Ortho Clinical Diagnostics

September xx, 2015

FOLLOW UP to URGENT FIELD SAFETY NOTICE
Software Anomaly during ADD Installation on VITROS® 5,1 FS Chemistry Systems using Software Versions 2.2.1 through 2.8

Dear Customer,

As part of a Field Safety Corrective Action, this is a follow up to an Urgent Field Safety Notice previously issued in June 2015 (Ref. CL2015-138_EU) involving the following:

VITROS® Product	Product Code	Unique Device Identifier No.
VITROS® 5,1 FS Chemistry System	6801375	10758750001132
	6801890	10758750001644

This notification provides additional information regarding the software anomaly that may occur during the installation of an Assay Data Diskette (ADD) using Software Versions 2.2.1 through 2.8. Please note that the anomaly is not caused by the ADD.

Summary of Anomaly

The anomaly is briefly summarized below. For a detailed description of the anomaly, please refer to the previously issued customer letter and the new information section.

Due to a software coding error, ALL default settings were restored from the ADD instead of retaining the user modified (configured) parameters and the operator was not alerted by the system. This issue may occur in two specific scenarios:

1. During installation of an ADD that supports a *new* assay, if the short assay name for the new VITROS® assay has the same name as a User Defined Assay currently in use, the VITROS® 5,1 FS System will post condition codes (UA7-239 and SYD-024).

2. During installation of an ADD, if the system becomes unresponsive (screen freeze occurs) the system will need to be restarted. If the anomaly occurs, the system will post a condition code (UZ0-047) after the restart is initiated.

Revised Rate of Occurrence

Analysis of e-Connectivity® data estimates the maximum probability of potential occurrence (per system) for scenario # 1 to be 0.016% and scenario # 2 to be 0.15% when installing an ADD.

As a reminder, it is important to note that the numerical results will be correct for the actual units reported on your VITROS System. However, the reporting units may not be consistent with those expected due to user modification. If all of the user defined parameters on your VITROS® 5,1 FS System are correct for your facility, then the anomaly has not occurred.

New Information

During our root cause investigation, we determined that, if the anomaly occurs, in addition to the UA7-239 condition code described in scenario # 1, **UA7-147 or UA7-153** condition codes may also be posted by the system.

In addition to impact on the reporting units described in the previous letter, if the anomaly occurs, there is also a potential for *other* user defined parameters to revert back to default settings as shown in the table on page two.

New Information (continued)

All of the content in the table below is new information:

Potential Impact to User Defined Parameters	Impact to VITROS® 5,1 FS System
User Adjusted Parameters (Slope, Intercept)	The default parameter is no adjustment. Results will not be flagged as Adjusted Result (AR) because the parameters reverted to default values.
Sample Indices User Adjustment Parameters (Slope, Intercept)	The default parameter is no adjustment. Hemolysis, Icterus, and Turbidity results will not be flagged as Adjusted Result (AR) for sample indices.
Reflex Dilution (Enabled/Disabled) Status and Reflex to same or selected assay	The default status is disabled. The system will not automatically perform the reflex dilutions or processing.
Reference Ranges (Lower or Upper Limit)	Results will not be flagged with HI or LO symbols because the parameters reverted to default ranges.
Reportable Ranges (Lower or Upper Limit)	Results will be flagged with < and > symbols based on default values, and not User Adjusted values, because the parameters reverted to default values.
Supplementary Ranges (SR) (Lower or Upper Limit)	Results will not be flagged with <SR and >SR symbols because the parameters reverted to default values.
Refer to the "*About Options and Configuration*" section in your VITROS® 5,1 FS Chemistry System Quick Reference Guide for descriptions of user-configurable items on your system.	

Required Actions

The required actions are fundamentally the same as the previous letter. The two additional condition codes (i.e., UA7-147 or UA7-153) were added and the instructions now specify that the anomaly may affect other user defined parameters instead of just the reporting units.

- **Prior to installing an ADD that supports a new assay;** verify that the new assay does not have the same name as any UDA currently on your system. If the names are the same, you are required to do the following:
  1. Rename the UDA using a name that is different from the short assay name for any VITROS® assay
  2. Install the ADD
- **Until a future software version is installed, if you experience a UA7-239, UA7-147 or UA7-153 condition code or your system becomes unresponsive during an ADD installation**, you are required to do the following if your system is configured with user defined parameters that are not the default parameters on the ADD:
  - ➢ If your system is unresponsive, restart your system.
  - ➢ Verify that the reporting units for all assays on your system are correct for your facility.
  - ➢ If you discover a discrepancy or your VITROS® 5,1 FS System utilizes **other** user modified parameters, verify that all of your user-modified parameters are correct.
    If any parameters have changed:
    1. Install the backup configuration files to restore your user modified parameters **OR** reenter user modified parameters and/or UDA parameters
    2. If appropriate, rename your UDA assay as indicated above.
    3. Re-install the ADD
    4. Calibrate only UDA assays that were renamed either by manual entry of calibration parameters or performing a calibration
- Post this notification by the VITROS® 5,1 FS System(s) or with the user documentation.
- Complete and return the Confirmation of Receipt form no later than <mark>September xx, 2015</mark>.

Resolution

OCD determined that the root cause of this anomaly is due to an error in the software code. A resolution will be available in the next version of software. In the interim, a Technical Bulletin will be issued and will remain in effect until the new software is installed on your VITROS® 5,1 FS Chemistry System.

Contact Information

We apologize for the inconvenience this may cause your laboratory. If you have any questions, please contact Customer Technical Services at insert appropriate number at any time.

Sincerely,

insert appropriate name
insert appropriate title