

### EasyLink™ Data Management System

#### System Limitations and Software Issues

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

**Table 1. Affected Products**

Product	Software Version	Siemens Material Number (SMN)
EasyLink Data Management System	All	10444799 10444800 10487219

#### Reason for Correction

Siemens Healthcare Diagnostics has received complaints regarding reference ranges, sample reports, user-initiated sample/result actions, and auto-verification and quality control processing for the EasyLink™ Data Management System software. Through internal investigation, Siemens has confirmed:

#### Custom Reference Ranges

As stated in the EasyLink Data Management System Operator's Guide, the units, sample fluid type, and instrument name are required fields when configuring reference ranges.

If the test results do not contain one of these required fields, the EasyLink Data Management System will not apply reference ranges or related auto-verification rules.

- Some instruments do not transmit sample fluid types (e.g. "P" for Plasma); therefore if the order originates at the instrument rather than at the LIS, the reference range on the EasyLink Data Management System will not be applied. Under normal conditions, the LIS downloads orders to the EasyLink Data Management System prior to running the sample and maintains the sample fluid type information in the order record throughout the life of the sample.

**NOTE:** The Dimension Vista, Dimension RxL and Dimension EXL instruments always supply sample fluid types in the results and will not encounter this situation.

- If the result does not contain units (e.g. ug/dL) in the order record, reference ranges are not applied. This may be encountered with certain assays that produce an index, qualitative results, or quantitative results without units.

### User-Initiated Sample and Result Actions

There are specific instances when a system deadlock can occur. Deadlock can potentially occur when the instrument is sending a result for a test or sample at the same time the user selects specific buttons for that same result or sample. Refer to Table 2 for the buttons that may trigger this deadlock.

**Table 2. Buttons on User Interface**

1. Release Patient	6. Delete Result
2. Release QC Result	7. Reset Result
3. Release Sample	8. Reorder Result
4. Release Result	9. Ignore Result
5. Release All Results	

When the system is deadlocked, the following issues may occur:

- Rules may not be applied and results could be released that should have been held.
- Incorrect or empty reference ranges could be applied and results could be released that should have been held.
- An incorrect reference range could be sent to the LIS for that result.

### Auto-Verification and Quality Control Rules

The custom reference range and sample/result action issues included in this communication are related to rule processing on the EasyLink Data Management System. Rule processing is commonly used for the auto-verification of test results as well as Quality Control processing.

After careful consideration, Siemens has decided to discontinue support for the Auto-Verification and Quality Control features and associated rule processing of the EasyLink Data Management System, effective May 1, 2016. For customers who use this functionality, Siemens will provide support to disable these features and transition to alternative options.

This decision aligns with our strategy to consolidate our Diagnostics IT portfolio and will better enable Siemens to streamline our service and support model to focus on fewer, more strategic solutions in the future.

### Sample Reports

There are several limitations with the use of sample reports in the EasyLink Result Manager that have not previously been communicated in the EasyLink Data Management System Operator's Guide. The following limitations apply to the sample report if it is viewed, printed, or exported:

- Ignored or Held results (with a result status of "I" or "H") are included on the report.
- Results that have Null or Blank values will not be included on the report. This may include results that generated a "below assay range" flag on the instrument.
- Result status indication (e.g. Held, Ignored, Transmitted) will not be included on the report.

- Reference ranges are not applied to results that do not have a sample fluid type or units. Reference ranges may not appear on the sample report as expected if the assay units were configured inconsistently.
- Please be aware that Comments/Flags derived from the instrument or manually entered by the user will not be included on the report.

Refer to Figure 1 in the Additional Information section for an example of a sample report and a description of its limitations and expected content.

### **Risk to Health**

When these events occur it is possible for operators of the EasyLink Data Management System to misinterpret the information contained in the sample report. The potential exists for the EasyLink Data Management system to release results that should have been held for review or cause a delay in the release of results to the LIS.

### **Actions to be Taken by the Customer**

#### **Custom Reference Ranges**

If your laboratory is using EasyLink Data Management System configured reference ranges or auto-verification rules:

- Please review assays that do not contain unit values to ensure there are no reference ranges defined on the EasyLink Data Management System.

