



Urgent Field Safety Notice
Product Correction
Immediate Action Required

Date Issued December 8, 2017

Product

Product Name	List Number	UDI
ARCHITECT c4000 Cuvette Segment	02P75-01	Not applicable
ARCHITECT c8000 Cuvette Segment	01G46-01	Not applicable
ARCHITECT c16000 Cuvette Segment	09D32-05	Not applicable

Explanation

The base of the ARCHITECT Cuvette Segment may become detached under specific conditions. When a cuvette segment base is detached, cuvettes may be seated lower than the designed height. This may result in inadequate dispense into specific cuvettes due to the sample probe being unable to make efficient contact with the cuvette bottom.

Reasons for the bottom of the cuvette segment to detach are

- Excessive force applied during manual cleaning of cuvettes or cuvette wash tower crashes
- Lack of sufficient glue during cuvette segment manufacturing (c4000 and c8000 only)

Based on post-market surveillance and internal data, Abbott is recommending the actions below to further reduce incidences associated with detached cuvette segments. Additionally, Abbott's supplier has implemented changes to its manufacturing process to prevent reoccurrence of cuvette segments with insufficient glue.

Patient Impact

Any assays run on the ARCHITECT c4000, c8000, and c16000 instruments may be impacted if the cuvette segment base is detached.

If a cuvette segment is detached, there is a potential to generate falsely depressed patient results in the cuvettes adjacent to the detached segment post for any assay run on your ARCHITECT clinical chemistry instrument. Falsely depressed results may or may not be accompanied by a result flag. The impact on the test result varies depending on the extent of the detachment observed and if samples were tested in the specific cuvettes adjacent to the detached cuvette segments posts. These impacted patient results may be accompanied by "<" or "LOW" result flags, indicating that the result is below the linear range or the defined normal range of the assay, respectively. See ARCHITECT System Operations Manual Section 5: Operating Instructions for more information on patient result flags. This failure mode will not cause falsely elevated results.

Necessary Actions

Abbott recommends the customer adhere to the new instructions listed in Appendix A to avoid damaging the cuvette segments. The procedures listed in Appendix A provide additional guidance for operators to avoid damaging the cuvette segments. The procedures will be updated in a future version of the ARCHITECT Operations Manual.

**Necessary
Actions
continued**

If a cuvette segment with a detached bottom is identified, replace it before performing any additional testing on your ARCHITECT Clinical Chemistry System.

If you have forwarded the product listed above to other laboratories, please inform them of this Product Correction and provide to them a copy of this letter.

Please retain this letter for your laboratory records.

**Contact
Information**

If you or any of the health care providers you serve have any questions regarding this information, U.S. Customers please contact Customer Service at 1-877-4ABBOTT (available 24 hours a day, 7 days a week). Customers outside the U.S., please contact your local area Customer Service.

Appendix A: Updated ARCHITECT System Operations Manual and Procedures

1. As-Needed Maintenance Procedure 6310 Clean cuvettes – manually:
 - a. Add the following note: Gently clean the cuvettes and do not apply significant downward pressure on the cuvette segment base.
 - b. After the manual cleaning of the cuvettes within a cuvette segment, and before placement back into the ARCHITECT, inspect the cuvette segment following the “**Cuvette Segment Inspection Procedure**” below.
2. ARCHITECT System Operations Manual Section 9 Service and maintenance, Component replacement, Replace the cuvette dry tip (c4000, c8000, and c16000):
 - a. In the Prepare for Operation section, use L2 (step down) within Diagnostic Procedure 5142 Wash Station Up/Down. The current instructions reference using L1 (down).
 - b. In the Prepare for Operation section, add the following note to the verification of the cuvette dry tip alignment: When stepping the cuvette washer down, if the cuvette dry tip appears to contact the top of either the cuvette or cuvette segment, inspect both the cuvette and cuvette segment for damage. Impact from the cuvette dry tip can potentially cause cuvette damage or cause the cuvette segment base to detach. See “**Cuvette Segment Inspection Procedure**” below.
3. Monthly Maintenance Procedure 6018 Clean cuvette washer nozzles:
 - a. Add the following note: Incorrect positioning of the cuvette washer on the alignment pins could result in misalignment of the cuvette washer. Such a misalignment can potentially cause cuvette damage or cause the cuvette segment base to detach.
4. Addition of a recommended inspection of the cuvette segments to all cuvette washer movement errors, error codes 5650 through 5667. See recommended “**Cuvette Segment Inspection Procedure**” below, and Appendix B for a list of these errors.

Cuvette Segment Inspection Procedure:

To remove the cuvette segments from the ARCHITECT for inspection, follow the procedure in ARCHITECT System Operations Manual Section 9 Service and maintenance, Component replacement, Replace a cuvette segment (c4000, c8000, and c16000). Wear gloves, as residual oil from an ungloved hand may cause imprecise optical reads. Once removed from the ARCHITECT, inspect each cuvette segment for damage by gently pulling downwards on the segment base at several points along the segment. If damage is discovered, replace the cuvette segment.

