SIEMENS

UPDATED UFSN

Urgent Field Safety Notice

UFSN2004

May 2014

IMMULITE® 2000
IMMULITE® 2000 XPi
VersaCell®
VersaCell® X3

Level Sensing Associated with Dropped Sample Tubes

Siemens Healthcare Diagnostics has updated the Urgent Field Safety Notice (UFSN) #UFSN2003 dated February 2014. Please discard UFSN #UFSN2003, retain a copy of UFSN #UFSN2004, and return your completed Field Correction Effectiveness Check form from UFSN #UFSN2004.

Information has been added to include the VersaCell® X3 system and to clarify that users with an IMMULITE® 2000/IMMULITE® 2000 XPi connected via a VersaCell® or VersaCell X3 system that are interfaced to a track system will experience the same issue and error message as systems that are not connected to a track. All information in UFSN #UFSN2003 is correct and included within UFSN #UFSN2004.

Our records indicate that your facility may have an IMMULITE 2000/IMMULITE 2000 XPi analyzer connected via the VersaCell or VersaCell X3 system.

Reason for Correction

Siemens Healthcare Diagnostics is conducting a correction for the IMMULITE 2000/IMMULITE 2000 XPi analyzer connected via a VersaCell or VersaCell X3 system. This configuration (IMMULITE 2000 connected via the VersaCell system) has been available since May 2003 and connection to the VersaCell X3 system has been available since January 2014.

Siemens has determined through investigation of a small number of customer complaints that there is a potential for incorrect results to be reported from processing of a sample tube if all of the following conditions occur on the IMMULITE 2000/IMMULITE 2000 XPi analyzer connected via a VersaCell or VersaCell X3 system:

a. The VersaCell/VersaCell X3 system drops a sample tube during transfer to the IMMULITE 2000/IMMULITE 2000 XPi automation rack. The use of non-approved tubes, caps on tubes, and incorrectly placed barcode labels increase the likelihood of dropped tubes.

b. The IMMULITE 2000/IMMULITE 2000 XPi system proceeds with level sensing in the empty position, leading to aspiration of air instead of sample.

c. The following errors are not addressed at the VersaCell or VersaCell X3 system:

- VersaCell system displays, "**Error 2019**: The robot arm is jammed. Please remove the tube from the gripper."
- VersaCell X3 system displays, "**Error 102019**: A robotic arm error occurred when placing a tube in the drawer. Remove the tube or gently pull the gripper toward you if no tube is present."

d. The IMMULITE LIS configuration for holding results allows the result to be transmitted to the LIS by the VersaCell/VersaCell X3 system.

e. The result is not verified at the VersaCell/VersaCell X3 and/or LIS prior to being reported.

This issue can only occur with VersaCell/VersaCell X3 systems that are connected via IMMULITE 2000/IMMULITE 2000 XPi systems. This issue does not affect any other analyzer that interfaces with the VersaCell/VersaCell X3 system.

Not every instance of a dropped tube will lead to incorrect results. Refer to the "Additional Information" sections for specific scenario information.

Risk to Health

This issue may lead to the misreporting of a patient sample as a discrepant low result or less than the lower limit of the assay. Look back is not required as any critical result would be addressed immediately. There are no reports of injury or illness due to this issue.

Actions to be Taken by the Customer

- Rerun any dropped sample tube associated with a VersaCell Error 2019 or VersaCell X3 Error 102019 and processed on the IMMULITE 2000/IMMULITE 2000 XPi analyzer prior to reporting patient results. Refer to the "Verify Results from the Dropped Tube" section for more information.
- Verify all dropped sample tube results at the VersaCell/VersaCell X3 system and/or LIS prior to reporting results.
- Please review this letter with your Medical Director.
- Perform the instructions provided in Additional Information (A) to correct the issue if it has occurred and/or Additional Information (B) to prevent this issue from occurring.

