Customer
Hospital
City
Postal code
Country
Attn.: XXX

Field Safety Notice: AQT90 FLEX Software Version 8.5.94

Priority Level: Urgent

Dear Customer

RADIOMETER has recently become aware of a potential clinical significant issue with the result transmitted to RADIANCE and AQURE and forwarded to HIS/LIS. The problem is that the AQT90 FLEX in the situation described below may lose a result. This means that no result will be available on the AQT90 FLEX but an erroneous result reported as below reportable range will be transmitted to RADIANCE/AQURE and forwarded to HIS/LIS.

The problem can occur in the following situation:

- The user leaves the main screen of the AQT90 Data Management System while a test is being completed, AND
- The result used for the diagnosis is taken from RADIANCE/AQURE or HIS/LIS (i.e. not from the AQT90 FLEX itself)

Where the result used for diagnosis is taken from the AQT90 FLEX you may realised that the result is missing and repeat testing even though an erroneous result was sent to RADIANCE/AQURE and HIS/LIS.

Depending on the parameter measured, the result in RADIANCE/AQURE and in HIS/LIS will be:

Beta hCG:	<2 IU/L
CKMB:	<2 µg/L
CRP:	<5 mg/L
D-dimer:	<80 µg/L
Myoglobin:	<20 µg/L
NT-proBNP:	<20 ng/L
Troponin I:	<0.010 µg/L
Troponin T:	<0.010 µg/L

The consequence of this error can be that the analyzer measures a high result which is displayed as no result on the analyzer screen and as a falsely low result in RADIANCE/AQURE.

Affected product:
AQT90 FLEX analyzers running with software version V8.5.94, which are connected to RADIANCE/AQURE or HIS/LIS systems.

Solution:
Your local RADIOMETER representative will contact you to arrange for an upgrade of your analyser software.

In the meantime, please ensure that the result used for diagnosis is taken from the AQT90 FLEX and **not** from RADIANCE, AQURE or HIS/LIS.

If you have any questions, please do not hesitate to contact us.

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

Best regards,
<Radiometer distributor>

Response Fax Form 1

Fax No.:

Concerning:

AQT90 FLEX Software Version 8.5.94

□ I acknowledge receipt of the customer letter and confirm that we have ensured that the result used for diagnosis is taken from the AQT90 FLEX and **not** from RADIANCE and AQURE or HIS/LIS.

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

Response Fax Form 2

Fax No.:

Concerning:

AQURE unit conversion

□ I confirm that the software of my analyzer has been upgraded to version 8.6.118.

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