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Healthcare

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To all users of syngo Workflow MLR using Portal Radiologist with versions

using Portal Radiologist with versions VB30C/VB30C_FP1,VB30E, VB30F, VB35A, VB35B, VB36A Fax E-mail Date +49 (9131) 84-4874 +49 (9131) 84-2792 michael.mib.braun@siemens.com

April 14, 2014

Our reference

14-02777-SY-0344

Customer Safety Advisory Notice

syngo Workflow: Display problems of laboratory values in customizable dialogs

Dear customer,

This letter is intended to inform you of a potential issue when using the Portal Radiologist in *syngo* Workflow MLR. In the customized dialog in Portal Radiologist, which shows the laboratory values, it can happen that incorrect laboratory values are displayed.

What is the issue and when does it occur?

The issue **only** happens if you use **customizable dialogs** to display or edit information, which is contained in the **database field examination2.rlvf.** The issue does not happen if you use the core product graphical user interface and dialogs (e.g. access laboratory data through the Clinical Information button on the patient banner). When a **customizable dialog** in Portal Radiologist is in use, which shows laboratory values, under special circumstances the laboratory values of the **previous** patient are displayed.

The error only appears when the previous patient has laboratory values and the current patient has no laboratory values.

The preconditions for the issue are as follows:

- 1. Patient A exists and has a request with contents in the database field examination2.rlvf (risk factors, laboratory values, diagnosis, and reason)
- Patient B exists and has a request with empty or partly empty contents in the database field examination2.rlvf (e.g. laboratory values are empty, the other three parts of the database field contain information)
- 3. Both the requests are completed in Classic Client.
- 4. In Portal Radiologist select patient A from the Read Images worklist.

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Letter of April 14, 2014 to all users with syngo Workflow MLR using Portal Radiologist with versions VB30C/VB30C FP1, VB30E, VB30F, VB35A,

- 5. Open a custom dialog; you are able to see the laboratory values of patient A. Close the dialog by clicking on the "X" button on top of the dialog, instead of "Ok" button.
- 6. Open the request of patient B from the Read Images worklist.
- 7. Open the same custom dialog as in step 5. to view the laboratory data, the patient name and date of birth of patient B is shown, but the laboratory values of patient A are shown.

This may occur for any customizable dialog, which references information of the database field examination2.rlvf. This means that also risk factors, diagnosis and reason may be affected.

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

The user can only recognize the wrong data by chance. From the graphical user interface there is no indication of the wrong relation to the data of a different patient, because the patient identification on the dialog header is consistent. The only way to recognize the wrong data is if reports for patients are created in a row and the radiologist recognizes that he sees exactly the same data for patient A and patient B. As a general measure radiologists should always take care to close dialogs in Portal Radiologist through available buttons at the bottom of the dialog instead of using the x button on top of the dialog.

How will the issue finally be resolved?

Siemens prepares an Update Instruction to change the configuration so that the issue can no longer appear. This Update Instruction is planned to be released at the end of Q2/2014.

We appreciate your understanding and cooperation 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

Date / Dr. Kaindl, Arthur

SYNGO CÉO

Date / Vedder, Meike

7 4 2014

SYNGO Vice President Quality