DiaMed GmbH
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Cressier, 26-01-2023

Field Safety Notice / *FSCA 001-23*

Affected products displaying the issue:

Product Name	UDI-DI	Catalog No	Software Version	Serial Number
IH-1000	07611969205516 03610522063680	001000 001000RECOND	**04.08.11**	All

Dear Customer,

This letter contains important information that requires your immediate and urgent attention. Bio-Rad is voluntarily conducting a Field Safety Corrective Action for the products identified above.

Description of the problem:

We would like to share with you, and your team, information about an issue that could be observed on the blood grouping analyzer **IH-1000 software version 04.08.11** intended to be used with the Data Management Software IH-Com version 5.2.5 Service Pack.

When one or multiple Crossmatch tests and Auto control tests are requested in IH-Com, under certain circumstances described below, there is a possibility that the IH-1000 inappropriately execute an auto-combined test leading to incorrect distributions in the wells of the ID-cards and uninterpretable (wR) results reported in the IH-Com. This could ultimately lead to a misinterpretation of the crossmatch testing (false positive or false negative) during the manual edition of the result.

The following combination of conditions is required to observe the issue:

1) *The end-user runs multiple crossmatch tests and autocontrol for a patient,*
2) *The automatic combination of tests function is active in IH-1000 connector* and a combined test is executed (see table 1), OR a combined test is installed in the IH-1000-Connector*
3) *The test is performed on a reusable ID-Card,*
4) *The return to drawer function is disabled for crossmatch tests and autocontrol.*

** Please contact your Local Bio-Rad representative to obtain more information on your IH-1000 configuration.*

When these conditions are fulfilled, separate tests (requested by IH-Com) will be treated as auto-combined tests (execution of PR80D / PR80E / PR80F / PR80H / PY80D) by IH-1000 and samples from the same patient and different donors might be incorrectly dispensed in the same well instead of separated wells (see example in Figure 1).

Once the tests are processed, the IH-Com displays the same well for all crossmatch results.

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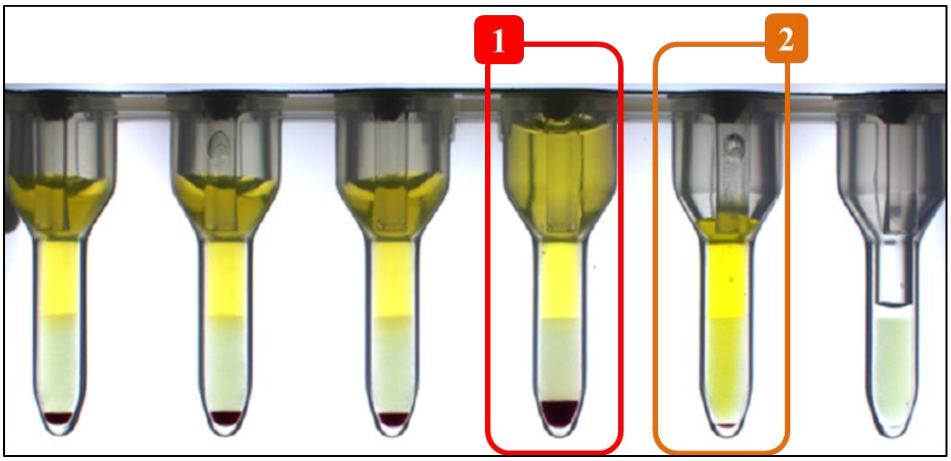
Tests requested separately in IH-Com	Combined Tests executed by IH-1000
PR70 AutoControl (Coombs) + **PR80** Crossmatch (Coombs)	**PR80D**: Crossmatch+ AC (Coombs)
PR80H Crossmatch (Papain)+Acp + **PR80A** Crossmatch (Saline)	**PR80E**: Crossmatch+AC (Saline)
PR70B Autocontrol (Bromelin)+ **PR80B** Crossmatch (Bromelin)	**PR80F**: Crossmatch+AC (Bromelin)
PR70A Autocontrol (Papain)+ **PR80** Crossmatch (Coombs)	**PR80H**: Crossmatch (Papain)+Acp
PY70 Autocontrol (Coombs Anti-IgG) **PY80** Crossmatch (CoombsAnti-IgG)	**PY80D:** Crossmatch+AC (Coombs Anti-IgG)

Table 1_list of separated test and corresponding auto-combined tests.



