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 December 2020 and
January 2021.
Please see summaries 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 4 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 December 2020:

Background

The communication relates to a potential issue with AQT90 FLEX analyzers with serial numbers of 393-838R0564 onwards. The issue relates to the AQT90 FLEX's internal clock and impacts the time shown on the display as well as the time stamp for calibration adjustment results, LQC results and patient results (all assays), both when viewed on the analyzer screen and on external systems such as AQURE and HIS/LIS.

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.

Risk for the patient (prior to the software update)

The described error has a remote risk of leading to serious adverse health consequences for the patient. The described error may, in a reasonably foreseeable worst-case scenario, result in an increase / decrease in TnI/TnT not being detected as the time interval between two measurements is too short and not being recognized as such. This may lead to no detection or severely delayed detection of acute myocardial infarction, AMI, potentially resulting in a new AMI and subsequent permanent heart damage. Thus, the described error may result in permanent impairment or serious injury that would require medical intervention to preclude irreversible impairment or damage.

Summary of previous communication, distributed January 2021:

Radiometer has released an update to the software, which is considered an interim solution to the original issue.
We have now installed the software update on your analyzer.

Consequence of the software update
The interim software update ensures that the analyzer will detect if the issue with the analyzer's internal clock shows.
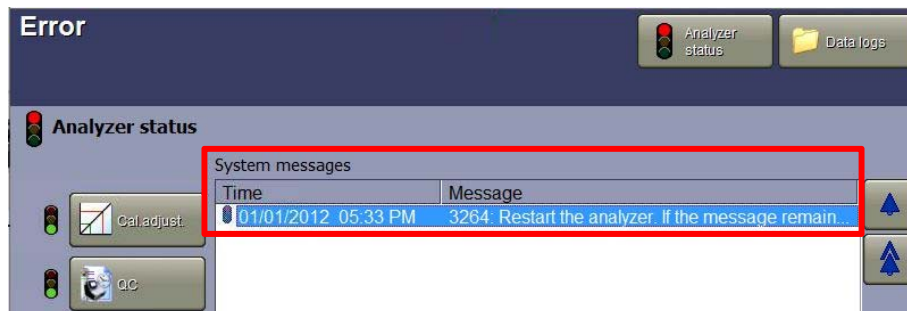
If detected:
- The analyzer will flag the condition to the operator by resetting the date and time to 01.01.2012 00:00 (or earlier) and start running from there. This causes the analyzer to enter the error state with message 3264.
- The operator must reset time and date (see overleaf).

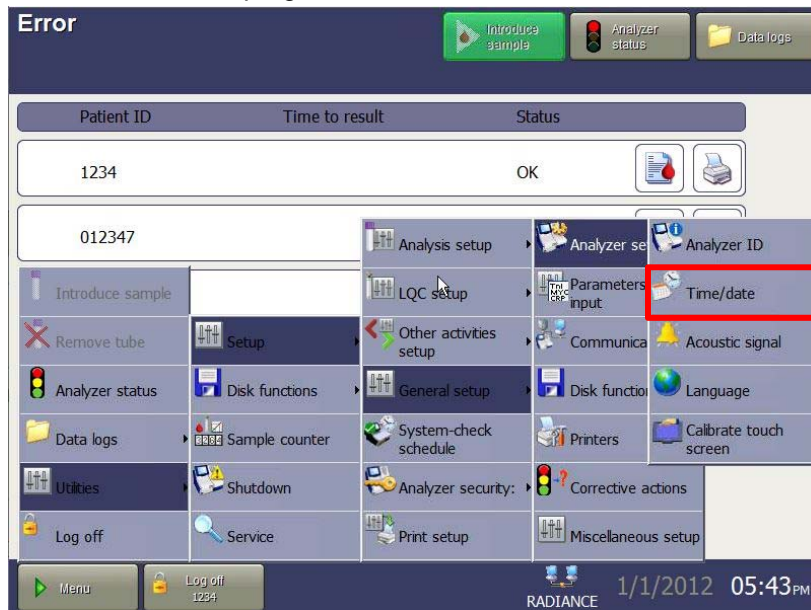**On the analyzer the error state shows as follows:**

