

IMPORTANT MEDICAL DEVICE RECALL/FIELD SAFETY NOTICE INFORMATION:

Instrument Manager (IM) Abbott Alinity ci-series (abdicqii) driver v8.00.0001 and QC results (KI IM-60678)

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IMPORTANT PRODUCT NOTICE

NOTIFICATION DATE: 29Aug2018

SOFTWARE AFFECTED: Instrument Manager (IM) Abbott Alinity ci-series (abdicqii) accessory driver v8.00.0001.

Instrument Manager is a software product that communicates with hospital computer systems (also called a Laboratory Information Systems [LIS]), and communicates with laboratory instruments. Instrument Manager uses accessory software called drivers written specifically for an instrument to enable this communication. In this case, a specific accessory driver for a specific instrument is affected.

ISSUE: QC results will not be processed from the Abbott Alinity ci-series instrument if Hold Results Until Complete is enabled.

ISSUE DETAILS: Quality control results are not processed for Abbott Diagnostics Alinity ci-series (abdicqii) instrument.

This has been determined to be an accessory driver malfunction. When an instrument transmits results from a quality control (QC) sample ID ("Q^Control" in SPM segment), and the option "Hold Results Until Complete" is enabled, the results do not parse into IM. The communication Trace shows the sample being transmitted, but no information is logged in the Specimen Event Log (SEL).

There is a potential for harm if QC results are not processed, downstream auto-verification rules may misfire based on missing QC results leading to a delay in, or incorrect treatment. QC results will not be available for evaluation by the lab.

There have been no reported instances of patient harm from this malfunction.

GROUP AFFECTED: Customers using v8.00.0001 of the Abbott Alinity ci-series (abdicqii) accessory driver and using the Hold Results Until Complete option with any version of Instrument Manager core software.

SOLUTION: Customers should apply the updated v8.00.0002 version (or higher) of the Instrument Manager abdicqii driver to correct this issue.

WORKAROUND: Disable the "Hold Results Until Complete" option in Instrument Manager (driver configuration). If Hold Results Until Complete logic is required, there is no workaround, discontinue use until updated driver is installed.

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Please pass this notification on to anyone in your organization that needs to be aware of it.

Please fill out the information below and fax to: 802-658-2782 Attention Quality Department or email to DINA-General@datainnovations.com upon receipt of this notification.

ISSUE: QC results will not be processed from the Abbott Alinity ci-series instrument if Hold Results Until Complete is enabled.

Name of Clinic, Laboratory, or Hospital _____

If the name of the Location has changed since obtaining the Instrument Manager license, please provide the former name as well:

City and State where Site is Located: _____

Instrument Manager License Number(s): _____

No, our site is not affected. We do not use the Hold Result Until Complete option in the driver.

No, our site is not affected. We do not use the Abbott Alinity instrument with Instrument Manager.

Yes, our site is affected. We have installed the updated v8.00.0002 driver version to correct this issue.

Yes, our site is affected. We would like the updated v8.00.0002 driver sent.

Send via email to: (email address) _____

Send via disc to: (address) _____

Yes, our site is affected. We understand the risks associated with this issue but have not yet applied the updated version or implemented the workaround. We are implementing an alternative solution.

Print Name and Title of Respondent: _____

Signature of Respondent: _____ Date: _____

If you have further questions regarding this notice, please feel free to contact us at the email or phone number shown above. For future reference, this, and other alerts are added to our Knowledgebase in the Customer Web Portal. The [Customer Web Portal](#) (CWP) can be accessed through the [Support](#) page on our website.