[ISSUE DATE]

Field Action Notice: ABL90 FLEX / ABL90 FLEX PLUS

Dear Customer

In September 2016 Radiometer informed about a potential risk that the analyzer may report patient results although analyzer performance has not been verified by running quality controls.

The issue may occur if the operator manually exits the Conditioning mode, which is active during the initial startup of a new Sensor Cassette.

The final solution to this issue, which is an upgrade of the ABL90 FLEX / ABL90 FLEX PLUS software to software version 3.3 or higher, is now installed at your analyzer(s). This new version ensures that the analyzer will now run quality controls before blood measurements are possible.

Affected product:

ABL90 software versions below V3.3

What you should do short term:

No actions, as the temporary counter measure has already been implemented.

Please Note:

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, <Radiometer distributor>