SIEMENS

Urgent Field Safety Notice

ISW-15-05.A.OUS

August 2015

syngo® Lab Data Manager

System Software Issues

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

Table 1. Affected Products

Product	Software Version	Siemens Material Number (SMN)
syngo® Lab Data Manager	VA12B	10638933 10624077 10804573

Reason for Correction

Siemens Healthcare Diagnostics has identified the following five feature issues with the *syngo*® Lab Data Manager (LDM). It is extremely unlikely your laboratory would experience any of the issues described below. If an issue were to exist the user would be made aware via system alerts, Quality Control processing status or standard *syngo* LDM rule validation. However, please review this letter in its entirety and ensure that all operators understand the information presented.

1. Result Unit Conversions

There are limitations when converting results from the instrument to an alternate unit for display and transmission to the LIS using the *syngo* LDM.

2. Quality Control Processing

There are limitations with processing of Quality Control (QC) Results in the *syngo* LDM.

a. In your lab, you may observe a missing QC result that has actually been processed at the instrument. This can happen under the following conditions:

- More than one instrument is running the same type of QC material
- Each instrument produces the identical result value for the QC material
- The timestamp for each result value is identical (to seconds) for each result value and QC material

In this instance, a QC result from one instrument is incorrectly identified as a duplicate result.

NOTE: This scenario can occur even if your lab is not using the Quality Control feature on the *syngo* LDM.

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b. You may encounter a situation where a QC result has been manually excluded by a user, but later the result's QC Alert appears in an unresolved state. Until the QC Alert is manually resolved again, results will be unnecessarily held due to the QC status verification checks.

NOTE: If your lab is not using Quality Control (QC) on the *syngo* LDM, no action is required.

3. Virus Protection

Virus definition automatic updates may not be installed as expected. If this occurs, virus protection will still be active, but will not be using the most current virus definition files.

4. System Performance Degradation

Over time the size of the database grows and the performance of some systems may slow down, eventually causing User Interface screen delays and delays with order and result transmissions.

5. Order Received from LIS is Rejected

Under certain conditions, the system may reject orders from LIS. In this instance, there will be a system alert indicating it is "Rolling back transaction because of an exception in workflow job list."

NOTE: If your lab is not using Patient Matching, with LIS Patient ID unique, on the *syngo* LDM system, no action is required.

Risk to Health

In circumstances where these issues could occur, they would be either caught during set up and validation of the rule or could potentially result in a delay in test results however the delay would be obvious and manageable. There is also the rare chance that results held by QC rules could be released. Siemens does not recommend a look back.

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Actions to be Taken by the Customer

Please perform the following:

1. Result Unit Conversion Actions

- Although the software has built in functionality to convert results from the instrument to an alternate unit (such as 500 g/l to 5000 g/dl) for display and transmission to the LIS, this is not a promoted or described feature in the Operator's Guide and should not be used.
- Reference ranges (defined per Assay) should always be defined using the Unit returned within the Instrument results.

As stated in the Operator's Guide:

- Rules are configured by Siemens support personnel. If you have any questions concerning this feature, contact your local Siemens Customer Care Center. Please do not create or modify rules.
- When defining/editing Assay Definitions, do not enter values for Mol Weight and IU Factor.

2. Quality Control Processing Actions

a. If you are employing more than one instrument to measure identical assays and identical QC material, please take the following actions:

- Stagger your QC runs by at least 2 minutes to minimize the possibility of the duplicate timestamp for QC material results.
- Always ensure that all QC results expected for the QC run have been received and processed by the *syngo* LDM such that the QC status is correctly updated on the *syngo* LDM prior to continuing to process patient results on the instrument for which the QC has been run.

NOTE: This scenario can occur even if your lab is not using the Quality Control feature on the *syngo* LDM.

b. If you are using the optional QC package be aware of the following:

- A QC result that has been manually excluded by a user may appear as a result with a QC Alert in an unresolved state. Until the QC Alert is manually resolved again, results will be unnecessarily held due to the QC status verification checks.
- If you encounter a situation in which results are being held due to QC status verification checks, it may be caused by a previously excluded QC result. To resolve the QC Alert again, navigate to Unresolved QC Alerts and resolve and exclude the unresolved QC Alert for the control in question.

NOTE: If your lab is not using Quality Control (QC) on the *syngo* LDM system, no action is required.

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3. Virus Protection Actions

- Siemens support personnel will review your system to determine if virus definitions are up to date.
- If your system is connected to Siemens Remote Services (SRS), required for automatic update, and the definitions are out of date, you will be contacted to support the correction process.
- If your system is not connected to SRS, please contact your Siemens service provider to establish a connection to allow your virus definitions to be updated.
- If you are unaware of your system's connectivity status with SRS, please contact your Siemens representative.

4. System Performance Degradation Actions

- If you determine that the *syngo* LDM is functioning slower than expected, please contact your Siemens service provider for assistance with performance of preventive maintenance on your system.

5. Rejected Order Actions

- If you determine that the *syngo* LDM is rejecting orders while Patient Matching, with LIS Patient ID unique, configured, please contact your Siemens service provider for assistance to perform a system configuration modification which will correct the issue.

Please review this letter with your Medical Director.

Complete and return the Field Correction Effectiveness Check Form attached to this letter and fax the form to (XXX-XXX-XXXX.)

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

System Limitations and Software Issues

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice [ISW-15-05.A.OUS] dated August 2015 regarding System Limitations and Software Issues. 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 confirm that I understand that if changes are required to the system that affect rules in the system I will need to revalidate the affected rules. Yes ☐ No ☐
2. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution: *syngo* 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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