While the segment is still removed from the ARCHITECT, also inspect the individual glass cuvettes within the segment for damage. If damage is discovered, follow the procedure in ARCHITECT System Operations Manual Section 9 Service and maintenance, Component replacement, Replace a cuvette (c4000, c8000, and c16000).

Once inspection has been completed, re-install the cuvette segments into the ARCHITECT and verify proper installation as instructed in ARCHITECT System Operations Manual Section 9 Service and maintenance, Component replacement, Replace a cuvette segment (c4000, c8000, and c16000).

The following pictures show examples of normal, undamaged cuvette segments:



c4000 cuvette segment

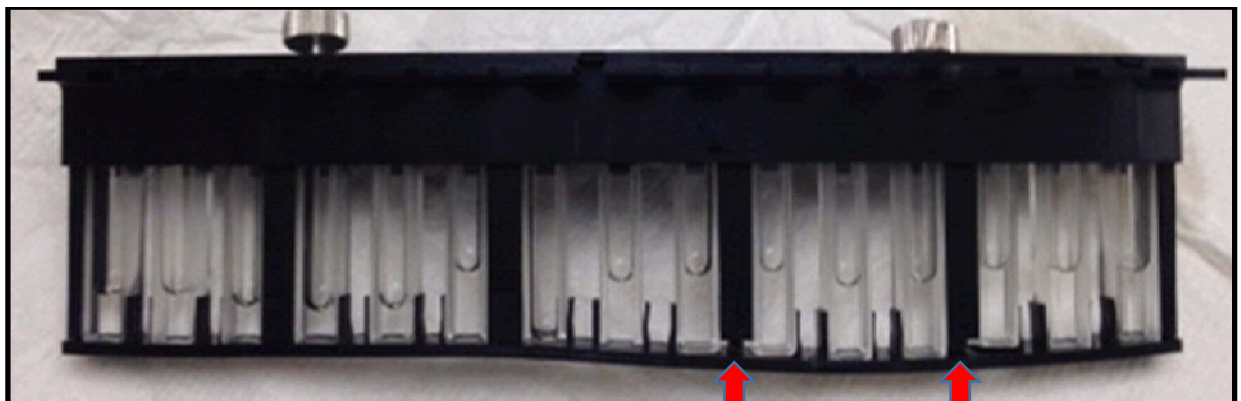
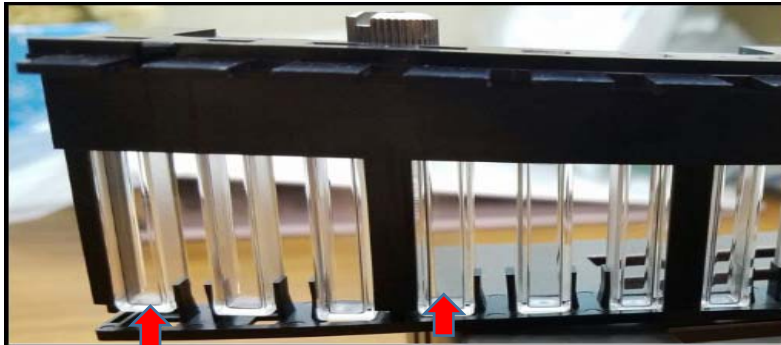


c8000 cuvette segment



c16000 cuvette segment

The following pictures show examples of cuvette segments where the base is detached from the vertical support post.



The red arrows indicate where the base has become detached from the vertical support posts

Appendix B: Cuvette washer movement errors, error codes 5650 through 5667

Error code	Description
5650	Cuvette washer timeout while moving to upper limit.
5651	Unexpected sensor status (Up, Down, and Down OK not activated) while moving Cuvette washer to upper limit.
5652	Unexpected sensor status (only Down activated) while moving Cuvette washer to upper limit.
5653	Unexpected sensor status (Up and Down activated) while moving Cuvette washer to upper limit.
5654	Unexpected sensor status (only Down OK activated) while moving Cuvette washer to upper limit.
5655	Unexpected sensor status (Up and Down OK activated) while moving Cuvette washer to upper limit.
5656	Unexpected sensor status (Down and Down OK activated) while moving Cuvette washer to upper limit.
5657	Unexpected sensor status (Up, Down, and Down OK activated) while moving Cuvette washer to upper limit.
5658	Cuvette washer timeout while moving to lower limit.
5659	Unexpected sensor status (Up, Down, and Down OK not activated) while moving Cuvette washer to lower limit.
5660	Unexpected sensor status (only Up activated) while moving Cuvette washer to lower limit.
5661	Unexpected sensor status (only Down activated) while moving Cuvette washer to lower limit.
5662	Unexpected sensor status (Up and Down activated) while moving Cuvette washer to lower limit.
5663	Unexpected sensor status (Only Down OK activated) while moving Cuvette washer to lower limit.
5664	Unexpected sensor status (Up and Down OK activated) while moving Cuvette washer to lower limit.
5665	Unexpected sensor status (Up, Down, and Down OK activated) while moving Cuvette washer to lower limit.
5666	Unexpected sensor status (Down and Down OK not activated) while moving cuvette washer to lower limit.
5667	Unexpected sensor status (Down activated and Down OK not activated) during Cuvette washer step down movement.