

IMPORTANT MEDICAL DEVICE RECALL/FIELD SAFETY NOTICE INFORMATION:

Instrument Manager (IM) v8.15.00, v8.15.01, v8.15.10 and Coded Entry Actions in SM Workspace (KI IM-54063)

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IMPORTANT PRODUCT NOTICE

NOTIFICATION DATE: 16Apr2018

SOFTWARE AFFECTED: Instrument Manager (IM) versions 8.15.00, 8.15.01, 8.15.10

ISSUE: An incorrect coded entry value may be set when using the "Insert Coded Entry" action from the Command Bar.

ISSUE DETAILS: Using the "Insert Coded Entry" Action in the Test or Run Worksheet may result in an invalid code entered into the coded entry field.

When using "Insert Coded Entry" Action from the Command Bar an entry selected from the Insert Coded Entry screen may update the Test or Run Worksheet Coded Entry field, but when you save or click in any other cell in the grid it changes the entry to a different coded entry value. Continued use of the device using "Insert Coded Entry" in the manner described may result in incorrect treatment of patients based on incorrect test results being reported.

This issue occurs under the following conditions assuming Coded Entries are being used in the Test or Run Worksheet:

1. User must be in the Test Worksheet or Run Worksheet. Note: This issue does not occur when user is in the Specimen Worksheet, using a Test Worksheet only view (i.e. no fields visible in Specimen Worksheet), or using Manual Results Entry or Cell Counter.
2. User must have the cursor in a Coded Entry field (Patient Comment(s), Specimen Reviewer Comment(s), Specimen Comment(s), Result, Test Reviewer Comment(s) or Test Comment(s)). Note: The cursor must be in the field and in "edit mode" (i.e. the cursor will be flashing). This issue will not occur if the Coded Entry field is selected but it is not in edit mode. (i.e. using keyboard to select the cell or click in the cell and press Esc key)
3. User must select the "Insert Coded Entry" Action from the Command Bar in SM Workspace or use a hot-key to perform the "Insert Coded Entry" Action. Note: This issue does not occur when selecting "Insert Coded Entry" from right-click menu, selecting a coded entry from the dropdown list, typing in a coded entry directly into the cell, or using the Edit Comments action.
4. The text returned from the Insert Coded Entry screen must match an individual entry in the coded entry dropdown list. If free-text is entered that does not match a code in the dropdown, the issue does not occur. Likewise, if multiple codes are selected and returned, the text in the coded entry field will not match an individual dropdown entry, and this issue does not occur.

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

GROUP AFFECTED: Customers using IM and using Coded Entry actions in the SM Workspace.

To determine if you are affected by this issue, please download the IM-54063 Coded Entry Checker utility from the Customer Web Portal (CWP) which can be accessed through the Support page on our website at <http://www.datainnovations.com/support/obtain-support>. From the Download area of the CWP, click the Select Resource dropdown list and select IM-54063 Coded Entry Checker Utility which is listed under the Instrument Manager Core Software Upgrades item. The utility will check the Coded Entry Setup and determine if there are any coded entries configured that could be set incorrectly and will display the following information: List of coded entries that could cause the issue; the Connection(s) and/or Test(s) the affected coded entries are configured on; the value the affected Coded Entries would have been changed to.

Data Innovations recommends you review this information and review results which may have been affected, including the incorrect treatment of patients based on the reporting of incorrect results.

SOLUTION: Customers should apply the updated 8.15.11 version of Instrument Manager to correct this issue when the updated version is available approximately on 20 April 2018.

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WORKAROUND: To temporarily prevent this issue from occurring, the following workarounds are available:

1. Select a code from the coded entry dropdown or type in the code.

OR

2. Right-click and select "Insert Coded Entry"

In addition, it is also recommended to customize SM Workspaces by removing the "Insert Coded Entry" menu item and any Hot-Keys associated with this action from all of the configured SM Workspaces Test and Run Worksheet. No customization of Manual Result Entry or Cell Counter is required, as this issue does not affect those configurations.

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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: +1 802-658-2782 Attention Quality Department or email to DINA-General@datainnovations.com upon receipt of this notification.**

ISSUE: An incorrect coded entry value may be set when using the Insert Coded Entry action from the Command Bar.

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 no longer use Instrument Manager.
- No**, our site is not affected. We do not use coded entries within Specimen Management Workspace.
- Yes**, our site is affected. We have installed the updated 8.15.11 version to correct this issue.
- Yes**, our site is affected. We would like the updated 8.15.11 version 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.