

### ADVIA Centaur® XPT

#### Probe Wash Onboard Stability (OBS) Timing Issue

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

**Table 1. ADVIA Centaur XPT Affected Products**

Product	Siemens Material Number (SMN)
ADVIA Centaur XPT System	10711433

#### Reason for Correction

Siemens Healthcare Diagnostics has confirmed that the time of initiation for onboard stability (OBS) on the ADVIA Centaur® XPT system software is calculated when probe wash reagent packs are pierced (used by the system). As stated in the Instructions For Use (IFU), the correct behavior is to calculate the OBS for Primary Probe Wash Reagent Packs (PW2, PW3, PW4) when initially loaded onto the system.

Because onboard stability (OBS) is calculated when the probe wash reagent pack is pierced, not when loaded onto the system, the probe wash reagent pack may be on the instrument longer than described in the IFU.

#### Risk to Health

Siemens has determined that there is no risk to health as the wash solutions remain stable and effective well beyond the OBS dating in the system.

#### Actions to be Taken by the Customer

To mitigate the issue, perform the following procedure when loading a probe wash reagent pack onto the instrument:

1. Load the probe wash reagent pack onto the instrument.
2. Select the **Reagent** icon.
3. Select the **Primary Reagent Compartment** tab.
4. Click on the probe wash reagent pack that was loaded to display details.
5. Select **Edit**. Refer to Figure 1.

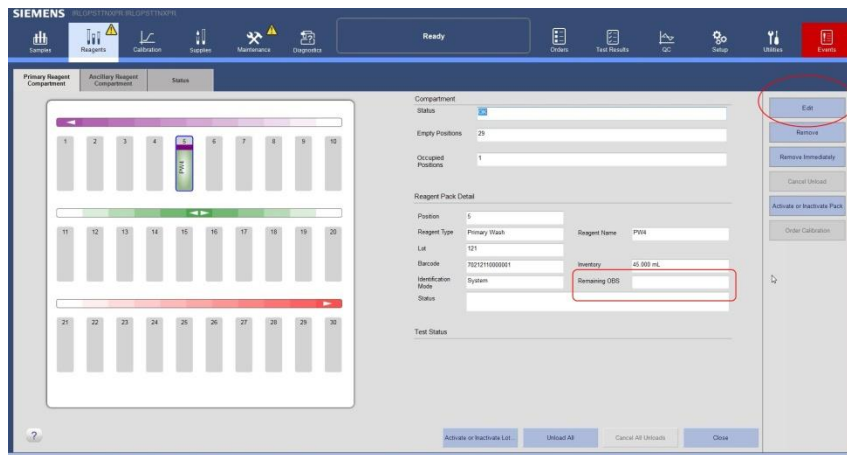
- In the pop-up window, select the **Remaining OBS** field and enter the values according to Table 2. Refer to Figure 2.

**NOTE:** OBS values cannot exceed the maximum number of days as defined in the IFU.

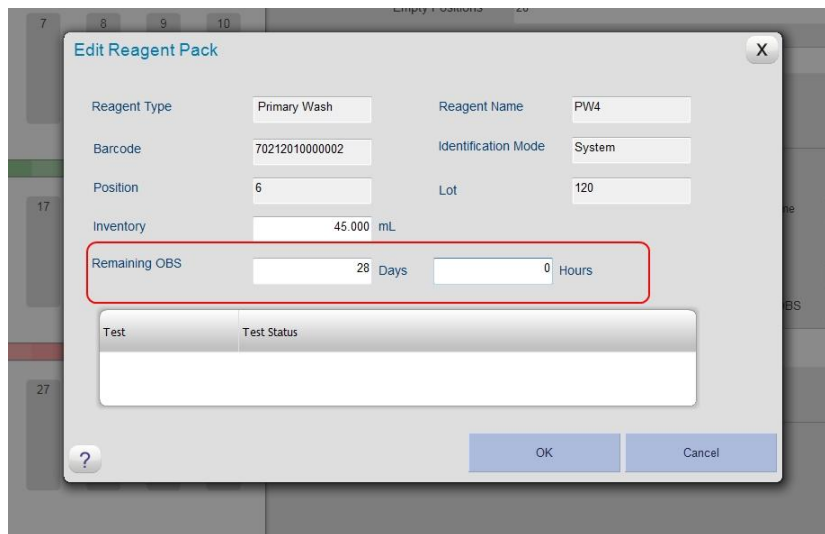
**Table 2. Probe Wash Information**

Probe Wash Name	OBS Days	OBS Hours
PW2	28	0
PW3	100	0
PW4	28	0

**Figure 1. Reagent Inventory Screen**



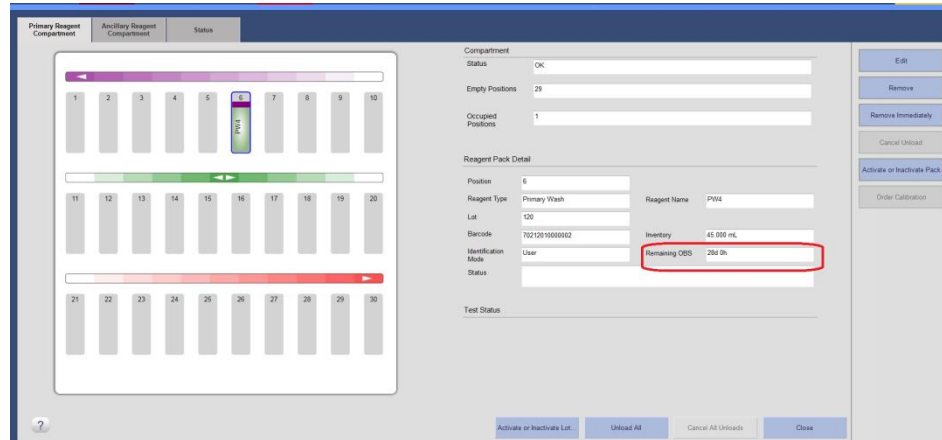
**Figure 2. Edit Reagent Pack OBS**



7. Click **OK**.

8. Ensure the correct OBS time displays for the reagent pack. Refer to Figure 3.

**Figure 3. Reagent Inventory Window with OBS Time**



9. Close the **Reagent** window.

In addition, perform the following:

- 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.

ADVIA Centaur is a trademark of Siemens Healthcare Diagnostics.

**FIELD CORRECTION EFFECTIVENESS CHECK**

Probe Wash Onboard Stability (OBS) Timing Issue

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 11220076, Rev. A dated March 2015 regarding Probe Wash Onboard Stability (OBS) Timing 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.