Touch **Analyzer status** to show the condition that caused the analyzer to enter the error state (reset time) and the corresponding message (3264):
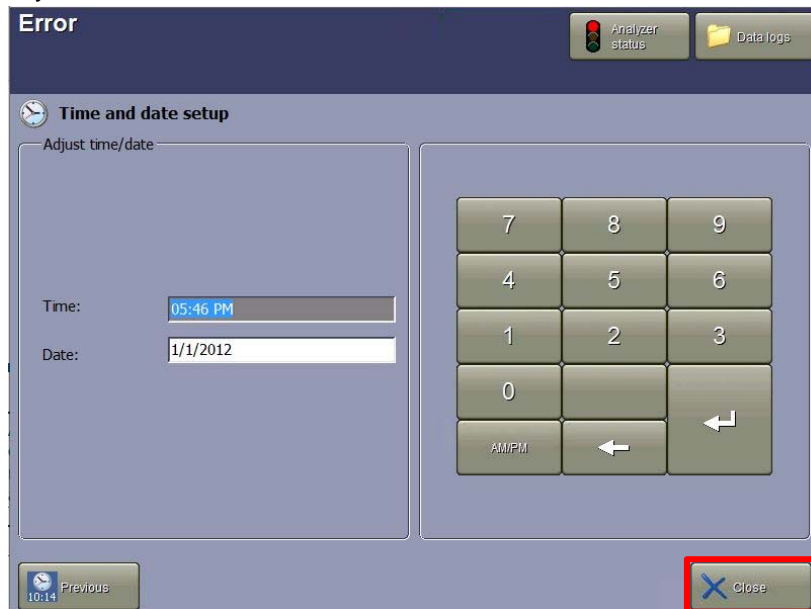
If the Error state is entered for the above reason, then reset the time and date
The time may be reset as per the instructions for use as follows:

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.

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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:
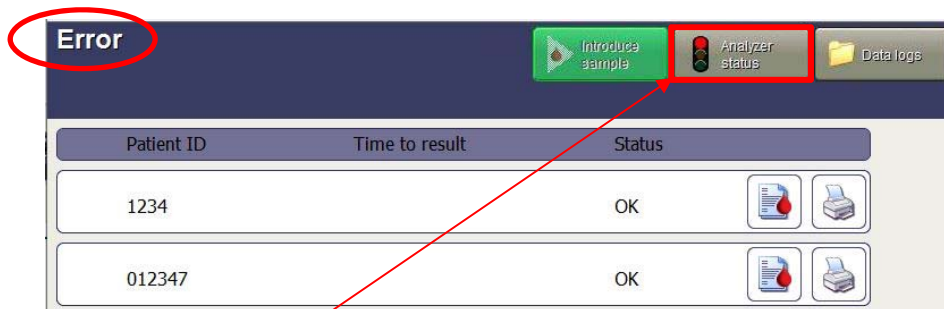
Background
Radiometer has identified an issue with the analyzers internal clock.
The issue may be triggered in case power is abruptly removed from the analyzer, by e.g. toggling the power switch on the analyzer itself or at the wall outlet, or a power failure occurs on the mains supply.
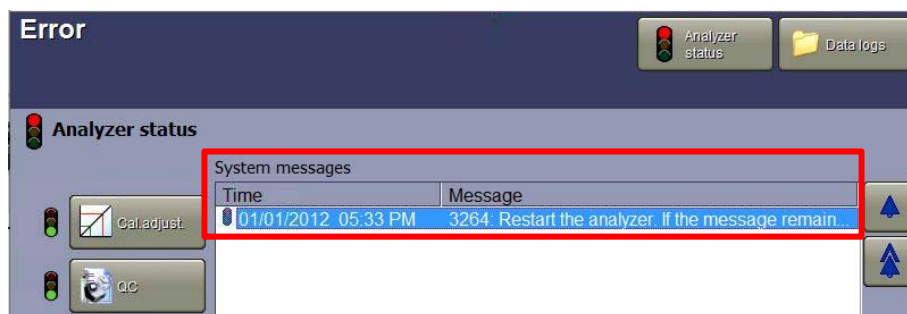If the issue occurs after having switched the analyzer on again, the date and time has been reset to 01.01.2012 00:00 (or earlier) and start running from there. This causes the analyzer to enter the error state with message 3264.

