

Customer
Hospital
City
Postal code
Country
Attn.: XXX

URGENT Field Safety Notice

ABL90 FLEX and ABL90 FLEX PLUS – Analyzer may unexpectedly "freeze" and restart during sample measurement

Dear Customer

Radiometer has become aware of a potential risk with ABL90 FLEX and ABL90 FLEX PLUS analyzers when operating with Radiometer Windows 10 versions (RWIN10 1.0 and 1.1). Specifically, the analyzer software may unexpectedly "freeze" and restart during a sample measurement, causing the analyzer to cease operation during the startup period.

The software includes a watchdog feature designed to detect such freezes and automatically restart the software, allowing the analyzer to resume operation. However, if a restart occurs, any sample being processed at that time will be lost.

Risk to the patient

There is a remote probability that the unexpected analyzer software restart could cause serious or life-threatening adverse health consequences, as the patient's blood sample may be lost, and treatment could be delayed.

Affected products

ABL90 FLEX and ABL90 FLEX PLUS analyzers running with RWIN10 versions 1.0 and 1.1.

For EU Countries only the following is to be included in the translated letter:

ABL90 FLEX: 57006900050MQ

ABL90 FLEX PLUS: 57006900051MS

(UDI = Unique Device Identifier – DI = Device Identifier)

Solution provided by Radiometer

Your local Radiometer representative will contact you to discuss upgrading your analyzer to RWIN10 1.2.

Your actions

Radiometer kindly requests that you do not use the analyzer without having an alternative solution readily available. Alternative solutions could include using an additional analyzer or sending the sample to a central laboratory. This also involves ensuring that there is enough

patient sample for a second measurement, in case the sample is lost due to the analyzer restarting.

Further, please complete the Recall Response Form (on the last page of this letter) and return it to your Radiometer representative within a week of receiving this letter.

Your help is appreciated

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

ABL90 FLEX and ABL90 FLEX PLUS
– Analyzer may unexpectedly "freeze" and restart during sample measurement

☐ I have received the customer letter and can confirm that:

☐ I have ensured I have an alternative solution readily available such as using an additional analyzer or sending the sample to a central laboratory.

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