Alaris™ System PC unit model 8015

Frequently Asked Questions (FAQ’s)

BD is issuing this Safety Notification letter to inform you of reports of customers experiencing a System Error (error code: 255-16-275) with Alaris System PC unit model 8015 that can result in interruption of infusions. The following information details the scenarios in which this system error can occur and the actions to avoid this error. The following FAQs are for the customer letter dated on June 12, 2017.

General Questions

1. What device is affected?
   Alaris System PC unit model 8015.

2. What is the issue associated with the Alaris System PC unit model 8015?
   System Error 255-16-275 can occur when a user selects two functions at the same time/rapid succession or not following typical workflows. This results in a synchronization issue between the PC unit and the modules.

   System Error Code 255-16-275 will occur in 5 known scenarios:
   1. Closing the pump module door and in rapid succession (less than 1 second apart) pressing START.
   2. Priming and starting system in PAUSE state and then attempting to remove the syringe.
   3. Starting an infusion using the DELAY OPTIONS. Then confirming the delay entry and pressing CHANNEL SELECT on another module at the same time.
   4. Locking PCA door simultaneously when an on screen popup occurs on another module.
   5. Pressing CHANNEL OFF on two syringe modules after completion of infusions at the same time.

3. What is a System Error message?
   The Alaris PC unit software runs "self-checking" programs before and during operation. A SYSTEM ERROR message means that the device has discovered an error either in the hardware or the software of the Alaris PC unit. Operation continues on all channels; current infusions will not be affected, but the pump will not be able to accept any new changes to the rate, dose or Volume to be Infused (VTBI).
4. **What is the potential risk of System Error Code 255-16-275?**

System error would result in a non-silenceable, high priority alarm and status indicator lights on modules will flash red. The PC unit displays an error code of 255-16-275 (error code 800.8000 is recorded in the PC unit error log). The module will show “Communication Error” on the channel message display.

If the system error occurs, all attached modules that are actively infusing will continue to infuse without the ability to titrate infusion parameters. The user may decide to reboot the system or re-program the device to titrate the infusion and/or to silence the alarms. This could result in the clinical decision to interrupt the infusions. An interruption in infusion can result in serious injury with the first two scenarios listed above.

5. **What is the probability of each scenario occurring?**

The table below indicates the probability of occurrence based on the reports BD has received:

<table>
<thead>
<tr>
<th>Scenario 1 – PCU and LVP</th>
<th>Brief Description</th>
<th>Probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scenario 2 – PCU and SYR</td>
<td>Closing pump module door and in rapid succession (less than 1 second apart) pressing START</td>
<td>0.005%</td>
</tr>
<tr>
<td>Scenario 3 – PCU and LVP or SYR</td>
<td>Priming and starting system in PAUSE state and then attempting to remove the syringe</td>
<td>0.001%</td>
</tr>
<tr>
<td>Scenario 4 – PCU and PCA</td>
<td>Starting an infusion using the DELAY OPTIONS. Then confirming the delay entry and pressing CHANNEL SELECT on another module at the same time</td>
<td>0.001%</td>
</tr>
<tr>
<td>Scenario 5 – Two SYR Modules</td>
<td>Locking PCA door simultaneously when an on screen popup occurs on another module</td>
<td>No reported issues but can be reproduced</td>
</tr>
<tr>
<td>Scenario 5 – Two SYR Modules</td>
<td>Pressing CHANNEL OFF on two syringe modules after completion of infusions at the same time</td>
<td>0.001%</td>
</tr>
</tbody>
</table>
6. **Has BD received any reports of death or serious injury as a result of this issue?**

There have been no reports of death or serious injury.

**Customer Notification Process**

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

BD is contacting all Alaris System PC unit model 8015 customers by mail to notify them of this Safety Notification. Customers will receive a customer letter, Frequently Asked Questions (FAQ), customer response card, and User Manual Addendum.

8. **Will BD make a software release to address this System Error?**

No, the PC unit was designed to fail safely when this type of error occurs by returning the system to a safe condition malfunction and allowing unaffected modules to continue running at their current rate and volume limits.

9. **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 (FAQ), User Manual Addendum, and a customer response card by overnight courier service delivered upon signed receipt. Notifications will be sent to the Director of Biomedical Engineering, Director of Nursing, Director of Risk Management of each facility. Copies of this information can be found on our website at [http://www.carefusion.com/customer-support/alerts-and-notices](http://www.carefusion.com/customer-support/alerts-and-notices).

