RADIOMETER

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

Dear Customer

We have become aware of a potential issue on AQT90 FLEX analysers with serial numbers 393-838R0564 onwards.

This 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
- Liquid Quality Control (LQC) results
- All patient results

The issue can occur whether viewing results on the analyser screen or external systems such as AQURE and Hospital / Lab information systems.

The error may be triggered by an abrupt loss in power; for example, by toggling the power switch on and off on the analyser or the wall socket, or a failure in the mains supply.
When the analyser is switched back on, the analyser's internal clock may behave as described below:

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

If this error occurs 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 error has been triggered will have a time stamp suggesting they have been run between 08:00 and 08:59 on the same day.

Patient Risk

There is a remote risk of this error leading to serious adverse health consequences for a patient.
The described error may in a reasonably foreseeable worst-case scenario, result in an increase or decrease in troponin measurements not being detected. This is due to the time interval between two measurements being too short, and not being recognised as such.

This may then 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 analyser listed below is installed in your hospital and it is possibly affected:

838R0570N006

Solution provided by Radiometer

We are working on the permanent countermeasure to resolve this and we will confirm our course of action shortly.

Your actions

Please check if the time displayed on the analyser's screen is correct, and then:

A. If the time is correct, please perform the actions detailed under "***Time is correct***"
B. If the time is **not** correct, please perform the actions under "***Time is not correct***"

Time is correct:

1. Ensure that the AQT90 FLEX never loses power. This could be achieved in two ways:
    a. Install a UPS (Uninterruptable Power Source) for the analyser.
    OR
    b. Confirm with the in-house technical department that the hospital's emergency power system can provide an uninterrupted supply for the analyser in case of mains power loss.

2. Instruct staff using and maintaining the AQT90 FLEX to, when needed; always shut down the analyser as per the procedure detailed in the AQT90 FLEX instructions for use (IFU).

    This is as follows:

    On the screen tap: **Menu – Utilities – Shutdown**

    <u>Do not use the power switch to shut down the analyser</u>

Please note that:

- If it is not possible to ensure an uninterrupted power supply for the analyser, then operators must check that the time displayed on the screen is correct before putting a sample into the sample inlet going forward.
- If the power to the analyser is lost abruptly then the operator must check that the time displayed on the screen is correct before putting a sample into the sample inlet.
- If at any point the time displayed on the screen becomes incorrect then perform the actions under "Time is not correct" below.

Time is not correct:

1. Immediately cease using the AQT90 FLEX for patient samples until we have re-set the analyser's internal clock.
2. Report the incident to us so that we can schedule a service engineer visit to reset the analyser's internal clock.

Important
Once the time has been reset by us then the actions under "Time is correct" above apply.

We really appreciate your help and support with this.

If you are not responsible for the management of the AQT90 FLEX analyser(s) within your hospital, please forward this notice on to the relevant person.

If you have any questions, then please contact us.

Yours faithfully

David Ruaux

Product Manager UK and Ireland: Immunoassay Testing

Recall Response Form

Regarding: **AQT90 FLEX analyser - Incorrect time displayed on the screen**

☐ I have received the customer advisory letter and I confirm that:

☐ The time displayed on the screen was correct, and that we have:

1. Ensured that the analyser never loses power by:

   ☐ Installing a UPS (Uninterruptable Power Source) for the analyser

   OR

   ☐ Confirmed that the hospital's emergency power system is capable providing an uninterrupted supply for the analyser in case of mains power loss

2. Instructed staff using and maintaining the analyser to always shut down the analyser when needed, as per the procedure detailed in the instructions for use.

☐ The time displayed on the screen was <u>not</u> correct and we have:

1. Ceased using the AQT90 FLEX analyser for patient samples until a Radiometer service engineer has reset the analyser's internal clock

2. Reported this occurrence to Radiometer so that a service engineer's visit can be arranged.

Hospital:	
Your Name:	
Date:	
Signature:	
Email Address:	