



Cressier, June 10th, 2013

Urgent: Field Safety Notice / 002-13

Dear **Distributors / Subsidiaries**,

This letter contains important information that requires your immediate attention.

Please note this notice has been communicated to the appropriate European Regulatory Agency.

Affected device

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

Please note that you are not concerned by this information if your customers work with the second reading function activated for all the test results.

Description of the problem:

Further to customer complaints, we have been made aware that in some specific conditions, inconsistent grading between the results in the well/card and the results returned by the IH-1000 may be observed.

After deep investigations, we have been able to confirm that in these very specific conditions, positive reactions might be read as negative by the system due to the analysis algorithm of the images.

Therefore, this issue might lead to a wrong result released to the host if all the 3 following conditions are met:

1. A result is returned as negative while the reaction is positive, DP, or requires a human interpretation and,
2. This negative result is consistent with the global interpretation of the test and,
3. The system is configured without the second reading function activated for all tests results.

Impact on the patient:

The probability of the occurrence of such cases is remote. However, considering that the described issue might affect the patient test results, we are informing you so that you can take the appropriate protective measures.

Immediate protective measure:

To exclude the residual risk, we advise you to immediately implement the following protective measures:

- 1. Log in as **“Administrator”**.
- 2. In the toolbar click on **“Configuration”**, then, choose **“Common”**.

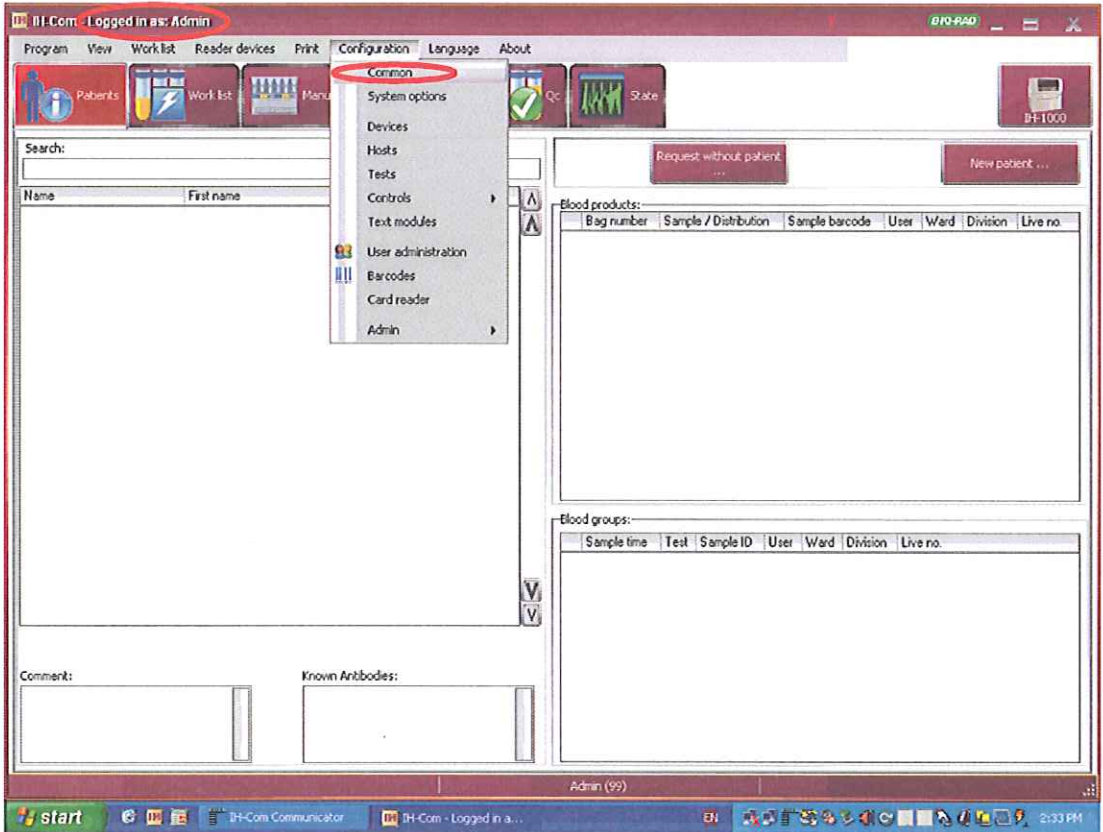


Illustration of IH-Com selection “second reading” function

3. Activate the “second reading” function **for all the test results**, this means that the results must be read again and accepted by the user before the sending to the host.

Please note there is no way to select only the negative results.

