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Urgent Field Safety Notice
Product Correction

Urgent - Immediate Action Required

Date Issued October 11, 2018

Product

Product Name: Alinity hq Analyzer and Alinity hs Slide Maker Stainer Module
List Number: 09P68-01 and 09P69-01
UDI Number: Not applicable
Serial Numbers: See Attachment 1

Explanation

Abbott has identified the issues shown below with the Alinity hq and Alinity hs Software Version 2.0.1, Alinity h-series Operations Manual (80000023-105 - 2017-10-18) and select hardware. The impacted product (hq and/or hs) are designated for each issue.

Software Version 3.0, Operations Manual (80000023-106), and hardware upgrades will correct these issues or provide ability to monitor performance through Quality Controls.

Note: To provide additional context for the items described below, it may be helpful to review with the actions provided in Table A.

1. **Message 5848** - Alinity h-series Operations Manual has no corrective action for message code 5848, Step Loss Detected on an Axis. (hq, hs)
2. **Patient and Panic Limit Set Ranges** - Patient result reports and transmitted results may not have the correct panic limit set ranges. Panic limit flag is correctly annotated as LL or HH when the result exceeds the limit set range. (hq)
3. **Message 8047** - Message code 8047, Invalid host order, is triggered for issues other than what is defined in the Operations Manual. (hq, hs)
4. **Calibration Results** - Calibration result printed reports do not match the calibration results display screen. The lower limit values are on the top row and upper limit values on the bottom row. All calculations are correct. (hq)
5. **Incorrect Message Code** - An incorrect message code will be given if the system is in process of lifting a tube out of the resuspension module and transitions to a stopped state. (hq, hs)
6. **Slide Picker Collides with Slide Shuttle** - No corrective action is provided if the slide picker collides with the slide shuttle when initializing after an error. (hs)
7. **Changing Units of Measure** - If units of measure are changed from USA to either SI or modified SI units, the action limit values displayed on the sealed batch display for HGB, HCT, MCH, and MCHC are incorrect. The system uses the correct action limit value for printed reports, determining if action limit is exceeded, or if system halts for batches. (hq)
8. **NR/W Percent Sign** - NR/W parameter is incorrectly displayed with a percent sign. The numerical result is correct. (hq)
9. **One Tube, One Rack** - Operations Manual does not specify that only one tube in one open rack may be inserted at a time. (hq)

Explanation Continued

10. **Replicates** - Independent of the number of replicates entered during calibration process, the system will do 2 (one from each block) and then eject the rack. The rack must be re-inserted additional times to complete the requested replicates. (hq)
11. **QC File Results** – While viewing inactive QC file results, all QC results with the matching lot number and level or SID from the file setup are displayed, even though some QC results are from another QC File. (hq)
12. **Enter ISBT Code 128 Barcode** – Checking the "Enter ISBT Code 128 Barcode" checkbox after clicking "Confirm Tube Mixed" button deletes set up requiring fields to be re-entered. (hq, hs)
13. **Special Characters** – Operations Manual does not exclude use of special characters for precision or QC file. System may not export precision or QC file with special characters. (hq)
14. **Operations Manual AMR and SW** – Discrepancy between Operations Manual Analytical Measurement Range (AMR) and software which displays chevrons when parameters are outside of AMR. Chevrons may not display when result is outside of AMR range. (hq)
15. **Editing Previous QC Files** – Software version 2.0.1 prevents users from being able to edit previous QC files. (hq)
16. **Print to File for Calibration in Progress** – Print to File for Calibration in Progress results are not uploaded and subtype on calibration screen does not match with print-out. (hq)
17. **Incorrect Message, Cause and Corrective Action** – The message description, cause and corrective action are incorrect for Message 5142. (hq)
18. **Levey-Jennings Screen** – If a user selects a module and a tab to view in the Levey-Jennings (LJ) screen and then selects another module to view, LJ plots displayed are inconsistent with the tab title. (hq)
19. **Bleach Tank Transfer Timeout Alert** – If there are two consecutive bleach tank transfer timeout alerts, an appropriate message code is not given to resolve the issue after the first time. (hq)
20. **TUBERobotZAxis "Busy" Error after Step loss** – Actions associated with message codes may not be able to resolve system "busy" state. (hq, hs)
21. **Naming of Precision Files** – Requirements for naming precision files is not provided. If precision files do not have unique names, then precision will not proceed. (hq)
22. **Done Button** – Done button on the System Control Center (SCC) orders search window is disabled if the user filters test orders by order origin only. (hq, hs)
23. **Print Button** – Print button is not enabled on the SCC retest tab. (hq, hs)
24. **Maintenance History Data** – System will print the maintenance history data for Module 1 and associate it with the requested Module type and serial number (other than Module 1). (hq, hs)
25. **Incubation/Injection Pumps** – Pumps could leak and may halt operation unexpectedly requiring replacement. (hq)
26. **Wash Block Tubing** – Wash block tubing could become kinked allowing reagent to drip from the sample probe into QC material or patient samples impacting 2nd aspiration test results. (hq)
27. **Repetitive System Message** – A repetitive message, 0 "WBC Flush required" may occur during open tube mode and does not have a corrective action link requiring WBC priming until resolved. (hq)
28. **Mixing Paddle Bearings** – Mixing paddle bearing may seize and halt the system requiring paddle replacement. (hq)
29. **Message Code 4611** – Message code 4611, "Laser power All/LPM ratio out of range" may display requiring an extended autoclean. In some cases, multiple extended autocleans may not resolve the issue and service/optics bench replacement may be necessary. (hq)

