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

BD has identified a software anomaly associated with software versions 9.17 and 9.19 for the Alaris™ PC Unit. For the remainder of this document, the two impacted software versions will be abbreviated as "Software". The following FAQs are for external use regarding the customer letter dated on May 31, 2016.

General Questions

1. What product is affected?
   
   Alaris PC unit model 8015 with software versions 9.17 and 9.19.

2. What is the issue?
   
   An incorrect patient weight can be displayed when using the optional restore feature for infusions that meet the following infusion programming sequence:
   
   1. Program a weight based continuous infusion with a weight based bolus dose
   2. Initiate a weight based bolus dose
   3. Change a patient weight after the bolus dose
   4. Turn off the channel
   5. Use the RESTORE feature to get back to the programming screen
   
   If these functions are performed in the order stated above, the RESTORE functionality will restore the "previous/older" patient weight programmed during the bolus infusion. This "previous/older" patient weight value impacts the auto-calculated value of either the rate or dose, depending on which value was entered last by the user.
   
   The weight restored is the LAST weight used for the bolus dose. Prior to confirming and starting the restored infusion, the clinician should confirm all parameters and adjust the patient weight if appropriate.

3. Does this issue occur only with Guardrails protected infusions?
   
   This issue occurs when using weight based continuous infusions with weight based bolus dose with either Guardrails protected infusions or with Drug Calculation (DRUG CALC) feature.

4. If an incorrect weight is restored, how does that impact the dose or rate?
   
   If an incorrect weight is restored, either an unanticipated dose or rate could be auto-calculated. If the user last programmed by rate, then during the restore, the device will restore the last entered rate and auto-calculate the dose based on the incorrect patient weight. If the user last programmed by dose, then during the restore, the device will restore the last entered dose value and auto-calculate the rate based on the incorrect patient weight.
5. **When is the RESTORE feature available to customers?**

The RESTORE softkey on the PC unit screen gives clinicians the ability to restart an infusion with a current patient after the channel is powered down. This feature is not shown when the PC unit is power cycled and the clinician selects YES to the NEW PATIENT option. The Directions for Use state: the RESTORE option is only available if the system is powered up within 8 hours of the last use and when the prompt for NEW PATIENT? is selected as NO.

6. **What should customers using software version 9.17 or 9.19 do?**

When using the optional RESTORE feature, follow Alaris System User Manual for proper programming sequences:

- Prior to starting the restored infusion, verify all values; on the screen pictured below, the PATIENT WEIGHT is a configurable field

- Between patients, always power cycle the PC unit and select YES to NEW PATIENT prompt

If at any time an infusion is observed with an incorrect weight, the clinician can select SETUP and adjust PATIENT WEIGHT at any point during the infusion.

As part of the mailer package, customers will receive a clinical Tip Sheet to help them communicate the information outlined in the recall letter.

7. **What is the potential risk?**

An incorrect patient weight can lead to an overinfusion or underinfusion.

8. **Has there been any death or serious injury related to this potential risk?**

No. There have been no reports adverse events reported.
9. What action is BD taking?

BD is releasing a software upgrade to address this issue. BD will contact all affected customers within 60 days to initiate the scheduling process for the software upgrade installation. Serial numbers of affected devices can be provided upon request.

10. How will affected customers and distributors be notified of this issue and to whom will the notification be addressed?

Each affected customer and distributor will receive a Customer Letter, Tip Sheet, FAQ, and Response Card by overnight courier service delivered upon signed receipt. Recall notifications will be sent to the Director of Nursing, Director of Risk Management, Director of Biomedical Engineering, and Director of Materials Management of each facility. Only affected customers will receive the notification. Copies of this information can be found on our website at http://www.carefusion.com/customer-support/alerts-and-notices.

11. Who issued this recall?

BD voluntarily issued this recall notification.

12. Has the FDA been notified?

Yes.

New Implementations and In Process Device Upgrades

13. Does this recall impact completed “go-lives”?

Yes. Any PC units with software version 9.17 or 9.19 will be upgraded to PC unit version 9.19.1 by our Global Customer Service team.

14. Does this recall impact IDN “go-lives” that have some hospitals live with the Software, and some hospitals that are scheduled to go live?

Yes. The IDN facilities that have gone live with Software will be upgraded to PC unit version 9.19.1. The remaining facilities will go-live with software version 9.19.1.

15. Does this recall impact customers currently in the implementation process?

Yes. Global Customer Service will stay onsite at the customer facility to upgrade the recall affected devices with software version 9.19.1.

