Customer
Hospital
City
Postal code
Country
Attn.: XXX

Urgent Field Safety Notice
ABL800 with FLEXQ sampler tray, Risk of patient mix-up

Dear Customer

This is a follow-up on previous communication, distributed May 2020.
Radiometer has released a new software version, V6.19 MR1, to correct this issue, and we have now installed the new software in your analyzer.

Consequence of software version 6.19 MR1 being installed
You may now revoke the countermeasure, CM #1 or CM #2, put in place as per our previous communication.

Recap of previous communication, distributed May 2020:

Background
The communication relates to a potential risk of patient mix-up on ABL800 analyzers with FLEXQ sampler tray. As mentioned, the mix-up would only occur if the analyzer was setup in a specific manner and a specific sequence of events occurs as detailed below.

Setup of the analyzer:
- Batch mode is not enabled - hence, each sample needs to be processed before placing another sample in the FLEXQ sampler tray
- Run a patient sample is not allowed as anonymous user - hence, the operator must log on to run a patient sample.
- Request patient demographics is enabled - hence, the analyzer requests the patient demographics from Radiance, AQURE or a HIS/LIS system upon reading the barcode on the sampler.

Sequence of events:
The mix-up can occur with the above setup if the operator after having placed the sampler in the FLEXQ, is viewing previous patient results when waiting for the patient demographics to be returned from the designated system (HIS/LIS, AQURE or Radiance), and the patient demographics are not returned.

In this case the previous patient result viewed will be overwritten with the sample results and sample number from the sample just placed.

Risk for the patient
The described error may lead to potentially assigning erroneous measurement results belonging to the current patient to another patient. In a worst-case scenario, where a critical parameter, such as K+ or pO_2 is interrogated, based upon wrongful clinical diagnosis inferred from the mixed-up results, a critically ill patient may be subjected to lack of vital treatment.

Affected product
All ABL800 analyzers with FLEXQ sampler tray.

Your actions
If you have the above described analyzer setup, you have to select one of the two countermeasures (CM) below:

CM #1:
Change the setup of operators so that
a) an operator allowed to perform a measurement cannot be allowed to edit data-logs
b) an operator allowed to edit data-logs cannot be allowed to perform a measurement

Or

CM #2
Instruct all operators to always log on to the analyzer before placing a sampler in the FLEXQ sampler tray, as this will prevent access to data-logs while processing the sample

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.

For our records we kindly request you to fill in, sign and hand over the last page of this letter to your Radiometer service engineer.

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

Best regards,
<Radiometer distributor>

Recall Response Form

Concerning:

ABL800 with FLEXQ, Risk of patient mix-up

□ I have received the customer advisory letter, and can confirm that:

□ Radiometer has now installed software version 6.19 MR1 on my analyzer

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