

Customer (Safety) Advisory Notice

To all users of

syngo Workflow MLR

With versions: VB30A_SP1, VB30A_SRV1

Name	[REDACTED]
Department	MED IKM IQ QC
Telephone	+49 (9131) 84-20 [REDACTED]
Fax	+49 (9131) 84-2752 [REDACTED]
E-mail	[REDACTED]@siemens.com
Our reference	[REDACTED]
Date	2008-10-09

***syngo* Workflow MLR: Potential mix up of patient reports**

Dear customer,

This letter is to inform you of a potential malfunction and hence a potential hazard to patients when using the *syngo* Workflow MLR application under certain circumstances in the versions listed above.

When does this malfunction occur and what are the potential risks ?

Not affected : All *syngo* Workflow MLR systems without "IWM_RAD_PORTAL" license.

Affected : All *syngo* Workflow MLR systems with version VB30A_SP1 or VB30A_SRV1 **and** license "IWM_RAD_PORTAL".

Siemens AG
Healthcare Sector
Head: Jim Reid-Anderson

Postal address:
Siemens AG
MED IKM IQ
P.O. Box 32 60
91050 Erlangen

Office address:
Hartmannstr. 16
91052 Erlangen
Tel: +49 (9131) 84 0

Siemens Aktiengesellschaft: Chairman of the Supervisory Board: Gerhard Cromme
Managing Board: Peter Loescher, Chairman, President and Chief Executive Officer; Wolfgang Dehen, Heinrich Hiesinger, Joe Kaeser, Jim Reid-Anderson, Hermann Requardt, Siegfried Russwurm, Peter Y. Solmssen
Registered offices: Berlin and Munich; Commercial registries: Berlin Charlottenburg, HRB 12300, Munich, HRB 6684
WEEE-Reg.-No. DE 23691322

If you don't know whether you are using an affected version you can perform a check in the syngo Workflow Administration (SWA) by following steps:

1. Login to SWA with your specific password.
2. Press the info link in the upper right corner (see screenshot).
-> the system version info will be displayed in a separate window.

If you don't know whether you are using the "Portal Radiologist" license you can perform a check in the syngo Workflow Administration (SWA) by following steps:

1. Login to SWA with your specific password.
2. Navigate to License Tab (System-->syngo Workflow Manager-->View Licenses)
3. Check whether in the column "Result" for the "IWM_RAD_PORTAL" license the text "no-license" is available (see screenshot).
-> if not you have a valid "Portal Radiologist" license and your system is potentially affected