Explanation continued

30. **Pierce Assembly** – There is the potential for damage to the pierce assembly due to a step loss error causing a collision between components and requiring service. Delay of patient results can occur with hq. (hq, hs)
31. **Sample Status Message** – On the SCC, sample status messages for the HL7 host interface will not transmit the module serial number, instead the SCC serial number is transmitted in the log. (hq, hs)
32. **Lot Change Procedure** – After performing reagent lot change procedure 5005 and pressing the resume button, the system will begin processing any samples left in the system and not automatically pause for background and QC checks. (hq, hs)
33. **Halt Behavior/Resume/Eject** – If halt behavior is activated and halts the system, resume/eject will not remove the system racks or racks on the conveyor and the system will continue processing samples requiring other action. (hq, hs)

Patient Impact

For the following issues, patient results may be impacted and previous results may need to be reviewed based on your laboratory practices:

(a) **Wash Block Tubing –** if the wash block tubing is kinked, results from a second sample of the same tube could be impacted. A patient sample or control material is progressively diluted after the first aspiration. Issue is detectable through consecutive runs of commercial QC material and when performing precision tests.

(b) **Operations Manual AMR and SW** – For WBC values between 0 and 0.06 x 10^9 cells/liter, RBC values between 8.1 and 8.50 x 10^{12} cells/liter, and PLT values between 0 and 0.47 x 10^9 cells/liter, chevrons will not indicate that the result is outside of the AMR requiring dilution or other review.

There is a potential for delay in generation of patient results if one of the following issues occurs resulting in unplanned service:

(a) **Incubation/Injection Pumps**

(b) **Wash Block Tubing**

(c) **Mixing Paddle Bearings**

(d) **Message Code 4611**

(e) **Pierce Assembly**

For the other issues, there is no increased risk of incorrect patient results or delay in generation of patient results.

Necessary Actions

- Your Abbott representative will begin scheduling mandatory software, hardware, and Operations Manual upgrades starting in November 2018. Refer to Table A for necessary actions until upgrades are completed on your system(s).
- When you receive the mandatory software upgrade, it may be necessary to download the Alinity h-series Operations Manual (80000023-106) for Software Version 3.0 onto a USB drive for use until the upgraded on-line help is installed. The Operations Manual is available by accessing the Technical Library through the Abbott Customer Portal.
- If you have forwarded the product listed above to other laboratories, please inform them of this Product Correction and provide to them a copy of this letter.
- Please retain this letter for your laboratory records.

Contact Information

We sincerely regret any inconvenience this may cause 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.

Table A

Issue	Necessary Actions Until Mandatory Upgrade(s) are Completed
(1) Message 5848 (5) Incorrect Message Code (6) Slide Picker Collides with Slide Shuttle (20) TUBERobotZAxis "Busy" Error after Step loss (30) Pierce Assembly	Follow "Recover the System" Procedure (page 485) in Section 10 "Troubleshooting" of the Alinity h-series Operations Manual. If the error continues, contact local area customer service. Provide information about the operation that was attempted when the error occurred.
(2) Patient and Panic Limit Set Ranges	If patient and panic limit set ranges are configured, the printed patient "Result Reportable Report" with the "Manual Diff Grid Report" shows the "panic" limit for one end that exceeds the panic limit of the limit set range and the "patient" limit for the other end of the range. For example: WBC patient limit range lower **4.00** 10e3/ul, upper 8.00 10e3/uL WBC panic limit range lower 1.00 10e3/uL, upper **30.0** 10e3/uL If print the "Manual Diff Grid Report" or transmit a specimen with a WBC of 50 10e3/uL (above the panic limit), the report shows: WBC 50.0HH 10e3/uL **4.00–30.0** But it should indicate: WBC 50.0HH 10e3/uL 1.00–30.0 Note in reports as appropriate.
(3) Message 8047	The following are reasons and actions for the system triggering an Invalid host order: (a) The host order for a patient sample contains demographic fields with invalid characters or exceeds the maximum number of characters. Correct the invalid patient sample information for the host order. The SCC sends the order. (b) The host order contains a test that is not supported on the system. Correct the invalid patient sample test selection for the Host order. The SCC sends the order. (c) The host order is a retest or a reflex. The SCC is not expecting the order and does not accept the order. Verify that the Rules on Host option is enabled on the Patient Rules screen. Create a new host order for the retest or reflex. (d) The host order is for a specimen type that conflicts with another order with the same SID on the system. Correct the invalid information for the order on the host. The SCC sends the order.
(4) Calibration Results	On the Calibration Results report reference section, the lower limit values are printed on the first row with lower limit as the label, the upper limit values are printed on the second row with Target as the label. The target values are printed on the third row with the upper limit as the label. Note in printed reports as appropriate.
(7) Changing Units of Measure	Print the seal batch report to see the correct Action Limit (%).
(8) NR/W Percent Sign	Ignore the percent sign. The numerical result is nucleated red blood cells per 100 WBC
(9) One Tube One Rack	Load only one open tube specimen at a time in an open tube rack. Load only one open tube rack at a time.
(10) Replicates	Inactivate historical Cal File and create a new Cal File if going to reuse the same Cal File Specimen ID or Lot Number.