16. Does this recall impact customers currently upgrading devices?

Yes. Global Customer Service will stay onsite at the customer facility to upgrade the recall affected devices with software version 9.19.1.

17. What should the customer do if they tied remediation efforts to their software upgrade effort?

For future remediation efforts tied to software upgrade, the Remediation Team will contact the customer to evaluate rescheduling remediation and software update. For remediation in process, BD will finish the remediation and align all PC Units on software version 9.19.1.
18. Does this recall impact customers who recently upgraded or are in process of upgrading their LVP and Syringe modules?

No, the Software issue is limited to PC Unit only, and there is no impact to the LVP and Syringe modules. The LVP and Syringe module upgrades are backwards compatible to PC Unit software version 9.1, 9.5, 9.12, 9.17 and 9.19.

19. What happens to customers who received starter devices?

Starter devices will be upgraded to software version 9.19.1 during the customer’s regularly scheduled implementation.

Customers with Software Version 9.17

20. What software version will customers with PC unit version 9.17 receive?

Customers with software version 9.17 will receive software version 9.19.1 as part of the remediation efforts. During the remediation, customers will also receive Alaris System Maintenance version 10.19 at no charge, as part of the standard upgrade process to 9.19.1.

21. What is the difference between software versions 9.17 and 9.19?

PC Unit software version 9.19 is compatible with the 802.11 a/b/g/n wireless card. The wireless 802.11 a/b/g/n is not required for version 9.19.1.

The 802.11 a/b/g/n wireless card offers advanced security, faster connectivity, and broad wireless coverage. A hardware upgrade from the 802.11 a/b/g card to the 802.11 a/b/g/n card is required to receive these benefits.

22. Will customers with software version 9.17 be upgraded to the 802.11 a/b/g/n wireless card at no charge?

No. However, customers can purchase the 802.11 a/b/g/n card.

Customer Actions

23. Who should the customer contact if they have additional questions about this recall?

Please contact the BD Recall Support Center directly at 888-562-6018.

24. How can customers with affected devices obtain a list of affected serial numbers?

Customers should contact the BD Recall Support Center at 888-562-6018 or SupportCenter@carefusion.com to receive a list of affected device serial numbers.

25. How will BD plan remediation efforts for customers that received affected devices and a Software CD kit?

All affected devices will be remediated by BD. BD will work with customers to identify and remediate the devices that were upgraded using the Software CD kit.
26. How will BD plan remediation efforts for customers that received a Software CD kit, but have no affected devices (i.e. Software CD kit was not used by the customer)?

BD will work with customers to identify the Software CD kit and provide the customer with the latest Point of Care software CD kit with version 9.19.1.

27. Will customers who received starter devices also receive a recall notification?

Yes. Customers who received starter devices with affected Software will receive a recall notification. However, these starter devices will be upgraded on software version 9.19.1 prior to implementation.

28. Can the customer perform the corrective action for the affected Alaris PC units?

No. BD must perform the corrective action.

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

BD will not be offering any customer compensation for the remediation.

30. Will BD provide loaner devices?

No. BD will not be offering additional Alaris PC unit model 8015 devices.

31. Where can the customer find more details about this recall?

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

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<th>Areas of Support</th>
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<tr>
<td>BD Support Center</td>
<td><strong>Phone:</strong> 888-562-6018&lt;br&gt;Phone hours: 7:00am to 4:00pm PT, Monday - Friday&lt;br&gt;Email: <a href="mailto:SupportCenter@carefusion.com">SupportCenter@carefusion.com</a></td>
<td>Recall Related Questions</td>
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<tr>
<td>Customer Advocacy</td>
<td><strong>Phone:</strong> 888-812-3266&lt;br&gt;Phone hours: 24 hours a day, 7 days a week&lt;br&gt;Email: <a href="mailto:customerfeedback@carefusion.com">customerfeedback@carefusion.com</a></td>
<td>Clinical Inquiries&lt;br&gt;Product Complaints&lt;br&gt;Clinical Troubleshooting</td>
</tr>
<tr>
<td>Technical Support</td>
<td><strong>Phone:</strong> 888-812-3229&lt;br&gt;Phone hours: 6:00am to 5:00pm PT, Monday - Friday&lt;br&gt;Email: <a href="mailto:DL-US-INF-Tech-Support@carefusion.com">DL-US-INF-Tech-Support@carefusion.com</a></td>
<td>Technical Questions for Alaris System</td>
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