

Customer
Hospital
City
Postal code
Country
Attn.: XXX

URGENT Field Safety Notice
AQT90 FLEX - Incorrect time on display and patient results

Dear Customer

This is a follow-up on previous communication, distributed January 2021.
Please see summary of previous communication on page 2 onwards of this letter.

As per the previous communication Radiometer originally considered the software update introduced in January 2021 to be an interim solution to the issue and we stated that we were working on a final solution.

However, since the software update implemented on your analyzer effectively eliminates the risk for the patient described in the communication distributed December 2020, Radiometer considers the software update to be the permanent solution to the issue and will not take further actions.

Risk for the patient

There is no risk associated with this issue.

Your actions

If the analyzer enters the error state (reset time) with the corresponding message (3264) then please reset the time and date as per the procedure in the instructions for use (also included on page 3 of this letter).

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>

Summary of previous communication, distributed January 2021:

Background

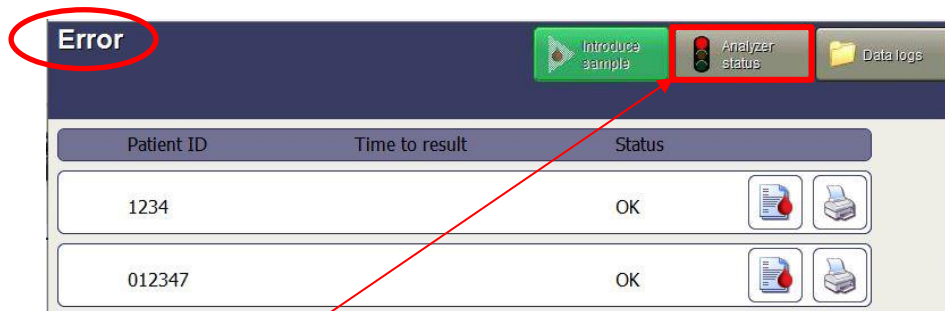
Radiometer has identified an issue with the analyzers internal clock.

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.

If the issue occurs after having switched the analyzer on again, the date and time has been reset to 01.01.2012 00:00 (or earlier) and start running from there. This causes the analyzer to enter the error state with message 3264.

If the issue occurs the operator must manually reset the date and time in the Setup program.

On the analyzer the error state shows as follows:

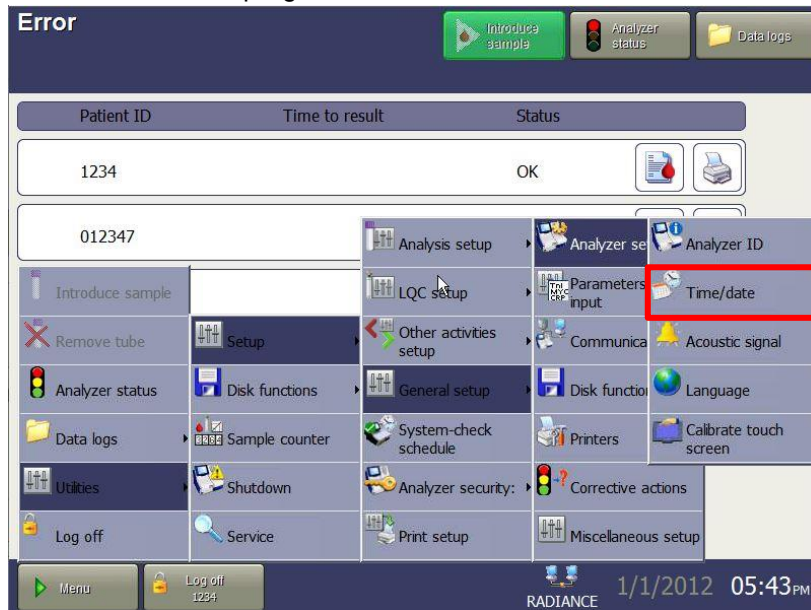


Touch **Analyzer status** to show the condition that caused the analyzer to enter the error state (reset time) and the corresponding message (3264):

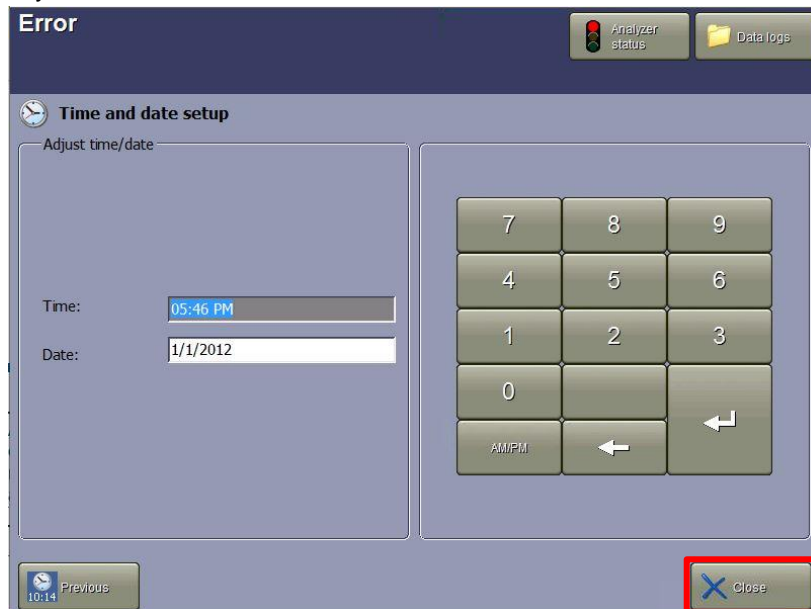


If the Error state is entered for the above reason, then reset the time and date
The time may be reset as per the instructions for use as follows:

1. An operator authorized to set time and date must log on to the analyzer:
 - a. Touch **Menu** and then **Log on**.
 - b. Enter your password and touch **Enter**.
2. Enter the Time/date program as follows:



3. Key in current Time and Date and touch **Close**.



The analyzer now shows the correct time and date and is ready for running tests.