10. **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**

11. **Where can the customer find more details on these scenarios and the actions to prevent these scenarios?**

This FAQ provides an explanation for this Safety Notification and the User Manual Addendum provides instructions on how to avoid the System Error.

Additional video content for each of the scenarios can be accessed in the BD customer portal ([bd.com/CustomerPortal](http://bd.com/CustomerPortal)).
12. What is the recommended action for users with a System Error Code 255-16-275?

The Alaris System modules will continue as programmed. Do not interrupt critical infusions if infusion parameters do not need to be edited. If it is safe to do so, manually stop the infusion in order to reprogram and re-start the pump following the instructions in the User Manual Addendum to avoid this error.

Power down the PC unit by pressing the SYSTEM ON key. Restart the device by pressing the SYSTEM ON key. Restart previous infusions and/or monitoring settings. If the System Error returns, power down the PC unit and replace it immediately. Return the PC unit to your Biomedical Engineering department for troubleshooting and data log retrieval.

13. In Scenario 1, how can a user close the pump module door and start an infusion in rapid succession?

The clinician uses two hands to quickly close the pump module door and press START in rapid succession (less than 1 second apart). BD recommends addressing the safety clamp alarm first and waiting one second before starting the infusion.

14. Can the user press the RESTORE soft key on the PC unit to restore the infusion settings after System Error 255-16-275?

The user can restore the PC unit infusion settings after System Error 255-16-275 only in Scenario 2 "Priming and starting system in delay pause".
15. **In Scenario 3, how can a user simultaneously confirm a delay and press CHANNEL SELECT on another Pump or Syringe module?**

The clinician uses two hands to CONFIRM the delay while simultaneously pressing CHANNEL SELECT on another Pump or Syringe module. BD recommends completing the programming sequence on one module and waiting one second before programming or interacting with another module.

![Image of Pump or Syringe module](image)

16. **In Scenario 4, what types of pop-up messages appear that result in System Error 255-16-275?**

Any pop-up message created outside of the PCA channel that causes an overlay on the “Close and lock the door” screen (e.g., preventative maintenance message). BD recommends confirming any pop-up messages that occur during PCA programming before turning the Security Lock to the Locked position.

![Image of Pump or Syringe module](image)

17. **In Scenario 5, how can a user press CHANNEL OFF on two syringe modules at the same time?**

The clinician uses two hands, simultaneously press and hold CHANNEL OFF keys on both Syringe modules until a beep is heard, approximately 1.5 seconds. BD recommends to turn off one module at a time or use the Options feature to power down all channels.

![Image of Pump or Syringe module](image)
18. In Scenario 5, will the System Error code 255-16-275 occur if near end of infusion (NEOI) alert is enabled?

Yes, System Error Code 255-16-275 can occur with NEOI enabled. The NEOI alert will be triggered before Infusion Complete or Syringe Empty. The clinician can silence the NEOI audio alert.

19. Will BD provide loaner devices?

No, BD will not offer additional Alaris PC units.

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

No, this medical device safety notification does not require any remediation for your Alaris System.

21. Where can the customer find more details about this notification?

More details of this safety notification 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:

<table>
<thead>
<tr>
<th>BD Contact</th>
<th>Contact Information</th>
<th>Areas of Support</th>
</tr>
</thead>
</table>
| BD Support Center  | Phone: 888-562-6018  
                      Phone hours: 7:00am to 4:00pm PT, Monday - Friday  
                      Email: SupportCenter@carefusion.com            | General Follow-up Questions: RGA/  
                                                                                     Affected Base/Field Remediation  
                                                                                     (Non-technical)                      |
| Technical Support  | Phone: 888-812-3229  
                      Phone hours: 5:00am to 5:00pm PT, Monday – Friday  
                      Email: DL-US-INF-Tech-Support@carefusion.com    | Technical Questions related to this notification        |
| Customer Advocacy  | Phone: 888-812-3266  
                      Phone hours: 24 hours a day, 7 days a week  
                      Email: customerfeedback@carefusion.com          | Clinical Inquiries  
                                                                                     Product Complaints  
                                                                                     Clinical Troubleshooting            |