

Urgent Field Safety Notice

3022

March 2015

IMMULITE[®] 2000
IMMULITE[®] 2000 XPi**Water and Liquid Waste Bottles Issue**

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

Table 1. IMMULITE 2000/IMMULITE 2000 XPi Affected Product(s)

Products	Siemens Material Number (SMN)
Water Bottle	10291586
Liquid Waste Bottle	10291587
Accessory Kit	10282965, 10373217, 10286080
Direct Water Feed Kit	10373222
Water Feed Kit	10288216, 10389714
Liquid Waste Bottle Kit	10386287

Reason for Correction

Siemens Healthcare Diagnostics is conducting a correction for the IMMULITE[®] 2000/IMMULITE[®] 2000 XPi Immunoassay Systems water and liquid waste bottles received starting May 2013.

Siemens has identified that the water and liquid waste bottle assemblies were manufactured with a quality issue. The smaller diameter opening of both bottles is undersized and/or deformed, preventing the cap from closing or fastening securely to the bottle.

Water Bottle

The water bottle cap, which is built with an integrated aspiration straw, may become dislodged from the bottle, causing the instrument to aspirate air into the fluidic line and/or insufficient water during the wash cycle. This may go undetected and cause the following errors:

- **False Clot Detection** – The instrument may generate the following false clot detection errors due to air bubbles being introduced into the fluid line:
 - **Event # 562** – *Clot detected in sample tube – sample will not be run.*
 - **Event # 563** – *Clot detected in sample tube. Clean exterior of sample probe before resuming operation.*
- **False Clot Detection Board Failure** – The instrument may generate the following false clot detection errors due to air bubbles being introduced into the fluid line:
 - **Event # 692** – *Test was reordered because of Clot Detection Board Failure.*

- **Event # 704** – *Error has forced Error Pause Mode. Run Button is deactivated until Stop Mode is entered. Wait for tests in progress to complete.*
- **Potential for Discordant Results** – Although clot detection errors will pause the instrument and stop new tests from launching, there is the potential that any tests previously launched will continue to completion and result with elevated counts per second (CPS) values, possibly yielding erroneous but believable results.

Liquid Waste Bottle

The small opening is used to pour waste from the bottle. If the cap dislodges during transport of a full bottle, care must be taken to avoid spillage.

Risk to Health

Water Bottle

Siemens has determined that, because there is the extremely low possibility of occurrence without detection, there is a negligible risk to overall patient health due to a dislodged cap on the water bottle.

Liquid Waste Bottle

There is no health risk associated with a dislodged cap during transport of the waste bottle. The IMMULITE 2000/IMMULITE 2000 XPi Operator's Guide informs the operator to wear Personal Protective Equipment (PPE) and take universal precautions when operating the instrument. This would also apply when transporting the waste bottle.

Siemens is not recommending a review of previously reported results due to the extremely low occurrence rate.

Actions to be Taken by the Customer

- Ensure that the small (38 mm) cap on the Water Bottle and Liquid Waste Bottle remains in place and tight. Refer to the instructions below.
- Wear appropriate PPE, particularly when transporting the Liquid Waste Bottle.

Water Bottle and Liquid Waste Bottle Visual Inspection Instructions

A defective water or liquid waste bottle will exhibit one or more of the following symptoms when the operator attempts to secure the small white cap onto the bottle:

- does not tighten onto the bottle,
- continues to spin when attempting to tighten, and/or
- becomes dislodged when attempting to tighten

If the bottle is defective:

1. Contact your Siemens Customer Care Center or your local Siemens technical support representative to order a replacement bottle.
2. Perform the mitigation instructions below until the replacement bottle is installed.
3. Discard the defective bottle.

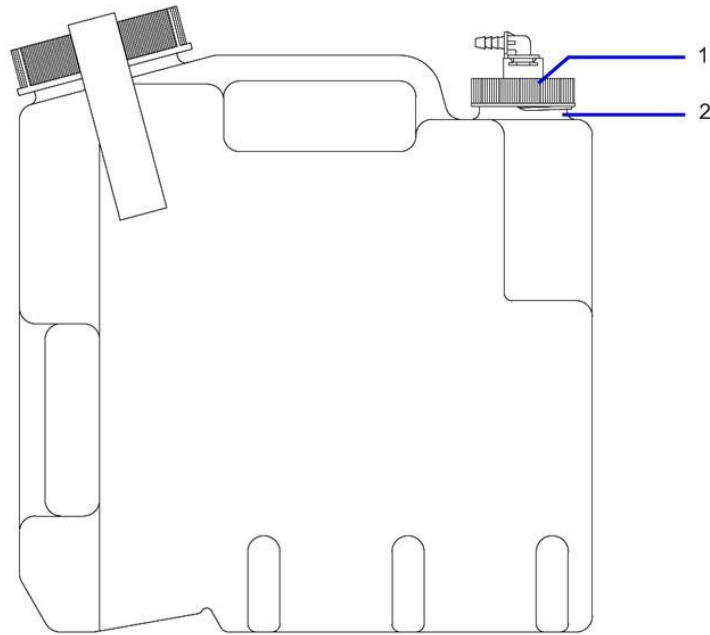
Defective Water Bottle Mitigation Instructions

Until the replacement water bottle is installed, perform the following instructions to minimize incorrect results from occurring, or to prevent the disruption of test processing.

