

NIS-310400/70
07 December, 2015



Product Notification

No. NIS-310400/70
Date: 07 December, 2015

FOR THE ATTENTION OF THE LABORATORY MANAGER/DIRECTOR AND REACTOVIGILANCE LOCAL CORRESPONDENTS

Products: IDS-iSYS Multi-Discipline Automated System **Code:** IS-310400
Technical Information: Issue with reported results with GUI software revision 14.02

Dear Valued Customer,

As part of the IDS process for the continual monitoring of product performance and quality, we have identified an issue concerning GUI software revision 14.02 for the IDS-iSYS Multi-Discipline Automated System (System).

This issue affects **only** Systems where the working unit assigned in the software for the specific assay are different from the default SI units. In order to report results in the selected working units, the System uses a conversion factor to automatically calculate the results.

Description of the defect:

Routinely when the System measures a sample having a concentration outside of the specific assay measuring range, the message OMR- or OMR+ is displayed.

With the "GUI revision 14.02" when a result is outside the measuring range, it is displayed as follows:

< "Value", with Value being the SI unit lower measuring limit, but expressed with working units

> "Value", with Value being the SI unit upper measuring limit, but expressed with working units

In such cases, the conversion factor is not applied by the System and the result has a discrepancy between the numerical value of the measurement limit and the units in which it is displayed. In all cases, the result is accompanied by an OMR- or OMR+ message indicating that it is outside of measurement limits of the assay.

This display issue only affects the results displayed in the work list, archiving and printed reports for all affected assays.

Note:

All results sent to LIS are correct, including results outside of the measurement range.

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Health risks:

This issue causes an unclear indication of assay measuring range limit values. But the display of signs < or > and the accompanying OMR- or OMR+ messages indicate that the result is outside the assay limits. IDS considers that there is no health risk.

Precautionary Measures:

We recommend that our customers pay particular attention to the results outside the measurement range and that patients results are reported from LIS and not read directly from the System.

Action to be implemented by IDS:

A correction of the software is underway to resolve this issue quickly. Once the new version is available, a representative of IDS will upgrade your system so you benefit from this update.

Transmission of this information:

IDS recommends:

- Transmit this information to anyone involved in your laboratory.
- The person responsible for the laboratory complete the attached form and return it to IDS as soon as possible.

The ANSM (French regulatory agency) was informed of this communication.

IDS is committed to providing quality products to its customers and apologize for any inconvenience this may cause in the organization of your laboratory.

Our Technical Support is at your disposal for any further information:

Email :
Support-technique@idsplc.com
Tél. 01 40 77 04 70

Stéphanie LONJARRET
Quality and Regulatory Manager
IDS France

Fabrice EPENOY
Group Product Manager

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Please, fax back this form to IDS Technical Support after completion

Complete, sign and fax this form to your local IDS office to acknowledge your receipt of this Product Notification NIS-310400/70 (Results display problem with GUI software revision 14.02).

I certify that I have received the above information from IDS for the product(s) mentioned in the Product Notification and communicated it to any relevant person(s) in my laboratory.

Organisation: _____

Signature: _____

Printed Name: _____

Date: _____

Please fax back to Technical Services at your local IDS office or distributor.