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

*safe*PICO A aspirating blood syringe

Dear Customer

Background
Radiometer has become aware of an issue with the *safe*PICO A aspirating blood syringe. The issue relates to the sterile barrier system for the product.

For this reason, Radiometer kindly requests you to stop using the affected product with immediate effect.

Risk for the patient
The described error may potentially result in bacterial bloodstream infection. The bloodstream infection may be asymptomatic but may also progress to sepsis or life-threatening septic shock. Immunosuppressed patients are at particular risk.

Affected product
All Lots of the *safe*PICO A aspirating blood syringe, 957-204.

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

EU Basic UDI-DI: 57006900067N9

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

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

Your actions
Radiometer kindly request you to stop using the affected product with immediate effect.

To ensure patient safety in your facility, kindly follow the steps below:

- Check your inventory of the above *safe*PICO A aspirating blood syringes.
- Check for the above *safe*PICO A aspirating blood syringes distributed in your institution.
- Collect any of the above *safe*PICO A aspirating blood syringes and put them in quarantine.
- Complete the Recall Response Form (last page of this letter) and return it to your Radiometer representative together with the quarantined *safe*PICO A aspirating blood syringes within two weeks of receiving this letter.

To ensure you receive credit for the *safe*PICO A aspirating blood syringes:

- Fill out a credit claim and send it to your Radiometer representative.

Solution provided by Radiometer
Currently, it is difficult to provide a specific resolution date for the *safe*PICO A aspirating blood syringe.
Please contact your Radiometer representative for information about alternative samplers.

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

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

Recall Response Form

Concerning:

*safe*PICO A aspirating blood syringe

☐ I have received the customer advisory letter and reviewed both my current inventory of *safe*PICO A aspirating blood syringes and those distributed in my institute.
All affected samplers have been collected and I have returned the quantities of samplers stated below to my Radiometer representative.

Returned quantities:

Item number	Description	Lot	Quantity (boxes of 100 pcs.)
957-204	*safe*PICO A aspirating blood syringe		

In case you have more than one Lot of any type of *safe*PICO A in your institute, then please insert extra row(s) in the table and then state Lot numbers and quantities.

□ I have no *safe*PICO A aspirating blood syringes in my institute.

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