SIEMENS

Urgent Field Safety Notice

12-20

May 2012

syngo® Lab Data Manager and syngo® Lab Process Manager, all versions

Multi-Rule Quality Control Configurations

Our records indicate that you are using the *syngo*® Lab Data Manager or *syngo*® Lab Process Manager, all versions. Siemens Healthcare Diagnostics has discovered that when using the *syngo* Quality Control package the system may not perform as intended for Multi-Rule QC violations [e.g., 2(2S), 4(1s) and 10x], unless configured using the instructions starting on page 2 of this document. When this situation occurs, QC status may not be flagged appropriately. If auto-verification rules are defined to hold patient results when QC status is out, the patient results will not be held as expected.

The problem is encountered under the following conditions:

1. The QC package within the *syngo*® system is being used to evaluate QC.

2. The *syngo*® system is configured with Multi-Rule QC [e.g., 2(2S), 4(1S) or 10x rules], and the Multi-level option is selected without following the instructions starting on page 2 of this document.

When these conditions are met the QC status is not set correctly for the level with the successive QC results failures. The failure will affect the Multi-Rule indications for all instruments (and associated tests) connected to the *syngo*® system.

Siemens recommends that the Multi-Rule option be re-set using the attached configuration instructions.

Multi-Rule QC is intended to detect shifts in assay performance. We recommend that you discuss the content of this letter with your laboratory director regarding the need to review any previous QC deviations and determine impact on previous test results. If you have technical questions or concerns, please contact the Siemens Technical Solutions Center at 800-441-9250 for further assistance.

Please complete the attached Field Correction Effectiveness Check form and fax it to (302)631-8467 to indicate that you have received this information **by June 15th**. Please complete and fax the form to Siemens even if your lab does not use the *syngo*® QC package or does not have Multi-Rule QC configured. Please forward this notification to anyone to whom you may have distributed this product.

We apologize for the inconvenience that this situation has caused. Thank you for your patience and continued support.

Siemens Healthcare Diagnostics Inc.

Multi-Rule Quality Control Configurations

Quality Control rules can be organized into rule sets. QC rules are used to check the QC results and alert the user if the results are outside of the conditions specified by the rule.

> **Note** If your laboratory does not utilize the *syngo®* QC package or does not have Multi-level QC rules (across Controls) configured, this procedure can be disregarded.

Multi-Rule QC tracks results across different Control levels; however, it uses previous data points outside the run as the basis for its rule interpretation. This issue prevents the QC from being tracked correctly across different QC levels. With multi-level enabled, QC results failing a Multi-level rule may not be flagged by the QC Software unless the rules are set up as follows:

> **Creating an Evaluation (within a Control) Rule Set**
>
> An Evaluation QC rule is applied within a single Control.
>
> 1. Log into *syngo®* as the User labadmin.
>
> 2. From the *syngo®* QC application, navigate to:
>
> **Administration > Rule Packages > Rule Sets**.
>
> > **Note** A Rule Set is comprised of one or more QC evaluation rules. One Rule
> >
> > Set must be defined for Evaluation rules (within a Control evaluation) and a
> >
> > second Rule Set must be defined for Multi-level rules (across Controls).
> >
> > **WARNING: In order for rules to be properly applied to QC results, do**
> >
> > **not create a single Rule Set that contains both Evaluation rules and**
> >
> > **Multilevel rules in the same set.**
>
> 3. Click **New Rule Set**.
>
> 4. Enter a required rule set **ID** and **Name**.
>
> > **Note** These can be titled the same or different. These are intended to
> >
> > remind the user what is contained in the rules set. Both are displayed in the
> >
> > Rules Sets list after being saved.
>
> 5. Click **Enabled** if rule set should be active. Leave **Enabled** deselected to
>
> disable rule set.
>
> 6. Open the **Kind** drop-down menu and click **Evaluation Rule**.
>
> > **WARNING: DO NOT click "Evaluation Rule- Multi-level" when creating**
> > **rules to be included in an Evaluation Rule set.**
>
> 7. Enter a **Version** number. If this is the initial definition of the rule set, choose
>
> 1.0. If modifying a previously created rule set, increment the version number

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appropriately.

8. Enter a note to define or explain how the rule set is used. This field is laboratory specific containing information important to the laboratory and users. Notes can be viewed when opening the rule set.

9. In the **Included Results** field, make sure "Standard QC Results Only" is selected.

10. Open the **Select Standard Rule** or **Select Custom Rule** drop-down menu to view lists of rules available in each category.

11. Click each rule to be included in this rule set.

   Note Verify that only Evaluation (within Control) rules are added to this rule set.

