SIEMENS

Urgent Field Safety Notice

HI17-02.B.OUS

December 2016

ADVIA® 560 Hematology System

Multiple Sample ID Records in Database

This is a follow up to the recent Urgent Field Safety Notice (UFSN) HI17-02.A.OUS sent by Siemens Healthcare Diagnostics dated October 2016.

HI17-02.B.OUS supersedes the previous UFSN HI17-02.A.OUS.

Our records indicate that your facility may have received the following product:

Table 1. ADVIA 560 Hematology Systems – All Serial Numbers

Product	Siemens Material Number (SMN)	Software Versions
ADVIA 560 Hematology System	11170842	1.4.2133 1.4.2333

Reason for Correction

Siemens Healthcare Diagnostics has confirmed that there is a potential to obtain multiple discordant records for the same Sample ID in the ADVIA 560 Hematology System database. The database should only contain one record of a Sample ID number for any given time and date. If there are multiple records for the same Sample ID, it is possible that multiple results may be manually or automatically sent to the Laboratory Information System (LIS), printed or displayed on the results report screen.

When this issue occurs, a dialog box will alert the user to take action. One of the following messages will appear with a red “x” on the dialog box.

- Rbc data missing
- Baso data missing
- Differential data missing
- Hgb data missing
- Wbc data missing
- Some raw data file are missing!

Below is an example of one of the dialog box messages you may receive.

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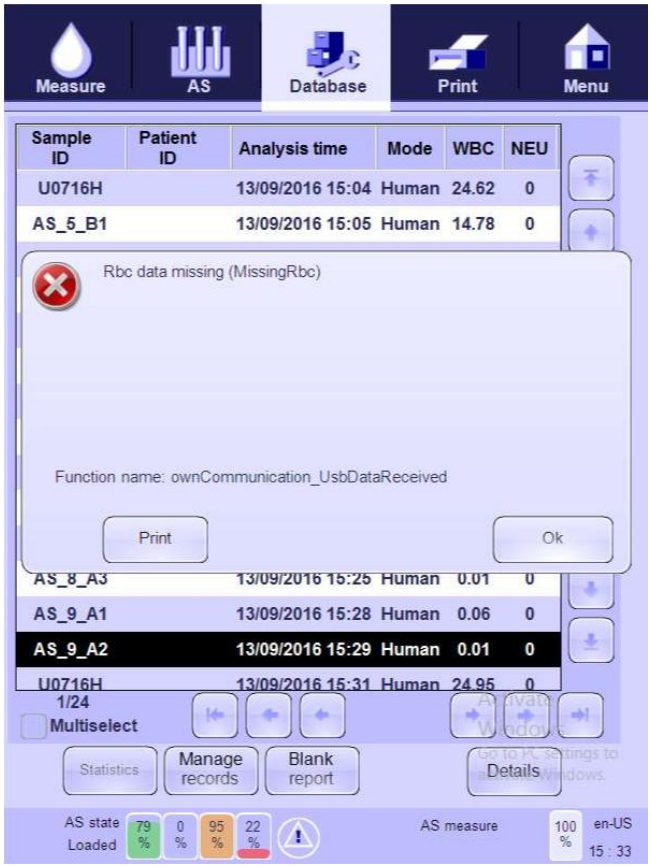

If manually operating the system, the message must be cleared to continue. If running samples with the autoloader, the instrument will continue to process samples when the dialog box appears.

This issue will be corrected in Software Version 1.4.2378, which will soon be available for installation on your system.

Risk to Health

Siemens has determined the potential for multiple results from the same Sample ID being generated in the ADVIA 560 Hematology System database. It is unlikely but possible for the multiple results to be discordant. When this issue occurs and a discordant result may be reported, the potential exists for misinterpretation of complete blood count values leading to additional testing for potentially abnormal results, inappropriate follow-up, or a delay in testing or follow-up depending on the magnitude of the discordance. In cases where this scenario may lead to reporting of discordant results, an overall risk to health exists but is remote as results would be used in conjunction with clinical presentation, medical history such as previous hematologic findings, and/or other biochemical markers. Siemens is not recommending a laboratory look back as a result of this issue.

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Actions to be Taken by the Customer

- The contents of this letter should be discussed with your Medical Director.
- If you obtain multiple results for one Sample ID, please contact your local Siemens technical support representative to report the issue.
- If any of the following errors are generated, do not release ADVIA 560 Hematology System results without checking the database screen on the system. To view the database, tap the Database icon at the top of the Home Screen.
    - Rbc data missing
    - Baso data missing
    - Differential data missing
    - Hgb data missing
    - Wbc data missing
    - Some raw data file are missing!
- When any one of the error messages is generated, the user will have to:
    1. Acknowledge the error by hitting the OK button in the dialog box. The message must be cleared to continue processing samples manually. If running samples with the autoloader, the instrument will continue to process samples when the dialog box appears. Press OK to clear the message.
    2. Check the database for Sample ID's run at the time of the error and discard all those sample results. To view the database, tap the Database icon at the top of the Home screen.
    3. Discard all sample results associated with multiple records in the database, the LIS and the printed records.
    4. Restart the system before continuing to process samples.
    5. Verify by reassaying samples if any Sample ID has multiple records.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.

Your Siemens Customer Service Engineer will contact you to schedule time for installation of the 1.4.2378 software when it is available.

Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

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FIELD CORRECTION EFFECTIVENESS CHECK

ADVIA 560 Hematology System – Multiple Sample ID Records in Database Issue

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice HI17-02.B.OUS dated December 2016 regarding ADVIA 560 Hematology Systems - Multiple Sample ID Records in Database Issue. Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

Please fax this completed form to the Customer Care Center at (XXX) XXX-XXXX. If you have any questions, contact your local Siemens technical support representative.

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