

Customer  
Hospital  
City  
Postal code  
Country  
Attn.: XXX

[ISSUE  
DATE]

## Field Safety Notice: AQT90 FLEX Analyzer

### Priority Level: Urgent

Dear Customer

RADIOMETER has recently become aware of a potential significant clinical issue where a measured parameter with a positive result may be reported as being negative.

The problem may occur in rare situations where the analyzer uses an incorrect Hct value equal to 0% as a result of sample transport issues.

#### Level of bias:

The table below shows the potential bias of the results (measured in %) for two levels of the Hct value, 62% (worst case) and 40% as follows:

Parameter	Bias (%) if Hct = 62 % *)	Bias (%) if Hct = 40 % *)
CKMB	-59	-37
MYO	-61	-39
TnI	-55	-34
TnT	-54	-37
B-hCG	-59	-37
NT-proBNP	-59	-33
CRP	-64	-42
D-dimer	-68	-44

\*) True Hct value of the sample.

#### Affected product:

AQT90 FLEX analyzer.

#### What you should do short term:

- Please ensure that 'System Clean' is performed regularly as recommended by the analyzer. Please refer to Instructions For Use.

(For software versions V8.6.118 onwards the System Clean is automatically requested by the analyzer).

- Please return the confirmation fax form to your RADIOMETER representative when the above action has been implemented.

**Temporary Countermeasure provided by RADIOMETER:**

Your RADIOMETER representative will contact you to perform a test to determine if your analyzer potentially is subject to this issue.

If required your RADIOMETER representative will perform corrective actions to eliminate the issue.

**Final Solution provided by RADIOMETER:**

An upgraded version of the analyzer software will include an analysis process check to eliminate the possibility of this error. The new software version will be installed by your local engineer when available.

**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 the test performed by your RADIOMETER representative shows that your analyzer is affected by this problem it is recommended that you review previous patient results.

RADIOMETER has informed your national competent authority of this Field Action as required.

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>

# Recall Response Fax Form

Fax No.:

Concerning:

## **AQT90 FLEX Analyzer**

- I have received the customer letter and I confirm that the short term action has been implemented.

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