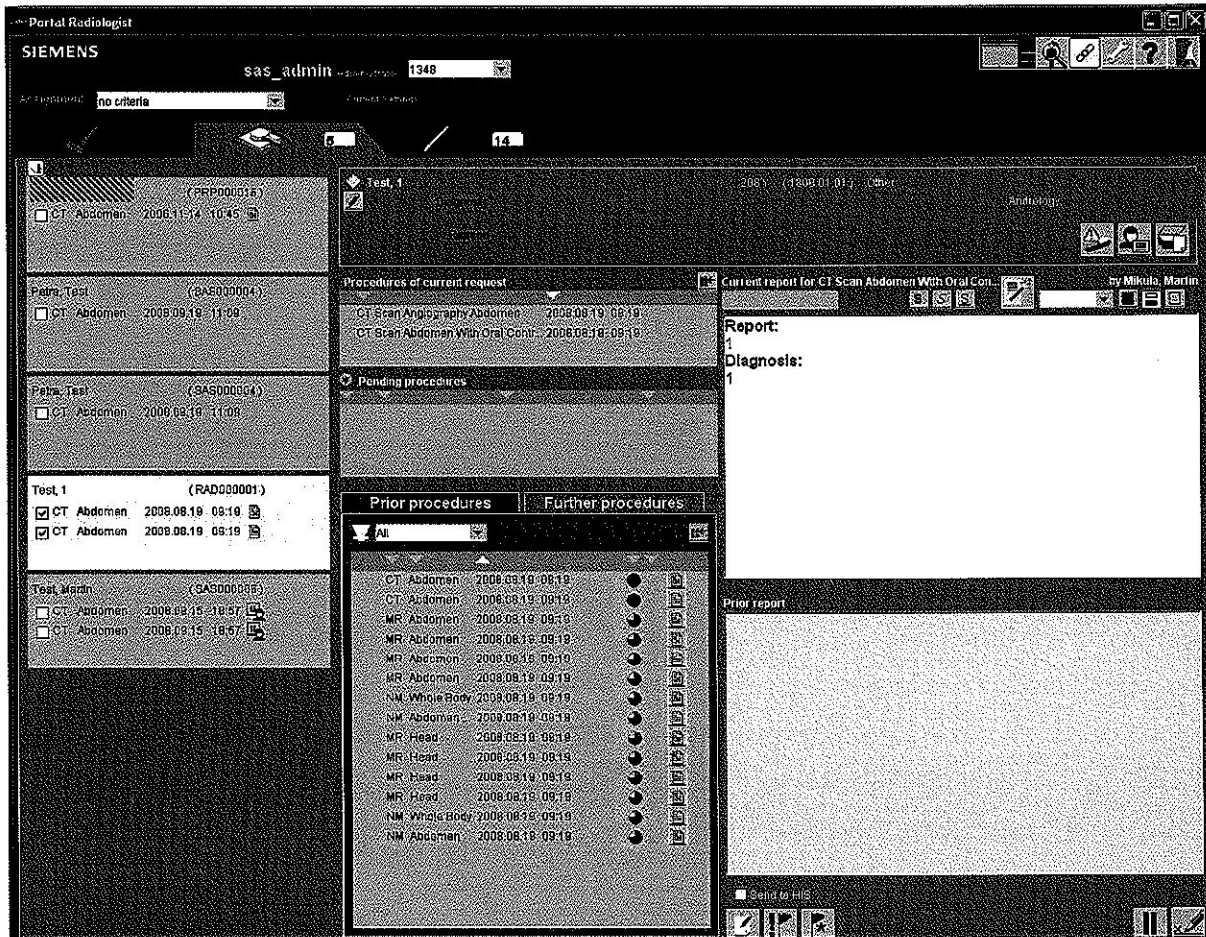
The screenshot shows the 'View Licenses' page in the syngo Workflow Manager. The table below lists various licenses with their details.

Name	Version	Result	Used	Configured
IWM_SERVER	5.000	no-license	n.a.	1
IWM_DWL	2.000	999999	n.a.	4
IWM_ARICOM	2.000	999999	n.a.	n.a.
IWM_MPPS	2.000	999999	n.a.	3
IWM_REPORT	2.000	999999	n.a.	n.a.
IWM_CLIENT	3.000	999999	1	24
IWM_SCHED	3.000	999999	n.a.	n.a.
IWM_HL7	2.000	999999	n.a.	n.a.
IWM_HL7_OE	2.000	999999	n.a.	n.a.
IWM_HL7_REP	2.000	999999	n.a.	n.a.
IWM_HL7_BILL	2.000	999999	n.a.	n.a.
IWM_HL7_SCHED	2.000	999999	n.a.	n.a.
IWM_WVOE	2.000	999999	n.a.	n.a.
IWM_WVOE_SCHED	2.000	999999	n.a.	n.a.
IWM_FAX	2.000	no-license	n.a.	n.a.
IWM_DICTAT	2.000	999999	n.a.	n.a.
IWM_ONLINE	2.000	999999	n.a.	n.a.
IWM_STATISTIC	1.000	999999	n.a.	n.a.
IWM_GERMAN_BILL	1.000	999999	n.a.	n.a.
IWM_HL7_SCHED_WF	1.000	999999	n.a.	2
IWM_RAD_PORTAL	1.000	no-license	n.a.	n.a.
IWM_PACS_ACCOUNT	1.000	999999	0.00%	9999990000
IWM_TRANS_PORTAL	1.000	999999	n.a.	n.a.

If you have questions or need support for the check you can also contact your local SIEMENS Uptime Service Center for support.

