

IMMULITE® 2000
IMMULITE® 2000 XPi

Reagent Carousel Temperature Sensor Issue

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

Table 1. IMMULITE 2000/IMMULITE 2000 XPi Affected Product

| Component | Siemens Material Number (SMN) |
|--|-------------------------------|
| Reagent Carousel Temperature Sensor Printed Circuit Board (PCB) Assembly | 10290607 |

Reason for Correction

Siemens Healthcare Diagnostics is conducting a correction for the IMMULITE® 2000/IMMULITE® 2000 XPi Immunoassay Systems reagent carousel temperature sensor Printed Circuit Board (PCB) assembly. Siemens has identified that your system may have been manufactured with a defective reagent carousel temperature sensor PCB or you may have had a part replacement with a defective PCB assembly.

A particular set of the temperature sensor boards were built incorrectly. The incorrectly assembled temperature sensor boards may cause icing on the reagent carousel casting. If there is icing within the reagent carousel, there is a potential for the reagent carousel to encounter a mechanical jam which will stop the system from processing samples and will generate errors.

Siemens has determined that the reagent contents do not freeze when the incorrectly assembled PCB assembly is installed in the reagent carousel assembly. Testing shows that the reagent liquid temperature may fall below 4 °C but not to the point when freezing or slush was observed. The reagents are not compromised; therefore, assay performance is not affected.

Risk to Health

There is no risk to health. The system will stop processing samples if a mechanical jam occurs.

Actions to be Taken by the Customer

If any of the following error conditions occur, contact your Siemens technical support representative to inspect the IMMULITE 2000/IMMULITE 2000 XPi system:

- Error message *[465] Reagent Carousel has jammed:*
 - Occurs while the instrument is processing samples
 - Occurs when a mechanical jam is detected
 - Occurs when the instrument software fails to transition from Stop to Run
- Error message *[302] Reagent Carousel has jammed:*
 - Occurs when the instrument software fails to launch from the Desktop

Your Siemens technical support representative will inspect the IMMULITE 2000/IMMULITE 2000 XPi system on the next service visit to check if the temperature sensor boards are affected and will replace if needed.

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.

IMMULITE is a trademark of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

Reagent Carousel Temperature Sensor Issue

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice # 3023 dated April 2015 regarding Reagent Carousel Temperature Sensor Issue. 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: _____

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