

Customer
Hospital
City
Postal code
Country
Attn.: XXX

Field Safety Notice: cCrea QC results on ABL800 analyzers

Priority Level: Urgent

[ISSUE DATE]

Dear Customer

RADIOMETER has become aware that the cCrea results for QC decreases to below the lower accept limit within the lifetime of the Crea membranes. This has been experienced on membranes down to five days after installation of new membrane units. The impact on blood sample results is currently being investigated.

Affected product:

All ABL800 analyzers measuring cCrea.

What you should do:

The following step must immediately be carried out on the affected product:

- Perform one quality control measurement using S7835 AutoCheck 6+, level 1 on already installed Crea membrane units to verify the cCrea performance. If the QC result is out of range, new Crea A and Crea B membranes must be installed.

Until further notice the following must be carried out every 24 hours:

- Perform one quality control measurement using S7835 AutoCheck 6+, level 1 to verify the cCrea performance. If the QC result is out of range, new Crea A and Crea B membranes must be installed.

Please do not report cCrea results unless the performance of the membrane units have been verified as described above.

Please complete and return the attached fax form, with your signature as soon as possible or within 7 days.

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 Fax Form no. 1

Fax No.:

Concerning:

cCrea QC results on ABL800 analyzers

- We acknowledge receipt of the Field Safety Notice
- Furthermore we acknowledge that cCrea results must NOT be reported unless performance of the membrane units has been verified as requested.

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