Customer
Hospital
City
Postal code
Country
Attn.: XXX

URGENT Field Safety Notice
ABL90 FLEX and ABL90 FLEX PLUS – Risk of incorrect time and potentially biased results

Dear Customer

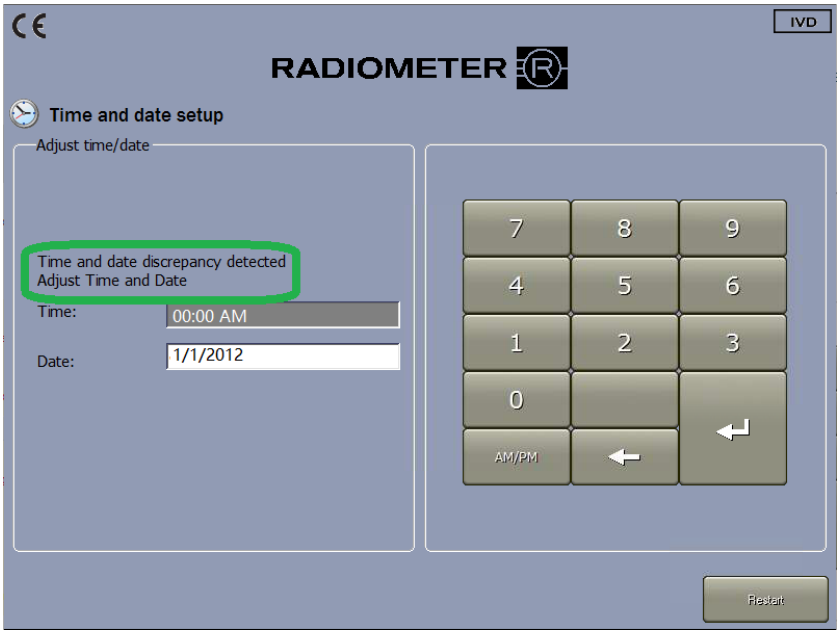
This is a follow-up on previous communication, distributed March 2021 (please see "Recap of previous communication, distributed March 2021" on page 3 of this letter).

Radiometer has now released an update to the software, which effectively eliminates the risk for the patient described in the previous communication.
We have now installed the software update on your analyzer.

Solution provided by Radiometer
The software update ensures that the analyzer will detect any date and time discrepancy that may appear during a startup following an abrupt power break.
When detected the analyzer will:

- Reset the date to 1/1/2012 and time to 00:00 (or earlier) and start running from there.
- Display the following screen prompt prior to full startup:

Time and date discrepancy detected
Adjust Time and Date



- The operator must then adjust time and date and touch Restart to confirm and restart the analyzer.

Your actions
If the analyzer shows the above screen during startup then adjust the time and date.

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,
<Radiometer distributor>

Recap of previous communication, distributed March 2021:

Background

The communication relates to a potential issue with ABL90 FLEX and ABL90 FLEX PLUS analyzers, which do not have an internal battery installed. The issue relates to the analyzer's internal clock as follows:

The issue may be triggered in case power is abruptly removed from the analyzer, by e.g. toggling the power switch on the analyzer itself or at the wall outlet, or a power failure occurs on the mains supply. When the analyzer is switched on again, the analyzer's internal clock may behave as in the example below:

- The clock starts at 08:00
- The clock runs normally until it reaches 08:59:59
- The clock resets to 08:00

Once the issue has been triggered the clock will continue to run in an infinite loop between 08:00 and 08:59 and the date will remain the same.

This means that all patient samples run after the issue has been triggered will have a time stamp suggesting they have been run between 08:00 and 08:59 on the same day.

This situation has the following additional consequences:

- Scheduled Quality Controls (QC) are not run
- Scheduled Calibrations are not run
- No notification of scheduled replacements & maintenance activities
- No notification of expiration of Sensor Cassette (SC) and Solution Pack (SP)
- Analyzer can accept expired consumables
- Expired Sample age not error marked
- Crea Calibration correction based on wrong insertion time
- GFR parameters calculated on wrong age based on birthdate
- Reference ranges and critical limits flagging based on wrong patient age
- Incorrect time stamp on results and messages sent to external systems such as AQURE and HIS/LIS.

Risk for the patient (prior to the software update)

The described error is considered to have a remote possibility of resulting in immediate as well as long range serious or life-threatening adverse health consequences to the patient.
The described error may lead to the ABL90 FLEX/PLUS analyzer reporting negative as well as positive biases for all parameters outside the analyzer specifications, as Calibrations are not performed, and Quality Controls are not run.

Affected products

The ABL90 FLEX and ABL90 FLEX PLUS analyzer(s) with the serial number(s) stated below is/are installed in your institution and is/are potentially affected:

393-090RxxxxNxxxx

393-092RxxxxNxxxx

(specific for each affected customer – to be filled in by subsidiary / distributor prior to distribution of letter)