**Note:** Siemens instruments connected to your EasyLink will not encounter this situation under standard operating conditions. If your laboratory has configured open-channel assays, those assays may not transmit units with results, and associated reference ranges should be reviewed.

- To prevent a scenario where the sample fluid type is not provided with a result transmission from the instrument, do not manually enter orders on the ADVIA Centaur/ADVIA Centaur XP, IMMULITE 2000/IMMULITE 2000 XPi, or Sysmex CA Systems. All orders must be received from the LIS prior to results being sent from the instrument.

#### **User-initiated Sample and Result Actions**

If your laboratory does not use the buttons in Table 2 within the EasyLink user interface, you are not affected.

**Note:** See Section 2 of Additional Information below for information regarding the identification of these buttons in the EasyLink user interface.

The Release Sample and Release Result buttons can be used under specific conditions in order to transmit held results or retransmit any results under specific conditions. Refer to Section 2 of Additional Information below for guidelines regarding when the use of these buttons is supported.

Please contact your local Siemens technical support representative for support in modified usage of the Release Sample and Release Result buttons or to transition to alternative solutions.

### **Auto-Verification and Quality Control Rules**

If your laboratory does not use Auto-Verification or Quality Control rules on the EasyLink Data Management system, you are not affected.

A Siemens representative will contact you to confirm if Auto-Verification or Quality Control rules are enabled on your EasyLink Data Management system. If the use of this functionality is confirmed, a member of Siemens service or support will assist in disabling these features and provide options for transitioning to alternative solutions prior to May 1, 2016.

As previously announced, End of Support for all EasyLink customers is scheduled for **December 31, 2016**.

In addition, please perform the following:

- Please review this letter with your Medical Director.
- Refer to the Additional Information section for information about the contents of the sample report for your future reference.
- Complete and return the Field Correction Effectiveness Check attached to this letter within 30 days.

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

### Section 1: Sample Reports

Figure 1. Sample Report Limitations and Expected Content

**Sample Report**
ResultManager

<div style="border: 1px solid black; padding: 2px;"> <b>Contact Information</b>                  Emergency Room                  Hospital Name                  123 Main Street                  Anywhere DC 123456                  USA             </div>	<div style="border: 1px solid black; padding: 2px;"> <b>Dr Generic Contact Information</b>                  Phone: 555-555-5555             </div>	<div style="font-size: 2em; opacity: 0.5;">[ LOGO ]</div>
<b>Patient Information</b> Patient ID: 200 Name: Smith, John R      Age (y): 86      Height (cm): 62 Sex: M      Date of Birth: Jun 8, 1928      Weight (kg): 100		
<b>Sample Information</b> Sample ID: 100 Volume: 100.00 mL Sample Type: S		
		<div style="border: 1px solid black; padding: 2px;">                     Release Date/Time: Sep 9, 2014 4:37:25 PM                 </div> <div style="border: 1px solid black; padding: 2px;">                     Collected Date/Time: Sep 9, 2014                 </div>

Test	Aspect	Result	Unit	Prio.	Reference Range
Acetaminophen (ACTM)		110	ug/mL	S	[ 10.0 - 30.0 ]
Result Comment: Instrument Result Comment EasyLink Result Comment					
Thyroid Stimulating Hormone (TSH)	DOSE	50	ng/mL	R	[ - ]
Result Comment: Centaur User Comment					
Thyroid Stimulating Hormone (TSH)	COFF	1.0	ng/mL	R	[ - ]
Result Comment: Centaur User Comment					
Thyroid Stimulating Hormone (TSH)	RLU	4482		R	[ - ]
Result Comment: Centaur User Comment					

**Sample Comments:**  
 Instrument Sample Comment

Sep 9, 2014

Signature \_\_\_\_\_

**Note:** The numbering in Figure 1 matches the numbering in paragraphs “Limitations” and “Expected Content”.

## Limitations

2 - The “Collected Date/Time” field only displays the date. The time is not displayed.

3 - The column header titles apply to the information displayed in the table.

**NOTE** The following information will be included on the report:

- Results, regardless of status, may be included on the report. This may include Ignored or Held results (with a result status of “I” or “H”).

