

## Urgent Field Safety Notice

10819365, Rev. A

August 2014

### CentraLink™ Data Management System

#### Task Scheduler Issue

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Our records indicate that your facility may have received the following product:

**Table 1. CentraLink Affected Product**

Product	Siemens Material Number (SMN)
CentraLink Software Version 14	10811600, 10811601, 10814296, 10814298, 10814877, 10814880, 10814881, 10811741, 10811742, 10811743, 10815474, 10816519, 10816520, 10816521, 10816522, 10816523, 10816524, 10815474, 10811596

#### Reason for Correction

Siemens Healthcare Diagnostics has identified a task scheduler issue with the CentraLink™ Data Management System, software version 14. The issue may cause the software to stop executing commands, including uploading validated results to the LIS. The issue is related to an internal software timer that overflows after 24 days. Automated rules triggered by task schedulers or by actions in the CentraLink user interface may also be affected. As each customer configuration is unique, in addition to the delay in uploading of validated results, the specific consequences of discontinued command execution will vary.

#### Risk to Health

- In the instance of rules or reflex testing not holding a result for review or confirmation, there is the possibility that a result is erroneously released without review. Circumstances will vary depending upon laboratory configuration of rules.
- A delay in reporting is possible. However, this would be noted by the operator.
- Siemens is not recommending a review of previously reported results.

#### Actions to be Taken by the Customer

To prevent the issue from occurring, log out of user sessions and restart the CentraLink services and translators as soon as it is convenient, then periodically restart going forward. Any restart frequency that occurs more often than every 24 days is acceptable and will prevent the issue from occurring. Refer to the Additional Information section for detailed instructions.

**NOTE:** Although the services and translators can be shut down and restarted at any time, Siemens recommends that customers perform the shutdown/restart during a time of minimal sample processing activity. On an idle system, the system may take approximately 3-5 minutes

to perform a restart. Additionally, some devices may need to be manually reconnected after the restart. The manual reconnection process is the same that is required when the Centralink Data Management System is rebooted.

In addition, please perform the following:

- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check attached to this letter within 30 days.
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Customer Care Center or your local Siemens technical support representative.

Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

### **Additional Information**

#### **Restart Instructions**

Please perform the following procedure to restart the Centralink Data Management System. This procedure only starts services and translators with the AutoStart attribute selected. Verify that services and translators are selected correctly. You must start any unselected required services and translators individually.

1. Log out of any Centralink sessions that may be open, including all client sessions:
  - a. Click **Start > Exit**, then click **Yes** to confirm closing the Centralink session.
  - b. Click the **Cancel** button to close the Login window.
2. Log into the Centralink application on the Centralink server as a System Administrator.
3. Navigate to the **Start** menu > **System Management > Security > Current Logins**.
4. Confirm that there are only two entries in the current login window: one entry for "centralink" and one entry for "genro"; these are the two logins for the session on which you are working.
  - a. If there are additional entries, then additional server or client sessions are in progress. Log out of those entries completely.
  - b. Click **Refresh** on the Current Login window to confirm that one entry for "centralink" and one entry for "genro" remain.
  - c. Click **Cancel** to close the "Currently active logins" browser. See Figure 1.

**Figure 1. Currently Active Logins Browser**

Database	Type	User	Device	Login
centralink	REMC	87	siemens-pllviaa	Sun Jan 02 13:53:22 *
genro	REMC	83	siemens-pllviaa	Sun Jan 02 13:53:22 *

5. Shutdown the services by navigating to the **Start** menu > **System Management** > **Services** > **Shutdown**. Click **OK** or **Yes** on all pop-up message windows to proceed.
6. Once the progress bar disappears, navigate to the **Start** menu > **System Management** > **Services** > **Startup** and start services and translators.
7. In the Mark Application Start window, leave the checkbox unselected and click **OK**.
8. Click **OK** to start the XML control service.

CentraLink is a trademark of Siemens Healthcare Diagnostics.

**FIELD CORRECTION EFFECTIVENESS CHECK**

Task Scheduler Issue

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 10819365, Rev. A dated August 2014 regarding Task Scheduler Issue. Please read the question and indicate the appropriate answer. Return this completed form to Siemens Healthcare Diagnostics at the contact details provided at the bottom of this page.

Ref: ISW 14-07 [C/2842]

I have read and understood the Urgent Field Safety Notice instructions provided in this letter.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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Name of person completing questionnaire:	
Title:	
Institution:	Server Serial Number:
Street:	
City:	Post Code:
Phone:	Email:
Signed:	Date:

It is important that your organisation takes the actions detailed in the FSN and replies immediately using the FIELD CORRECTION EFFECTIVENESS CHECK attached to this FSN. Your organisations reply is evidence which, Siemens Healthcare, and subsequently the MHRA, needs to monitor the progress of the FSN. Without your reply Siemens Healthcare cannot verify the completeness of the FSN and the MHRA may need to issue a Medical Device Alert.

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