1. IH-1000 dispensed 3 different auto-combined tests in well 4
2. The excess sample was distributed in well 5

Figure 1_Example of misdistribution of the auto-combined test

Impact on the patient:

Out of the entire installed fleet of instruments, one complaint related to this issue was brought to our attention. The probability of this issue and the likelihood it leads to a false result for a crossmatch test is low but cannot be completely ruled out.

The impacts on the patient of a false positive or a false negative are respectively:

- Possible delayed transfusion
- Missing an allo-antibody which might lead to a transfusion reaction. The severity of this reaction depends on the specificity present.

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Immediate protective measure for the user:

You are affected by the described issue **if both of the following conditions are present**:

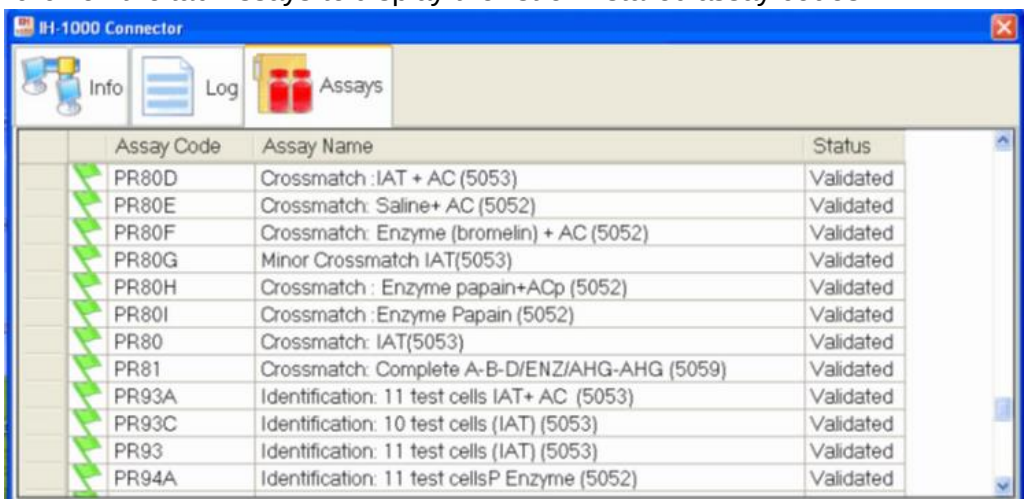
a) You are working with IH-1000 software version 04.08.11. The IH-1000 software version is displayed on the top right corner of the IH-1000 User Interface next to the date/time/user.

AND

b) Any of the Tests listed in table 1 (either separately or combined) are installed in the IH-1000 Connector. To check the list of assays:

- click on the "IH-1000 connector" icon on the IH-1000 PC to open the IH-1000 connector

- click on the tab Assays to display the list of installed assay codes.



Assay Code	Assay Name	Status
PR80D	Crossmatch :IAT + AC (5053)	Validated
PR80E	Crossmatch: Saline+ AC (5052)	Validated
PR80F	Crossmatch: Enzyme (bromelin) + AC (5052)	Validated
PR80G	Minor Crossmatch IAT(5053)	Validated
PR80H	Crossmatch : Enzyme papain+ACp (5052)	Validated
PR80I	Crossmatch :Enzyme Papain (5052)	Validated
PR80	Crossmatch: IAT(5053)	Validated
PR81	Crossmatch: Complete A-B-D/ENZ/AHG-AHG (5059)	Validated
PR93A	Identification: 11 test cells IAT+ AC (5053)	Validated
PR93C	Identification: 10 test cells (IAT) (5053)	Validated
PR93	Identification: 11 test cells (IAT) (5053)	Validated
PR94A	Identification: 11 test cellsP Enzyme (5052)	Validated

- Check if any of the test codes provided in table 1 is listed with the status Validated.

