

FIELD SAFETY NOTICE
ILAB TAURUS SYSTEMS WITH ISE

February 2015

Dear Valued ILab Taurus Customer,

This notification is intended to advise your facility regarding a potential problem of wrong ISE electrolytes results (Sodium, Potassium and Chloride) on ILab Taurus with ISE (p/n 00001070302) with 1.20k software and 2.04 firmware or with 1.10g software and 1.07 firmware (or earlier). This problem has a potential impact on patient results.

ILab Taurus Systems without ISE module (p/n 00001070301) are not affected by this problem.

Issue Description and Impact:

Our internal investigation identified that, on ILab Taurus with ISE (p/n 00001070302) with 1.20k software and 2.04 firmware or with 1.10g software and 1.07 firmware (or earlier), the carousel is rotated to wrong ISE sampling position for ISE analysis, when the following conditions occur simultaneously:

1. A sample ("Sample A") has orders for ISE tests;
2. The following sample ("Sample B") has orders for at least 2 photometric test with "in-cuvette sample dilution"
3. "Sample B" has also orders for ISE test.
4. Sampling on "Sample B" happens immediately after sampling on "Sample A";
5. No temporary masked cuvette;
6. No temporary masked channels for ordered tests on "Sample B";
7. No carry-over logic activated for ordered tests on "Sample B";
8. No periodic ISE calibration happens during sampling sequence at step 4;

The frequency that all the above conditions occur simultaneously is estimated as "remote" (less than 1:100.000) on serum samples and "occasional" (less than 1:1000) on urine samples.

In the conditions reported above the ILab Taurus wrongly controls dispensing sample and carousel rotation. As a consequence, wrong ISE results may be produced on sample B.

Mandatory customer actions on ILab Taurus Systems with ISE (p/n00001070302):

- Firmware mandatory upgrade is necessary:
 - ILab Taurus System using 1.20k software and 2.04 firmware should upgrade to 2.05 firmware version: this maintains compatibility to 1.20k software version.
 - ILab Taurus System using 1.10g software and 1.07 (or earlier) firmware should upgrade to 1.07a firmware version: this maintains compatibility to 1.10g software version.
- Contact your local IL Representative to implement the firmware upgrade procedure on your ILab Taurus System.
- Share this information with your laboratory staff.
- Retain a copy of this letter as a record of the notification.

We apologize for this inconvenience and appreciate your prompt attention to this notification. Please contact your local representative with any questions.

Best regards,



IL Regulatory Affairs Director