

Customer
Hospital
City
Postal code
Country
Attn.: XXX

URGENT Field Safety Notice

AQURE System

– possible incorrect reply on patient queries from LumiraDx device

Dear Customer

Radiometer has become aware of a potential problem relating to the AQURE System that may result in the patient mix-up when connected to the LumiraDx device. Please note that per default, the LumiraDx driver is disabled on your AQURE System.

Affected products

AQURE Systems with versions:

- 2.5.2
- 2.5.3
- 2.5.4
- 2.6.0
- 2.6.1

The patient mix-up may occur in the following scenario:

Patient A:

User draws a patient's blood sample or nasal swap (Patient A).

- The sample is taken to the LumiraDx device, where the user should either scan in patient details using the barcode scanner or enter patient details manually.
- If there's an active connection to the HIS/LIS, Patient details can be searched using the search function.
- After entering patient details, a patient query is sent to AQURE for which AQURE does not respond, meaning that no patient details will be returned to the LumiraDx device.
- When AQURE does not provide a response to the patient query, the user will then have the option to confirm and proceed with manually entered patient details.
- Sample is inserted into the device and a result is shown on the screen of the LumiraDx device with manually entered patient details.

Patient B:

User is drawing a blood sample or nasal swap from a patient (Patient B)

- This new sample is taken to the LumiraDx device where the user should follow the same procedure as described for Patient A, either scan in patient details using the

barcode scanner, enter patient details manually, or search for patient information using the search function on the LumiraDx device.

- A patient query is then sent to AQUIRE which AQUIRE responds with patient details for Patient A instead of Patient B.
- The user shall confirm the patient details before continuing with the sample analysis.
- User will notice that patient details are incorrect and can choose to decline them and instead enter patient details manually and confirm those.
- If the user does not notice that AQUIRE has transmitted patient identification data for an incorrect patient, there is a risk that measurement results from Patient B will be connected to patient A

Risk for the patient

The described error may potentially result in a patient with critically or life-threatening elevated levels of D-dimer or NT-pro-BNP being diagnosed as having levels of D-dimer or NT-pro-BNP within the normal range. This will put the patient at risk of not being diagnosed with and treated for deep venous thrombosis or pulmonary embolus, potentially resulting in permanent organ damage or death, or not being diagnosed with and treated for heart failure, potentially resulting in permanent heart damage or death.

Your actions

Radiometer kindly requests you to perform the following actions:

1. With immediate effect, cease using the LumiraDx devices if connected with an AQUIRE system with the above versions.
2. Within two weeks of receipt of this letter, complete and email a copy of the Recall Response Form (last page) and return it to your Radiometer representative.

Solution provided by Radiometer

Your local Radiometer representative will contact you to schedule a visit or a remote session.

- If you use LumiraDx devices connected with AQUIRE, your AQUIRE system must be upgraded. Your local Radiometer representative will contact you when a solution is available.
- If you do not use LumiraDx devices, your Radiometer representative will contact you and remove the LumiraDx driver from the AQUIRE system, hence preventing the usage of LumiraDx devices in context with your current AQUIRE system(s).

Your help is appreciated

If you are not the end-user of the affected product, please ensure that this letter is distributed to the final end user.

If you have any questions, please contact your Radiometer representative.

Radiometer sincerely apologizes for the inconvenience this situation may cause you.

Best regards,

<State Radiometer distributor name>

Recall Response Form

Concerning:

AQURE

– possible incorrect reply on patient queries from LumiraDx device

- I have received the customer advisory letter, and do not have any LumiraDx devices connected.

or

- I have received the customer advisory letter and hereby confirm that we, with immediate effect, have ceased using the LumiraDx devices connected with an AQURE system of the affected versions.

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