IMPORTANT MEDICAL DEVICE RECALL NOTIFICATION:

Instrument Manager versions 8.12.01, 8.12.02, 8.12.10, 8.12.11, 8.12.20, and 8.12.21 using Specimen Management or Rules-Only packages

Subsequent child rules may not be evaluated if a rule attempts to divide by zero or another error occurs in a large rule set.

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IMPORTANT PRODUCT NOTICE   DATE: December 13, 2013

GROUP AFFECTED: Instrument Manager customers with Specimen Management Rules Processing or Rules-Only packages using rules in Compatibility Mode - No (New Mode) with the above listed affected versions of Instrument Manager.

ISSUE: Subsequent child rules may not be evaluated if a rule attempts to divide by zero or another error occurs in a large rule set.

ISSUE DETAILS: If a rule set contains enough rules to create a routine larger than 64KB in size and an error occurs or if a rule attempts to divide by 0, subsequent rules may not be evaluated.

During the saving of rules, the rules are converted from their display format into generated routines that get compiled and executed at runtime. If the size of the routine is larger than 64KB, this issue may occur when an error occurs.
For this issue to occur the following criteria must be met:
1. The Generated Routine must be greater than 64kb
2. If the Parent of the Child Rule does not have an IF statement, the error must occur in the second Child or subsequent Child Rule. However, if the Parent of the Child Rule has an IF statement, the error could occur in any Child Rule.
3. The rule set is defined as Compatibility Mode – No (New Mode)

If the above criteria are met, the subsequent sibling rules in that group of the child rule that erred will not be evaluated.

Legacy Rules are not affected
Compatibility Mode- Yes is not affected

Please see page 2 for examples of this issue.

CLINICAL IMPACT: If rules are not evaluated it could produce undesired and/or incorrect results, because rules are fired in the order configured and rules may depend on each other to produce the desired outcome. This could cause harm to the patient if a medical decision is made based upon the erroneous result of the rule processed, or not processed.

WORKAROUND: N/A

SOLUTION: Apply one of the patch versions: 8.12.03, 8.12.12, or 8.12.22 or upgrade to v8.13.00

Examples:

An example of this issue when an error occurs:

- Rule 1 (Parent)
  - Rule 1.1 (Child of Rule 1)
  - **Rule 1.2 (Sibling of Rule 1.1) – Error Generated – Logged on Status Screen**
  - **Rule 1.3 – Test A/Test B – Not Executed**
  - **Rule 1.4 – Not Executed**
    - **Rule 1.4.1 – Not Executed**
  - **Rule 1.5 – Not Executed**
  - **Rule 1.6 – Not Executed**
- Rule 2 (Sibling of Rule 1)--Evaluated

An example of this issue when a rule attempts to divide by zero:

- Rule 1 (Parent)
  - Rule 1.1 (Child of Rule 1)
  - Rule 1.2 (Sibling of Rule 1.1)
  - **Rule 1.3 – Test A/Test B and Test B = 0**
  - **Rule 1.4 – Not Executed**
    - **Rule 1.4.1 – Not Executed**
  - **Rule 1.5 – Not Executed**
  - **Rule 1.6 – Not Executed**
- Rule 2 (Sibling of Rule 1)--Evaluated

An example of this issue when an error occurs in a grandchild rule. The error is in rule 1.2.2, but instead of continuing at rule 1.2.3, Rules Processing continues at rule 2:

- Rule 1 (Parent)
  - Rule 1.1 (Child of Rule 1)
  - Rule 1.2 (Sibling of Rule 1.1)
    - Rule 1.2.1 (Child of Rule 1.2)
    - **Rule 1.2.2 – Test A/Test B –> Test B = 0**
      - **Rule 1.2.2.1 – Not Executed**
    - **Rule 1.2.3 (Sibling of Rule 1.2.2) – Not Executed**
  - **Rule 1.3 – Not Executed**
  - **Rule 1.4 – Not Executed**
- Rule 2 (Sibling of Rule 1) – Evaluated

An example of this issue when an error occurs in a great-grandchild rule. The error is in rule 1.2.2.2, but instead of continuing at rule 1.2.3, Rules Processing continues at rule 2:

- Rule 1 (Parent)
  - Rule 1.1 (Child of Rule 1)
  - Rule 1.2 (Sibling of Rule 1.1)
    - Rule 1.2.1 (Child of Rule 1.2)
    - Rule 1.2.2 (Sibling of Rule 1.2.1)
      - Rule 1.2.2.1 – (Child of Rule 1.2.2)
      - **Rule 1.2.2.2 – Test A/Test B –> Test B = 0**
    - **Rule 1.2.3 (Sibling of Rule 1.2.2) – Not Executed**
  - **Rule 1.3 – Not Executed**
  - **Rule 1.4 – Not Executed**
- Rule 2 (Sibling of Rule 1) - Evaluated

Subsequent child rules may not be evaluated if a rule attempts to divide by zero or another error occurs in a large rule set.

Please fill out the information below and fax to: 802-658-2782 Attention Quality and Regulatory Department or email to europe-support@datainnovations.com **by December 20, 2013.**

ISSUE: Subsequent child rules may not be evaluated if a rule attempts to divide by zero or another error occurs in a large rule set.

Site / Location / Laboratory: _____

Print Name and Title of Respondent: _____Date: _____

Signature of Respondent: _____

☐ **Yes,** our site is affected. We have downloaded and installed one of the available patches (v8.12.03, v8.12.12, v8.12.22) from the Customer Web Portal.

☐ **Yes,** our site is affected. We upgraded to the latest version of Instrument Manager v8.13.00

☐ **Yes,** our site is affected. We are unable to download one of the available patches (v8.12.03, v8.12.12, v8.12.22) from the Customer Web Portal and would like a disc to be sent to us for installation.

☐ **No,** our site is not affected. We no longer use Instrument Manager.

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.