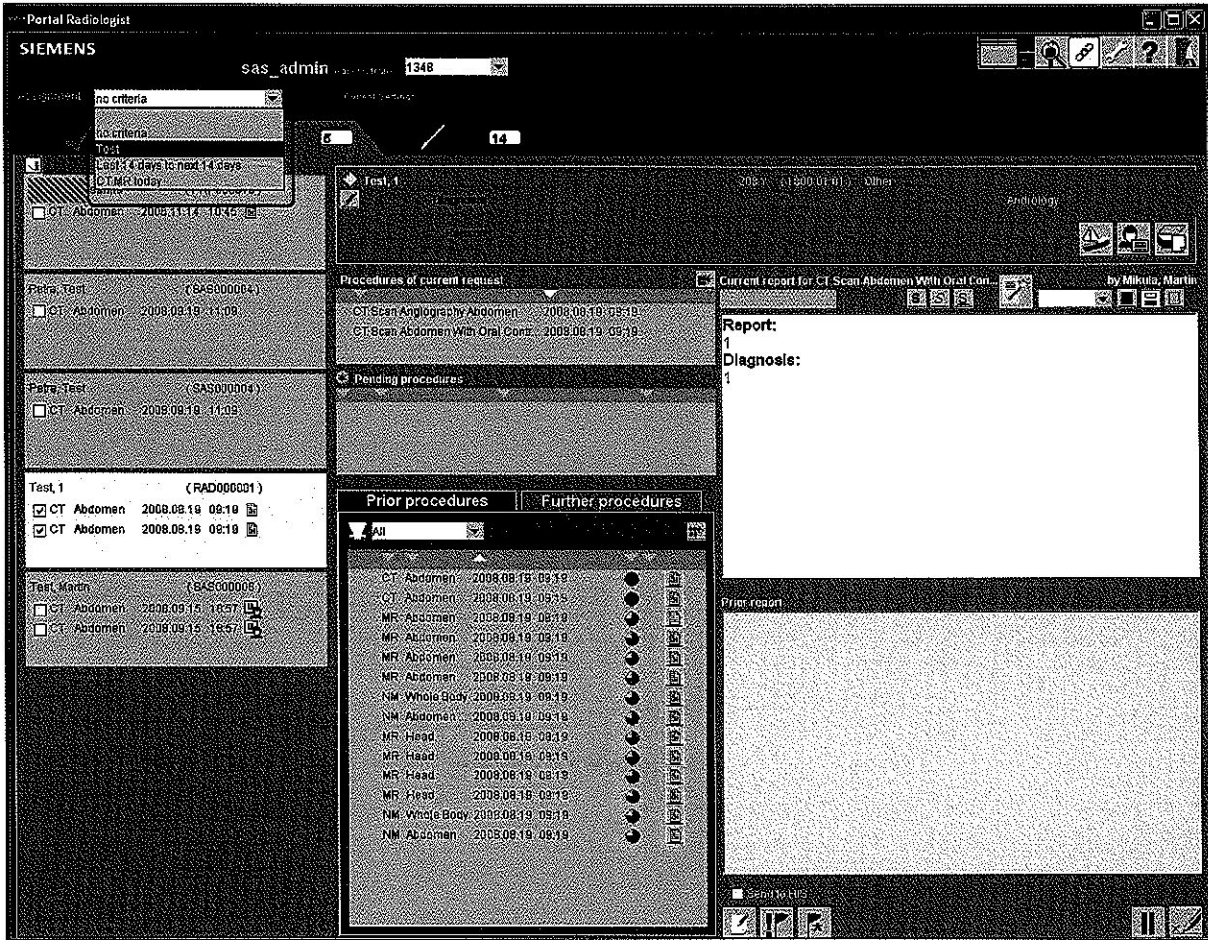
In case you are affected the issue can occur under the following scenario:

- Select an examination in "Read Images" task
(Examination is selected as shown in screen shot below)



