

Customer
Hospital
City
Postal code
Country
Attn.: XXX

[ISSUE
DATE]

Field Safety Notice: PICO70 Arterial Blood Sampler

Priority Level: Urgent

Dear Customer

Background

Radiometer has become aware of an issue with PICO70 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.

During internal stress testing on PICO70 Arterial Blood Samplers a breach in the sterile barrier system was observed in one sample.

Risk for the patient

The described error is considered to have a remote possibility of resulting 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 following PICO70 samplers:

Ordering number	Description
956-518	PICO70 w/o needle
956-519	PICO70 w/o needle
956-522	PICO70 22G x 25 mm
956-525	PICO70 22G x 32 mm
956-529	PICO70 23G x 16 mm
956-533	PICO70 23G x 25 mm
956-534	PICO70 23G x 32 mm
956-547	PICO70 25G x 16 mm

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 PICO70 Arterial Blood Samplers
- Check for the above PICO70 Arterial Blood Samplers distributed in your institution.
- Collect any of the above PICO70 Arterial Blood Samplers
- Complete the Recall Response Form (last page of this letter) and return to your Radiometer representative together with the collected PICO70 Arterial Blood Samplers.

To ensure you receive credit for the PICO70 Arterial Blood Sampler:

- 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,
<Radiometer distributor>

Recall Response Form

Concerning:

PICO70 Arterial Blood Sampler

- I have received the customer advisory letter, and reviewed both my current inventory of PICO70 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:

Ordering number	Description	Lot	Quantity (boxes of 100 pcs.)
956-518	PICO70 w/o needle		
956-519	PICO70 w/o needle		
956-522	PICO70 22G x 25 mm		
956-525	PICO70 22G x 32 mm		
956-529	PICO70 23G x 16 mm		
956-533	PICO70 23G x 25 mm		
956-534	PICO70 23G x 32 mm		
956-547	PICO70 25G x 16 mm		

In case you have more than one Lot of any type of PICO70 in your institute, then please insert extra row(s) in the table and then state Lot numbers and quantities.

- I have none of the affected PICO70 Arterial Blood Samplers in my institute.

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