

Field Safety Notice: PICO50 Arterial Blood Sampler
Priority Level: Urgent

Dear Customer

Background

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

Please stop using the affected product with immediate effect.

Affected product:

Part number	Description	Lot number
956-552	PICO50 Arterial Blood Sampler	All lot numbers

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.

Your actions

Please stop using the affected product with immediate effect.

To ensure patient safety in your hospital/institution, please follow the steps below:

1. Check your inventory of the above listed PICO50 Arterial Blood Sampler distributed in your hospital/institution and quarantine any in-date stock.
2. Please dispose of all quarantined stock in accordance with your hospital/institution guidelines.
3. Complete the Recall Response Form (last page of this letter) and email it to service@radiometer.co.uk

Solution provided by Radiometer

We can offer the product listed below as an alternative, please contact us for further information.

Ordering number	Description
956-518	PICO70 Arterial Blood Sampler

Your help is appreciated

If you are not the end-user of the affected products, please ensure that this letter is distributed to the final end-user.

If you have any questions, please contact us.

We sincerely apologise for the inconvenience this situation causes.

Yours faithfully



Aishah Malik
Product Manager – Samplers, UK & Ireland

Recall Response Form

Concerning:

PICO50 Arterial Blood Sampler

- I have received the customer advisory letter and reviewed both my current inventory of in-date PICO50 Arterial Blood Samplers and those distributed in my hospital/institution. I have disposed of all the affected samplers in accordance with our hospital/institution guidelines.

Quarantined 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 hospital/institution, then please insert extra row(s) in the table and then state Lot numbers and quantities.

- I have none of the affected PICO50 Arterial Blood Samplers in my hospital/institution.

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

Once complete please email to service@radiometer.co.uk