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To all users of *syngo* Workflow MLR with version VB36A_HF05 or higher

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Customer Safety Advisory Notice

***syngo* Workflow MLR: Update order messages from HIS may not be processed and lost**

Dear customer,

this letter is intended to inform you of a potential issue when using *syngo* Workflow MLR with version VB36A_HF05 or higher. During import or processing of update order messages from HIS (Hospital Information System), such messages may not be processed and get lost, in case a specific configuration at the site is applied.

What is the issue and when does it occur?

When an "update order" message to an already existing order is received from the HIS, our system will check in the corresponding procedure tree (structure that contains all orderable procedures) whether a specific status change is required. In order to do this, the procedure needs to be looked up in the tree.

In order to improve performance a new caching mechanism was introduced, so that the tree data required for this lookup are not read every time from the database. However, in case now a procedure tree is loaded in the cache, no other tree will be loaded into this cache. So the first order update message determines which tree is held in the cache. All subsequent order update messages received from the HIS and referencing a different procedure tree will fail.

The issue can only occur, if more than one procedure trees exist and are used at a site.

Example:

Step1: Update order message for procedure code 1 in tree A. The tree A is loaded into the cache and A1 is looked up in the tree.

→ This works without error.

Step 2: Update order message for procedure 2 in tree B. The procedure code 2 doesn't exist in the procedure tree A, which is still in the cache.

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→ The error is detected by the system, no change in our *syngo* Workflow MLR database is applied, the message is lost without notification to the user and the error can only be seen in the "error event log".

Step 3: Update order message for procedure 3 in tree B. There is a procedure code 3 in tree A, but it is a different procedure than the procedure 3 in tree B. The system will not recognize it and adapt the status of the procedure based on wrong information.

→ No error is returned but the status might be unnecessarily set back. No safety related issue, but a user will unnecessarily need to set the procedure back to status "planned".

Possible impact:

In case an update order message referencing a specific procedure tree is processed and a different procedure tree is cached, the message processing will fail and no information from the message will be updated in the RIS (*syngo* Workflow MLR) database. Depending on the way the HIS system queues and sends messages, affected data can include:

- 1) Patient data including allergies and alerts
- 2) Visit data
- 3) Order and procedure data including risk factors, lab data...

What steps can the user take to avoid the potential risk of this issue?

The issue cannot be avoided by any action of the user. To increase the detectability of the issue, the "error event log" should be checked by the clinical administrator (recommendation is to search for "SYSTEM_ERROR") on a daily basis at minimum until the issue is solved in the software.

In case you are affected of this issue we recommend to contact the local Siemens Service for support.

How will the issue finally be resolved?

The issue will be solved in the *syngo* Workflow MLR software version VB36A_HF09 which is planned to be released in Q2/2015. For planning this update please contact your local Siemens Service.

We appreciate your understanding with this safety advisory and ask you to immediately instruct your personnel accordingly. Please include this safety advisory notice in your operator's manual. In the interests of safety, we ask that you perform the above preventive measures and inform all affected personnel immediately.

If you have sold this device/equipment and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this device/equipment. Please inform us about the new owner of the device/equipment.

We regret any inconvenience that this may cause, and we thank you in advance for your understanding.

Sincerely Yours



SYNGO CFO

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