

**DEVICE
CORRECTION**

November 19, 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.

Affected Product

Product Code	Product Name	Serial Number
115641	CWP 800 RO1 220-240V/ 380-415V 50Hz	All
115645	CWP 800 HW 220-240V/ 380-415V 50Hz	All
115942	Clinic Panel	All

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. **If you purchased this product directly from Baxter, complete the enclosed Baxter Customer Reply Form** and return it to Baxter by faxing it to 044 908 50 40 or scanning and e-mailing it to Switzerland_SHS_CQA@baxter.com. 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.

Further information and support

For general questions regarding this communication, contact Baxter at 044 908 50 50, or send us an e-mail at Switzerland_SHS_CQA@baxter.com.

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

Sincerely,

Thomas Koch
Mgr Field Service TS
Technical Service

Silvia Anthoine Dietrich
CQA Manager
Country Quality Assurance

Enclosure:
Customer Reply Form

Confirmation of receipt of communication

(DEVICE CORRECTION LETTER DATED *XX* NOVEMBER 2018 (TO BE COMPLETED LOCALLY))

CWP 800_ Water Treatment**Affected Product Codes:** 115641, 115645 115942 / **Serial Numbers:** All

Please complete and return one copy of this form per facility by fax or e-mail

Fax Nr. 044 908 50 40
Switzerland_SHS_CQA@baxter.com

A fax cover sheet is not required.

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

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.

Signature/Date: REQUIRED FIELD	 _____
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