

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

Name Department Christiane Eschler HC SV DS QT PMS

Telephone Fax +49 (9131) 84-5477 +49 (9131) 84-2792

Fax Email

christiane.eschler@siemens-healthineers.com

Our reference

PM00083179

Date

June 23, 2017

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.

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.

June 23rd, 2017 Sm Will June 23rd, 2017 1. Selleda

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

Sincerely Yours

Date / Kaindl, Arthur

Digital Health Services CEO

Date / Schneider, Roland

Digital Health Services Head of Quality

and Technology

SCF 02/2015 V13.06 Page 2 of 2