



Product Correction

Immediate Action Required

Date Issued

August 07, 2018

Product

Product	List Number (LN)	UDI
Alinity ci-series System Control Module (SCM)	03R70-01	N/A

Explanation

Alinity ci-series Software Version 2.5.0 (List Number 04V20-03) contained changes to how the Alinity i processing module handled process path movement issues. After installing this new software version, customers have reported an increase in the occurrence of message code 5752: "Process path move error on (0) lane. 0 = Process path lane." When this message code occurs, all tests are sent to exception.

Recovery from the error requires the operator to initiate or resume sample processing on the Alinity i processing module. The increase in the message code 5752 is due to a less effective auto-recovery procedure contained in software version 2.5.0.

Software Version 2.5.1 (List Number 04V20-05) is now available. This software version will restore the previous auto-recovery procedure. This software version will not eliminate all process path jams if some underlying hardware issue restricts the process path movement, but it will reduce the occurrence of message code 5752.

Patient Impact

There is no impact to patient results.

Necessary Actions

Your Abbott representative will be contacting you to schedule the installation of Software version 2.5.1.

Please complete and return the attached customer reply form.

Please retain this letter for your laboratory records.

Contact Information

We sincerely regret any inconvenience this may have caused your laboratory. If you or any of the health care providers you serve have any questions regarding this information, U.S. Customers please contact Customer Service at 1-877-4ABBOTT (available 24 hours a day, 7 days a week). Customers outside the U.S., please contact your local area Customer Service.