10020 Pacific Mesa Blvd
San Diego, CA 92121
1-888-876-4287 (toll-free)

www.bd.com

ACKNOWLEDGEMENT

BD Alaris™ System Software Update to Address Class I Software Recall

On February 4, 2020, BD initiated a recall of the Alaris™ System that addressed specific software issues. The associated Customer Recall Notification included important actions that users should implement to help mitigate the potential risks. The issues outlined in the recall have been associated with serious injury and death. The U.S. Food and Drug Administration (FDA) classified it as a Class I recall, which can be found on FDA's website at https://www.fda.gov/medical-devices/medical-device-recalls/2020-medical-device-recalls.

BD is committed to providing safe and secure products to our customers given their important benefits to patient health. As such, BD has recently submitted a new 510(k) notice for the Alaris™ System with software v12.1.2 and associated ancillary software. The 510(k) notice also includes all modifications to the Alaris™ System since its last 510(k) clearance, implements updated features, and includes remediations intended to address all open recalls. This device has not been cleared by FDA, and any FDA determination regarding the device may take several months to over a year and may not result in a cleared product.

After consultation with FDA, BD is releasing the Alaris™ System software v12.1.2 and associated ancillary software as part of our medical necessity program to remediate the issues in the February 4, 2020 software-related recall letter.

This acknowledgement confirms that your facility is aware of the aforementioned recall notification and that the 510(k) submission for the Alaris™ System with software v12.1.2 has not been cleared by FDA. It further confirms that your facility has evaluated the benefits and risks and would like to initiate remediation of your existing Alaris™ System devices to software v12.1.2, which addresses the issues outlined in the February 4, 2020 software-related recall letter.

Please note that there are open hardware recalls issued on June 30, 2020 and August 4, 2020 that will not be addressed in this remediation. BD has assessed the potential risks with the issues outlined in the recall letters and determined that affected products can continue to be used in accordance with the Alaris™ System with Guardrails™ Suite MX User Manual, User Manual Addendum, Service Bulletins, and the Customer Recall Notification letters until they are serviced by BD and affected hardware is replaced. Until we can release additional recall remediations, the following hardware issues from the June 30 and August 4 recalls will remain open on devices upgraded to software v12.1.2:

- Dim Segment. The LED display on the affected module may have some segments that appear dim, and therefore, the number may not be clearly displayed. (June 30,2020)

- PC Unit Keypad. Affected BD Alaris™ PC unit keypad may have one or more keys that become unresponsive or stuck (i.e., constantly pressed state) due to fluid ingress. (August 4, 2020)

- Syringe or PCA module syringe barrel clamp. Excessive force when extending and rotating the syringe barrel clamp either clockwise or counterclockwise can damage the internal mechanism of the syringe barrel clamp. Damage to this mechanism on either the Alaris™ Syringe Module or Alaris™ PCA Module may result in the Alaris PC unit displaying incorrect syringe types and/or sizes or in display of a "Syringe not Recognized" prompt. (August 4, 2020)

10020 Pacific Mesa Blvd
San Diego, CA 92121
1-888-876-4287 (toll-free)

www.bd.com

Return completed and signed form to the BD Recall Support Center at SupportCenter@bd.com

Customer Name: _____

Address (end-user location): _____

City, State, Zip: _____

Authorized Signature: _____

Name (Print): _____

Title: _____

Date: _____ **Telephone #:** _____ **Email Address:** _____