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

www.bd.com

Medical Device Product Notification

AFFECTED DEVICE: Alaris™ $EtCO_2$ Module (Model 8300)

July 3, 2019

Dear Valued Alaris™ System Customer:
Director of Biomedical Engineering
Director of Nursing
Director of Risk Management

BD has identified an issue with the Alaris™ $EtCO_2$ Module Model 8300 that is detected during device implementation. This notification is intended to provide information about the importance of testing and recommended steps for users to take.

Affected Products
Alaris™ $EtCO_2$ modules model 8300 that were calibrated during production between December 13, 2017 through December 30, 2017. See **Attachment A** for a list of affected serial numbers.

Issue
Alaris™ $EtCO_2$ modules were calibrated with an incorrect CO_2 gas concentration during production between December 13, 2017 through December 30, 2017.

Potential Risk
Device implementation testing should be performed prior to installation of the $EtCO_2$ module as specified in the Alaris System Maintenance Manual and the Alaris System User Manual. If device implementation testing is not performed, the Alaris $EtCO_2$ may provide lower readings of CO_2 (up to 20% error) during patient use. If a patient is monitored with a device providing 20% inaccurately low readings compared to real values, the inaccuracies could mislead clinicians and delay the identification of early respiratory depression. There have been no reports of serious injury or death.

Required Action for Users
Customers with the affected serial numbers should call the BD Support Center at 888-562-6018 to schedule service of the devices at the BD Service Depot.

Follow-up Actions by BD
BD will contact all affected facilities within 60 days to initiate the return process for the affected $EtCO_2$ modules. BD will recalibrate the $EtCO_2$ modules using a 5% CO_2 gas concentration and send the devices back to the customer.

The US Food and Drug Administration has been notified of this action. Any adverse reactions experienced with the use of this product, and/or quality problems 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, or by

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- Mail: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787

If you have any questions regarding the products, please contact:

Contact	Contact Information	Areas of Support
BD Support Center	Phone: 888-562-6018 Phone hours: 7:00am to 4:00pm PT, Monday – Friday Email: SupportCenter@bd.com	General Follow-up or Product Notification Questions
BD Customer Advocacy	Phone: 888-812-3266 Phone hours: 7:00am to 5:00pm PT Monday - Friday Email: customerfeedback@bd.com	Product Complaints
BD Technical Support	Phone: 888-812-3229 Phone hours: 6:00am to 5:00pm PT, Monday – Friday Email: DL-US-INF-TechSupport@bd.com	Technical Questions on the Alaris System

Please promptly complete and return the enclosed Customer Response Card to acknowledge receipt of this notification.

BD sincerely regrets the inconvenience this may cause you. BD is committed to serving your infusion product needs and our primary objectives are patient safety, exceptional product reliability, and the highest level of customer support.

Sincerely,

[redacted]

Keith McLain
Worldwide Vice President of Quality for Medication Management Solutions

Enclosures:

- **Attachment A: List of Affected Serial Numbers**
- **Attachment B: Customer Response Card**

Serial #	SKU/Model #
14976629	8300ADXEN933
15090452	11634567
15091016	11634567
15091061	11634567
15090987	8300ADXEN933
15091002	8300ADXEN933
15091053	8300ADXEN933
15091069	11634567
15091118	11634567
15091228	8300ADXEN933
15091270	8300ADXEN933
15091272	8300ADXEN933
15091274	8300ADXEN933
15091297	8300ADXEN933
15091311	8300ADXEN933
15091350	8300ADXEN933
15091321	8300ADXEN933
15091347	8300ADXEN933
15091352	8300ADXEN933
15095743	8300ADXEN933
15095794	8300ADXEN933
15095805	8300ADXEN933
15091045	11634567
15095827	11634567
15095732	11634567
15095813	11634567
15095837	11634567
15095838	11634567
15102989	11634567
15096360	11634567
15096411	11634567
15098573	11634567
15098699	11634567
15099681	11634567
15111502	11634567
15101540	8300ADXEN933
15096388	11634567
15098536	11634567
15098577	11634567
15099809	11634567
15099880	11634567
15100031	11634567
15101644	11634567
15101802	11634567
15102453	11634567
15102532	11634567
15095745	11634567
15096145	11634567

15096189	11634567
15096165	11634567
15096179	11634567
15096789	11634567
15098732	11634567
15101800	11634567
15101856	11634567
15101878	11634567
15101902	11634567
15101956	11634567
15101984	11634567
15102450	11634567
15102465	11634567
15102463	11634567
15102547	11634567
15102604	11634567
15102565	11634567
15102627	11634567
15102639	11634567
15102674	11634567
15102694	11634567
15102901	11634567
15102911	11634567
15104015	11634567
15104017	11634567
15104041	11634567
15102955	11634567
15111524	11634567

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Attachment B

Medical Device Recall Notification

Customer Response Card

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July 3, 2019

Please assist us in making this Medical Device Safety Notification follow-up process efficient and convenient for you by completing and returning this card to BD via mail, email, or fax; which serves as a confirmation that you have received this notification and took appropriate action. A cover sheet is not required.

ADDRESS: **BD Support Center**
10020 Pacific Mesa Blvd.
San Diego, CA 92121

PHONE: **1-888-562-6018**
FAX: **1-858-617-4851**
EMAIL: **SupportCenter@BD.com**

(PLEASE PRINT)

Facility Name: _____

Facility Address: _____

_____

_____

Completed By: _____

Title: _____ Phone: _____

Signature: _____ Date: _____

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San Diego, CA 92121
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Return Address

_____

_____

_____

BD Support Center
10020 Pacific Mesa Blvd
San Diego CA 92121

FOLD HERE

(Tape here)