Issue	Necessary Actions Until Mandatory Upgrade(s) are Completed
(11) QC File Results	When reviewing inactive QC File results, change the inactive QC File to active to review and return to inactive when done.
(12) Enter ISBT Code 128 Barcode	Do not select the checkbox "Enter ISBT Code 128 Barcode" after you have pushed the Open Tube sample into the system.
(13) Special Characters	Do not use special characters when naming precision or QC files (\, /, ", ?, *, :, <,>, or |)
(14) Operations Manual AMR and Software	Dilute and re-run or review RBC samples above 8.1 x 10^{12}. Review WBC and PLT samples below 0.06 x 10^{9} and 0.47 x 10^{9} respectively.
(15) Editing Previous QC Files	Previous software version 2.0 QC files are history. Create new QC files after the 2.0.1 software upgrade.
(16) Print to File for Calibration in Progress	A Print Screen may be used and it will contain the Subtype on the Calibration Screen.
(17) Incorrect Message, Cause and Corrective Action	An error was detected with the optical sensors on the slide picker. No corrective action is required.
(18) Levey-Jennings Screen	In the Levey-Jennings Screen when reviewing different module data, before selecting the module to review, select the 1st tab (Summary).
(19) Bleach Tank Transfer Timeout Alert	Cycle power to the module, (page 278) in Section 5 "Operating Instructions" of the Alinity h-series Operations Manual.
(21) Naming of Precision Files	Use a unique name for precision files.
(22) Done Button	If searching the Orders search window by Order Origin, include an Order Date From Date to activate the "Done" button on the search window.
(23) Print Button	There are three ways to print the results report for either the original or retest results. (a) auto print all results when auto print is enabled; (b) print original results in Reportable tab in the Result Details screen; and (c) select the retest results from the Results screen and print the Reportable report.
(24) Maintenance History Data	When printing the Maintenance History Report from the Procedures Log, ensure Module 1 (or desired Module) is selected from Procedures view prior to printing from the Procedures Log View.
(25) Incubation/Injection Pumps	Ensure the lab has a back-up instrument or an alternative method of generating hematology patient results should the instrument become inoperable. Confirm that quality control results are within the acceptable limits before patient results are reported.
(26) Wash Block Tubing	Ensure the lab has a back-up instrument or an alternative method of generating hematology patient results should the instrument become inoperable. Run commercial QC materials in replicates and review for lower recovery in repeated runs.
(27) Repetitive System Message	(a) Exit the open tube screen, tap cancel; (b) Perform Run a Background count (Alinity hq LUI), with a CBC+Diff test; and (c) Return to the Open Tube Screen to begin the test.
(28) Mixing Paddle Bearings	Ensure the lab has a back-up instrument or an alternative method of generating hematology patient results should the instrument become inoperable.
(29) Message Code 4611	Ensure the lab has a back-up instrument or an alternative method of generating hematology patient results should the instrument become inoperable. When Software Version 3.0 is installed, Optics Moving Averages will be enabled allowing detection of issue prior to system being inoperable. User should contact local area customer service if Optics Moving Average alert limit is triggered.

Issue	Necessary Actions Until Mandatory Upgrade(s) are Completed
(31) Sample Status Message	If the lab uses a HL7 host interface, the equipment detail in the sample/specimen update status message is the serial number of the SCC, not the module serial number.
(32) Lot Change Procedure (33) Halt Behavior/Resume/Eject	Cancel any queued transport to the module, remove the racks on the conveyor by opening the module cover, eject each rack from all the lanes, and run QC and/or background counts as appropriate.