



DiaMed GmbH
Pra Rond 23
1785 Cressier FR / Switzerland
Phone: +41 (0)26 674 51 11
Fax: +41 (0)26 674 54 45

Cressier, March 27, 2015

FSN 003-14 follow-up letter

Affected device

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

Dear colleagues,

We would like to update you on the last developments of the FSCA 003-14.

In November 2014, we informed you about an issue related to the sample management which might occur when using the IH-1000 "Emergency button" in some very specific conditions.

The permanent corrective action of this FSCA consists in an update of the IH-1000 software version. The release of the updated version was initially announced for the end of Q1 2015.

Since the issue awareness, we focused our efforts on designing a complete software solution that both meets the needs of all immunohematology laboratories and ensures the quality, safety and efficacy of our system.

The software version has been developed, fully verified and is currently undergoing final validation. It will be released by the end of June 2015.

In the meantime, we ask you to remind your customers to maintain the protective measure which consists in not using the "Emergency button" and processing all emergency samples exclusively on the "Emergency rack".

In case of questions or additional information, please contact us:

RA-request_Cressier@bio-rad.com

Sincerely,

Agnès Eude Goethals
DiaMed GmbH
RA/QA Manager

Marc Meyer
DiaMed GmbH
IHD Marketing Director