



# Urgent Field Safety Notice Product Correction

Immediate Action Required

**Date Issued** July 28, 2009

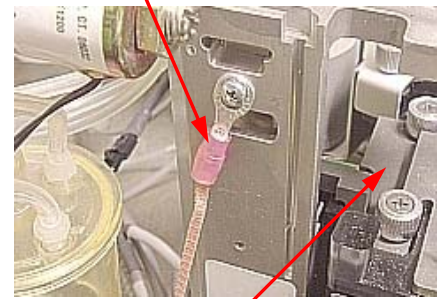
**Product**

Product Name	List Number	Part Number
ARCHITECT i2000 System	8C89 1G17	
ARCHITECT i2000SR System	3M74	
Concentrated Wash Buffer (1 L)	6C54-58	
Concentrated Wash Buffer (10 L)	6C54-88	
Wash Zone Mechanism Grounding Kit		7-201369-01

**Explanation**

Based on a single customer report and our internal investigation, we have determined that under specific conditions (such as spills, leaks, or improper maintenance) on the ARCHITECT i2000 or i2000SR Systems, the concentrated wash buffer (containing sodium azide) can come in contact with the wash zone mechanism ground straps (cables) on either of the two wash zones. The copper in the ground strap may corrode and form an unstable chemical substance (metal azide) that may be sensitive to direct pressure and impact.

**Ground strap (cable)**



**Wash zone**

**Patient Impact**

Based on our analysis, this issue has no significant impact on patient results.

**Operator Safety Impact**

Ground straps that are covered with residual solids and/or show other signs of chemical effects may react to impact or other pressure, possibly resulting in a popping noise and release of particulates from the cables. Please follow your laboratory procedures related to use of personal protective equipment (safety glasses, lab coat, gloves, etc.).

**Necessary Actions**

Some ARCHITECT i2000 and ARCHITECT i2000SR systems contain a wash zone mechanism ground strap. Please check during your weekly maintenance for the wash zones, if this is applicable for your system.

When performing weekly maintenance procedure 6015 WZ Probe Cleaning – Manual, observe the condition of the ground strap. If there is corrosion on the cable, **DO NOT TOUCH IT**. Contact Abbott immediately.

If no corrosion is observed, continue to follow procedures in the ARCHITECT System Operations Manual and Material Safety Data Sheets pertaining to:

- Prompt and proper cleanup of spills
- Proper routing and connecting of tubing
- Hazards associated with sodium azide
- Weekly maintenance for the wash zones
- Proper handling of wash buffer containing sodium azide

In case your system does not contain a wash zone mechanism ground strap, no action is required.

We are actively working to develop solutions and will communicate a resolution soon.

**Contact  
Information**

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Please retain this letter for your laboratory records.

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We apologize for any inconvenience this may cause your laboratory. If you or any of your health care providers you serve have any questions regarding this information, U.S customers should call Abbott Customer Service at 1-877-4ABBOTT. Customers outside the U.S. should contact your local area Customer Support.

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