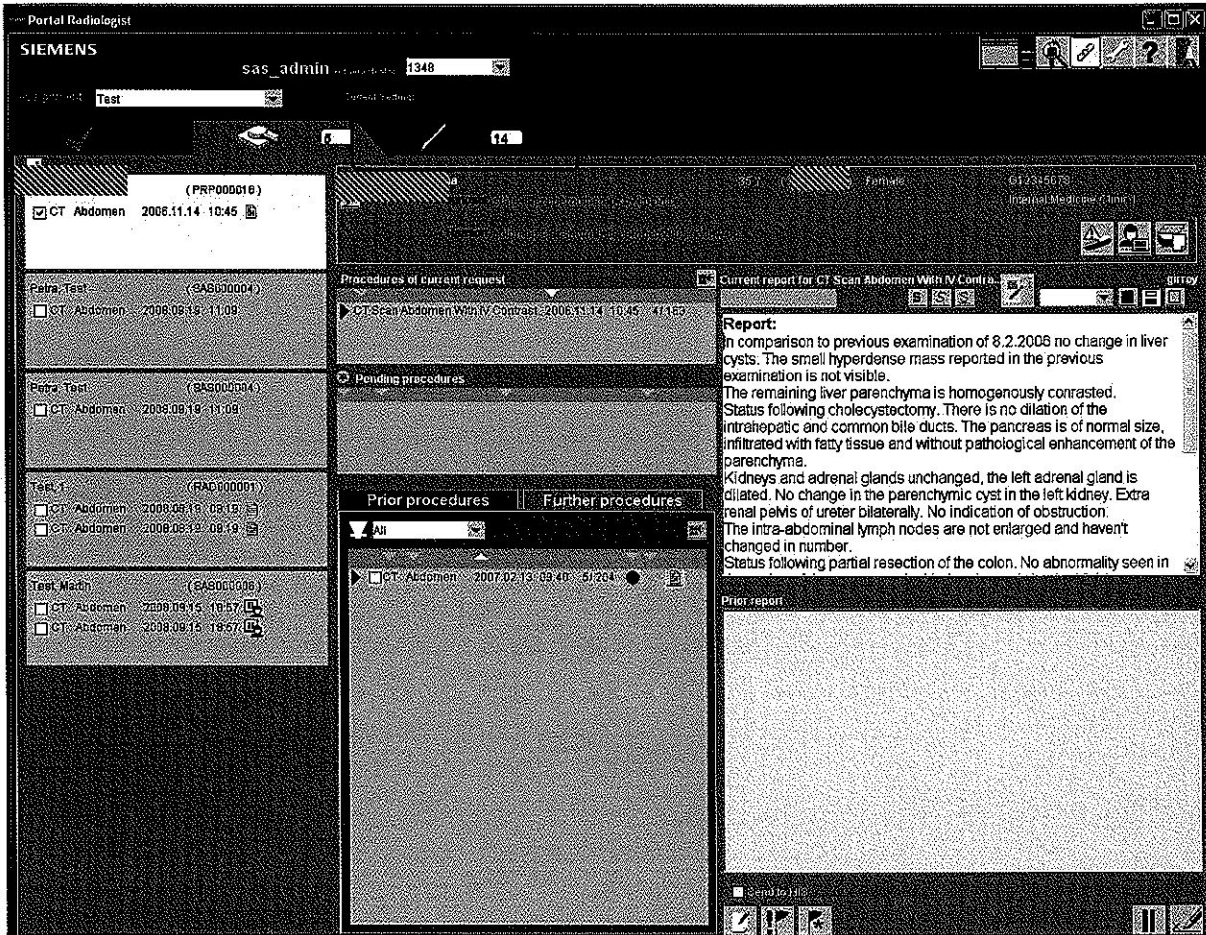
Technical information -> Internal state will be changed:
2008-09-22 11:35:24,301 INFO [de.siemens.med.pacs.iwm.client.actions.ChangeStateAction] new current portal state: readimages

