DiaMed GmbH
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Cressier, November 05, 2014

Urgent: Field Safety Notice / 003-14

Dear **Distributors / Subsidiaries**,

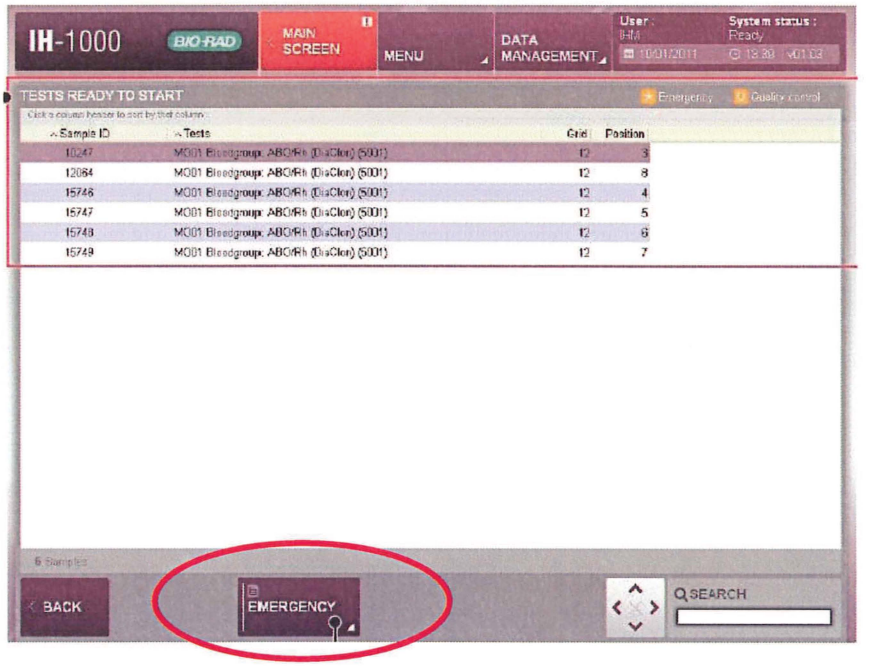
This letter contains important information that requires your immediate attention.

Please note that the relevant European Regulatory Agency has been advised of this FSCA.

Affected device

Product name:	**IH-1000**
Product REF:	**001000**
IH-1000 software version:	**all versions**

This information only concerns the use of the "Emergency button".



For further details related to this function, please refer to the appropriate chapter of the User Manual.

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Description of the problem:

Further to a customer complaint, we have confirmed that in the specific conditions described below, the IH-1000 software may lose the link sample/"test in progress". This loss might in the worst case lead to a mismatch between the test result and the sample.

Our in depth investigation has determined this issue is linked to the sample management when using the "emergency button" and might occur **ONLY** in the following conditions:

1. A Not Urgent rack (green label) is inserted with more than one sample AND;
2. **ALL** the samples on this rack are manually selected as "Emergency" by clicking on the "Emergency button";
   Then once the first emergency sample is processed, the instrument ejects the rack before all processing is completed.
3. If a rack is then reloaded with new samples in the exact same positions and reinserted in the same slot, the link sample/"test in progress" is lost.

Please note that all our investigation's results have demonstrated this issue does not occur **when samples are processed on the Urgent rack (red label)**.

Impact on the patient:

The potential for reporting an erroneous result is remote because the occurrence of this issue is dependent on random factors. To date, no incident with patient outcome was reported.

Nevertheless, we are informing you so that you can take the appropriate protective measures.

Actions to be taken by the customers:

This issue will be permanently corrected in the next IH-1000 software version.
This version will be released by the end of Q1 2015.

In the meantime, customers should immediately discontinue using the "emergency button" and should process **ALL** emergency samples exclusively on the urgent rack (red label).

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Actions to be taken by the distributor / Subsidiary:

- Please translate the above text into your national language(s) and share this information with the concerned customers.
- Please complete the Field Safety Notice Reply Form (Annex I) and return to DiaMed GmbH.
- Retain this notification as part of your Quality System documentation as well as the completed Field Safety Notice forms of your respective customers (Annex II).

Actions to be taken by the customer:

- Please complete the Field Safety Notice reply form (Annex II) and return to your distributor.
- Please share this information with the relevant laboratory staff, to ensure that the appropriate protective measures are taken.

In case of questions, in the first instance, please contact our Help desk:

+41 (0) 26 674 51 60
support.instr_cressier@bio-rad.com

Our collaborators are briefed to help you manage this situation.

We would like to apologize for any inconvenience that may have been caused by this action and we appreciate your prompt cooperation in this matter.

Yours sincerely,

DiaMed GmbH
RA/QA Manager
Agnes Eude Goethals

DiaMed GmbH
IHD Division Manager
Ann Madden

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