

Customer
Hospital
City
Postal code
Country
Attn.: XXX

Cleaning Solution for AQT90 FLEX - Incorrect barcode on tubes

Urgent Field Safety Notice

Dear Customer

Radiometer has become aware that certain Lots of Cleaning Solution tubes for the AQT90 FLEX has been produced with an incorrect barcode label. Upon scanning the barcode on the analyzer prior to running a System Clean the analyzer software ceases to operate and as a consequence the analyzer must be restarted.

Risk for the patient

The described error is considered to have a remote risk of leading to serious adverse health consequences for the patient. The described error may potentially lead to a delay of up to 60 minutes in availability of measurement results for cardio-pulmonary markers such as TnI, TnT, CKMB, Myoglobin, D-Dimer and NT-proBNP in a critically ill patient with cardiac failure, pulmonary embolism or deep venous thrombosis. The delayed measurement of up to 60 minutes may delay critical treatment of the patient and may put the patient at increased risk for cardio-pulmonary failure. Thus, the described error is considered capable of resulting in permanent impairment or serious injury that would require medical or surgical intervention to preclude irreversible impairment or damage.

Affected products

Cleaning Solution Tubes, 905-843, Lots 0265 and 0266.

Solution provided by Radiometer

Your Radiometer representative will exchange the incorrectly labelled Cleaning Solution Tubes with ones that are correctly labelled.

Your actions

Radiometer kindly request you to:

- Check your inventory of Cleaning Solution Tubes, 905-843, from the affected Lots
- Check for Cleaning Solution Tubes, 905-843. from the affected Lots distributed in your institution
- Collect any Cleaning Solution Tubes, 905-843, from the affected Lots
- Complete the Recall Response Form (last page of this letter) and return to your Radiometer representative together with the collected Cleaning Solution Tubes, 905-843, Lots 0265 0266.

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:

Cleaning Solution for AQT90 FLEX - Incorrect barcode on tubes

- I have received the customer advisory letter and reviewed both my current inventory of Cleaning Solution Tubes, 905-843, Lots 0265 and 0266, and those distributed in my institution.

All unused Cleaning Solution Tubes of Lots 0265 and 0266 have been collected and I have returned the quantity stated below to my Radiometer representative.

Returned quantities: Lot 0265: _____ pcs.

Lot 0266: _____ pcs.

- I have none of the affected Lots in stock.

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