



## Urgent Field Safety Notice Product Correction

Urgent - Immediate Action Required

**Date Issued** October 29, 2019

**Product**

Product Name	List Number (LN)	Serial Number	UDI
Alinity ci Level Sensor, Bulk Solution	04S68-02	All	N/A
Accessory kit, Alinity i	03R66-03	All	N/A
Accessory kit #2, Alinity c	03R69-03 03R69-04	All	N/A

**Explanation** This communication is an update to the Product Correction letter FA16SEP2019 dated September 16, 2019 and Product Information letter PI1031-2019.

Update Summary:

1. The redesigned bulk solution level sensor (LN 04S68-03) will no longer be available in the fourth quarter of 2019, as previously communicated. Abbott will notify all customers when the redesigned part is available.
2. You may continue to use bulk solution level sensor (LN 04S68-02). Prior to installation of the bulk solution level sensor (LN 04S68-02), inspect the part for cracks per the instructions in Appendix A included in the original version of this Product Correction or per the instructions in the Product Information letter. Continue to follow the weekly maintenance procedure after installation.
3. Previously Generated Results section of original version of the Product Correction has been updated to include additional information:

Previously generated results: The following messages are potentially associated with a cracked bulk solution level sensor and incorrect results.

- Alinity i: 1043, 1044, 1072, 1402, 1403
  - The Alinity i message codes are exceptions and are retained for 24 hours on the system. Please contact your Abbott representative regarding options for obtaining message codes older than 24 hours.
- Alinity c: 3687, 3689
  - The Alinity c message codes are retained in the Alinity ci-series system logs.

As stated in letter dated September 16, 2019, if your laboratory had previously identified cracks on the bulk solution level sensor before receipt of this communication, and there are message codes associated with patient results, Abbott recommends following your laboratory procedure for review of results generated from time of the message codes to the previous successful Quality Control (QC).

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**Patient Impact** Cracks in the Alinity ci-series bulk solution level sensor at the Trigger Solution, Pre-Trigger Solution, Acid Wash or Alkaline Wash reservoirs have the potential to impact patient results on the Alinity c and the Alinity i.

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**Necessary Actions** If a crack has been identified in a bulk solution level sensor (LN 04S68-02), please discard and contact your Abbott representative.

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**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 via 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.

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