BIO·RAD

Cressier, April 20th, 2012

Urgent: Field Safety Notice / 001-12

Dear valued customer and IH-Com user,

This letter contains important information concerning an issue that requires your immediate attention.

- **Details of affected device**

Product name:	**IH-Com Full kit version** (Data Management and Result Interpretation Software)
Product REF:	**009000**
IH-Com software versions:	**03.0.43 / 03.0.52 / 03.0.59**

- **Description of the issue :**

If different patients (e.g. A & B) **having the same first name, last name and date of birth** are tested in the system, the data management system IH-Com could merge the files of these patients even if patients ID are used. In the worst case, IH-Com could assign the results of patient B to patient A.

This risk exists only if you use patient Demographic data: first name, last name and date of birth, for the identification of a patient.

Please note that you are not concerned if you are working only with sample ID in IH-Com.

The occurrence of having different patients with exactly same first name, last name and date of birth is remote.

Nevertheless, considering that the residual risk could affect the test results for these patients, we inform you so that you can take the appropriate protective measures.

H006001 10.10

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

- **Protective measures:**

This issue will be permanently corrected in the next IH-Com software version (currently in validation).

In the meantime to exclude the residual risk, we advise you to implement the following immediate protective measures:

1) For customers who **don't use any Host (LIS) connection** to IH-Com:

   a) When you have to manage different patients with same first name, last name, and date of birth, add a unique patient ID number after the patient last name (ex. Smith (01)) when you enter this data to create a patient file, or

   b) Do not work with patient demographic data but only with the sample ID for the identification of a patient in IH-Com.

2) For customers that use any Host with an **ASTM communication** mode with IH-Com:

We have developed a software patch (dll) that automatically adds the unique patient ID number (which has to be available in the Host system) to the patient last name for all new requested tests and removes it when sending the results back to the Host.

Note: The patient file will be then treated as a new one in IH-Com.

As of now, this software patch is available and the deployment will be ensured by your field service engineers.

3) For customers that use any Host with a **Maestro emulation** communication mode with IH-Com:

We are actively developing a software solution similar to the one described in point 2) which will be available within 3 weeks.

In the meantime we strongly recommend you to apply one of the protective measures described in point 1).

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In case of questions please contact, in the first instance, 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.
Please send us the completed "Confirmation of Receipt".

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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Confirmation of Receipt

Urgent: Field Safety Notice Reply Form for Distributors / Subsidiaries / 001-12

Product name:	**IH-Com Full kit version** (Data Management and Result Interpretation Software)
Product REF:	**009000**
IH-Com software versions:	**03.0.43 / 03.0.52 / 03.0.59**

Please fill out and sign the information below and return the completed form to DiaMed GmbH including <u>a copy of the translated letter</u> within 10 calendar 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 laboratory staff that uses this product.

_____

Distributor / Subsidiary Name

_____

Address

_____

Phone Number

_____

Completed by: Name / Signature / Title / Date

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