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 has caused. Siemens is investigating this issue and will inform customers when a solution is available. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

Additional Information (A)

If a dropped tube occurs on your laboratory's IMMULITE 2000/IMMULITE 2000 XPi analyzer connected via the VersaCell/VersaCell X3 system, an error message will always display on the VersaCell/VersaCell X3 screen. Perform the following based on the error displayed, then verify the results from the dropped tube:

- VersaCell system displays, "**Error 2019**: The robot arm is jammed. Please remove the tube from the gripper."
- VersaCell X3 system displays, "**Error 102019**: A robotic arm error occurred when placing a tube in the drawer. Remove the tube or gently pull the gripper toward you if no tube is present."

Explanation: The VersaCell/VersaCell X3 system robotic arm encountered an error when placing a tube in the drawer or track system if the VersaCell/VersaCell X3 is configured in track mode. The VersaCell/VersaCell X3 system automatically stops. In addition to the error, if the sample was transferred from a VersaCell/VersaCell X3 drawer, a tube status of **Transfer Error** displays for the sample tube that was processed at the time of the error. Often, the robotic arm will present the tube in the gripper to the operator. However, there are instances when a tube is not present in the gripper. This may be an indicator that a tube was dropped.

When the VersaCell/VersaCell X3 system displays a message to remove a sample tube from the gripper, as instructed in the VersaCell/VersaCell X3 Operator's Guide, perform the following:

1. Select **Unlock Door**.
2. Lift the main door.
3. Hold the sample tube and gripper, angle them toward you and remove the tube. If there is no tube in the gripper, gently pull the gripper toward you. You hear the sound of air being released.

Note: Please refer to the below instructions if there is no tube in the gripper.

4. Resolve the error.
5. Close the main door.
6. Select **Lock Door**.
7. Select **Run**.

Error 2019 or Error 102019 with no tube in gripper

Explanation: If this error displays but there is no tube in the gripper, verify the location of the tube.

Before selecting **Run** on the VersaCell/VersaCell X3 system, perform the following:

1. If the sample came from the VersaCell/VersaCell X3 drawer, check the VersaCell/VersaCell X3 Drawer screen for samples with a tube status of **Transfer Error**.

2. Select the tube position on the screen with the Transfer Error. This will display the sample accession number and any related result information, if available.
3. Visually check the physical drawer position for the presence of the sample tube that corresponds with the Transfer Error status. If the tube is in the VersaCell/VersaCell X3 drawer position, the VersaCell/VersaCell X3 gripper returned the tube successfully. If the VersaCell/VersaCell X3 is configured in track mode, check for the presence of the tube at the track's gate. If the tube is present, the VersaCell/VersaCell X3 successfully returned the tube to the track system.
4. Select **Run** and continue processing.

If the tube is not present in the physical drawer position that corresponds to the Transfer Error on the VersaCell/VersaCell X3 Drawer screen or if the tube is not on the track system, perform the following:

1. Perform a visual inspection of the VersaCell/VersaCell X3 drawer area and inside the VersaCell/VersaCell X3 cavity and if in track mode, inspect the track's gate area.
2. If the tube is not found in the VersaCell/VersaCell X3 system or track system, place the IMMULITE 2000/IMMULITE 2000 XPi system in **All Pause** mode, then open the IMMULITE 2000/IMMULITE 2000 XPi main cover.
3. Perform a visual inspection of the IMMULITE 2000/IMMULITE 2000 XPi sample carousel and surrounding areas.

If the tube is not found during initial inspection of either system, the tube may have dropped in an area of the analyzer that is not easily visible or accessible. Closer inspection of both systems, and the track's gate area if in track mode, may be necessary to locate the tube.

Verify Results from the Dropped Tube

To verify results from the dropped tube, perform the following:

1. Search for the sample accession number on the VersaCell/VersaCell X3 LIS screen to determine if patient results were received from the IMMULITE 2000/IMMULITE 2000 XPi.
2. Review the patient results, if available, and follow your laboratory procedures for rerunning samples.
3. Follow your laboratory procedures for handling and cleaning possible sample spillage using protective equipment, if necessary.

Note: It is recommended that test orders for the dropped sample tube for the IMMULITE 2000/IMMULITE 2000 XPi system be rerun.

