

Customer
Hospital
City
Postal code
Country
Attn.: XXX

Urgent Field Safety Notice: ABL800 analyzers, risk of patient mix-up

Dear Customer

In June 2018, Radiometer informed that the ABL800 series analysers potentially could induce patient mix-up when “Confirmation of Demographics” is enabled (default disabled) as part of the query to AQUIRE, Radiance, or a HIS LIS system.

As informed earlier Radiometer has been working on a solution, which involved a redesign of the analyser software.

Affected product:

All ABL800 series analyzers with software versions 6.14 through to 6.18.

Permanent countermeasure provided by Radiometer:

Radiometer can now announce that a permanent countermeasure to this issue have been implemented in software version 6.18 MR1. Your analyzer(s) has been upgraded with this software version.

This means that the interim countermeasures are no longer needed:

- Or
- | | |
|----------------|--|
| Interim CM #1: | Disable “Confirmation of Demographics”. |
| Interim CM #2: | Instruct all operators of the analyzer(s) not to introduce a new sample when the menu for “Confirmation of Demographics” is being displayed. |

And Confirmation of Demographics can now be used again.

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>