

RDNZ Urgent Customer Bulletin

DATE: March 13th 2008

REFERENCE: CB 08/11

Urgent Field Safety Notice: Modular Software v8.02

Current Situation:

We have had notification of an instance of a data mismatch on a **MODULAR ANALYTICS** <DPE> analyser using software version 8.02 when a QC request was made at the same time the analyser was writing patient data to the instrument hard drive. This resulted in the wrong data being sent to the host computer. While the probability of this occurring is extremely low with **MODULAR ANALYTICS** <PE> combinations, we wish to advise of a work around until the issue is resolved in the next software revision which currently being written by Hitachi High Technologies.

Actions Required:

As a workaround, please either:

- Avoid QC Test Selection while the system is in "Operation" mode (selections should be made while the instrument is in "Standby")
- The "Routine QC TS" feature can be enabled by selecting (ticking) "Routine QC TS" in <Utility> <System> <QC Setting>. Once enabled, if a QC sample is placed on the analyser, it will be automatically run for all activated tests for this control without having to manually program it).

It is a Medsafe requirement that you acknowledge receipt of this bulletin by completing the attached Acknowledgement Form and return it to Roche using the pre-paid envelope.

We apologise for any inconvenience. Please contact us on Techline if you would like to discuss this further, or require any additional information. .

Acknowledgement Form
Of In Vitro Diagnostic Device Notification.

Please complete this form and return to Roche Diagnostics NZ

Product Advice Notification Description:

Modular Software v8.02
Roche Customer Bulletin CB 08/11

Date:

13 March 2008

Returning organisation name and address:

Site/Lab Name: _____

Site/Lab Address: _____

Site Telephone: _____

Site Fax: _____

Signature, name and position of person making the return/declaration:

Name: _____

Position: _____

Date: _____

Signature: _____