

Customer
Hospital
City
Postal code
Country
Attn.: XXX

[ISSUE
DATE]

Field Safety Notice: AQUIRE FLEXLINK

Priority Level: Urgent

Dear Customer

RADIOMETER has recently become aware of a potential risk of patient mix-up when using the FLEXLINK application with AQUIRE versions 1.8.2 and 1.8.3, build 348.

The potential risk of patient mix-up may occur under the following circumstances:

- A FLEXLINK registration is open for patient A which has been scanned
- The operator wants to scan a sample from patient B and opens a new FLEXLINK registration without closing the previously opened FLEXLINK registration

When the new FLEXLINK registration is opened the patient information from patient A will be prefilled. If this is not noticed by the operator patient mix-up can occur as the sample will be scanned as belonging to patient A, even though it belongs to patient B

Affected product:

When using the FLEXLINK application with AQUIRE the following AQUIRE versions are affected:

AQUIRE version 1.8.2,
AQUIRE version 1.8.3, build 348

Solution

All affected AQUIRE installations listed above using the FLEXLINK application must be upgraded to version 1.8.3 with a build number higher than 348. Your local RADIOMETER IT specialist will contact you in order to schedule the upgrade at your earliest convenience.

In the meantime then:

- Please ensure that all operators are instructed to always close a previous FLEXLINK registration before opening a new registration
- Please return the confirmation fax form no. 1 to your RADIOMETER representative when the above action has been completed
- Please return the confirmation fax form no. 2 to your RADIOMETER representative when your AQUIRE installation has been upgraded to version 1.8.3 with a build higher than 348.

RADIOMETER has informed your national competent authority of this Field Action as required.

If you have any questions, please contact your RADIOMETER representative. RADIOMETER sincerely apologizes for the inconvenience this situation may cause you.

Best regards,
<Radiometer distributor>

Recall Response Fax Form no. 1

Fax No.:

Concerning:

AQURE FLEXLINK

- I have received the customer letter and I confirm that all operators are instructed to always close a previous FLEXLINK registration before opening a new registration.

Hospital Name:	
Your Name:	
Date:	
Signature:	
Email Address:	

Recall Response Fax Form no. 2

Fax No.:

Concerning:

AQURE FLEXLINK

- My AQURE installation has now been upgraded to version 1.8.3 with a build number higher than 348.

Hospital Name:	
Your Name:	
Date:	
Signature:	
Email Address:	