BD to Begin Remediation for BD Alaris™ System Software

FRANKLIN LAKES, N.J., July 29, 2021 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced the company will begin remediation for the February 4, 2020 BD Alaris™ System[1] recall through a new version of software.

The February 4, 2020 voluntary recall action notified customers of the following areas where the infusion pump may not operate as expected:

- 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 Custom Concentrations Programming

Under U.S. Food and Drug Administration (FDA) guidance, BD will release Alaris™ System software version 12.1.2 and associated ancillary software to remediate the affected software. Effective today, customers can begin scheduling remediation by contacting the BD Recall Support Center at 1-888-562-6018. The new software, which will be available at no cost to customers, is expected to remediate the issues identified in the February 4, 2020 recall notice and provide programming, operational and cybersecurity updates to affected devices; however, this software update has not been reviewed or cleared by the FDA.

In April 2021, BD announced that the company has submitted a 510(k) submission to the FDA for the BD Alaris™ System, which is intended to bring the regulatory clearance up to date. This submission covers all modifications to the BD Alaris™ System since its last 510(k) clearance, including updated hardware features as well as software version 12.1.2. Additional details related to software version 12.1.2 and the recommended steps for BD customers can be found at https://www.bd.com/en-us/support/alerts-and-notices/recall-and-distribution-hold-of-the-bd-alaris-system.

"Frontline clinicians continue to rely on the BD Alaris™ System to deliver medications, fluids and blood products to support the care of their patients," said Michael Garrison, worldwide president of Medication Management Solutions for BD. "This remediation is a positive step forward for our customers while the FDA reviews our 510(k) submission."

The BD Alaris™ System allows clinicians to deliver medications, fluids and blood products through a single integrated platform that includes large volume pumps, syringe pumps and patient-controlled analgesia (PCA) modules for adult, pediatric and neonatal patients.

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 70,000 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 or connect with us on LinkedIn at www.linkedin.com/company/bd1/ and Twitter @BDandCo.

Forward Looking Statement
This press release contains certain forward-looking statements regarding BD's 510(k) premarket notification to the FDA for the BD Alaris™ System. Forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements, and there can be no

assurance that BD will obtain 510(k) clearance from the FDA for the BD Alaris™ System or as to the timing of any such clearance. Many of these risks and uncertainties are beyond the company's control, including without limitation, risks relating to regulatory clearance and market acceptance of the BD Alaris™ System, the remediation of our infusion pump business and other factors listed in our 2020 Annual Report on Form 10-K and other filings with the SEC. BD expressly disclaims any undertaking to update any forward-looking statements set forth herein to reflect events or circumstances after the date hereof, except as required by applicable laws or regulations.

Contacts:

Media:	**Investors:**
Troy Kirkpatrick	Kristen M. Stewart, CFA
VP, Public Relations	SVP, Strategy & Investor Relations
858.617.2361	201.847.5378
troy.kirkpatrick@bd.com	kristen.stewart@bd.com

[1] The BD Alaris™ System is manufactured by CareFusion 303 Inc., a subsidiary of BD.

SOURCE BD (Becton, Dickinson and Company)

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