



Urgent Field Safety Notice
Product Correction
Immediate Action Required

Date Issued

October 11, 2017

Product

| Product | List Number (LN) | UDI |
|--|------------------|-----|
| Alinity i Processing Module | 03R65-01 | N/A |
| TED (Thermo-Electric Device) Engine, Reagent cooler | A-30103732-01 | |
| TED and coolant pump | A-30105227-01 | |

Explanation

Abbott has identified the potential for a loose cable connection on the reagent cooler, which could result in temperature errors and eventual reagent cooler failure. The loose cable connection has the potential to heat up over long periods of time and cause damage to the wire and connector. This would be detected by the operator in the form of a burning smell. The cable connection to the reagent cooler is located within the processing module and is not accessed by the operator. Due to the very low flammability rating of the materials used, the heat damage is localized to the connector.

Patient/Safety Impact

The instrument operator may be injured (electrical shock or burn) if he/she were to touch or come in direct contact with the exposed wire when the failure mode occurs.

Necessary Actions

If you experience unexpected reagent supply temperature errors, detect a burning smell or visible smoke, power off your Alinity i instrument and contact your Abbott representative.

Your Abbott representative will be scheduling a mandatory upgrade of your Alinity i Processing Module to resolve this issue in the upcoming weeks.

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 please contact your local area Customer Service.