Customer
Hospital
City
Postal code
Country
Attn.: XXX

[ISSUE DATE]

Field Safety Notice: AQT90 FLEX Test Kit Box and CAL Cartridge

Priority Level: Urgent

Dear Customer

RADIOMETER has recently become aware of a potential risk of receiving false negative results with the AQT90 FLEX Test Kit Boxes and CAL Cartridges mentioned below.

Five lots of test kits and calibration adjustment cartridges have been manufactured with misaligned protective foil on the cartridge. The cartridges are delivered in sealed pouches containing an absorbent and the cartridges also contain an absorbent. As long as the pouch is sealed, the cartridge is protected by the pouch absorbent and the cartridge absorbent. However, when the pouch is opened, the misalignment of the foil may or can cause the absorbent in the cartridge to be in contact with the environment and may impact or affect the drying capacity which may result in it being used quicker than normal. As the cups in the cartridge are sensitive to humidity, the issue may affect in-use stability of the cups causing an increased risk of false negative results.

Affected product:
AQT90 FLEX Test Kit Boxes and CAL Cartridges are affected:

Analyte	Test Kit Box	CAL Cartridge	Lot No.
TnI	942-903	944-212	11348
D-Dimer	942-915	944-220	11350
NT-proBNP	942-930	944-258	11360
TnT	942-940	944-268	11379
TnT 8 Test	942-967	944-268	11380

Please note that the Lot numbers refer both to the Test Kit Boxes and the CAL Cartridges.

What you should do:

- Please check your inventory and discard any AQT90 FLEX Test Kit Boxes and CAL Cartridges from the affected lots listed above.
- Please check the AQT90 FLEX Test Kit Boxes and CAL Cartridges distributed within your institution and discard any items from the affected lots.

- If any of the affected products have been used for clinical evaluation the results affected by this should be reviewed.
- Please complete page 2 of this letter and return to your RADIOMETER representative.

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.

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

Your RADIOMETER representative will replace the quantity of AQT90 FLEX Test Kit Boxes and CAL Cartridges discarded by you.

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 no. 1

Fax No.:

Concerning:

AQT90 FLEX Test Kit Box and CAL Cartridge

□ I have received the customer letter and reviewed my current inventory of AQT90 FLEX Test Kit Boxes and CAL Cartridges.

All Test Kit Boxes and CAL Cartridges of the affected lots have been removed and discarded.

I have discarded the following quantities

Test Kit Box	QTY
842-903	
942-915	
942-930	
942-940	
942-967	

CAL Cartridge	QTY
944-212	
944-220	
944-258	
944-268	
944-268	

□ I have none of the affected lot in stock.

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