



Urgent Field Safety Notice

Product Correction

Immediate Action Required

Date Issued

October 1, 2010

Product

CELL-DYN Sapphire
List Numbers 08H00-01, 08H00-03: All serial numbers

Explanation

Release of Software Version 4

The purpose of this letter is to inform you of a new version of software, Version 4, for the CELL-DYN Sapphire System and to provide a summary of the changes you will see once the system software is upgraded. This software corrects the problem reported to you in the Product Correction Letter dated 28 April 2010 related to the Aspiration Bottom Sensor. With Version 4 software, your CELL-DYN Sapphire will execute sensor checks to determine the status of the sensor and use the System Initiated Message (SIM) 1050 if a problem is found. Once Version 4 software is installed, you no longer need to run with 1 inch of blood in your specimen tube, as previously directed in Product Correction Letter dated 28 April 2010 Revision 01. Within the next 6 months, your local Abbott Diagnostics Field Service Representative will install this **mandatory** software upgrade on your CELL-DYN Sapphire.

The *CELL-DYN Sapphire System Operator's Manual* was updated to include information regarding the new features included in Version 3 software. No additional changes were required for the Version 4 software release. Additional improvements are the result of customer feedback and requests. Please note that two changes to the recommended maintenance schedule were made:

- 1) A new maintenance procedure for rinsing the RBC Transducer has been added to the "As-Needed Procedures" maintenance schedule.
- 2) The schedule for cleaning of the Hemoglobin syringe has been changed from "Weekly" to "Monthly".

These changes may be found in **Section 9: Service and Maintenance** of the Operator's Manual and will replace those sections already in your current CELL-DYN Sapphire System Operator's Manual (Text version Part Number 9140426 Revision A and CD-ROM version Part Number 9159954 Revision E, released November 2009).

Patient Impact

There is no impact to analytical patient results if the upgrade to Software Version 4 is performed.

Necessary Actions

Please review the letter and discuss with your Laboratory Manager.

Complete the Customer Reply Form.

Once the software has been installed, you will no longer need to run with at least 1 inch of blood in your specimen tube, as previously directed in Product Correction Letter FA05APR2010 Revision 01. CELL-DYN Sapphire Version 4 Software uses the System Initiated Message (SIM) 1050 if a problem is found with the Aspiration Probe sensor system.

Please save a copy of this letter for your records.

Contact Information

If you or any of the health care providers you serve have any questions regarding this information, U.S. customers should call Customer Support at 1-877-4ABBOTT. Customers outside the U.S., please contact your local hematology customer support representative.