

RAPIDPoint® 500 System

Dual LIS Port Invalid Result Transmission

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

Table 1. RAPIDPoint® 500 System Affected Product

System	Siemens Material Number (SMN)
RAPIDPoint® 500 Blood Gas Analyzer	10492730, 10696855, 10696857, 10697306

Reason for the Urgent Field Safety Notice

This issue potentially impacts only those customers who enable the dual-port LIS transmission feature on the RAPIDPoint 500 system.

When both ports (Serial and Ethernet) are configured to transmit data, the data stream from one port could potentially affect the data stream from the other port.

This could cause the message received by the LIS (data management system) to include either

- Duplicate data
- Missing data
- Data from a different patient. Siemens has not observed this scenario and the expected frequency of occurrence is extremely unlikely.

If this issue occurs, only one analyte has the potential to be affected (i.e., if a panel of analytes is ordered, only one could be affected).

Risk to Health

A duplicate or missing analyte as described above is of no risk to health. The results are readily available on the instrument to use and resubmit to the LIS. The risk to health is limited to the extremely unlikely situation in which an analyte is switched between two patients. A transposed sodium, potassium, glucose, lactate, carboxyhemoglobin, methemoglobin, or neonatal bilirubin result may lead to a potential risk to health when the true value is critical. In all cases, the probability of occurrence is extremely unlikely due to the low frequency of the software issue and correlation with patient clinical presentation, history, and concurrent laboratory testing.

Actions to be Taken by the Customer

- Determine if your system is configured to use Dual Port LIS Transmission.

If the system is currently set up with dual LIS transmission enabled, one of the ports (either Serial or Ethernet) needs to be disabled.

To Disable the Serial Port Connection:

1. At the **System** screen, select **Setup**. Enter your password if required.
2. Select **Printer and Devices > Communications > LIS Communications**.
3. Select **Configure** in the **Serial** column.
4. Select **Port Status > On** to disable the Serial port.
The port is disabled when the button is blue and there is no checkmark.

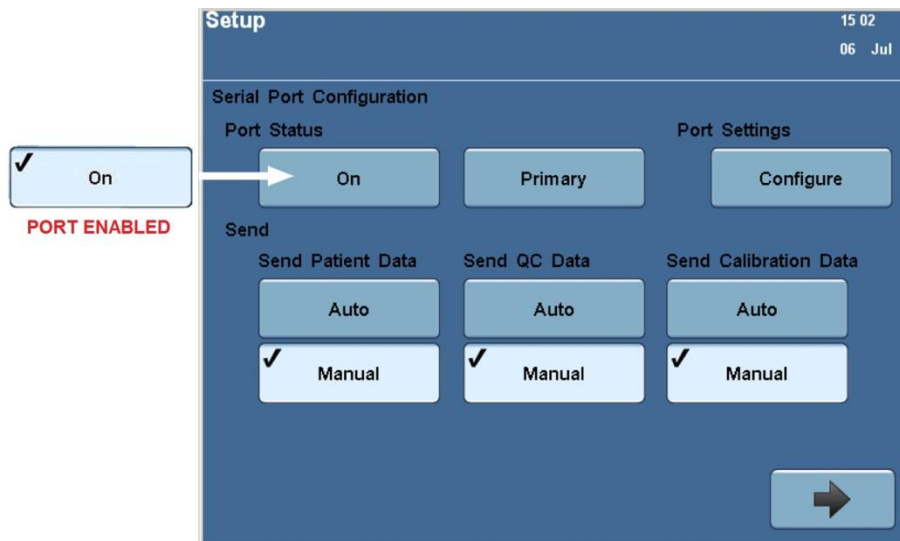


Figure 1. Serial Port Configuration Screen Showing Enabled and Disabled States of the Port

To Disable the Ethernet Port Connection:

1. At the **System** screen, select **Setup**. Enter your password if required.
2. Select **Printer and Devices > Communications > LIS Communications**.
3. Select **Configure** in the **Ethernet** column.
4. Select **Port Status > On** to disable the Ethernet port.
The port is disabled when the button is blue and there is no checkmark.

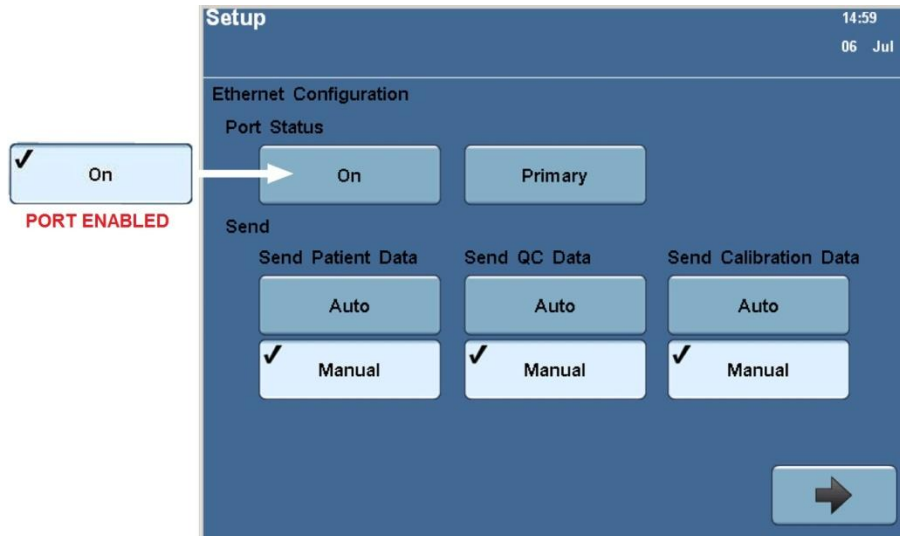


Figure 2. Ethernet Configuration Screen Showing Enabled and Disabled States of the Port

- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 7 days.
- Please retain this letter with your laboratory records, and forward it to anyone to whom you may have distributed this product. We apologize for the inconvenience that this situation has caused. Thank you for your understanding and patience during this period.

Additional Information

The resolution of this issue will be implemented in the next software release for the RAPIDPoint 500 system.

If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

RAPIDPoint is a trademark of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

Dual LIS Port Invalid Result Transmission

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 33114 Rev. A dated July 2015 regarding Dual LIS Port Invalid Result Transmission. Please read the 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.

I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes No

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Customer Sold To #: _____ Customer Ship To #: _____

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