- Select another assignment in "Read Images" task



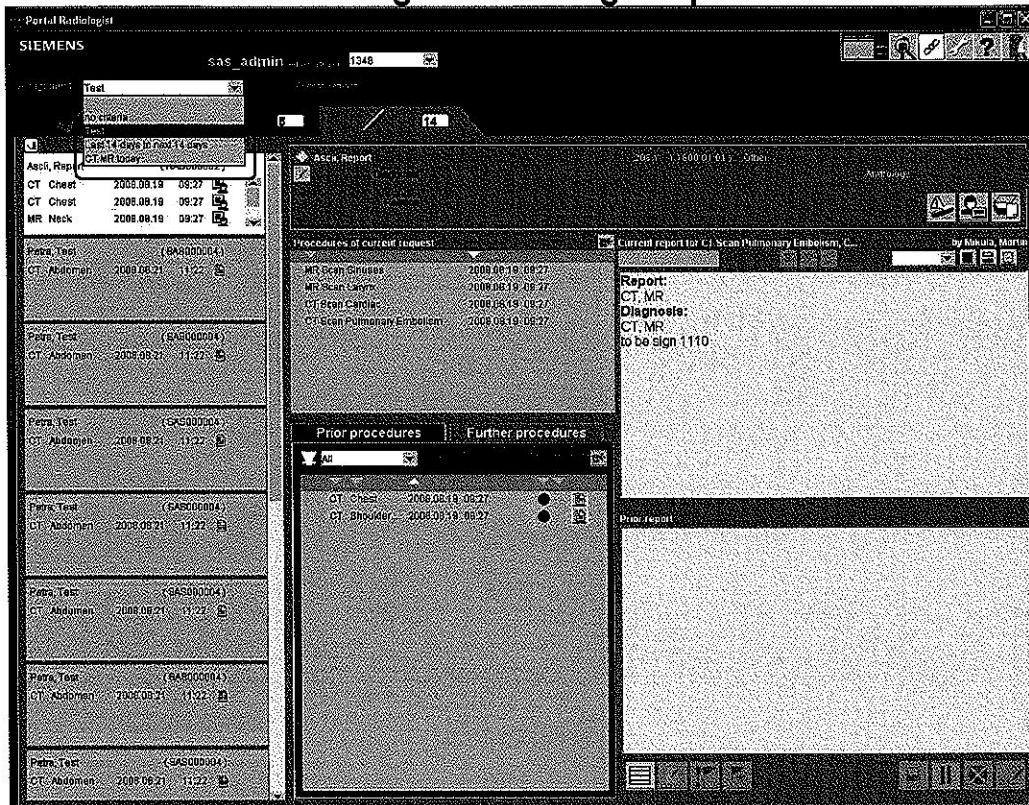
Technical information -> Internal state will be changed:
2008-09-22 11:35:26,214 INFO [de.siemens.med.pacs.iwrη.client.actions.ChangeStateAction] new current portal state: readimages

The first examination is now selected and loaded automatically in "Read Images" task
- Perform a manual change to "Sign Reports" task.



Technical information -> Internal state will be changed:
2008-09-22 11:38:33,314 INFO [de.siemens.med.pacs.iwm.client.actions.ChangeStateAction] new current portal state: signreports

- Select another assignment in "Sign Reports" task



Technical information -> Internal state will be changed:
 2008-09-22 11:42:46,734 INFO [de.siemens.med.pacs.iwm.client.actions.ChangeStateAction] new current portal state: readimages

As from now on the wrong editor (from "Read Images" task) is used unless you select a new examination in "Sign Reports" task by a mouse click.

This can result in a mix up of other patients report texts to the selected patients report when updating/saving the changes. The original patient reports are not changed !

This causes a potential risk of an indirect patient harm in following scenarios :

Scenario1:

Report of a patient with disease is applied to a healthy patients report.

-> Healthy patient is treated based on the wrong report text without having the necessity for a treatment.

Scenario2:

Report of a patient with no disease is applied to a diseased patients report.

-> Diseased patient is not treated based on the wrong report text but patient has the necessity for treatment.

