

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

Radiometer has become aware of a potential issue with ABL90 FLEX and ABL90 FLEX PLUS analyzers. The issue relates to the ABL90 analyzers internal clock, which may become incorrect.

For analyzers which do not have an internal battery installed the incorrect time 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 send to external systems such as AQUIRE and HIS/LIS.

Risk for the patient

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)

Please note that analyzers which have an internal battery installed are NOT affected by the potential health hazard, but they still need to have the solution being worked on implemented.

Solution provided by Radiometer

Radiometer is currently working to find a solution to resolve this issue and we will get back to you as soon as possible.

Your actions

Based on the above Radiometer kindly requests you to check if the time displayed on the analyzer's screen is correct, and then:

- If the time is correct perform the actions under "***Time is correct***"
- If the time is **not** correct perform the actions under "***Time is not correct***"

Time is correct:

Perform the following two actions (1. and 2.):

1. Ensure that the ABL90 analyzers never abruptly loses power. This may be ensured by carrying out either action a., b., or c. below:
 - a. Have your in-house technical department confirm that your institution's emergency power system is capable of providing an uninterrupted supply for the analyzer in case of mains power loss and ensure that the analyzer is powered by this emergency power system.

Optional:

- b. Install an internal battery in the analyzer.
 - c. Install a UPS (Uninterruptable Power Source, a battery backup) for the analyzer.
2. Instruct the employees handling the ABL90 analyzers to always shut down the analyzer, if needed, as per the procedure in the Instructions For Use, as follows:
 - a. On the screen tap "Menu", then "Utilities, and finally "Temporary Shutdown".

Do not use the power switch to shut down the analyzer.

Please note that:

- If you cannot ensure an uninterrupted supply for the analyzer the operators must check that the time displayed on the screen is correct prior to measuring a sample going forward.
- If the power, by mistake, has been abruptly removed from the analyzer the operator must check that the time displayed on the screen is correct prior to measuring a sample.
- If, at any point in the time displayed on the screen becomes incorrect perform the actions under “Time is not correct”

Time is not correct:

Perform the following actions:

1. Cease using the ABL90 analyzers for patient samples until your Radiometer representative has reset the analyzer’s internal clock
2. Report the occurrence to your Radiometer representative who shall then visit and reset the analyzer’s internal clock.

Important

Once the time has been reset by your Radiometer representative the actions under “Time is correct” above apply.

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>

Recall Response Form

Concerning:

ABL90 FLEX and ABL90 FLEX PLUS - Risk of incorrect time and potentially biased results

I have received the customer advisory letter and can confirm that:

The time displayed on the screen was correct, and that we have:

1. Ensured that the analyzer never abruptly loses power by:

Confirming that your institution's emergency power system is capable providing an uninterrupted supply for the analyzer in case of mains power loss

Optional:

Installing an internal battery in the analyzer

Installing a UPS (Uninterruptable Power Source) for the analyzer

2. Instructed the employees handling the ABL90 FLEX and/or ABL90 FLEX PLUS analyzer to always shut down the analyzer, if needed, as per the procedure in the instructions for use.

The time displayed on the screen was not correct and we have:

1. Ceased using the ABL90 FLEX and/or ABL90 FLEX PLUS analyzer for patient samples until our Radiometer representative has reset the analyzer's internal clock

2. Reported the occurrence to our Radiometer representative.

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