



Urgent Field Safety Notice Product Correction

Urgent - Immediate Action Required

Date Issued

May 1, 2019

Product

Product Name	List Number	Serial Number	UDI
Mixer	09D59-01 09D59-02 09D59-03	All	Not applicable

Explanation

This Product Correction letter is to inform you of an issue with the ARCHITECT c Systems Mixer (LN 09D59-01, 09D59-02, and 09D59-03). There is the potential for the mixer blade, attached to the mixer with a screw and nut, to separate from the mixer. The missing mixer blade will result in inadequate mixing of the reaction mixtures leading to potential incorrect results (failed assay calibration, Quality Control (QC) out of range, and/or incorrect patient results). The impact on the test result may vary depending on the assay being performed and the viscosity of the patient sample.

The root cause of this issue is unknown and currently under investigation.

Patient Impact

There is a potential to generate incorrect patient results for any assay on your ARCHITECT Clinical Chemistry instrument if the mixer blade becomes detached during assay processing.

Necessary Actions

1. Immediately inspect all mixers on your ARCHITECT c System(s) and verify the screw and mixer blade are present using the instructions in **Appendix A**.
2. Incorporate the **Mixer Inspection Procedure**, in **Appendix A**, into your daily maintenance activities.
Note: For customers that have the premium software feature, a user defined daily maintenance procedure may be created to inspect the mixers. Refer to *User-Defined maintenance (Premium feature)*¹.
3. If you hear an unusual noise generated from the rear of the instrument in the mixer area, inspect the mixer for a missing screw and/or mixer blade. Please follow instructions located in **Appendix A**.

**Necessary
Actions
continued**

4. If you observe one of the error codes listed in **Appendix B**, immediately verify the mixer is intact using the **Mixer Inspection Procedure** located in **Appendix A** and perform the **Cuvette Inspection Procedure** in **Appendix C**.
5. During your routine weekly maintenance procedure *6021 Clean Mixers (c4000, c8000, c16000)*¹. Please follow the additional precautions provided in **Appendix D**.

If you become aware of a mixer with a detached blade, please consult your medical director regarding previously generated results.

Abbott will provide updated information on these procedures once the investigation on the mixers is completed.

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.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online (<http://www.fda.gov/MedWatch/report.htm>), by mail (<http://www.fda.gov/MedWatch/getforms.htm>), by phone (1-800-332-1088), or by fax (1-800-FDA-0178).

If you have experienced any patient or user injury associated with this Field Action, please immediately report the event to your local area Customer Service.

