



Mr. Gavin McGowan
Product Manager (Acting) - Medical Devices
Health Products Regulatory Authority (HPRA)
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

**Urgent Field
Safety Notice**

15th November 2018

Subject: Field Safety Notice – Central Water Plant (CWP) 800 system – Compliance update to latest standard

Product names: CWP 800 RO1 220-240V/ 380-415V 50Hz & CWP 800 HW 220-240V/ 380-415V 50Hz

Product codes: 115641 & 115645

Serial Numbers: All

Dear Mr. McGowan,

Baxter Healthcare will be implementing design improvements in the CWP 800 (Central Water Plant) systems in order to make them compliant with the newest International Electrotechnical Commission (IEC) standard.

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

Our records indicate that 2 customers have received this product in Ireland.

Please find attached the communication that is being sent to those customers for your review and approval.

Should you have any questions, please contact me at the number below.

Yours Sincerely,

Jessica Morris
QA Specialist
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