

Customer
Hospital
City
Postal code
Country
Attn.: XXX

URGENT Field Safety Notice

PICO50 Arterial Blood Sampler

Dear Customer

Background

Radiometer has become aware of an issue with PICO50 Arterial Blood Sampler. The issue relates to the sterile barrier system for the product.

For this reason Radiometer kindly request 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 PICO50 Arterial Blood Sampler, 956-552.

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)

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 PICO50 Arterial Blood Samplers
- Check for the above PICO50 Arterial Blood Samplers distributed in your institution.
- Collect any of the above PICO50 Arterial Blood Samplers and put on quarantine
- Complete the Recall Response Form (last page of this letter) and return to your Radiometer representative together with the quarantined PICO50 Arterial Blood Samplers.

To ensure you receive credit for the PICO50 Arterial Blood Samplers:

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

Solution provided by Radiometer

Please contact your Radiometer representative for further information.

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>

Recall Response Form

Concerning:

PICO50 Arterial Blood Sampler

- I have received the customer advisory letter and reviewed both my current inventory of PICO50 Arterial Blood Samplers 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.)
956-552	PICO50 Arterial Blood Sampler		

In case you have more than one Lot of any type of PICO50 in your institute, then please insert extra row(s) in the table and then state Lot numbers and quantities.

- I have no PICO50 Arterial Blood Samplers in my institute.

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