

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. Radiometer has released an update to the software, which is considered an interim solution to the original issue (please see “Recap of previous communication, distributed December 2020” on pages 4 and 5 of this letter). 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.

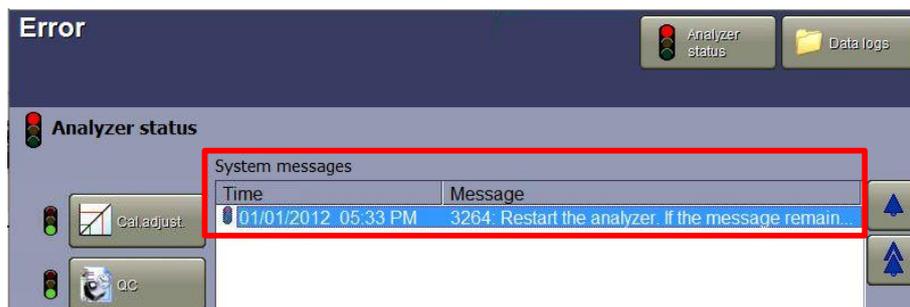
If detected:

- 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):

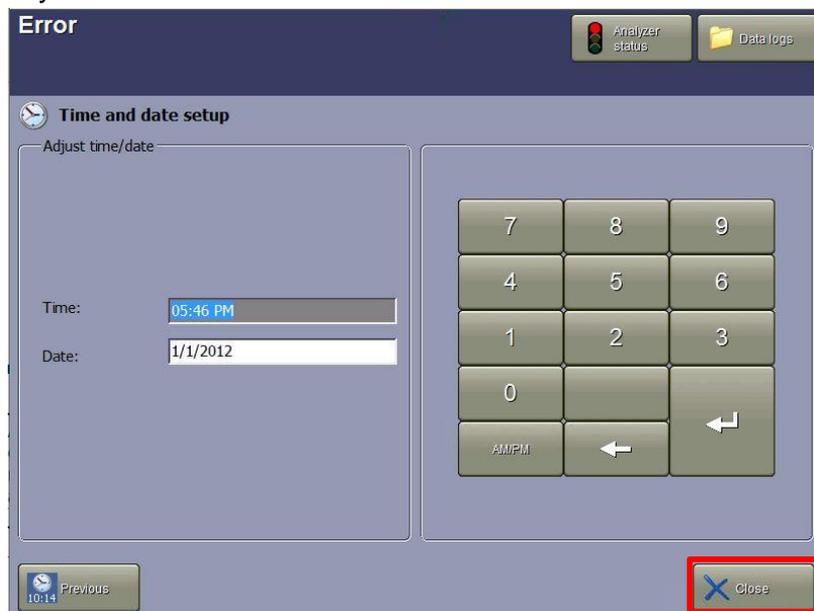


If the Error state is entered for the above reason, then reset the time and date
The time may be reset as per the instructions for use as follows:

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.

Solution provided by Radiometer

Radiometer is currently working on the final solution to resolve this issue and we will get back to you as soon as possible.

Your actions

The actions mentioned under ***Time is correct*** in “Recap of previous communication, distributed December 2020” on pages 4 and 5 of this letter **still apply**. This is because they will reduce the occurrence of the message 3264 with date and time reset to 01.01.2012 00:00.

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 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 AQUIRE 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

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.

Affected products

The AQT90 FLEX analyzer(s) with the serial number(s) stated below is/are installed in your institution and is/are potentially affected:

393-838RxxxxNxxx

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

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:

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

Time is correct:

Perform the following actions:

1. Ensure that the AQT90 FLEX analyzer never loses power. This may be ensured in two ways:
 - a. Install a UPS (Uninterruptable Power Source, a battery backup) for the analyzer.
 - OR
 - b. 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.
2. Instruct the employees handling the AQT90 FLEX analyzer to always shut down the analyzer, if needed, as per the procedure in the instructions for use, as follows:

On the screen tap "Menu", then "Utilities, and finally "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 putting a sample tube into the sample inlet 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 putting a sample tube into the sample inlet.
- 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 AQT90 FLEX analyzer 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.