Abbott GmbH & Co. KG
Max-Planck-Ring 2
65205 Wiesbaden, Germany

Product Correction

Urgent - Immediate Action Required

Cc Chairman Medical Board and relevant Head of Departments

Date Issued February 26, 2019

Product

Product Name	List Number (LN)	Serial Number	UDI
Alinity i Processing Module	03R65-01	All	Not Applicable
Alinity c Processing Module	03R67-01	All	

Explanation

Abbott has identified that the safety interlock covering the septum piercing probes within the bulk solution bottle holder may not deploy when a bulk solution bottle is removed from the Alinity ci-series.

The Alinity ci-series uses bottles for the required bulk solutions:

Alinity i	Alinity c
Alinity i Concentrated Wash Buffer	Alinity c-series Acid Wash
Alinity Pre-Trigger Solution	Alinity c-series Alkaline Wash
Alinity Trigger Solution	Alinity c-series ICT Reference Solution

The bulk solution bottles are loaded into the door of the bulk solution storage area. The bottle is loaded by inverting it and placing it in the appropriate bottle holder. A septum ensures the bulk solution does not spill as the bottle is inverted. As the bottle is placed into the bottle holder, a safety interlock is pushed back exposing the septum piercing probes to puncture the septum. When the bottle release button is depressed and the bottle is removed, the safety interlock should re-cover the septum piercing probes. If the safety interlock does not cover the septum piercing probes, the probes represent a probe stick hazard if the user were to place their hand in this area.

Explanation continued

Alinity i System bottle holders

1. *Shows the safety interlock deployed*
2. *Shows the safety interlock not deployed and the septum piercing probes exposed*

The Alinity c bottle holders are a different size due to the different sized solution containers, but the safety interlock functions the same.

Safety Impact

The septum piercing probes could cut or puncture the user's hand.

As there may be residual bulk solution in the area, this could also expose the user's unprotected skin to the bulk solution. The specific hazards associated with the bulk solutions are:

Alinity i

Alinity Trigger Solution (LN 06P11) contains sodium hydroxide at a concentration that may cause skin irritation.

Alinity i-series Concentrated Wash Buffer (LN 06P13) contains 5-Bromo-5-nitro-1,3-dioxane that may produce an allergic reaction.

Alinity c

Alinity c-series Alkaline Wash (LN 08P78) contains sodium hydroxide at a concentration that may cause severe skin burns.

Alinity Pre-Trigger Solution (LN 06P12), Alinity c-series ICT Reference Solution (LN 08P76) and Alinity c-series Acid Wash (LN 08P77) do not present any chemical exposure hazards to unprotected skin.

Necessary Actions

Please continue to follow the instructions provided in the Alinity ci-series Operations Manual when replacing the bulk solutions. Use caution when accessing bulk solution bottle holders or replacing bulk solution bottles as you may be exposed to a sharp hazard. The Alinity ci-series Operations Manual will be updated in the future to add the appropriate hazard information to the procedure.

If the safety interlock or bottle release does not function correctly, please contact your area customer support for assistance.

Your Abbott representative will contact you to schedule the placement of hazard labeling in the bulk solution area to increase awareness of this hazard.

Please complete and return the attached Customer Reply form.

If you have forwarded the bulk solutions 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

We sincerely regret any inconvenience this may have caused your laboratory.

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.