

11 June 2021

URGENT Field Safety Notice

Re: AQT90 FLEX - Incorrect time on display and patient results

Dear valued customer

Following on from the communications in December 2020 and January 2021, this notification is to update you on this Field Safety Notice.

Page two onwards summarises the previous two communications.

Our original plan for implementing the January 2021 software update was for it to be an interim solution whilst we continued working on a final countermeasure. However, as this update effectively eliminates the risk to the patient described in the December 2020 notification, this new software is now our permanent resolution. No further actions are planned.

Risk for the patient

There is no risk associated with this issue.

Actions

If an analyser enters an error state with corresponding code 3264, please reset the time and date as per the procedure in the instructions for use. These instructions are also detailed on page four of this notification.

If you are not the end-user of the AQT90 FLEX, please ensure that this letter is distributed to the final end-user and the Point of Care Testing team.

If you have any questions, please contact us on 01293 517 599.

Yours faithfully

David Ruaux

Product Manager – Immunoassay Testing: UK and Ireland

Summary of previous communications

December 2020

Background

We have identified a potential issue with the internal clock on our AQT90 FLEX analysers with serial numbers 393-838R0564 onwards.

If this issue occurs then it impacts the time shown on the display as well as the time stamp for calibration adjustment, LQC and patient results across all assays - both when viewed on the analyser screen and on external systems such as AQUIRE and HIS/LIS.

A trigger for this issue may be an abrupt loss in power to the analyser, for example; by toggling the power switch on the analyser itself, at the wall outlet or by a power failure at the mains supply.

If the issue occurs, then once the AQT FLEX is restarted the date and time may behave as follows:

- The clock starts at 08:00
- The clock runs normally until it reaches 08:59:59
- The clock resets to 08:00

Once this happens 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 this will have a time stamp suggesting they have been measured between 08:00 and 08:59 on the same day.

Risk for the patient (prior to the software update)

This error has the remote risk of leading to serious adverse health consequences for a patient.

In a reasonably foreseeable worst-case scenario, this issue may, for example; lead to an increase or decrease in TnI/TnT results not being detected as the time interval between two measurements is too short, and not being recognised 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.

January 2021

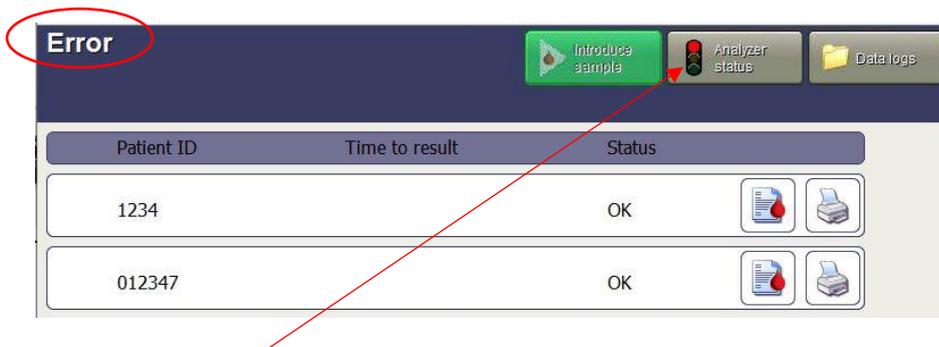
We have released and installed on your analyser(s) a software update for the AQT90 FLEX as an interim solution.

This software update ensures that the analyser will detect if the issue with the internal clock occurs.

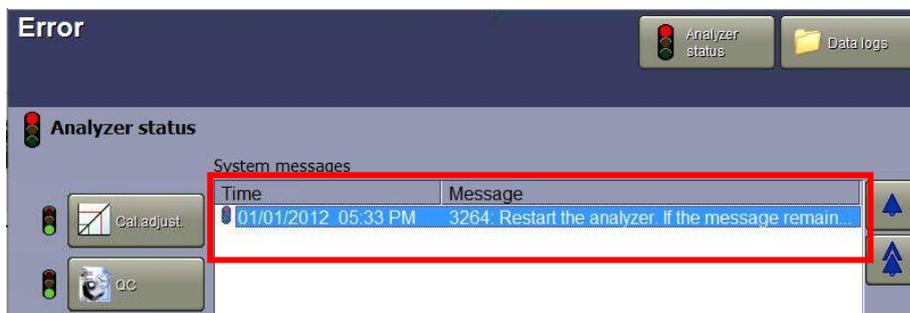
If detected:

- The analyser will flag the condition to the operator by resetting the date and time to 01.01.2012 00:00 (or earlier) and continue running from there. When this happens, the analyser enters its error state and displays error message 3264.
- The operator must then manually reset the date and time.

The analyser displays this as follows:



Press **Analyzer status** to show the condition that’s causing the analyser to enter the error state and the corresponding message (in this case error code 3264):



If the error state is due to the above reason, then please reset the time and date manually.

How to reset the time and date

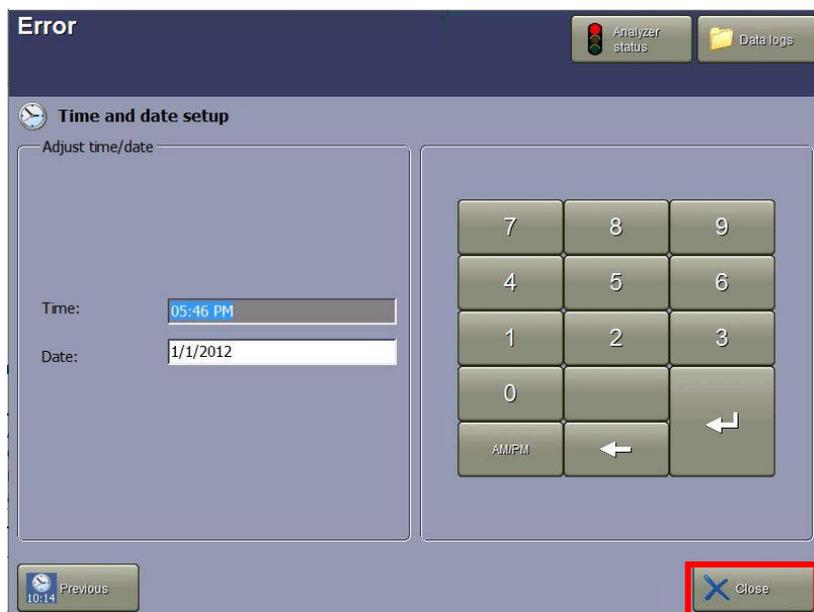
Resetting the time and date is only accessible to an authorised operator

Once logged on to the analyser access the Time/date program as follows:

Menu – Utilities – General setup – Analyser setup – Time/date



Enter the correct time and date and press **Close**.



The analyser now displays the correct time and date and is ready for measuring samples.