

Customer  
Hospital  
City  
Postal code  
Country  
Attn.: XXX

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

Dear Customer

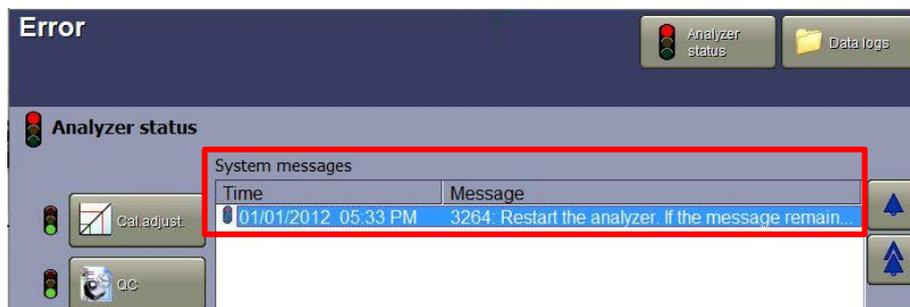
Radiometer has identified an issue with the analyzers internal clock. The issue may be triggered in case power is abruptly removed from the analyzer, by e.g. toggling the power switch on the analyzer itself or at the wall outlet, or a power failure occurs on the mains supply. If the issue occurs after 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):

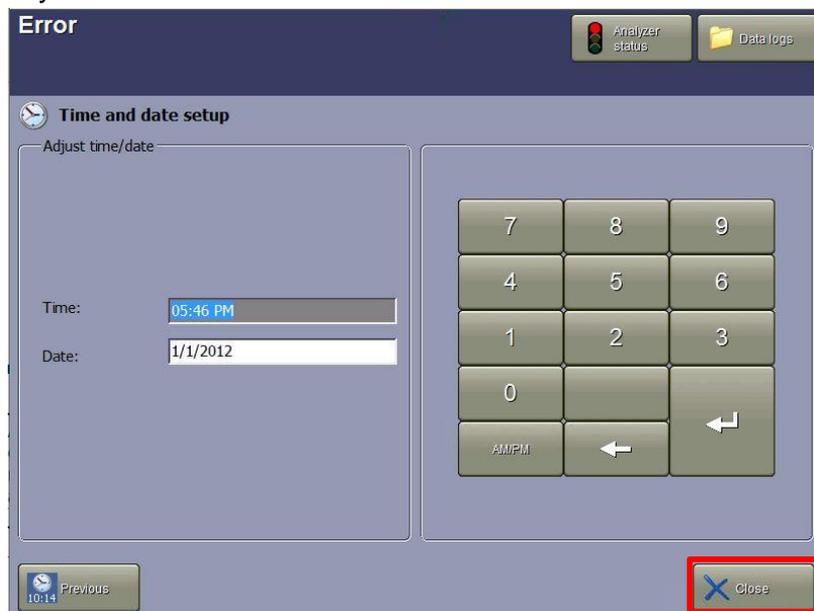


**If the Error state is entered for the above reason, then reset the time and date**  
The time may be reset as per the instructions for use as follows:

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.

### **Risk for the patient**

There is no risk associated with this issue.

Having to manually reset the time and date in Setup is an inconvenience to the operator only.

### **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 suggests you perform the following actions to reduce the occurrences of power being abruptly removed from the analyzer, and, hence, occurrences of the analyzer entering the error state with message 3264:

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.

### **Solution provided by Radiometer**

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

### **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>