30 Tuas Avenue 2
Singapore 639461
Registration No. 201114149N

bd.com

Medical Device Safety Notification

AFFECTED DEVICE: Alaris™ System PC unit models 8000 and 8015

30th November 2016

Dear Customer,

BD has identified an issue with the Alaris System PC unit. We have received reports of Alaris PC units operating on battery power where the Low Battery alarm and/or the Very Low Battery alarm are not being triggered before the battery is discharged and all infusion channels are stopped (issue will not occur if the device is plugged into an AC outlet). Over the past 12 years we have received 58 reports of this issue occurring. The following information details the issue and recommended steps for the users to take.

Affected Product: Alaris System Point of Care Unit (PC unit) models 8000 and 8015

Issue:
If the PC unit is running on battery power, a Low Battery alarm and Very Low Battery alarm should activate when 30 minutes and 5 minutes of estimated battery runtime remains. In some cases, these low battery alarms will not be generated before the PC unit displays a BATTERY DISCHARGED ALARM and all infusion channels are stopped.

The root causes of the problem are itemized below:

- Batteries not adequately maintained
- Use of non-CareFusion authorized batteries
- Batteries near end of their useful life
- Battery Conditioning Test in Maintenance Mode (Fast or Optimal Conditioning)

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Potential Risk:
If the system is running on battery power and the operator is unaware of a low battery power state because low battery alarms have not been generated, there will be an interruption of infusion due to lack of power. The infusion will stop until the user can provide an alternate means of power or a replacement device. If the infusion is stopped due to this issue, the user has the following options:

1. Clinician can plug the system into an AC outlet to operate under AC and recharge batteries.
2. Clinician can utilize gravity infusion outside the pump or IV syringe push in certain clinical applications.
3. Clinician can utilize another Alaris System PC unit. Clearly mark and sequester (e.g. Biomed department) the Alaris PC unit that exhibited a battery discharge without any low battery alarms.
4. Notify CareFusion Customer Advocacy at 888-812-3266 or customerfeedback@carefusion.com.

Required Action for Users:
Whenever possible, keep the PC unit plugged into AC power. If the PC unit is disconnected from AC power and the battery is used, ensure that the PC unit is returned to AC power as soon as possible. After the device has been used on battery power, ensure that the battery is fully charged prior to using the device on battery power again.

Special care should be taken for critical infusions to ensure that AC power is used whenever possible and that batteries are fully charged before the battery is used (e.g. when transporting patients).

Additional Actions for Biomedical Engineering:

1. If PC units have had the Battery Conditioning Test performed in Maintenance Mode (Fast or Optimal Conditioning) on the Alaris PC unit with their existing battery, then they must be reconditioned with the Manual Battery Conditioning Test in order to update the battery capacity estimate. The Manual Battery Conditioning Test is described in Technical Service Bulletin 592 (attached).
2. Follow recommended battery conditioning and maintenance per User Manual Addendum (Part number P00000203). The battery should be replaced every 2 years by qualified service personnel.
3. If a battery is more than 2 years of age and a replacement battery is not available, then:
    a. Minimize the use of the battery until a new battery is available. When the battery is not being used, plug the PC unit into an AC outlet.
    b. Perform the Manual Battery Conditioning test. Manual Battery Conditioning can extend the life of the battery.
4. Replace batteries that are non-CareFusion authorized parts.

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Follow-up Actions by BD:
BD has made an addendum to the User Manual (attached and located at http://cp.carefusion.com) and has released a Technical Service Bulletin 592 (attached and located at http://cp.carefusion.com) to address this issue.

YOU NEED TO TAKE THE FOLLOWING ACTIONS:

1. Please fill in the attached form whether or not you have any inventory remaining so that we may acknowledge your receipt of this notification. Simply complete the attached form, sign and fax the completed form to your local BD contact.

2. We also request that you forward this notice to any other person or groups within your organization for whom this information may be relevant.

For all other inquiries please contact your local BD representative and they will ensure that you are put in contact with the most appropriate individual to address your concerns.

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. Thank you for your continued support while we address these challenges.

Sincerely,

[redacted]

Rose Kwong
Senior Regulatory Affairs & Compliance Executive

Enclosures:
- **FAQs**
- **User Manual Addendum (Part number P00000203)**
- **Technical Service Bulletin 592**

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(CUSTOMER ACKNOWLEDGEMENT)

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Please fill in the information below so that we may acknowledge your receipt of this notification. Simply complete and return the completed form to your local BD contact.

- ❑ I confirmed that I have read and understood the Medical Device Safety Notification dated 30 November 2016, regarding the above BD products.
- ❑ Other comments:

_____

_____

_____

_____

Completed by:

Name: _____ **Signature / Date:** _____

Facility: _____
Please use full, current facility name. Do not use initials.

Street Address: _____

Telephone No.: _____ **Fax No.**: _____

Company stamp:

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