Additional Information (B)

The use of non-approved tubes, tubes with caps, and incorrectly placed barcode labels may result in a dropped tube event. To minimize the possibility of a dropped tube incident:

- Use uncapped tubes
- Use only supported tube types
- Ensure properly placed barcode labels

Sample Tubes Supported

- Sizes: 12 x 75 mm to 16 x 100 mm
- Types: primary (gel separator), secondary (round bottom), glass and plastic, flat bottom

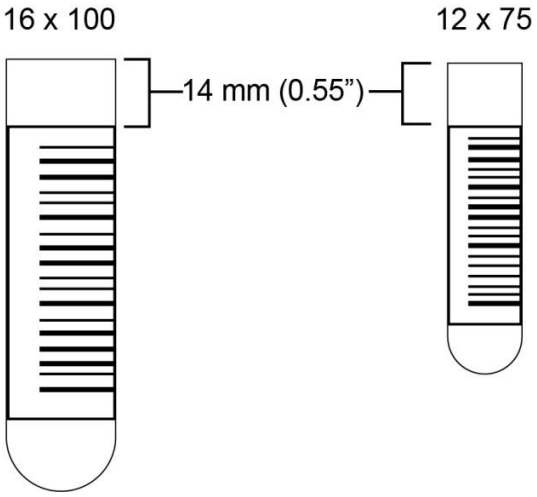
Note: Flat bottom sample tubes are only supported on VersaCell software version 3.6a or later using SDX-07 racks and VersaCell X3 system using the SDX-07 rack.

- The VersaCell/VersaCell X3 can process sample tubes from many different vendors. Some sample tube types are known to generate errors or cause hazards and are considered to be at risk. Examples of these tubes and the potential hazards/errors are shown below:
  - Sample tubes with a lip around the edge
  - Screw top sample tubes of a size other than16 mm cause the gripper to pick up the tube in a non-vertical orientation.
  - Sample tubes with protruding edges.
  - Tubes with tube top sample cups or smaller sample tubes inside larger tubes.
  - False-bottom sample tubes.
  - Sample tubes made of pliable plastic materials.

Placement of Barcode Labels

Careful placement of the barcode labels on the sample tubes is critical. In addition to ensuring proper reading of the barcode, proper placement aids in avoiding possible dropped tubes. Sticky residue from barcode label glue or uneven labels from multiple labels on a single tube may cause the tube to stick to the arm gripper fingers.

Place each label with the barcode portion as high as possible on the sample tube, while leaving approximately 0.5” of tube for the gripper to grasp the tube. Refer to the diagram below.



The following specifications are referenced in the VersaCell Operator’s Guide and the VersaCell X3 Operator’s Guide:

- Place the barcode label at least 14 mm (0.55 inches) from the top of the sample tube and at least 20 mm (0.79 inches) from the bottom of the sample tube.
- Ensure that the barcode label is at least 10 mm (0.4 inches) high.

Siemens Healthcare Diagnostics
511 Benedict Ave.
Tarrytown, NY 10591
www.siemens.com/diagnostics

FIELD CORRECTION EFFECTIVENESS CHECK

Level Sensing Associated with Dropped Sample Tubes

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice # UFSN2004 dated May 2014 regarding Level Sensing Associated with Dropped Sample Tubes. Please read the question and indicate the appropriate answer. Fax or email this completed form to Siemens Healthcare Diagnostics.

IMS 14-01B [C/2668]

Name of person completing questionnaire: Block Capitals:		Date:	
Title:		Account Number:	
Hospital:		Instrument Serial Number:	
Street:			
City:		Post Code:	
Phone:		Email:	
Email		Signed:	

It is important that your organisation takes the actions detailed in the FSN and reply immediately using the FIELD CORRECTION EFFECTIVENESS CHECK attached to the 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 Diagnostics cannot properly verify the completeness of the FSN and the MHRA may need to issue a Medical Device Alert.

Fax: 0845 605 6800

Email: robert.davies@siemens.com