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Product Correction

Immediate Action Required

Attn	**The Laboratory Manager/ Technicians**
Cc	**Medical Director/ Head of Dept**
Date Issued	November 21, 2017
Product	**Product Name:** Alinity hq Analyzer **List Number**: 09P68-01 **UDI Number:** Not applicable Serial Numbers: hq00102, hq00103, hq00105, hq00106, hq00107
Explanation	Abbott has identified the following issues with Alinity hq Analyzer Software Version 1.0:

1. Patient limit setup allows a range of 000-999. If a value more than 3 digits is entered, it will be truncated to the first 3 digits. An error icon will appear if the input value is not between 000-999; If the user does not respond to icon and scrolls off screen, the error icon will disappear, not re-alerting the user.
2. During calibration verification, the system does not allow on-screen comparison of current calibration factors versus new calibration factors.
3. The following Analyzer Initiated Message (AIM) codes are not addressed fully in the Analyzer and/or Operations Manual (On-Line Help):
    a. 9999 Restore error message, “UnexpectedGetAvailableBackupFailure"
    b. 0000 Westgard Rule violation occurs
    c. 5135 Aim_CapDetectFailed Cap detection error
    d. 8006 Aim_HI7UnknownError Host Communication error
    e. 8047 Aim_InvalidHostOrderInvalidSampleId invalide host order
    f. 9505 Aim_ModuleConfigBackupStatusFailed Module
4. When setting the date/time, the embedded analyzer within the Local User Interface (LUI) may not consistently synchronize with System Command Center (SCC) for date/time changes.
5. On the work order screen, the sorting by SID sorts by date/time instead of SID. When printing or exporting a results summary by patient sequence range, it may not print/export the selected sequence range.
6. In the Levey-Jennings screen and QC screens, the system defaults to 1 standard deviation (SD) for its calculations of upper/lower limits instead of using the value on the QC screen.
7. If Customer has Retic mode disabled and then selects Retic for a sample, the LUI will become unresponsive and no test order is processed.
8. When reviewing results, some of the WBC scattergrams may show a black screen with the correct run and results displayed.

Explanation continued	9. Action limit in sealed batch screen for parameters is being incorrectly converted from % unit to SI unit. 10. Factors and history screens/printouts don't display the calibration type and subtype. 11. If user loads a leaking or partially full bottle of retic, then system may not complete the Retic flush. 12. Under rare circumstances, HGB measurement can be potentially impacted by electrical interference without associated flagging. 13. Tube robot may not release a tube after an emergency stop or system crash. 14. When WBC low flag appears, the flag for hardware clot detector appears also when exporting results from user interface option. Software Version 2.0 and associated Operations Manual will correct these issues.
Patient Impact	Patient results are not impacted and there is no delay in results.
Necessary Actions	• Your Abbott representative will begin scheduling mandatory software upgrades (Software Version 2.0) including install of the latest Alinity h-series Operations Manual starting in November 2017. See Table A for necessary actions until software is installed on your system. • If you have forwarded the product listed above to other laboratories, please inform them of this product information 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 (abbreviated)	Necessary Actions until mandatory upgrade is completed
1. Patient limit set-up allows a range of 000-999. Values are truncated to 3 digits with an initial error icon	Enter patient limit values between 000-999 and address any error icon immediately without scrolling to next screens
2. System does not allow on-screen comparison of current calibration factors versus new calibration factors	Record new calibration factors manually to allow for on-screen comparison with current calibration factors
3. (a-d) AIM codes 0000, 5135, 8006, 9999 not defined	Contact Customer Service for these AIM codes, as appropriate
3. (e) AIM code 8047 not defined	Download order again with correct SID
3. (f) AIM code 9505 not defined	Other AIM codes displayed at the same time will help determine appropriate actions
4. Synchronization of date/time between LUI and SCC	If date/time is changed on the Analyzer, ensure the LUI and SCC are displaying the same date/time. Repeat if not correct or contact Customer Service
5. Printing, sorting, or exporting SID by sequence number range may not be possible	Print using other sorting functions such as date/time
6. The Levey-Jennings screen and QC screens default to 1 SD alerts instead of user entered values	Ensure awareness of issue. Westgard rules are working as intended, but the display will be showing 1 SD values. The QC will show a tighter range than expected
7. When Retic mode is disabled and Retic order is entered, system will become unresponsive and no test order is processed	Ensure Retic mode enabled prior to entering Retic test order. If system is unresponsive, restart the LUI and enable Retic
8. WBC scattergram may not display on results screen	Select previous or next on the screen and then return to the sample results screen and the scattergram will appear
9. Software converts % for action limits to SI units	Ensure awareness of issue. Flagging is determined correctly using US units. This only impacts the display of the moving average sealed batch screen.
10. Factors and history screens/printouts don't display the calibration type and subtype	If needed, manually record the calibration type and subtype on an appropriate record
11. If user loads a leaking or partially full bottle of retic, then system may not complete the Retic flush	The Alinity h-series Operations Manual requires full bottles of reagent to be installed for usage tracking purposes. Load only full, non-leaking bottles of reagent onto the system
12. In rare circumstances, HGB background may be potentially impacted by electrical interference	HGB flagging due to electrical interference is already a feature of the Alinity hq Analyzer. Flagging is being further optimized
13. Tube robot may not release a closed tube after an emergency stop or system crash	Refer to instructions below for tube removal from robot
14. WBC low flag is incorrectly accompanied by a hardware clot detector flag when exporting results using the user interface option	User Interface Screen, Middleware transmission, and printed results are not impacted. Compare exported results as appropriate

Tube Removal from Robot

1. On the LUI Home screen, power off the module. NOTE: The SCC remains on during the entire procedure.
2. Remove all tube racks, carrier racks, and slides from the module loading area.
3. Open the module cover.
4. Position the collection container on the loading area.
5. Move the robot by using the gantry to position the specimen tube over the collection container. IMPORTANT: Do not use the gripper to move the robot. This may damage the robot.
6. Close the module cover.
7. Power on the module.
8. Log on to the LUI.
9. Clear all error messages related to the cause of the module stopping (for example, an axis error or an unexpected tube or rack in the gripper). NOTE: Do not cycle power to the module.
10. Tap Start.
11. The module releases the specimen tube from the gripper into the collection container.
12. Wait for the module to initialize.
13. Tap Pause.
14. Open the module cover.
15. Remove the collection container with the released specimen tube.
16. Close the module cover.
17. To prepare the module for operation, tap Run.