BD Provides Update on Previously Disclosed Recall of BD Alaris System Hardware

Majority of June 30 Recall Designated as Class I Recall by FDA

FRANKLIN LAKES, N.J., Aug. 20, 2020 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today provided an update on a previously announced voluntary recall of the BD Alaris™ System.

Three of the situations described in this recall, which BD announced onJune 30, 2020, have been designated as Class I recalls by the U.S. Food and Drug Administration (FDA), which means that there is a reasonable probability that the use of the product will cause serious adverse health consequences or death. One of the situations was designated as a Class II recall, which means use of the product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

This FDA classification does not change the guidance BD provided in the company's June recall announcement to customers.

BD initiated the voluntary recall to notify customers of the potential for four hardware situations that may result in the infusion pump not operating as expected. BD has provided instructions to correct and/or mitigate the situations. The four situations include:

1. Damaged Inter-Unit Interface (IUI) Connectors (Situation 1 – Class I)
2. Broken elements on Alaris™ Pump Module platen (Situation 2 – Class I)
3. Improperly secured PC unit Battery (Situation 3 – Class I)
4. Dim LED Segment(s) on the Alaris™ modules (Situation 4 – Class II)

Customers should review and follow the instructions in the recall letter:www.bd.com/en-us/support/recall-notifications/recall-notification-for-alaris-system-infusion-pump-hardware

Affected Products

Product Name	Situation 1	Situation 2	Situation 3*	Situation 4
Alaris™ System PC Unit Model 8000	X		X	
Alaris™ System PC Unit Model 8015	X		X	X
Alaris™ Pump Module Model 8100	X	X		X
Alaris™ Syringe Module Model 8110	X			X
Alaris™ PCA Module Model 8120	X			X
Alaris™ EtCO2 Module Model 8300	X			X
Alaris™ SpO2 Module Model 8210 and Model 8220	X			X
Alaris™ Auto ID Module Model 8600	X			

*Note: Since Situation 3 affects the batteries of the PC Units, it may cause power loss to any attached module.

Note that some affected devices may be branded under the CareFusion name. Customer inquiries related to this action should be addressed to BD's Recall Support Center at 888-562-6018 or SupportCenter@bd.com.

FDA MedWatch Reporting

Adverse reactions/events experienced with the use of either of these products should also be reported to the FDA's MedWatch Program by:

- Web: MedWatch website atwww.fda.gov/medwatch
- Phone: 1-800-FDA-1088
- Fax: 1-800-FDA-0178
- Mail: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787

About BD
BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its 65,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to accurately detect disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care. For more information on BD, please visit bd.com.

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