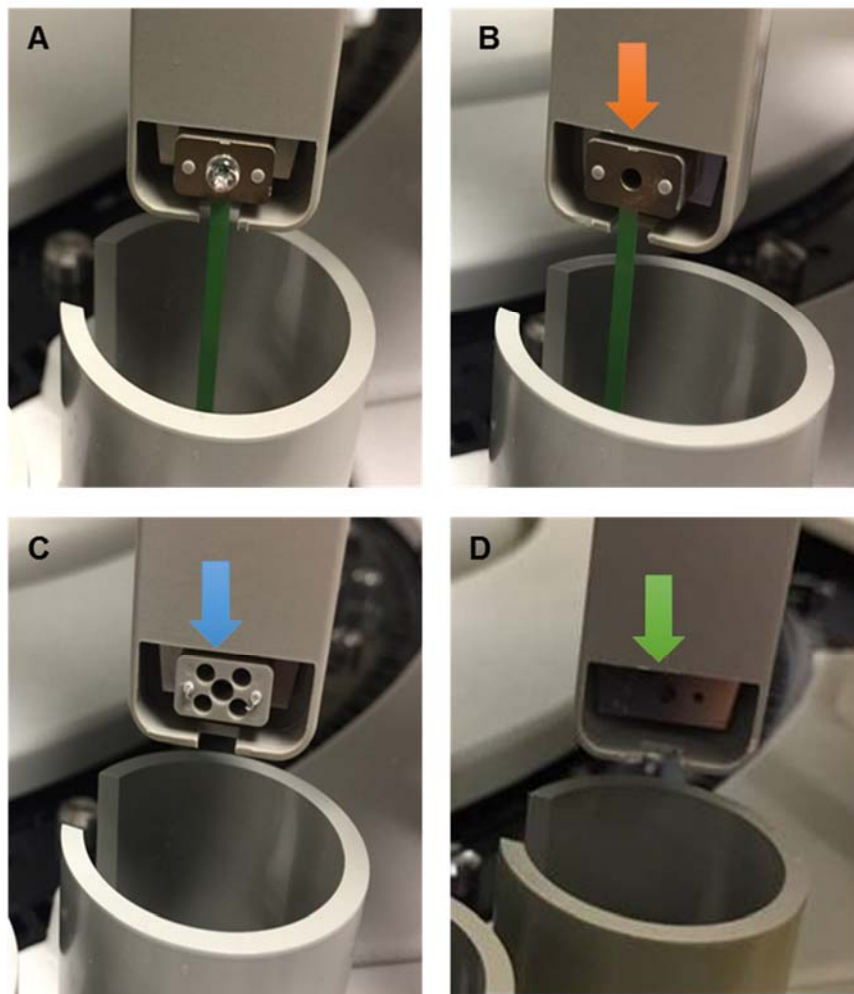
Appendix A: Mixer Inspection Procedure

To inspect each mixer, open the rear cover of the processing module and inspect the mixer. Verify the mixer blade and screw is present.

If a mixer blade and/or screw are missing

1. Replace broken mixer. Refer to *Replace the Mixer (c4000, c8000, c16000)*¹.
2. Replace the cuvette dry tip. Refer to *Replace the cuvette dry tip (c4000, c8000, c16000)*¹.
3. Follow the instructions in **Appendix C** to inspect all cuvettes to ensure that the screw or nut did not fall into an individual cuvette.

The following pictures show a A) normal mixer B) mixer missing the mixer screw (orange arrow pointing to missing screw), C) missing mixer blade with spacer shim present (blue arrow pointing to missing mixer blade), and D) missing mixer and spacer (green arrow pointing to missing mixer blade and spacer).



Appendix B: Cuvette washer movement errors.

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.
6506	Cuvette integrity check failed on cuvette (x). x = Cuvette #

Appendix C: Cuvette Inspection Procedure

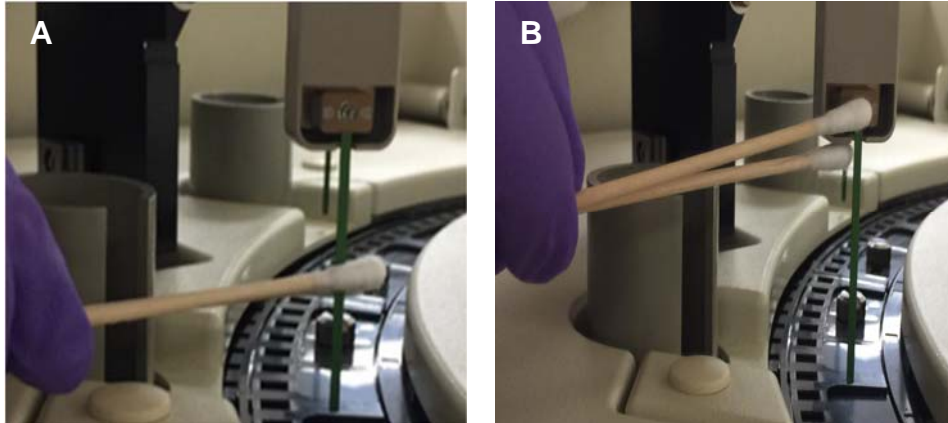
1. Inspect cuvettes for a missing screw or nut:
 - a. Remove each cuvette segment from the reaction carousel. Refer to *Replace a cuvette segment (c4000, c8000, c16000)*¹ if further assistance is required.
 - b. Inspect each cuvette in the cuvette segment for the presence of a mixer screw or nut.
 - c. Repeat the inspection for all cuvette segments in the reaction carousel.

2. If a mixer screw or nut is found in a cuvette,
 - a. 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 following the procedure *Replace a cuvette segment (c4000, c8000, c16000)*¹.
 - i. If the segment is undamaged, replace the individual cuvette in the cuvette segment. See the procedure in *Replace a cuvette (c4000, c8000, c16000)*¹.

Appendix D: Additional Precautions for Weekly procedure *6021 Clean Mixers*¹:

When performing weekly maintenance procedure *6021 Clean Mixers*¹, it is recommended to not let the mixer screw and 70% isopropyl alcohol come in direct contact.

The below pictures show A) the proper cleaning of the mixer and B) improper contact of the 70% isopropyl alcohol with the mixer screw.



Reference

¹ ARCHITECT Systems Operation Manual, Section 9: Service and Maintenance, Component Replacement