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# Product Correction

**Immediate Action Required**

**To** Chairman Medical Board and relevant Head of Departments

**Date Issued** July 10, 2018

**Product**

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

**Explanation**

Abbott has identified the following issues with the Alinity ci-series which may present a potential performance issue in Alinity ci-series Software version 2.10. Abbott is releasing Alinity ci-series Software version 2.50 to correct these issues (see details in **Appendix A**).

1. Removing racks during the Maintenance state is not detected by the system. Issues with orders may occur when reloading a rack with samples and returning to Running state.
2. Orders created using more than one of the i-series, c-series, or Calculated options to select assays will only include the assays selected in the last filtered view, if the order is saved prior to returning to the All option.
3. Enabling an assay when the processing module is in the Running or Processing status causes the assay to be re-installed.
4. A sample with 270 test orders remained in the Scheduled status and would not process.
5. Some maintenance and diagnostic procedures can appear to have completed successfully when there was insufficient inventory.

In addition, three improvements were made to the Alinity ci-series software to improve your experience with Alinity PRO:

1. The incorrect test type data is appearing in Alinity PRO inventory sharing when an onboard vial rack contains both calibrator and control vials. The vial type of the first vial is applied to every vial in the rack regardless of its type.
2. Alinity i calibrators run in a vial rack with Alinity PRO inventory sharing enabled are labeled suspect/expired and do not run.

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| | 3. If the connection between Alinity and Alinity PRO is lost, a software shutdown can occur when a vial rack is returned to the loading area. The software shutdowns will continue until the Alinity PRO connection is re-established. |
| **Patient Impact** | Refer to **Appendix A** for details concerning any patient or safety impact related to the issues identified in Alinity ci-series System Software version 2.10. |
| **Necessary Actions** | Your Abbott representative will be scheduling a mandatory upgrade of your Alinity ci-series SCM to Software version 2.50 to resolve each of these issues. Refer to **Appendix A** for necessary actions required until software version 2.50 can be installed.<br><br>Software version 2.50 also provides enhancements and additional changes to increase the usability of your system. If you require additional information, please contact Abbott Customer Service.<br><br>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, please contact your local area Customer Service. |

**Appendix A - Alinity ci-series software issues resolved in version 2.50**

| Issue | System/Assay Impacted | Patient or Safety Impact | Necessary Actions until mandatory upgrade is completed |
|---|---|---|---|
| Removing racks during the Maintenance state is not detected by the system.<br><br>If additional orders are added to samples on this rack, and the rack is re-introduced after the system is transitioned back to running, duplicates add-on orders will be created. One set of orders will be sent to exceptions. The second set will remain in the Scheduled state. | Alinity ci-series | Potential for a delay in patient result reporting. | If this situation occurs, transition to the Idle or Stopped state to send the scheduled tests to exceptions. Refer to *Rerun a test or an exception for a specimen or control* in Section 5, Specimen, calibration, and control orders. |
| Orders created using more than one of the i-series, c-series, or Calculated options to select assays will only include the assays selected in the last filtered view, if the order is saved prior to returning to the All option. | Alinity ci-series | Potential for a delay in patient result reporting. | If multiple options are selected to create an order, do not select **Add Order** before returning to the All option in the Assays area. |
| Enabling an assay when the processing module is in the Running or Processing status causes the assay to be re-installed. | Alinity i-series | Potential for patient result impact**.** | Do not enable an assay when the instrument status is Running or Processing. |
| A sample with 270 test orders remained in the Scheduled status and would not process. | Alinity c-series | Potential for delay of results**.** | Order no more than 220 tests on a single sample. |
| Some maintenance and diagnostic procedures can appear to have completed successfully when there was insufficient bulk solution inventory.<br><br>A list of the impacted Maintenance and Diagnostic procedures are provided below:<br><br>**<u>Maintenance procedures</u>**<br>*5601 Clean Cuvettes with Detergent A (c series)*<br>*5805 Check and Change ICT Check Valves (c series)*<br>*5910 Wash Cuvettes (c series)* | Alinity ci-series | Potential for patient result impact**.** | Review the Results window of the maintenance or diagnostic procedure to ensure no error conditions occurred. If a message code indicating insufficient bulk solution inventory is displayed in the Results window or the Alert Center during the procedure, resolve the inventory issues and repeat the procedure. |

