Medical Device Safety Notification

Important Product Information for
Alaris™ System PC unit Model 8015

June 12, 2017

Dear Valued Alaris™ System Customer:

> Director of Biomedical Engineering
> Director of Nursing
> Director of Risk Management

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. Your Alaris System will not need to be remediated.

Products included in this notification:
- Alaris System PC unit model 8015.

Issue:
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. Below are five examples:

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 new 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 before confirming on screen popup that occurs on another module.
5. Pressing CHANNEL OFF on two syringe modules after completion of infusions at the same time.

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

Potential Risk:
The 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. 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.

Required Action for Users:
Your Alaris System will not need to be remediated. Refer to the User Manual Addendum to avoid the occurrence of this System Error.

If the System Error occurs, 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.

Follow-up Actions by BD:
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
- Mail: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787

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

BD 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@carefusion.com	General Follow-up Questions
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

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. Thank you for your continued support while we address these challenges.
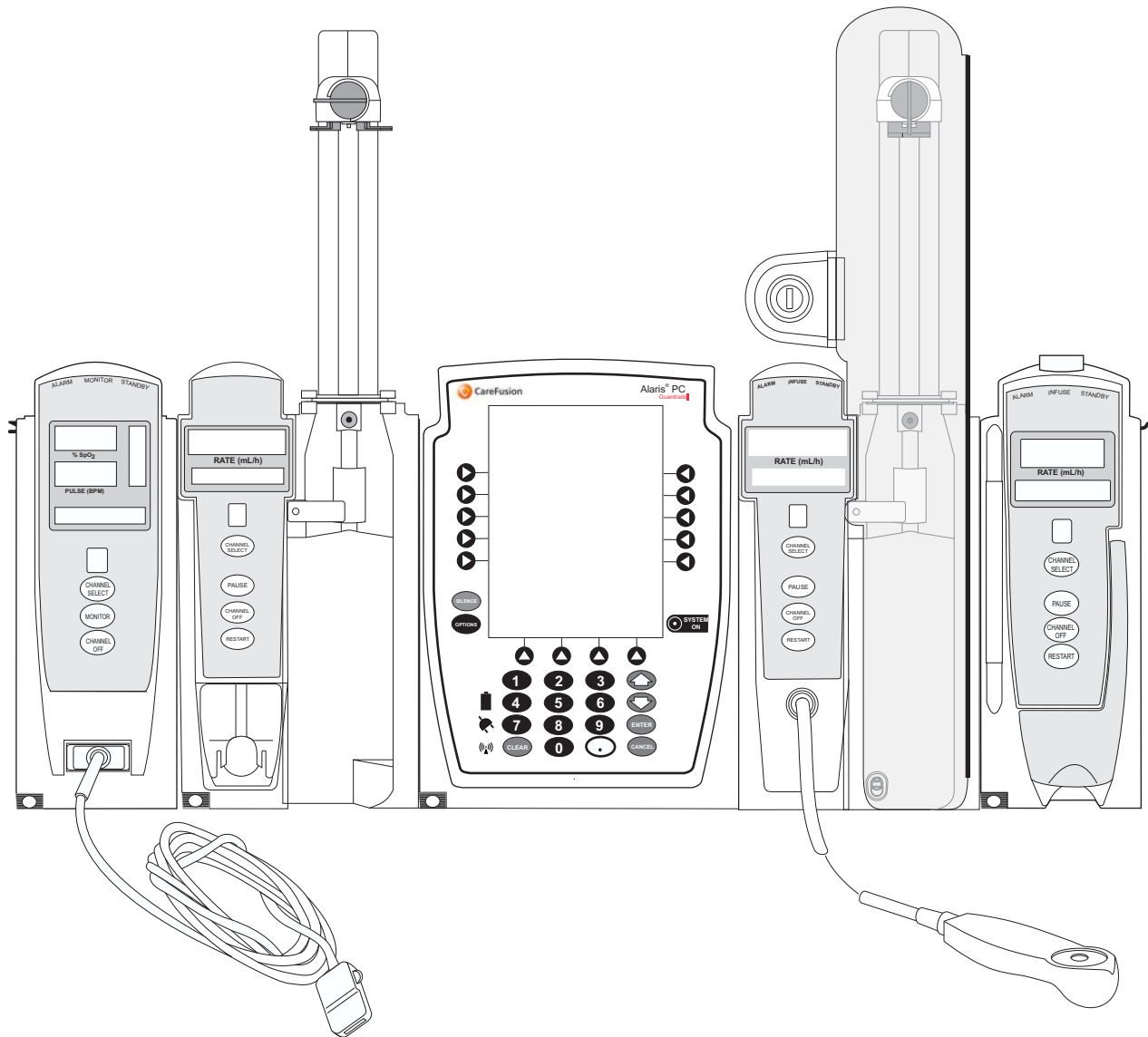
Enclosures:
- **FAQs**
- **User Manual Addendum**
- **Customer Response Card**