**NOTE** The following information will **not** be included on the report:

- Results that have Null or Blank values will not be included on the report. This may include results that generated a “below assay range” flag on the instrument.
- Information not shown includes the status of the results (e.g. Held, Ignored, Transmitted), and the date and time of each result.

4 - Reference ranges may not appear on the sample report as expected if the assay units were configured inconsistently.

6 - Comments that were entered manually from the Sample Review screen are not displayed.

## Expected Content

1 - The “Release Date/Time” field of the sample report will display if the sample has been released.

3 - The reference range shown is:

The range sent by the instrument

Or

The age-specific or gender-specific range configured on EasyLink.

5 - The date the report was generated.

6 - The “Sample Comments” field displays the general sample comments sent from the instrument.

7 - Aspects display on separate lines of the report.

8 - The “Result Comment” field displays manually entered result comments, in addition to instrument generated comments, errors, and flags from the Sample Review screen

9 - Patient location information displays from the LIS: Location Description. Contact information from the EasyLink Location Details screen displays.

**Section 2: User-Initiated Sample and Result Action Buttons**

**Table 3. User-Initiated Sample and Result Action Buttons: Location and Description**

<b>Action Button</b>	<b>EasyLink User Interface Page</b>	<b>EasyLink User Interface Page Section</b>	<b>Button Name</b>
<b>Release Patient</b>	Patient	All	Release
<b>QC Result</b>	QC Today's Result	All	Release
<b>Release Sample</b>	Sample Review	Sample Details	Release
<b>Release Result</b>	Sample Review	Results	Release
<b>Release Result</b>	Result Details	Result Value	Release
<b>Release Result</b>	Sample Details	Results	Release
<b>Release All Results</b>	Sample Details	Results	Release All
<b>Delete Result</b>	Sample Review	All	Delete
<b>Reset Result</b>	Sample Review	All	Reset
<b>Reorder Result</b>	Sample Review	All	Reorder
<b>Ignore Result</b>	Sample Review	All	Ignore

