Baxter

Urgent Field Safety Notice Follow-up

07th June 2016

Subject: Follow-up Important Product Information - Vivia - Failed Water tests with Calcium and Formaldehyde

Affected Product	**Product Name**: Vivia System **Product Codes:** 5H51101 **Serial numbers:** All

Dear Customer,

As a follow-up to the communication issued by Baxter on 25th May 2016 related to the elevated levels of formaldehyde and calcium found in 5 water samples collected from the Vivia water sampling port in Ireland, Baxter is providing the following additional recommendations:

As a precaution to assess patients who have been using Vivia to determine if there is any clinical evidence suggestive of adverse effects, Baxter recommends that the clinician assess the patient's calcium level and hemoglobin/hematocrit in the context of his/her historical laboratory values and other confounding factors, e.g., calcium intake, calcium phosphate binders, erythropoietin usage history, etc.

If there is a high index of suspicion for hemolysis, a hemolytic workup should be considered. In the event of unexpected hypercalcemia and/or anemia, these adverse events should be reported promptly to Baxter, and appropriate treatment should be initiated by the healthcare professional.

Please note that we have not received any adverse events involving these patients/sites, nor any safety signals since the initial communication.

Action to be taken by the user

Besides clinical recommendations mentioned here-above, Baxter is kindly asking that you take the following actions:

1. Complete the enclosed customer reply form, and return it to Baxter by either faxing it to 01 206 5577 or scanning and e-mailing it to QA_Dublin@baxter.com or sending it by post to Quality Department, Baxter Healthcare Ltd, Unit 7 Deansgrange Business Park, Blackrock, Co. Dublin. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

2. Please forward a copy of this letter to other facilities or departments within your institutions to ensure that those locations are aware of this action.

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For general questions regarding this communication, contact your local Baxter representative.

The HPRA has been informed about this follow-up Field Safety Notice.

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

Sincerely,

Ian Gavigan
Head of CQA UK/Ireland
Baxter Healthcare Ltd.
Deansgrange Business Park
Blackrock
Co. Dublin
Ph: 01 2065500

Attachment 1: Customer Reply Form

Baxter

Attachment 1

Customer Reply Form

IMPORTANT PRODUCT INFORMATION DATED 07 JUNE 2016

Product name: Vivia

Product code: 5H51101

Please complete and return one copy of this form per facility either by fax (01 206 5577) or by e-mail (QA_Dublin@baxter.com) as confirmation that you have received this notification. A fax cover sheet is not required.

Facility Name and Address: *(Please Print)*	
Product code and Serial Number of Machine	
Reply Confirmation Completed By: *(Please Print Name)*	
Title: *(Please Print)*	
Email and/or Telephone Number (Including Area Code):	

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

Signature/Date: REQUIRED FIELD	_____