this issue.

Please note that ***BAXTER CANNOT PROCESS UNSIGNED FORMS.***

Completed By: _____ **Title:** _____
Print Name

Phone Number: _____

Signature: _____ **Date:** _____/_____/_____

Your signature above indicates understanding of the contents of the attached letter, that you performed the actions outlined and disseminated this information, if applicable.