

Siemens Healthcare GmbH, HC SV DS, Henkestr. 127, 91052 Erlangen

Name	Christiane Eschler
Department	HC SV DS QT PMS
Telephone	+49 (9131) 84-5477
Fax	+49 (9131) 84-2792
Email	christiane.eschler@siemens-healthineers.com
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CUSTOMER SAFETY ADVISORY NOTICE

To all users of *syngo* Workflow MLR using Portal Radiologist

Affected versions:

VB30C, VB30E, VB30F, VB35A, VB35B, VB36A, VB37A

***syngo* Workflow MLR: Reports signed off in Portal Radiologist are not transferred to external systems sporadically**

Dear customer,

This letter is intended to inform you of a potential issue when using Portal Radiologist in *syngo* Workflow MLR for signing off reports.

What is the issue and when does it occur?

Whenever a report is signed off in Portal Radiologist there has to be information exchange between RIS and other external system (HIS, PACS). Due to sporadic synchronization issues within an MLR application internal process, it can fail to return the appropriate data. The report will not be shared with external systems. The report content is intact within *syngo* Workflow MLR.

Siemens Healthcare GmbH
Management: Bernhard Montag, Vorsitzender;
Thomas Rathmann, Michael Reitermann

Henkestr. 127
91052 Erlangen
Deutschland

Tel.: +49 (9131) 84 0
Fax: +49 (9131) 84 0
www.siemens.com/healthcare

Chairman of the Supervisory Board: Michael Sen;
Registered office: München, Germany; Commercial Registry: Munich, HRB 213821
WEEE-Reg.-Nr. DE 64872105

What steps can the user take to avoid the issue?

The clinical workflow in life-threatening or critical patient situations shall not be report driven. Routine reporting of imaging findings is communicated through the usual channels established by the hospital or diagnostic imaging facility (e.g. information exchange to external systems like HIS, PACS). In **emergent or other non-routine clinical situations**, the interpreting physician should expedite the delivery of a diagnostic imaging report (preliminary or final) in a manner that reasonably ensures timely receipt of the findings. This communication will usually be to the ordering physician/health care provider or his/her designee.

How will the issue finally be resolved?

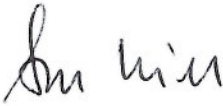
For the 'Affected versions' of syngo Workflow MLR, a fix of this potential malfunction is in preparation by Siemens Healthcare GmbH. With the upcoming syngo Workflow MLR version VB37B, the issue will be resolved as well. Both solutions are planned to be released end of June 2017.

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 update is performed. 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

June 23rd, 2017 

Date / Kaindl, Arthur
Digital Health Services CEO

June 23rd, 2017 

Date / Schneider, Roland
Digital Health Services Head of Quality
and Technology