RADIOMETER
Legal Manufacturer: Radiometer Medical ApS
Åkandevej 21, 2700 Brønshøj, Denmark
Telephone: +45 38 27 38 27

Customer
Hospital
City
Postal code
Country
Attn.: XXX

URGENT Field Safety Notice

ABL90 FLEX PLUS
– Analyzer may abort capillary samples

Dear Customer

Radiometer has become aware of a potential issue with your ABL90 FLEX PLUS analyzer(s) with the following serial number(s): 393-092R0xxxN00xx.
A defect in the inlet module may prevent it from returning to its closed position after sample aspiration for capillary samples, resulting in an aborted measurement.

The analyzer operates correctly for syringe samples.

Affected product
ABL90 FLEX PLUS analyzers with the following serial number(s): 393-092R0xxxN00xx.

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

ABL90 FLEX PLUS: 57006900051MS

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

Solution provided by Radiometer
Your Radiometer representative will contact you to arrange a visit to replace the inlet module.

Your actions
With immediate effect, Radiometer requests that you do not run capillary samples on the affected analyzer(s) until the inlet module has been replaced.
You may continue to use the analyzer for syringe samples.

Please complete the Recall Response Form (on the last page of this letter) and return it to your Radiometer representative within two weeks of receiving this letter.

Your help is appreciated
If you are not the end user of the affected product, please ensure this letter is distributed to the end user.

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

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

Best regards,
<State Radiometer distributor name>

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Recall Response Form

Concerning:

ABL90 FLEX PLUS
– Analyzer may abort capillary samples

☐ I have received the customer advisory letter and confirm that we do not run capillary samples on our analyzer(s) with the following serial number(s): 393-092R0xxxN00xx until the inlet module has been replaced.

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