Customer
Hospital
City
Postal code
Country
Attn.: XXX

Urgent Field Safety Notice:
ABL800 analyzers; Low *c*Crea results on patient samples

Dear Customer

This is a follow-up to previous communication regarding ABL800 analyzers which could potentially report lower than expected *c*Crea results on patient samples issued June 2018 and September 2019.

Radiometer has now successfully completed the final verification of the improved Crea membranes. The improvements have been implemented in the following Lots of Crea membrane units:

942-073, D8088+D8089 Crea membrane box A+B, for ABL8XX, of Lot **R1024 onwards**

Affected product:
All ABL800 analyzers measuring *c*Crea.

Your actions

This means that two scenarios exist depending of the Lot number being used:

Scenario 1 – Using 942-073 below Lot R1024
If you are still using these Lots the temporary countermeasure put in place as per previous communication (and stated overleaf) still apply.

Scenario 2 – Using 942-073 of Lot R1024 onwards
If you have started to use these Lots the temporary countermeasure put in place as per previous communication (and stated overleaf) is no longer required.

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

If you have any questions, please contact your Radiometer representative.

Best regards,
<Radiometer distributor>

Temporary countermeasure put in place as per previous communication:

What you must do:

1. Until further notice, carry out the following every 24 hours and upon replacement of Crea A and Crea B membranes:
    - Perform one quality control (QC) measurement using S7835 AutoCheck 6+, level 1, to verify the *c*Crea performance.
      If the *c*Crea QC result is out of range, you must install new Crea A and Crea B membranes.