Scenario3:

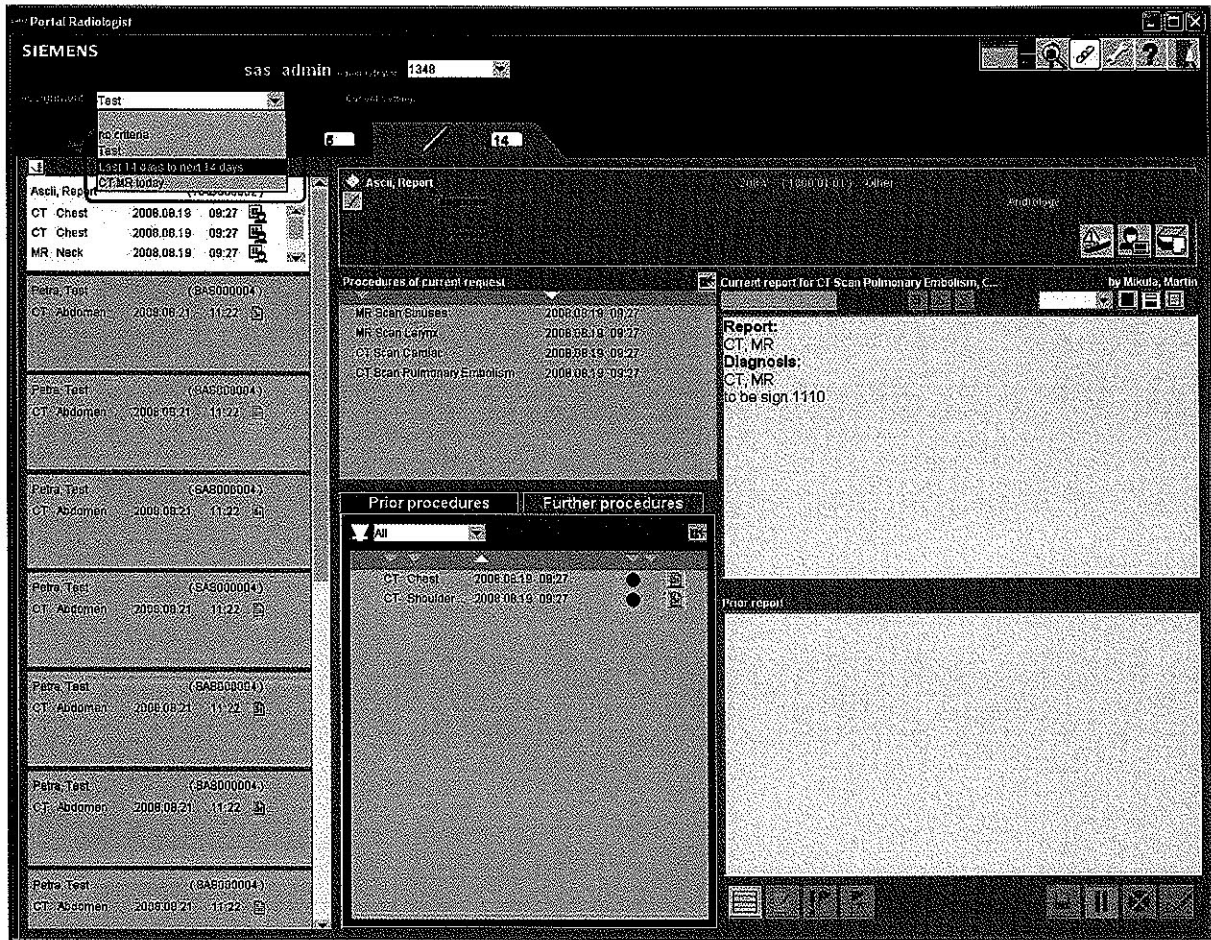
Report of a patient with serious disease is applied to a diseased patients report but the content of report is wrong.

-> Sick patient is treated wrong based on the wrong report text.

