

URGENT FIELD SAFETY NOTICE

Product Name	Software Version
LabPro Data Management System with Axeda enabled systems	Not software version specific

Attention Beckman Coulter Customer,

Beckman Coulter is initiating a field safety corrective action for the product listed above. This letter contains important information that needs your immediate attention.

ISSUE:	<ul style="list-style-type: none"> • A Microsoft security-only update was released by Beckman Coulter via Remote Diagnostics (Axeda) on January 14, 2020 to LabPro Axeda enabled customers with Windows 7 operating system. Shortly after the update was released, some customers reported that LabPro computers would not restart.
IMPACT:	<ul style="list-style-type: none"> • If you are unable to restart the LabPro Computer, then LabPro Data Management System cannot download data generated from MicroScan instruments or manually entered microbiology test results, thus there is the potential to cause delayed results. <ul style="list-style-type: none"> ○ Some in-progress panels may be lost because they have processing errors that cannot be resolved without an active connection to the LabPro computer. ○ Some in-progress panels may be lost because available results cannot be retrieved without an active connection to the LabPro computer.
ACTION:	<ul style="list-style-type: none"> • We have records that your account is connected to Remote Diagnostics and have received this update: <ul style="list-style-type: none"> ○ If you have received a prompt to restart the LabPro computer on or after January 14, 2020 and have not yet restarted the computer, then do not restart the computer and you will be contacted by your Beckman Coulter Representative for further instructions. <ul style="list-style-type: none"> ▪ If you are unsure if you have received the restart prompt, then monitor the LabPro computer for at least an hour to see if the restart prompt appears. The prompt will redisplay hourly, if prompted, do not restart the computer. ○ If you have received a prompt to restart the LabPro computer on or after January 14, 2020, and successfully restarted the computer, then no further action is required.
RESOLUTION:	<ul style="list-style-type: none"> • Beckman Coulter is investigating the root cause of the issue and appropriate actions to prevent recurrence will be implemented.



The national competent authority has been informed of this field safety corrective action.

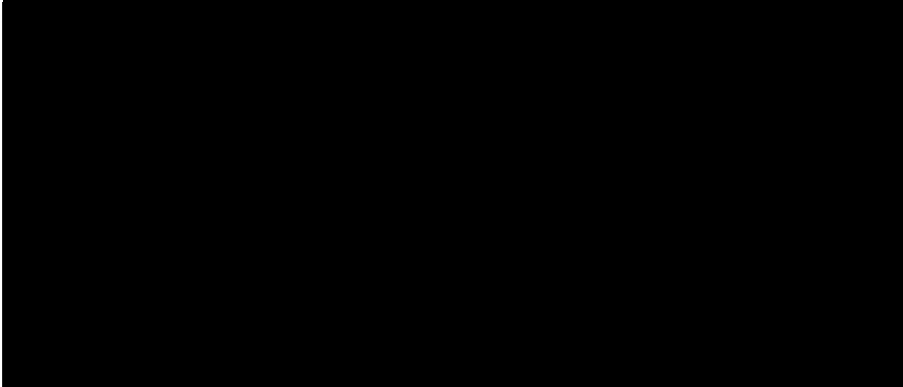
Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation.

Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact your local Beckman Coulter Representative.

- Via our website: <http://www.beckmancoulter.com>

We apologize for the inconvenience that this caused your laboratory.



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