12. Define a **Trigger** rule or set one of the **Rules Listed** as a **Trigger**, if desired.

   Note A trigger is a rule that must be violated prior to any other rule in the set being evaluated.

13. Click **Save** located at the top of the **Rule Set Details** section.

   Note The Record(s) have been saved successfully appears at the top of the screen once the rule set has been saved.

14. Add Assays to the Rule Set

   WARNING: In order for the rules to be properly applied to the QC results, each Rule Set must have assays defined. When adding a new assay to the *syngo*® in the future, it is extremely important to ensure that the new assay is added to the rule set.

   a. Click **Add Assay(s) to Rule Set**.

   b. Select the required assay(s). To select multiple assays, press and hold **CTRL** then select each assay. To select all assays, select the first assay in the list, scroll to the bottom of the list, press and hold SHIFT, and select the last assay in the list.

   c. Select the appropriate sample type(s). To select multiple sample types, press and hold **CTRL** then select each sample type. To select all sample types, select <all>.

   d. Click **Add Assay(s) to Rule Set**.

   e. Click **Save**.

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Note The Record(s) have been saved successfully appears at the top of the screen once the assays have been added to the rule set.

f. Return to the Rule Sets menu.

Create the Multi-level (across Controls) Rule Set:

1. From the Rule Sets menu, select **New Rule Set**.

2. Enter a required rule set **ID** and **Name**.

   Note These can be titled the same or different. These are intended to remind the user what is contained in the rules set. Both are displayed in the Rules Sets list after being saved.

3. Click **Enabled** if rule set should be active. Leave **Enabled** deselected to disable rule set.

4. Open the **Kind** drop-down menu to display the rule types and click **Evaluation Multi-Rule**.

   WARNING: You must select Evaluation Multi-Rule when creating rules to be included in a Multi-level rule set.

5. Enter a **Version** number. If this is the initial definition of the rule set, choose 1.0. If modifying a previously created rule set, increment the version number appropriately.

6. Enter a note to define or explain how the rule set is used. This field is laboratory specific containing information important to the laboratory and users. Notes can be viewed when opening the rule set.

7. In the **Included Results** field, make sure "Standard QC Results Only" is selected.

8. Open the **Select Standard Rule** or **Select Custom Rule** drop-down menu to view lists of rules available in each category.

9. Click each rule to be included in this rule set.

   Note Verify that only Multi-level rules (across Controls) are added to this rule set.

10. Define a **Trigger** rule or set one of the **Rules Listed** as a **Trigger**, if desired.

    Note A trigger is a rule that must be violated prior to any other rule in the set

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being evaluated.

11. Click **Save** located at the top of the **Rule Set Details** section.

    Note The Record(s) have been saved successfully appears at the top of the screen once the rule set has been saved.

12. Add Assays to the Rule Set

    WARNING: In order for the rules to be properly applied to the QC results, each Rule Set must have assays defined. When adding a new assay to the *syngo*® in the future, it is extremely important to ensure that the new assay is added to the rule set.

    a. Click Add Assay(s) to Rule Set.

    b. Select the required assay(s). To select multiple assays, press and hold **CTRL** then select each assay. To select all assays, select the first assay in the list, scroll to the bottom of the list, press and hold SHIFT, and select the last assay in the list.

    c. Select the appropriate sample type(s). To select multiple sample types, press and hold **CTRL** then select each sample type. To select all sample types, select <all>.

    d. Click **Add Assay(s) to Rule Set**.

    e. Click **Save**.

    Note The Record(s) have been saved successfully appears at the top of the screen once the assays have been added to the rule set.

Siemens Healthcare Diagnostics Inc.

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FIELD CORRECTION EFFECTIVENESS CHECK

syngo® **Lab Data Manager and** *syngo*® **Lab Process Manager, all versions**

Multi-Rule Quality Control Configurations

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated May 2012 regarding the *syngo*® Lab Data Manager or *syngo*® Lab Process Manager system, all versions.

Please complete the statement below by indicating Yes or No. Fax this completed form to Siemens Healthcare Diagnostics at the fax number indicated at the bottom of this page. Please complete and fax the form to Siemens even if your lab does not use the *syngo*® QC package or does not have Multi-Rule QC configured.

I have read and understood the information provided in this letter.   Yes ☐   No ☐

   Name of person completing questionnaire:

Title:

Institution: *syngo*® Serial Number(s):

Street:

City: State: Phone:

PLEASE FAX THIS COMPLETED FORM TO THE SIEMENS TECHNICAL SOLUTIONS CENTER AT 302-631-8467 **BY JUNE 15**^th **.**

Siemens Healthcare Diagnostics Inc.