Figure 2. EasyLink User Interface Sample and Result Action Button Details

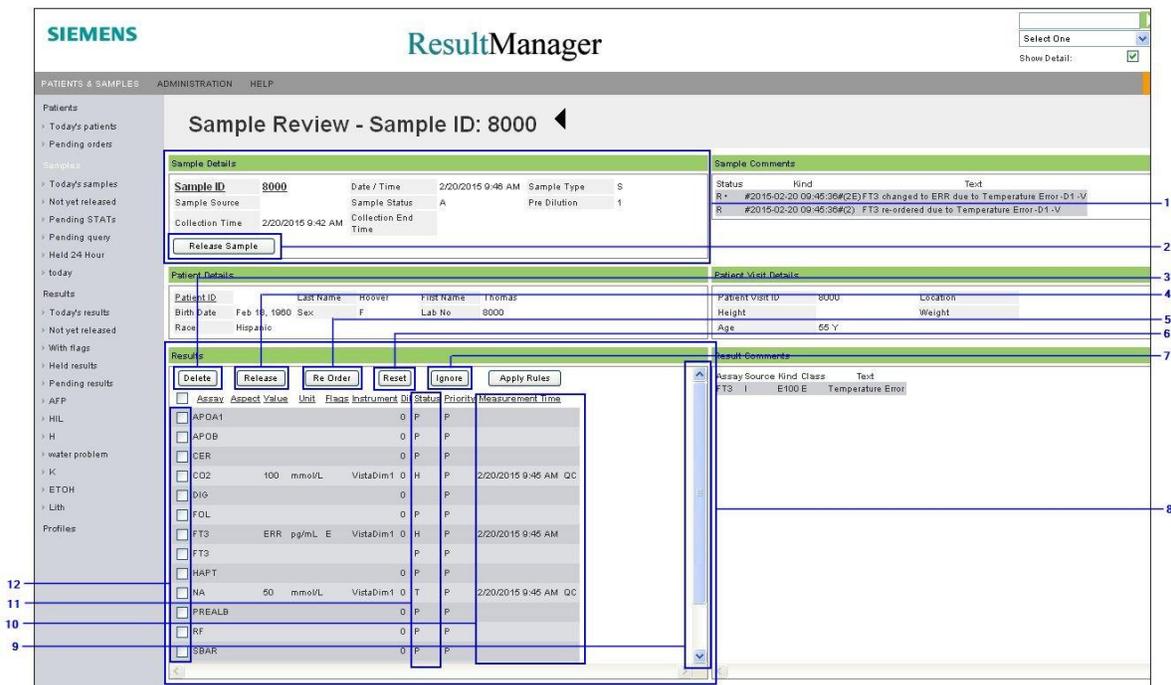


Table 4. EasyLink User Interface Areas and Buttons

1. Sample Details section	7. Ignore Result button
2. Release Sample button	8. Results section
3. Delete Result button	9. Results scrollbar*
4. Release Result button	10. Results Measurement Time column
5. Reorder Result button	11. Results Status column
6. Reset Result button	12. Results Checkbox column

\*Present if there are rows that are not displayed in the window.

Use of the Reorder Result, Release Sample and Release Result buttons is necessary when releasing held results or retransmitting any results to the LIS. In this instance, the following guidelines must be followed in order to avoid a system deadlock and the associated risk:

### **Limited Use of User-initiated Sample and Result Action Buttons**

The Reorder Result, Release Sample and Release Result buttons should not be used if results have not been received from the instrument. These buttons can be used for reordering results, releasing held results, and retransmitted results ONLY under the conditions listed below for Limited Use instructions.

**Note:** A result has not been received from the instrument if the assay result has a blank status in the Results Status column.

### **Reordering Results: Limited Use of Reorder Result Button**

The Reorder Result button can be used to reorder individual results that have been received from the instrument and have no further testing pending. To reorder an individual result, check the checkbox in the result row in the Results section then click on the Reorder Result button.

#### **IMPORTANT:**

- Only select results that have a status of "H" indicated in the Status column and a measurement time indicated in the Measurement Time column.
- Do not use these buttons for results with blank status or status "P" (pending) in the Status column or blank measurement time in the Measurement Time column.

### **Releasing Held Results: Limited Use of Release Result Button**

The Release Result button can be used to release individual results that have been received from the instrument and have no further testing pending. To release an individual result, check the checkbox in the result row in the Results section then click on the Release Result button.

#### **IMPORTANT:**

- Only select results that have a status of "H" indicated in the Status column and a measurement time indicated in the Measurement Time column.
- Do not use these buttons for results with blank status or status "P" (pending) in the Status column or blank measurement time in the Measurement Time column.

### **Retransmitting Results: Limited Use of Release Sample Button**

The Release Sample button can be used to release all results for a sample after they have all been received from the instrument and have no further testing pending.

#### **IMPORTANT:**

- Do not release the sample if any results in the Results section have blank status or status "P" (pending) in the Status column or blank measurement time in the Measurement Time column. The Release Result button can be used to release individual results that have been received from the instrument and have no further testing pending. To release an individual result, check the check box in the result row in the Results section.

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- Use the Results scrollbar to ensure that all results are reviewed for the sample prior to using the Release Sample button.
- Only select results that have a status of “H” indicated in the Status column and a measurement time indicated in the Measurement Time column.
- Do not use these buttons for results with blank status or status “P” (pending) in the Status column or blank measurement time in the Measurement Time column.

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**FIELD CORRECTION EFFECTIVENESS CHECK**

System Limitations and Software Issues

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice ISW-15-01.A.OUS dated May 2015 regarding System Limitations and Software Issues. Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

1. I confirm that I understand that if changes are required to the system that affect rules in the system I will need to revalidate the affected rules. Yes  No
2. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes  No

Name of person completing questionnaire: \_\_\_\_\_

Title: \_\_\_\_\_

Institution: \_\_\_\_\_

EasyLink Serial Number: \_\_\_\_\_

Street: \_\_\_\_\_

City: \_\_\_\_\_

State: \_\_\_\_\_

Phone: \_\_\_\_\_

Country: \_\_\_\_\_

Please fax this completed form to the Customer Care Center at (###) ###-####. If you have any questions, contact your local Siemens technical support representative.