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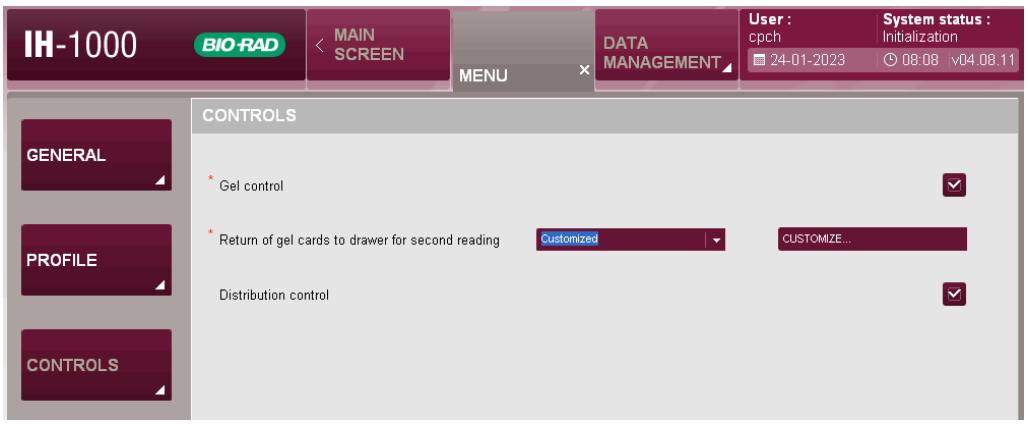
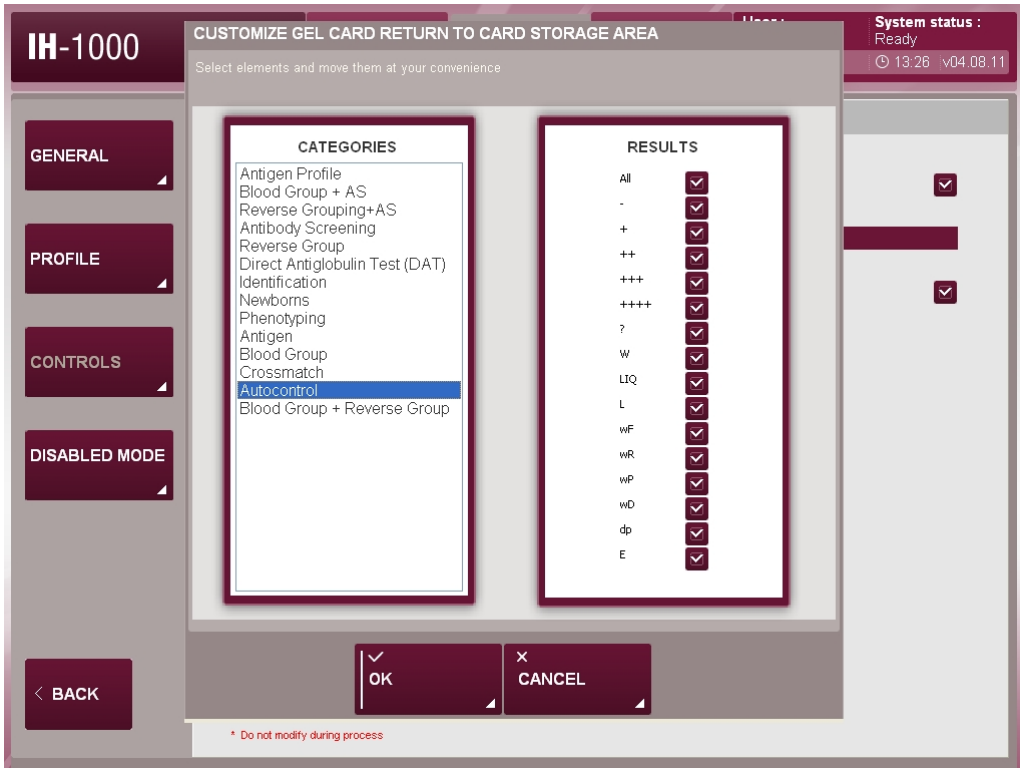
If the 2 above listed conditions are gathered, we recommend that you:

1) Access the IH-1000 Options Menu and, on the “Control” tab, enable the “return of gel cards to drawer for second reading” function selecting the “Customized” option (Refer to IH-1000 User Manual Section 8.4 and 6.1.4 c)



Click “CUSTOMIZED” and in the emergent Menu, select “All” for the Test Categories “Autocontrol” and “Crossmatch”.



