Alaris™ System PC unit models 8000 and 8015

Frequently Asked Questions (FAQ’s) – For External Use

BD has identified an issue with the Alaris System PC unit Low Battery alarm and Very Low Battery alarm when operating on battery power. 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 (issue will not occur if the device plugged into an AC outlet). The following FAQs are for external use only regarding the customer letters dated on November 1, 2016.

General Questions

1. What device is affected?

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

2. What is the issue associated with the Alaris System PC unit models 8000 and 8015?

   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 issue will not occur if the PC unit is plugged into an AC outlet.

   Over the past 12 years, there have been 58 reports of the issue occurring. The probability of occurrence based on the reports BD has received is 0.0098%.

   The root causes of the problem are itemized below. The percentages given are the proportion of reports BD received with the corresponding root cause.

   • 34% of cases indicate batteries not adequately maintained
   • 27% of cases indicate batteries are not supplied by BD
   • 17% of cases indicate batteries are near end of their useful life
   • 12% of cases indicate the root cause is unknown
   • 10% of cases indicate overestimation of the battery capacity due to the Battery Conditioning Test in Maintenance Mode (Fast or Optimal Conditioning)

3. Has BD received any reports of death or serious injury as a result of this issue?

   There were serious injury reports filed due to the interruption in therapy.

4. What is the recommended 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).
5. Has the Alaris System had a change to the battery that is prompting this notification of “Updated Battery Care & Conditioning”?

No. The Alaris System has not changed the battery since its initial release. BD’s current Technical Service Manual recommends battery replacement after 500 charge cycles. Our User Manual Addendum for Battery Care and Maintenance recommends battery replacement with an authorized CareFusion supplied battery every 2 years. BD is issuing this safety notification to inform all customers of the updated process for manual battery conditioning and reinforcing our existing labeling.

6. Why is BD making these labeling and procedure changes for the battery?

This safety notification will emphasize the proper use and maintenance of batteries and clarify the useful life of batteries.

Our investigation determined that the following issues contributed to this issue:
- Improper use of the battery (e.g. using the device on battery power and not properly recharging it)
- Lack of maintenance of the battery (e.g. not performing annual maintenance)
- Use of non-CareFusion supplied batteries
- Batteries beyond their useful life

7. What is the life expectancy of an authorized CareFusion battery for the PC unit?

Normally, a battery will last 2 years if used under proper maintenance. The life expectancy of the battery is dependent on the amount of use, the depth of discharge, and the state of the charge that is maintained. Generally, the battery has the longest life if the instrument is plugged in and battery use is infrequent. Frequent use of the battery power and insufficient battery charge cycles significantly decrease the life of the battery.

8. What is the expected battery runtime of an authorized CareFusion battery for the PC unit?

According to our User Manual (version 9 Model 8015): Battery run time is a function of the number of modules attached and module activity. With a new, fully charged battery, the system operates as follows before a "BATTERY DISCHARGED" message occurs:
- 6 hours with one Pump Module infusing at 25 mL/h
- 6 hours with one Pump Module infusing at 25 mL/h and one Auto-ID Module
- 3 hours with four Pump Modules infusing at 25 mL/h
- 3 hours with four Pump Modules infusing at 25 mL/h and one Auto-ID Module
- 4.5 hours with one active SpO2 Module
- 6 hours with one Syringe Module or PCA Module infusing at 5 mL/h
- 3 hours with four Syringe Modules, or one PCA Module and three Syringe Modules, infusing at 5 mL/h
- 4 hours with one active EtCO2 Module

9. If the PC unit is running on battery and the user plugs in the battery, what is the expected battery charge rate of an authorized CareFusion battery?

The instrument provides a multi-phase charge cycle which results in about 80% capacity in the first 2 hours after fast charge.
10. **What is the recommended action for biomedical engineering?**

- Review Service Bulletin 592 and the User Manual Addendum for Battery Care and Maintenance for details on battery care and maintenance.
- Review device maintenance records to ensure the battery has been adequately maintained.
- Review device maintenance records to identify if the battery is a CareFusion Alaris battery. Use only CareFusion Alaris supplied batteries.
- Review device maintenance records to determine age of battery and when the battery was last replaced. The battery should be replaced every 2 years by qualified personnel.
- Review device maintenance records to determine if and when the conditioning procedure was last performed. 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.

11. **How does the customer know the maintenance history of their devices?**

The customer should consult their device maintenance records.

12. **How does the customer know if the PC unit has a CareFusion Alaris battery installed?**

All PC units from BD are shipped with CareFusion Alaris authorized batteries.

If the customer has replaced their battery they should consult their device maintenance records to verify if a CareFusion Alaris battery has been installed.

Additionally, the customer can perform a visual inspection of the PC unit battery. Performing this visual inspection will require removal of the battery from the PC unit. If the battery is removed from the PC unit and the same battery is reinstalled, the PC unit and battery need to be conditioned with the Manual Battery Conditioning Test (Refer to Service Bulletin 592).

