

RDNZ Urgent Customer Bulletin

DATE: June 11th 2008

REFERENCE: CB 08/24

Medical Device Recall for Product Correction

This notice is being distributed following consultation with Medsafe, Ministry of Health

**<SW V 08-02> < MODULAR ANALYTICS / MODULAR ANALYTICS EVO >
Configurations with multiple <E> modules**

Current Situation:

In rare cases, the following two issues have been identified with Modular *Analytics* / Modular *Analytics* Evo running SW v 08-02.

1) Pipetting from an unintended reagent pack. There is a mismatch between the displayed or printed out reagent inventory information and the actual reagent placement on the reagent rotor. The identical reagent pack information may be displayed on two reagent positions, where one of these positions is a reagent pack of a different assay.

2) After reagent registration, calibration curve parameters are wrongly assigned to a newly inserted reagent pack. If the calibration curve parameters are wrongly assigned to a reagent pack, the effective signal measurement is correct whereas the calculated result is incorrect.

The root cause has been identified and only occurs on systems with multiple <E> Modules when reagent registration is done simultaneously for all the <E> modules. A new software version rectifying these issues is planned for July 2008.

Actions Required:

Please use the following workarounds:

1. Please don't place any new reagent packs into the reagent rotor as long as the instrument is switched OFF.
2. Before switching ON the instrument, please record on paper the on board reagent packs names as well as their location on the reagent rotor.
3. After switching the instrument ON or whenever you have to place new reagent packs into the reagent rotor, please perform reagent registration for each one of the <E> modules as follows:
 - Perform reagent registration on the first <E> module by opening the reagent rotor cover, placing reagents and then closing it. Wait about 3 minutes for registration to complete.
 - After the system reaches Standby, repeat the above mentioned step with the second <E> module.

In case of placing new reagent packs on a masked <E> module:

- Please perform reagent registration on the masked <E> module by opening the reagent rotor cover, placing new reagent packs onto the reagent rotor and then closing the reagent cover. Wait about 3 minutes for registration to complete.
- After the module reaches Standby, Unmask the module.
- Repeat the above steps for each one of the masked <E> modules.

4. After the reagent registration process is finished and only as a cross check, please make sure that the displayed pack status in the screen is the same as that which you have noted in step 2.

5. Perform Quality Control (QC) measurement for the various concentration ranges. QC values obtained should fall within the defined limits.

6. In case implausible QC results are obtained, and persist with newly inserted reagent packs of the same reagent lot, a new lot calibration with a reagent pack of a different reagent lot might be tried. Afterwards perform a QC measurement for the calibrated reagent pack. If the QC measurement falls within the expected range, avoid using reagent packs with the reagent lot causing the implausible QC results.

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