



Instrumentation  
Laboratory

**URGENT FIELD SAFETY NOTIFICATION**  
**GEM<sup>®</sup> PREMIER 4000 – K+ REPORTING**

June 2011

Dear Valued GEM<sup>®</sup> Premier 4000 Customer:

This notification is intended to alert your facility regarding a serious issue identified with the K+ sensor on the GEM Premier 4000 cartridge. Instrumentation Laboratory Co. fully understands the implications and is working to expedite the release of an effective mitigation to prevent this occurrence in the near future. Until available, we require that you follow the Mandatory Customer Actions described below.

NOTE: The GEM 4000 Blood Gas/CO-Ox only cartridges are unaffected by this notification.

• **Issue Description:**

We recently confirmed rare occurrences of **falsely lowered K+ results** (potential negative bias of 0.6 to 1.2 mmol/L) can occur during cartridge life on patient blood analysis, leading to erroneous results with potentially severe impact to patient treatment.

**Frequency:** The event is considered rare based on an internal investigation that identified an incidence rate of 0.0013% (1 out of 77,000 samples) from an estimated 1.7 million sample results.

• **Mandatory Customer Actions:**

Please use whichever of the following options that works best for your institution. Both options will have the same effect to eliminate the impact of a potential erroneous K+ result from being reported.

• **Option No. 1**

• **Verify K+ results prior to reporting as follows:**

- Verify all K+ results from the GEM Premier 4000 using an alternative analyzer (e.g. GEM Premier 3000/3500 or other chemistry analyzer) prior to reporting.

NOTE: Ensure that the GEM Premier 4000 K+ results are not transmitted to your LIS system prior to verification.

- If the bias between the GEM Premier 4000 and the alternative analyzer is  $\geq \pm 0.6$  mmol/L **do not report the result and proceed as follows:**

- Either discontinue use and replace the cartridge immediately
- Or,

- Disable the K+ parameter as detailed under Option No. 2 and continue to use the cartridge for all other parameters.

- Option No. 2
  - **Disable the K+ (Potassium) Parameter as follows:**
    - Go to MENU and perform the following steps.
      - Management
      - Log-in
      - Configuration
      - Tab 3
      - Parameters Setup
    - Deselect Potassium by pressing the check mark (√) on the K+ button.
    - Press OK to save change.
    - After disabling, K+ results will no longer be reported, either on the screen or on printouts. All other measured parameters will be reported as currently configured.

**NOTE:** If connected to the GEMweb Plus server and require support, please contact your local IL representative.

- Share this information with your staff.
- Retain a copy of this letter in your files as a record of the notification.
- Please return the enclosed **mandatory Response Tracking Form** to your local representative offices for their tracking purposes.

We apologize for any inconvenience that the above required action may cause to your facility. Please contact your local representative with any question.

Sincerely,

Carol Marble  
Regulatory Affairs Director