

Customer
Hospital
City
Postal code
Country
Attn.: XXX

URGENT Field Safety Notice

D513 Disposable waste container for ABL800 analyzers – Potential risk of blood spillage

Dear Customer

Background

Radiometer has become aware of a potential issue with the D513 Disposable waste container for the ABL800 analyzers (details below). The issue is that an over-pressure may be built up in the waste container during use due to lack of venting. In extreme situations the waste container may appear swollen.

When detaching a pressurized waste container from the analyzer (to replace a full container by an empty one) the over-pressure may cause the contents of the waste container to be forcefully cleared out of the entry port.

Risk for the operator

When the contents of the waste container is forcefully cleared out of the entry port there is a potential risk that blood waste is sprayed over the operator. In a worst-case scenario this may lead to serious adverse health consequences to the operator because of infection with various diseases.

Affected product

The following product is potentially affected:

Item number: 905-802

Lots: MA02, MA03, MA04, MA05, MA06, MC01, MC02, and MC03
<NB! Delete Lots not relevant for your market!>

Description: D513 Disposable waste container for ABL800 analyzers

EU Basic UDI-DI: 57006900088NH

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

Your actions

Radiometer kindly requests you to stop using the affected product with immediate effect.

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

- Check your inventory of the affected D513 disposable waste containers
- Check for the affected D513 disposable waste containers distributed in your institution.
- Detach any of the affected D513 disposable waste containers already installed on ABL800 analyzers as follows:
 - Use protective face shield or combination of glasses and mouth shield and wear gloves
 - Place a cloth over the waste container (this serves to reduce the dispersion of the contents of the waste container (if pressurized) when detaching it from the analyzer
 - Detach the waste container
 - Dispose of the waste container as hazardous material as per local requirements
 - Clean and disinfect the analyzer (and surroundings), if necessary
- Collect any of the above D513 disposable waste container and dispose of them
- For documentation purposes please complete the Recall Response Form (last page of this advisory letter) and return to your Radiometer representative.

To ensure continued operation of your analyzer in case your entire inventory of waste containers is affected:

- Pull an unused (full) bottle of S4980 Rinse solution from your inventory, empty the bottle, peel off the Rinse solution label (as shown on the Rinse solution label) to expose the waste container label and use the empty bottle as a waste container.
If you do not have any unused bottles of S4980 Rinse solution in your inventory, please contact your Radiometer representative.

To ensure you receive credit for the disposed of D513 waste containers:

- Complete the Recall Response Form (last page of this advisory letter) and return to your Radiometer representative.

Solution provided by Radiometer

Radiometer will compensate for the affected product discarded as well as for the full bottles of S4980 Rinse solution emptied to be used as waste containers.

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

D513 Disposable waste container for ABL800 analyzers – Potential risk of blood spillage

- I have received the customer advisory letter and reviewed both my current inventory of affected D513 disposable waste containers and those distributed in my institute.
- All affected waste containers have been collected and I have disposed of the quantities stated below. **<NB! Delete rows (Lots) not relevant for your market!>**

| Item number | Description | Lot | Quantity |
|-------------|------------------------------------------------------|------|----------|
| 905-802 | D513 Disposable waste container for ABL800 analyzers | MA02 | |
| | | MA03 | |
| | | MA04 | |
| | | MA05 | |
| | | MA06 | |
| | | MC01 | |
| | | MC02 | |
| | | MC03 | |

- I have none of the affected D513 Disposable waste containers for ABL800 analyzers in my institute.
- My entire inventory of waste containers was affected, and I have used the following quantities of unused Rinse solution bottles in place of a waste container (item number is country specific). **<NB! Delete rows not relevant for your market!>**

| Item number | Description | Lot | Quantity |
|-------------|-------------------------------------------------------------|-----|----------|
| 944-130 | S4980 Rinse Solution, for ABL800 analyzers, US market | | |
| 944-131 | S4980 Rinse Solution, for ABL800 analyzers, Japanese market | | |
| 944-132 | S4980 Rinse Solution, for ABL800 analyzers | | |

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