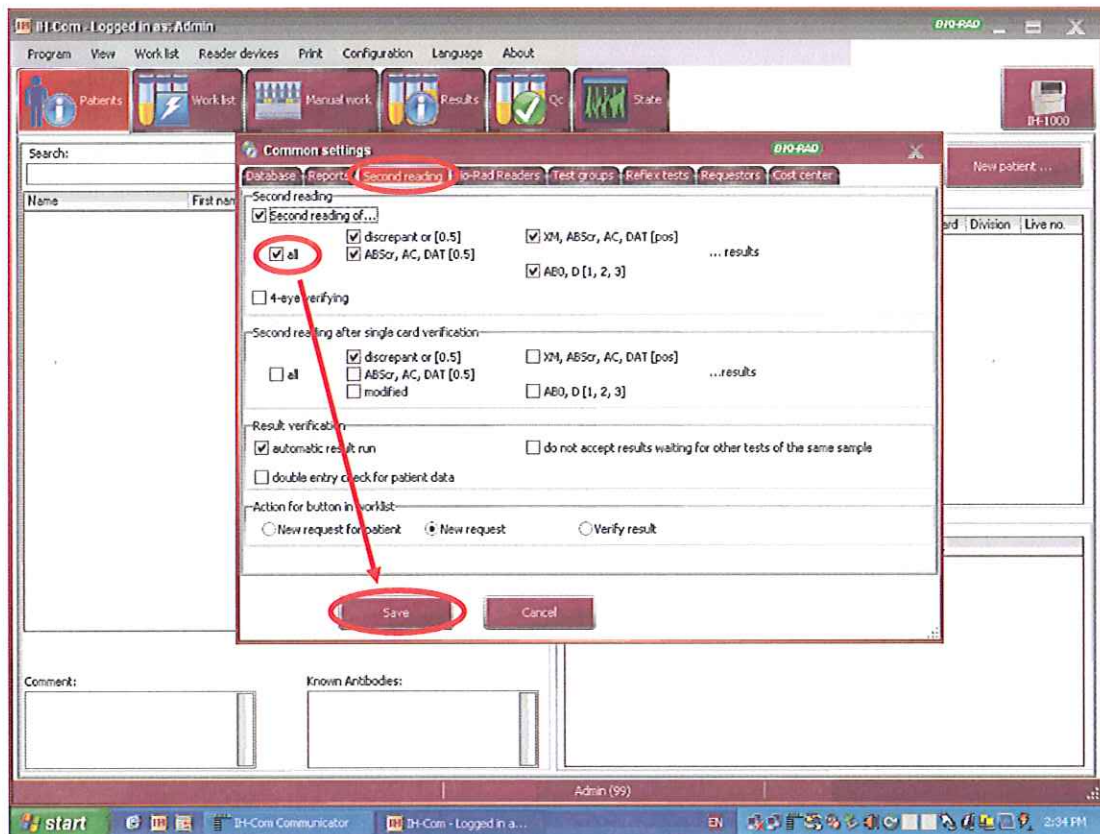


Illustration of IH-Com “second reading” function

4. Check the consistency between the result in the well/card and the result returned by the system.

Long term corrective action:

This issue will be permanently corrected in the next IH-1000 software patch. The patch will be available in the **end of August**.

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.

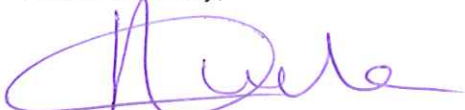
In case of questions, in the first instance, please contact our Help desk:

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

Our collaborators are briefed to help you manage this situation.

We apologize for any inconvenience and would like to thank you in advance for your cooperation.

Yours sincerely,



DiaMed GmbH
RA/QA Manager
Agnes Eude Goethals



DiaMed GmbH
BU Marketing Manager
Armin Köchli



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Annex I

Urgent: Field Safety Notice Reply Form for Distributors / Subsidiaries / 002-13

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

Please fill out and sign the information below and return the completed form to DiaMed GmbH including a copy of the translated letter within 5 working days:

- by email at RA-request_Cressier@bio-rad.com
- by Fax at: + 41 26 674 54 69

I have read and understood this Field Safety Notice, and shared this information with concerned laboratories.

Distributor / Subsidiary Name

Address

Phone Number

Completed by: Name / Signature / Title / Date



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

Annex II

Urgent: Field Safety Notice Reply Form for Customers / 002-13

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

Please fill out and sign the information below and return the completed form to your **distributor** within 10 working days.

I have read and understood this Field Safety Notice, and shared this information with laboratory staff that uses this product.

Hospital / Laboratory

Address

Phone Number

Completed by: Name / Signature / Title / Date