SIEMENS Healthcare Sector

Customer Safety Advisory Notice

To all users with *syngo* Workflow MLR with version VB30C_FP1, VB30E, VB35A, VB36A and "Portal Radiologist" license.

Name	Michael Braun
Department	H IM SY QM DCU
Telephone	+49 9131 84 4874
Fax	
E-mail	michael.mib.braun@siemens.com

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***syngo* Workflow MLR: Potentially outdated clinical information (risk factors, lab data, diagnosis and reason) displayed and saved in Portal Radiologist**

Dear customer,

This letter is intended to inform you of a potential issue when using the *syngo* Workflow MLR with Portal Radiologist. In specific workflows it can happen that outdated clinical information (risk factors, lab data, reason, diagnosis) is displayed or even lost.

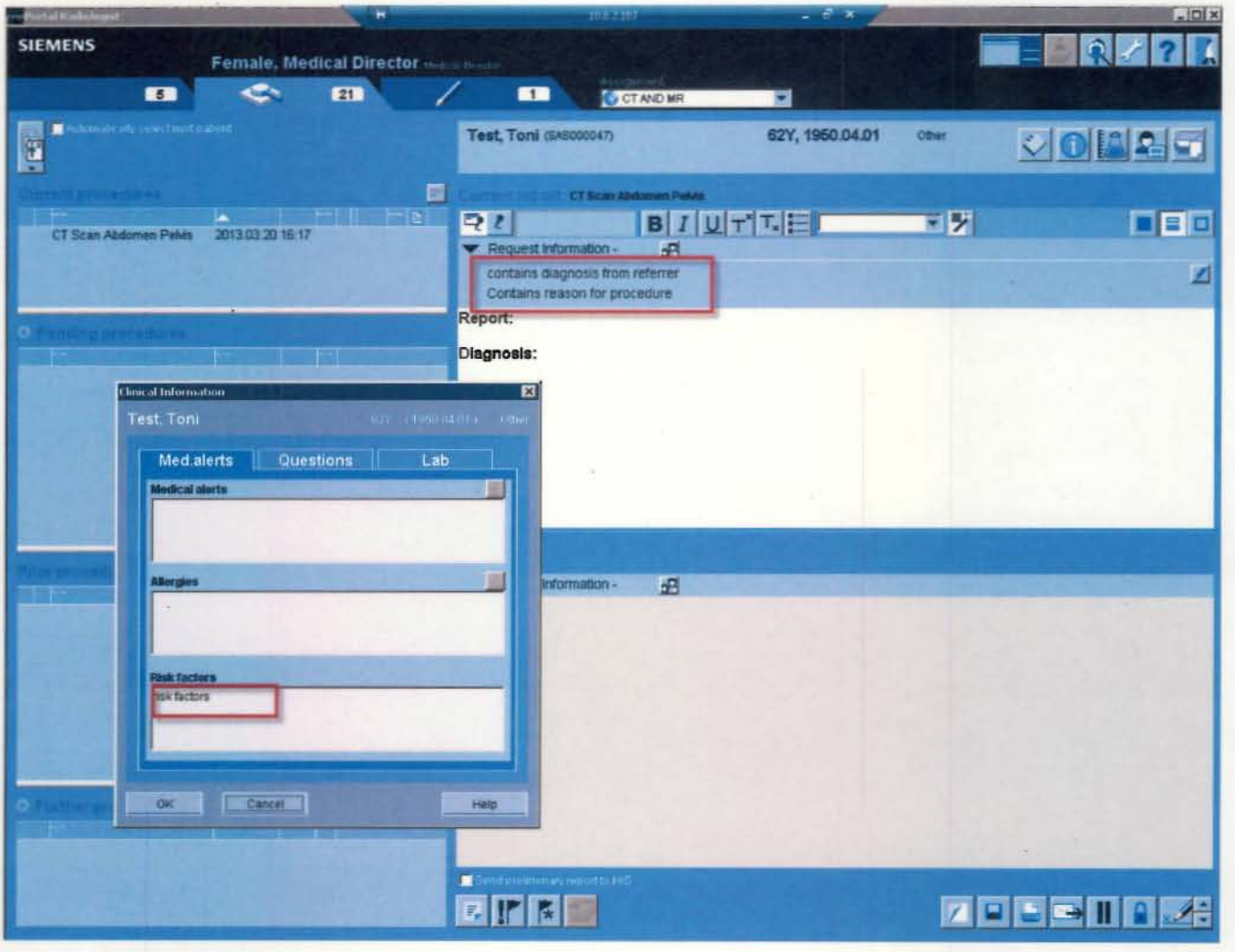
What is the issue and when does it occur?

