

Customer
Hospital
City
Postal code
Country
Attn.: XXX

Urgent Field Safety Notice

ABL800 with FLEXQ sampler tray, Risk of patient mix-up

Dear Customer

Background

Radiometer has become aware that there is a potential risk of patient mix-up on ABL800 analyzers with FLEXQ sampler tray.

The mix-up will only occur if the analyzer is:

- Setup in a specific manner

And

- A specific sequence of events occurs

As described 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, AQUIRE 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, AQUIRE 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 pO₂ 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

Then Radiometer kindly requests you to:

- Complete the Recall Response Form (last page of the customer advisory letter).
- Within two weeks from receipt of the customer advisory letter e-mail a copy of the Recall Response Form to your Radiometer representative.

Solution provided by Radiometer

Radiometer is working on revising the software to correct this issue. Once the revised software is released, your Radiometer representative will contact you to schedule a visit for the software upgrade.

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 distributor.

Best regards,

<Radiometer distributor>

Recall Response Form

Concerning:

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- ☐ I have received the customer advisory letter, and can confirm that:
 - ☐ None of our analyzers has the described setup
 - ☐ We have implemented CM #1, all operator rights have been changed so no operator is allowed to both run a sample and edit data-logs
 - ☐ We have implemented CM #2; all operators have been instructed to always log on to the analyzer before placing a sampler in the FLEXQ sampler tray

Please note, that Radiometer will provide the solution described to your analyzer irrespectively of the answers above.

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