If the issue occurs the operator must manually reset the date and time in the Setup program.
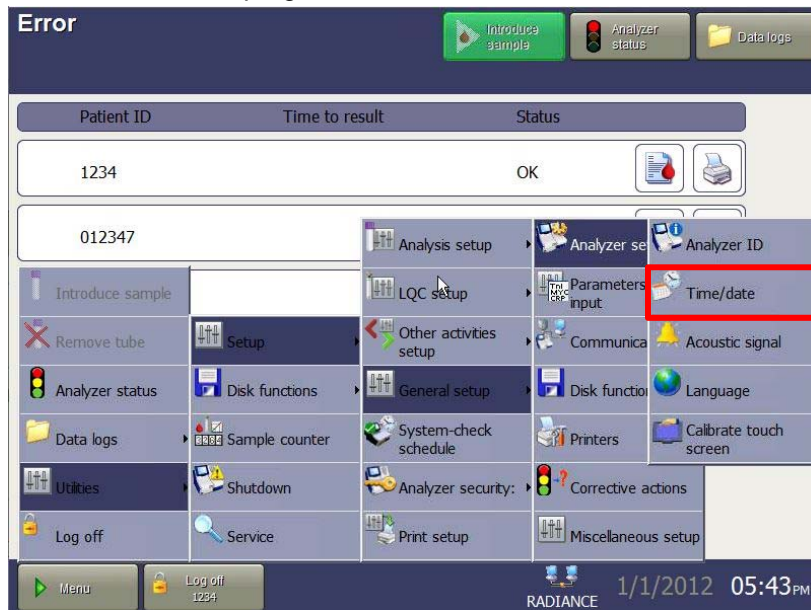
On the analyzer the error state shows as follows:

Touch **Analyzer status** to show the condition that caused the analyzer to enter the error state (reset time) and the corresponding message (3264):
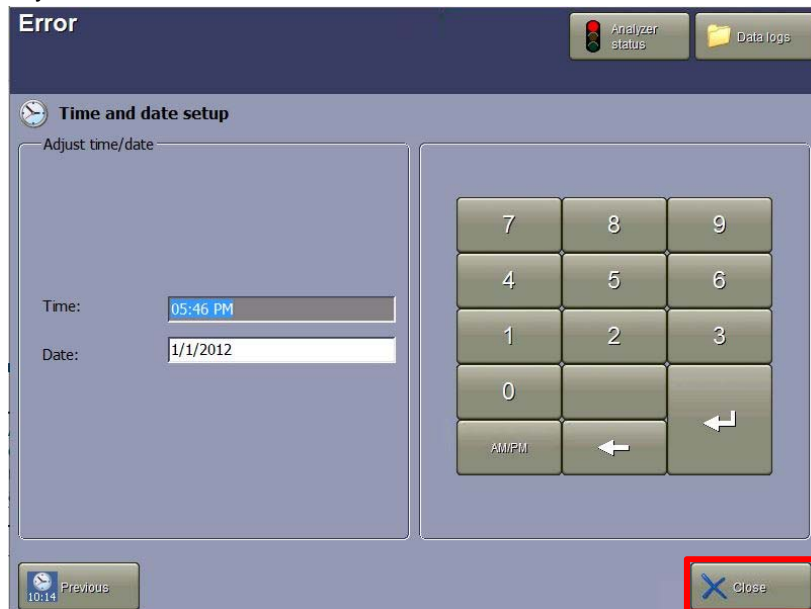
If the Error state is entered for the above reason, then reset the time and date
The time may be reset as per the instructions for use as follows:

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.