

Customer
Hospital
City
Postal code
Country
Attn.: XXX

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

Dear Customer

Radiometer has recently become aware 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. An example of the sequence of actions, which may result in patient mix-up, is described on page 3 of this letter.

Risk for the patient

The described error may potentially impact upon patient management as the physician may subject the patient to unnecessary treatment or erroneously withhold necessary treatment from the patient based upon the mixed-up patient identification. In a worst-case scenario, where a critical parameter, such as K⁺ or pO₂, is interrogated, based upon a false clinical diagnosis inferred from the erroneous measurement, a critically ill patient may be subjected to lack of critical treatment.

Affected product:

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

What you must do:

1. If "Confirmation of Demographics" is disabled on your analyzer
 - a. The issue addressed with this Urgent Field Safety Notice is not present on your analyzer(s)
 - b. Please tick off CM # 1 on the Recall Response Fax Form and submit this to your Radiometer representative.

2. If "Confirmation of Demographics" is enabled, one of the two following counter-measures (CM) must be implemented:

- CM #1:** Disable "Confirmation of Demographics" as follows:
- a. Logon to the analyzer.
 - b. Select "Menu" -> "Utilities" -> "Setup" -> "General Setup" -> "Communications" -> "Automatic Data Request"
 - c. Remove the checkmark for "Confirm requested data", if present.
 - d. Select "Close".

Or

CM #2: If disabling the “Confirmation of Demographics” (CM #1) is not possible due to e.g. internal procedures, then you must instruct all operators of the analyzer(s) to not introduce a new sample when the menu for “Confirmation of Demographics” is being displayed.

Please complete the recall response fax form (last page of this customer advisory letter) and submit to your Radiometer representative

Countermeasure provided by Radiometer:

Radiometer is working on revising the software to correct this issue. Once the revised software is released your Radiometer representative will contact you to schedule a visit for the software upgrade.

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>

Sequence of actions which may result in patient mix-up:

1. "Confirmation of Demographics" is enabled.
2. The user views the patient results log for a sample which has no (or incorrect) patient demographic information (figure 1) and selects sample #161 (figure 2). We will call this Patient A in our example.

Figure 1:

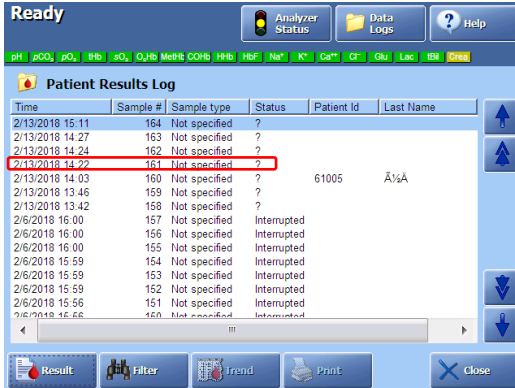
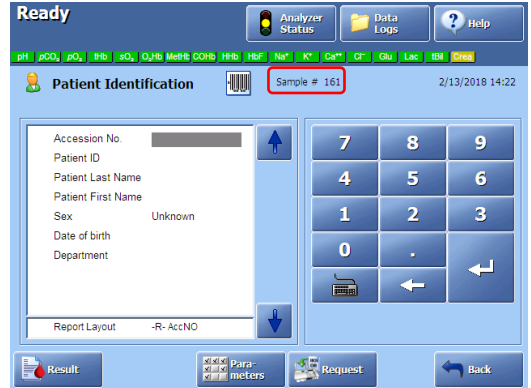
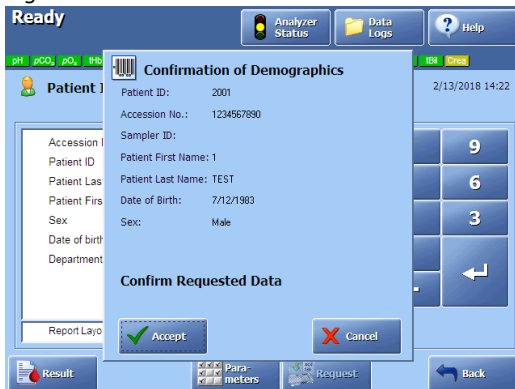


Figure 2:



3. The user initiates a query by entering an accession number (or patient ID) (e.g. 1234567890), and a query is sent to HIS/LIS. Patient data for the accession number (or patient ID) is received and a "Confirmation of Demographics" window opens (figure 3).

Figure 3:

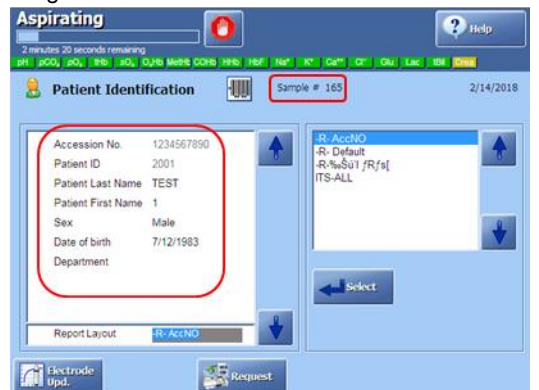


4. A new sample measurement (from patient B), in this example sample #165, is started before closing (pressing "Accept" or "Cancel") the "Confirmation of Demographics" for the previous sample #161. This causes the patient demographics from sample #161 to be transferred to sample #165. The Patient Identification field for sample #165 should be blank at this point of time.

Figure 4:

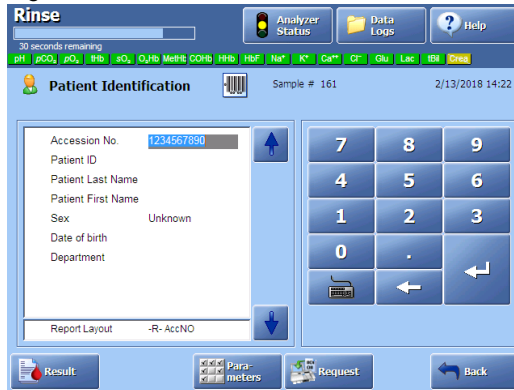


Figure 5:



5. Sample #161 is saved only with Accession number entered (figure 6).
6. Sample #165 is saved with the patient data belonging to #161 (figure 5 above).

Figure 6:



Hence, the results for patient B is stored with patient A's demographics.

Recall Response Fax Form

Fax No.:

Concerning:

ABL800, risk of patient mix-up

I have received the customer advisory letter and hereby conform that the following countermeasure (CM) has been implemented:

- CM #1: "Confirmation of Demographics" is disabled on our ABL800 analyzers.

Or

- CM #2: All operators have been instructed to not introduce a new sample while a previous result is being edited

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