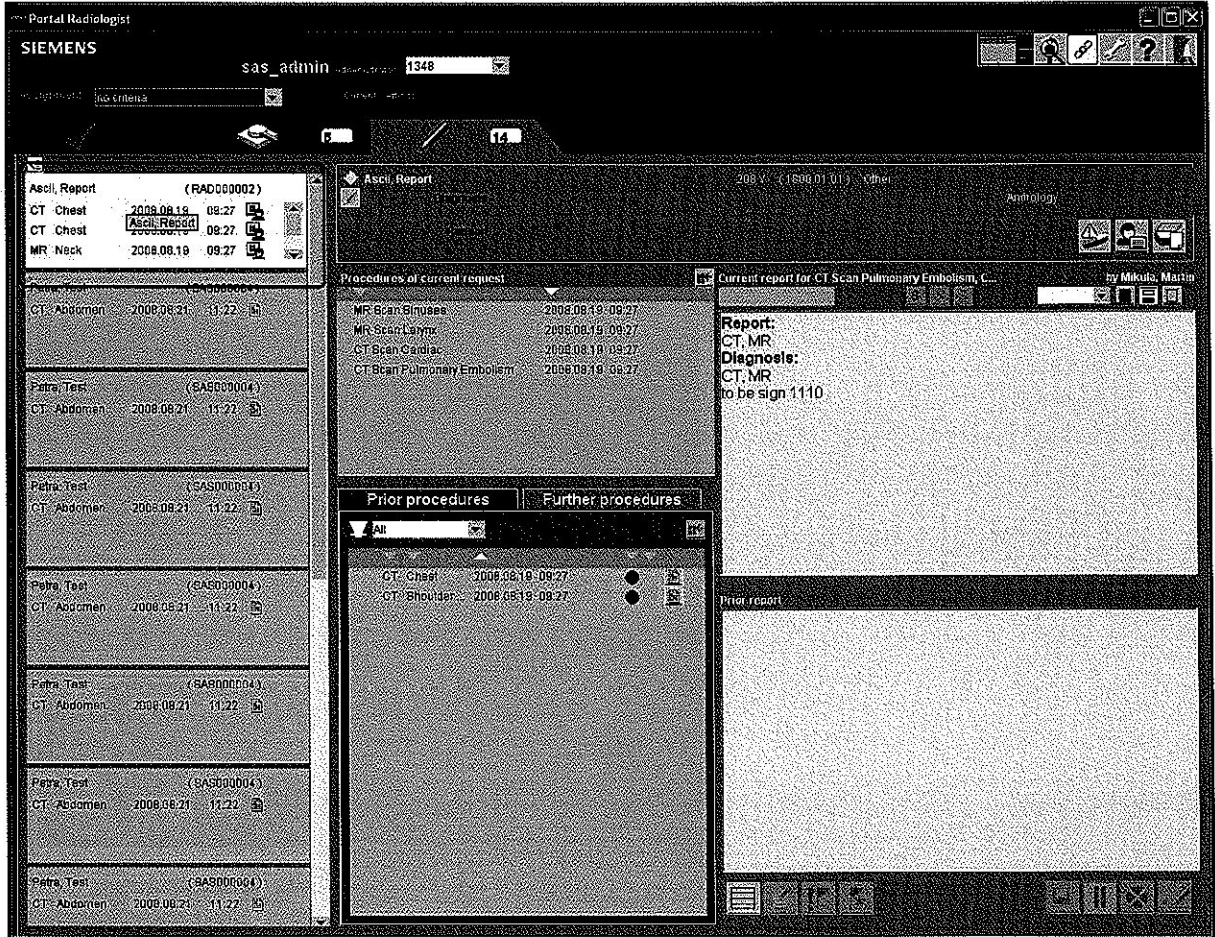
What steps can the user take to avoid the potential risk of this issue ?

Affected sites can most easily remove this risk entirely by taking care of following actions during their clinical workflow :

- Based on the scenario described before after selection of a new assignment in „Sign Reports“ task the first examination is selected and loaded automatically.



- To avoid the problem you have to explicitly select the desired entry - even if it was selected automatically - by a mouse click which prevents from the potential mix up of patient reports.



How will the issue finally be resolved ?

Siemens is preparing a modification "VB30A_SRV6" under the UI IM105/08/S for the affected versions of *syngo* Workflow MLR that will resolve the potential malfunction.

As soon as the field modification is available it will be immediately distributed and installed by our Service on the affected systems.

We appreciate your understanding and cooperation with this safety advisory and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory is placed in the system's instructions for use. Your personnel should maintain awareness of this issue until the modification is installed on the system.

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.

If you have further questions regarding this issue do not hesitate to contact your local SIEMENS Uptime Service Center.

Sincerely Yours

U / A

[REDACTED]
Head of development

[REDACTED]
Head of quality management)