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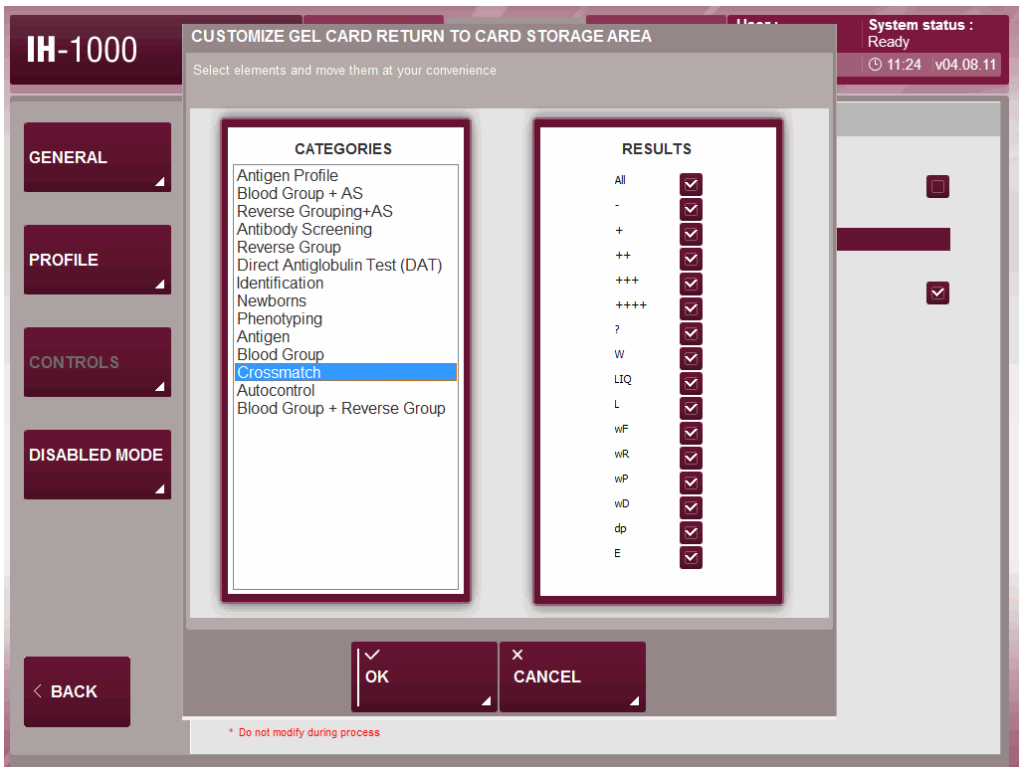

This will prevent the inappropriate execution of an auto-combined test. The gel cards will be put returned to positions 4, 5, 9, 10, 13, 14,15, 18, 19, 20 of the drawer. Make sure that these positions are available and with empty card trays. To ensure a proper identification of the empty trays, use the white trays (REF 009888) for the cards returned to the drawer.

2) Please contact immediately your customer services team to ensure proper adjustment of your IH-1000/IH-Com settings is carried out. Once the IH-1000/IH-Com Setting is adjusted, the “return to drawer function” could be disabled to recover the nominal status of your IH-1000. Our representatives are trained to assist you in implementing appropriate and lasting corrective measures at your site.

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We ask that you ensure the transfer of this information to all persons impacted in your institution and/or forward it to establishments where products may have been transferred.

Please note that the relevant European Regulatory Agency has been advised of this Field Safety Corrective Action.

In case of any questions, in the first instance, please contact our customer technical support representatives:

[Indicate here local contact]

We regret that any inconvenience may have been caused by this action and we appreciate your prompt cooperation in this matter.

Yours sincerely,

Quality Assurance Representative	International Product Manager Automated Solutions
…	…

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CUSTOMER FIELD ACTION RESPONSE FORM

Field Action Reference Number: FSCA 001-23
Bio-Rad Product Segment: IH
Single Registration Number (SRN): CH-MF-000020826

PRODUCT

Product Name	UDI-DI	Catalog No	Software Version	Serial Number
IH-1000	07611969205516 03610522063680	001000 001000RECOND	**04.08.11**	All

CUSTOMER INFORMATION

Account Name:	
Undersigning Manager Name:	
Address:	
Telephone Number / Fax:	
Customer Account Number:	

STATEMENT:

I am aware of the information about the field action concerning the above reference product(s) and:

- ❑ I am not impacted by the described issue because one or several of the following apply to my laboratory:
  - ❑ I'm not using the IH-1000 software version 04.08.11 but a previous version
  - ❑ The tests described in the Table 1 are not installed on my device.
- ❑ I am impacted by the issue described, have implemented the immediate protective measure described in point 1) and have contacted Bio-Rad customer services team for assistance.

Number of affected devices installed: (N/A if not affected)	

Date: Customer Signature (and Stamp if applicable)

Please return this form to: [enter local details]