| Issue | System/Assay Impacted | Patient or Safety Impact | Necessary Actions until mandatory upgrade is completed |
|---|---|---|---|
| **Diagnostic procedures**<br>*4102 Sample Pipettor Calibration (c-series)*<br>*4205 Flush Water Lines (c-series)*<br>*4206 Flush Bulk Solutions (c-series)*<br>*4208 Probe and Mixer Wash (c-series)*<br>*5101 Flush ICT Reference Solution Cup (c-series)*<br>*1115 Sample Pipettor LAS Calibration (i-series)*<br>*1510 Vortexer Test (i-series)*<br>*1600 RSM Transport Calibration*<br>*1830 Buffer Run (i-series)* | | | |
| Some calibrator tests remained in the Scheduled state with a calibration status of "In Process" after the calibration failed due to a Reagent and Sample Manager (RSM) hardware failure. | Alinity c-series | No patient or safety impact. | Transition the module to the Idle or Stopped state to send the scheduled tests to exceptions and repeat the calibration. Refer to *Pause the processing module* or *Stop the processing module and the reagent and sample manager (RSM)* in Section 5, System cycle power, start, pause, and stop. |
| Message code "9999 - Unable to run the system. One or more maintenance procedures are overdue", is not translated for non-English languages. | Alinity ci-series | No patient or safety impact. | Review the procedures under the Maintenance tab to see which procedures are overdue. Perform and complete the overdue maintenance procedures before attempting to run the system. |
| If an assay parameter is edited for an Index assay, the system does not display an asterisk next to the assay number to indicate that the assay was modified. | Alinity c-series | No patient or safety impact. | When assay parameters are edited, a message is recorded in the Message History log. Review the Message History log to verify if the assay was edited. |

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| A derived quality control order cannot be run at the same time on redundant modules if the constituent assays are installed on both systems. | Alinity ci-series | No patient or safety impact. | Ensure only one processing module is eligible to process the derived control order by performing one of the two options below:<br>1. Temporarily unload or disable the constituent assay reagents from one of the modules.<br>2. Ensure only one processing module is in a Running or Processing state when running the control. |
| No notification is given when a new calibrator lot is saved. | Alinity ci-series | No patient or safety impact. | The calibrator lot is saved. No corrective action is required. |
| Message code 9403 was generated unnecessarily after an archive file was created successfully. | Alinity ci-series | No patient or safety impact. | No corrective action is required. |
| Vial racks that are not stored onboard may fail to generate message code 0269 informing the user to remove the rack from the loading area and return it to refrigerated storage. | Alinity ci-series | No patient or safety impact. | Remove the rack from the loading area when the status indicator is green (blinking), indicating processing is complete. |
| During the cuvette fill, a sample at the LAS aspiration point fails to start processing due to a system error is never released. | Alinity c-series | No patient or safety impact. | Pause the processing module. Refer to *Pause the processing module* in Section 5, System cycle power, start, pause, and stop. |
| The Alinity i supports sample pipetting for two different tests from a sample within a single lockstep. If this occurs when aspirating from the LAS, the second aspiration may not occur. The second unaspirated test is sent to Exception. | Alinity i-series | No patient or safety impact. | Rerun the exception. Refer to *Rerun a test or an exception for a specimen or control, in Section 5,* Specimen, calibration, and control orders. |
| When performing diagnostic procedure *1111 Sample Pipettor Check and Calibration (i-series)*, the updated sample positioner calibration data may not be saved. This can cause the sample pipettor to be incorrectly positioned when attempting to aspirate from the sample positioner. | Alinity i-series | No patient or safety impact. | Cycle power to the Reagent and Sample Manager (RSM) after performing the diagnostic procedure to update the sample positioner calibration data. Refer to the *Power on the reagent and sample manager (RSM)* and *Power off the reagent and sample manager (RSM)* procedures in Section 5, System cycle power, start, pause, and stop. |

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| When the calibrator barcode is scanned while configuring a new calibrator lot, the message "*Unable to change lot selection, level data for current lot has not been saved*" is generated. | Alinity ci-series | No patient or safety impact. | When configuring a new calibrator lot, go to the Calibrators Set View/Edit screen and perform one of the two options below:<br>1. Select "New Lot" and manually enter the calibrator lot and expiration date.<br>2. Scan the barcode on the calibrator carton without selecting the "New Lot" option.<br>Confirm the configured calibrator values are correct. |
| After installing a new Alinity c assay, the assay cannot be enabled and the reagent name is not displayed in the assay parameters screen. This occurs if a user-defined assay was previously created using the same reagent name. | Alinity c-series | No patient or safety impact. | Do not use Abbott reagent names when creating user-defined assays. |
| The system will not display some Japanese and Chinese characters on the Sample Laboratory Report, Result List Report, Calibration Details Report, and Procedure Report when the Automatic Report Generation feature is configured for "Save to File". | Alinity ci-series | No patient or safety impact. | If your system is configured in the Japanese or Chinese language, do not configure the Automatic Report Generation feature for "Save to File". Print reports to the default printer. |