BD Provides Update on Feb. 4, 2020 Voluntary Recall of the BD Alaris™ System PC Units and Modules

FRANKLIN LAKES, N.J. (March 9, 2020) – 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 regarding software for the PC Unit and certain modules. BD has notified customers affected by this recall, and there is no change to those recall instructions.

This recall, which BD announced on Feb. 4, 2020, has been designated as a Class I recall by the U.S. Food and Drug Administration (FDA) and has been associated with medical device reporting (MDR) submissions. This FDA classification does not change the guidance BD provided in the company's February recall announcement to customers.

BD initiated the voluntary recall to notify customers of five issues where the infusion pump may not operate as expected and provide corrections and mitigations to protect patient safety. The five items include:

- Software errors related to System Error Code 255-XX-XXX;
- Delay options programming;
- Low Battery Alarm Failure;
- Keep vein open (KVO)/End of Infusion alarms priority;
- Use errors related to Customer Concentrations Programming.

Customers should review and follow the instructions in the recall letter bd.com/alaris-system-software-recall.

As previously communicated, BD is committed to seeking clearance of a comprehensive 510(k) filing for the Alaris™ System, which will remediate the issues identified in the Feb. 4, 2020 recall notification.

In the interim, BD is providing important user actions in the recall notification letter to help mitigate the potential risks until these software issues are fully remediated. BD has also created a dedicated team of clinical consultants to support training for health care providers. For more information and to review all of the available resources provided by BD, please visit: bd.com/alaris-system-software-recall.

Affected Products

- BD Alaris™ System PC Unit Model 8000, software versions 9.5 and prior
- BD Alaris™ System PC Unit Model 8015, software versions 12.1.0 and prior
- BD Alaris™ Pump Module Model 8100, software versions 12.1.0 and prior
- Alaris™ Syringe Module Model 8110, software versions 12.1.0 and prior
- Alaris™ PCA Module Model 8120, software versions 12.1.0 and prior

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 at www.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.

Contacts:

Troy Kirkpatrick
BD Public Relations
858.617.2361
troy.kirkpatrick@bd.com

Monique N. Dolecki
BD Investor Relations
201.847.5378
Monique_Dolecki@bd.com

---

https://news.bd.com/2020-03-09-BD-Provides-Update-on-Feb-4-2020-Voluntary-Recall-of-the-BD-Alaris-TM-System-PC-Units-and-Modules