1. Install the water bottle onto the instrument.
2. Verify that the 38 mm cap is securely fastened onto the water bottle. This will ensure that the aspiration tubing attached to the cap reaches the bottom of the water bottle. Refer to Figure 1.
3. Fill the water bottle.
NOTE: If filling the water bottle while the instrument is running, verify that the 38 mm cap remains securely fastened to the water bottle during refilling. Refer to the Performing Maintenance section of the IMMULITE 2000/IMMULITE 2000 XPi Operator's Guide for instructions on how to fill the water bottle while the instrument is running.
4. After refilling is completed and the water bottle placed back onto the instrument, verify that the cap remains securely fastened. Refer to Figure 2.
5. Keep the water bottle at least 50% filled at all times. This prevents air from being introduced into the system in the event the 38 mm cap becomes dislodged from the water bottle.
6. Periodically verify that the 38 mm cap remains securely attached to the water bottle during instrument operation. Refer to Figure 2.
7. If the 38 mm cap is dislodged from the water bottle, perform the following:
 - a. Place the instrument into **Stop** mode.
 - b. As results may be affected, verify test results reported up to the last time the 38 mm cap was securely attached to the water bottle.
 - c. While in **Stop** mode, refill the water bottle. After reinstalling the water bottle onto the instrument, verify that the 38 mm cap is securely fastened onto the water bottle.
 - d. Thoroughly prime the instrument and the water probe until all the air is removed from the fluid lines, then return to **Run** mode.
 - e. Run Quality Control to verify the instrument is running properly, then proceed to run patient samples.
8. If any of these clot related errors post (562, 563, 692, or 704), perform the following:
 - a. Confirm if the 38 mm cap has dislodged from the water bottle to determine if this caused the false clot detection error(s) to post.
NOTE: If the 38 mm cap is securely fastened and there is no air in the tubing from the water bottle or in the clot transducer, then the clot detection errors are valid.
 - b. If the 38 mm cap is dislodged from the water bottle, place the instrument into **Stop** mode.
 - c. As results may be affected, verify test results reported up to the last time the 38 mm cap was securely fastened onto the water bottle.

- d. While in **Stop** mode, refill the water bottle. After reinstalling the water bottle onto the instrument, verify that the 38 mm cap is securely fastened onto the water bottle.
- e. Thoroughly prime the instrument and the water probe until all the air is removed from the fluid lines, then return to **Run** mode.
- f. Run a control to verify the instrument is running properly, then proceed to run patient samples.

Figure 1. Water Bottle Assembly



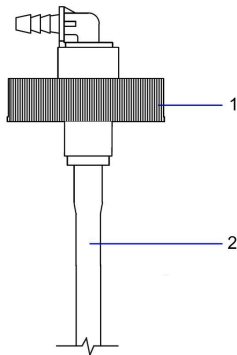
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- 1 Water bottle cap (38 mm) with an attached aspiration straw
 - 2 Water bottle small diameter opening
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Figure 2. Securely Fastened 38 mm Water Bottle Cap



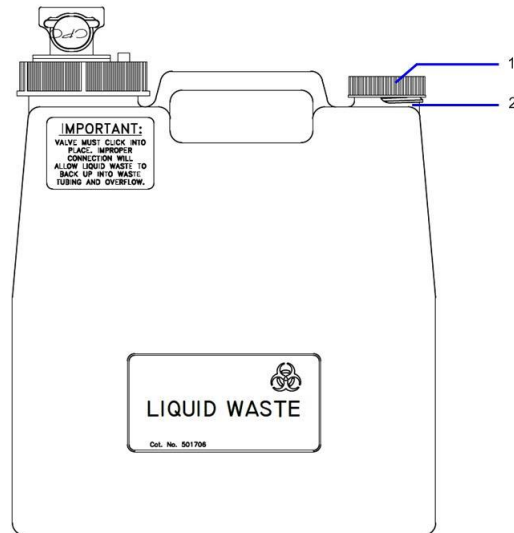
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- 1 Water bottle cap (38 mm) securely fastened
 - 2 Water bottle assembly properly seated in compartment
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Figure 3. Water Bottle Cap (38 mm)



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- 1 Water bottle cap (38 mm)
 - 2 Aspiration straw
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Figure 4. Liquid Waste Bottle Assembly



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- 1 Liquid waste bottle cap (38 mm)
 - 2 Liquid waste bottle small diameter opening
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Defective Liquid Waste Bottle Mitigation Instructions

Ensure when transporting the Liquid Waste Bottle (Figure 4) that you are wearing appropriate Personal Protective Equipment (PPE). There are no other mitigation instructions as a defective liquid waste bottle will not disrupt test processing and there is no potential risk to health as long as you are wearing proper PPE.

Please 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.