Task "Medical Check of request":
The radiologist checks a request based on clinical information, reason and diagnosis and decides whether the procedures of the request are the appropriate ones.
If procedures of the request have been **deleted or changed** (e.g. because a procedure was replaced by a better fitting one in *syngo* Workflow browser or Portal Radiologist), and the **clinical information (risk factors, lab values, reason, diagnosis) was changed AFTER the procedure was changed,** then outdated clinical information (risk factors, lab values, reason, diagnosis) could be displayed in the user interface and saved (reason is that the outdated procedure with the outdated clinical information is used).

Tasks "Read Images", "Sign Reports":
The radiologist creates/reviews a report for a request in which procedures were changed or deleted and, while creating the report:

- **Changes the request information** (diagnosis, reason). This can result in saving outdated lab data, risk factors.
- **Looks at clinical information** (via a user preference there is also an option that the clinical information dialog opens automatically when risk factors exist) and **clicks on the OK** button.
  This action can result in outdated clinical information being saved.

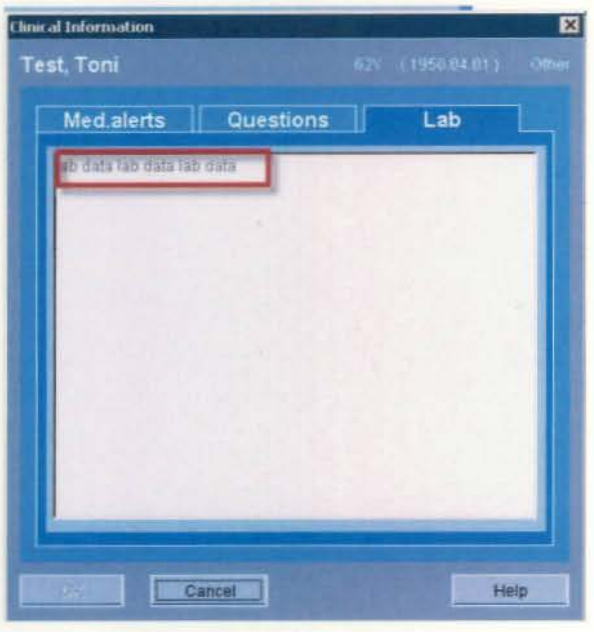
See screenshots below on how clinical information can be displayed in the GUI.



Siemens AG
Healthcare Sector; Management: Hermann Requardt
Imaging & Therapy Division; Management: Bernd Montag
SYNGO; Management: Arthur Kaindl

Hartmannstr. 16
91052 Erlangen
Germany

Tel.: +49 (9131) 84 0



HIS-RIS interface:
The observed issue can also happen with the **HIS-RIS interface**, if messages from HIS to RIS do not contain all 4 clinical information segments diagnosis, reason, risk factors, lab values.

Configuration at site:
We have also observed that this issue can be caused by configuration at site, for example, if the ID used for identification of a procedure in PACS happens to be the alphabetically first procedure in a request.
In this case any update to clinical information may result in data loss of risk factors, lab data, reason, and diagnosis.

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

Until the issue is finally solved in the software (see UIs listed on page 4), the following has to be considered:
In all versions the function “Edit Request information” in combination with the "Ok" button must not be used.
In version VB36A additionally the function “Clinical information dialog” in combination with the “Ok” button must not be used.

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In case it is absolutely necessary to use these functionalities, please contact your local Siemens Service to apply an interim solution described in the Siemens Knowledge Base under SKB0024949.

How will the issue finally be resolved?

The issue will be solved in the following Software updates:

For VB30C_FP1: No software fix will be provided for this version, but the issue will be obsolete by disabling the affected functionality. This will be done by UI SY082/13/S, planned to be released in April 2013.

For VB30E line: VB30E_SRF9 (UI SY047/13/S), planned to be released in Q2/2013.
For VB35A line: VB35A_SV10 (UI SY049/13/S), planned to be released in Q2/2013.
For VB36A line: VB36A_HF03 (UI SY062/13/S), planned to be released in Q3/2013.

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 where it should remain until the software update is applied. 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

27.03.2013 i.V.

Date / Christian Klaussner
SYNGO CFO

2013-03-27 i.V. Eva Reiter

Date / Reiter, Eva-Maria
SYNGO Vice President Quality

Siemens AG
Healthcare Sector; Management: Hermann Requardt
Imaging & Therapy Division; Management: Bernd Montag
SYNGO; Management: Arthur Kaindl

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