CareFusion Alaris batteries have the Alaris label on the battery casing (Figure 1) and will also have a manufacturing label listed with P/N 49000167 (Figure 2).
13. **What should the customer do if they have a non-CareFusion Alaris battery?**

The customer should replace the battery with an authorized CareFusion Alaris battery. Authorized CareFusion Alaris batteries (P/N: 49000167) can be ordered through Customer Order Management at 1-800-482-4822.

14. **How does the customer know the age of a PC unit battery?**

The customer should consult their device maintenance records to determine the age of the battery.

15. **How does the customer know if a PC unit battery has the Battery Conditioning Test performed in Maintenance Mode (Fast or Optimal Conditioning)?**

The customer should consult their device maintenance records.

16. **Why must customers perform the Manual Battery Conditioning Test 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?**

The Battery Conditioning Test available in Maintenance Mode (Fast or Optimal Conditioning) may result in an overestimation of battery runtime. Performing the Manual Battery Conditioning Test will update the battery capacity estimate.

17. **Will BD release software to enable use of the Battery Conditioning Test in non-manual mode?**

Yes. BD is currently working on a software release for a non-manual conditioning test. (estimated release in 2017)

18. **What is the customer benefit to conditioning the battery?**

Performing the Manual Battery Conditioning Test will update the battery capacity estimate and has the potential to restore lost battery capacity.

**Customer Notification Process**

19. **What action is BD taking?**

BD will contact all Alaris System model 8000 and 8015 customers by mail to notify them of this safety notification. Customers will receive a customer letter, Frequently Asked Questions, customer response card, User Manual Addendum for Battery Care and Maintenance (PN P00000203), and Service Bulletin 592.

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1 CareFusion may not make the Product available for commercial sale.
20. How will affected customers be notified of this issue and to whom will the notification be addressed?

Customers will receive a Customer Letter, Frequently Asked Questions, User Manual Addendum for Battery Care and Maintenance (PN P00000203), and Service Bulletin 592 by overnight courier service delivered upon signed receipt. Notifications will be sent to the Director of Nursing, Director of Risk Management, Director of Biomedical Engineering of each facility. Copies of this information can be found on our website at http://www.carefusion.com/customer-support/alerts-and-notices.

21. Can an IDN submit a response card on behalf of all their facilities?

Yes. The IDN can sign on behalf of the affected facilities by identifying each facility it is representing. The IDN must acknowledge that they will notify their affected facilities on the response card.

Customer Actions

22. Can the customer send devices into the BD Service Depot for remediation?

No, there is no remediation required.

23. Will BD offer any compensation to customers for this remediation?

No, BD will not offer any customer compensation for the remediation.

24. Will BD provide loaner devices?

No, BD will not offer additional Alaris PC units.

25. Will BD provide battery replacements?

Authorized CareFusion Alaris batteries (P/N 49000167) can be purchased through Customer Order Management at 1-800-482-4822. BD will offer replacement batteries at a 30% discount for orders over 100 batteries. BD will also offer replacement batteries at a 30% discount for orders under 100 batteries for accounts with less than 100 PC units.

26. How can the customer order the Four Test IV Segments for the Alaris Pump Module that is needed to perform the manual battery conditioning test?

Part number 2220-07 can be ordered through Customer Order Management at 1-800-482-4822. This part will be available in boxes of 20 and is a no charge item until further notice. Customers will be limited to one case of 20 at this time. Test IV Segments can, and should, be used multiple times until they no longer function as intended.

27. What is BD doing to increase the inventory of authorized CareFusion Alaris batteries?

BD is actively working with our suppliers to increase our inventory of batteries to support increase in order volume resulting from this notification.
28. Where can the customer find more details about this notification?

More details of this notification can be found on our website at [http://www.carefusion.com/customer-support/alerts-notices/](http://www.carefusion.com/customer-support/alerts-notices/) or use the chart provided below for questions and support:

<table>
<thead>
<tr>
<th>BD Contact</th>
<th>Contact Information</th>
<th>Areas of Support</th>
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| BD Support Center   | Phone: 888-562-6018
Phone hours: 7:00am to 4:00pm PT, Monday - Friday
Email: [SupportCenter@carefusion.com](mailto:SupportCenter@carefusion.com) | Notification Related Questions           |
| Customer Advocacy   | Phone: 888-812-3266
Phone hours: 24 hours a day, 7 days a week
Email: [customerfeedback@carefusion.com](mailto:customerfeedback@carefusion.com) | Clinical Inquiries
Product Complaints
Clinical Troubleshooting |
| Technical Support   | Phone: 888-812-3229
Phone hours: 6:00am to 5:00pm PT, Monday – Friday
Email: [DL-US-INF-Tech-Support@carefusion.com](mailto:DL-US-INF-Tech-Support@carefusion.com) | Technical Questions for Alaris System    |