User Manual Addendum

Alaris™ System with Guardrails™ Suite MX

Alaris PC unit, Model 8015, Software Version 9.x

June 2017

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General Contact Information

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Authorized Australian/New Zealand Representative
CareFusion Australia and New Zealand
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Australia

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Customer Advocacy - North America
(Clinical and technical feedback.)
Phone: 888.812.3266 Email: CustomerFeedback@carefusion.com

Customer Advocacy - International
(Clinical and technical feedback.)
Email: cai@carefusion.com

Technical Support - North America
(Maintenance and service information support; troubleshooting.)
Phone, United States: 888.812.3229
Phone, Canada: 800.387.8309

Technical Support - United Kingdom
(Maintenance and service information support; troubleshooting.)
Phone: 0800 389 6972
Email: GMB-INTL-TechnicalSupportInfusion@carefusion.com

Customer Order Management - North America
(Product return, service assistance, and order placement.)
Phone, United States: 800.482.4822
Phone, Canada: 800.387.8309

Customer Care - United Kingdom
(Product return, service assistance, and order placement.)
Phone: 0800 917 8776
Email: UK-Customer-Service@carefusion.com

Technical Support and Customer Service - International
(Maintenance and service information support. Product return, service assistance, and order placement)
www.carefusion.com/customer-support/customer-service

Technical Support - Australia/New Zealand
(Maintenance and service information support; troubleshooting, service assistance.)
Phone: 1300 729 258
Email: techservice-au@carefusion.com

General Contact Information (Continued)

Customer Care - Australia
(Product return and order placement.)
Phone: 1800 833 372
Email: au-customerservice@carefusion.com

Customer Care - New Zealand
(Product return and order placement.) Phone: 0508 422 734
Email: nz-customerservice@carefusion.com

Alaris System PC Unit System Error 255-16-275

General Information

Products Affected

- Alaris™ PC unit, Model 8015

References

- *Alaris PC Unit, Model 8015, and Alaris Pump Module, Model 8100 Technical Service Manual*
- *User Manual Alaris™ System with Guardrails™ Suite MX (with Alaris™ PC unit, Model 8015)*

Accessing Documentation

For North American customers, service manuals, service bulletins, and software upgrade instructions are available through the CareFusion Customer Portal. The link below takes you to the portal's Welcome screen:

https://cp.carefusion.com/

1. If you are registered, enter your email and password, and click **LOGIN**. If you are not registered yet, click **SIGN UP**, and follow the prompts.

2. On the CareFusion Customer Portal home page, click **CONTENT LIBRARY**.

3. When the library page appears, select Service bulletins and manuals in the Content Type field to find the information you seek.

For customers outside of North America, contact CareFusion Customer Support with Infusion Technical queries/questions at:

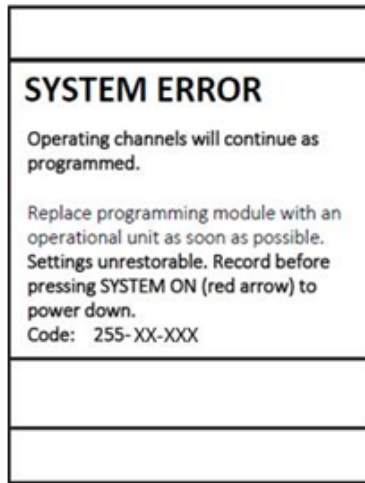GMB-INTL-TechnicalSupportInfusion@carefusion.com

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System Error Code 255-16-275

The System Error Code 255-16-275 is a category of System Errors from the Alaris PC unit.

If the error occurs while infusing or monitoring, all attached Alaris System modules will continue as programmed. Programmed settings cannot be edited. The Alaris System will provide a non-silenceable, high priority alarm and status indicator lights on modules will flash red. In addition, a System Error message will be displayed on the PC unit screen, similar to the message shown below:

SYSTEM ERROR

Operating channels will continue as programmed.

Replace programming module with an operational unit as soon as possible. Settings unrestorable. Record before pressing SYSTEM ON (red arrow) to power down.
Code: 255-XX-XXX

Example of System Error Message

Although the modules will continue as programmed, the programmed settings cannot be edited. If editing of programmed settings is critical, it may be necessary to interrupt and restart the infusion using a different PC unit.

Receiving this System Error could result in a delay to the start of an infusion.

What should I do if I get this error?

When it is safe to do so, power down the PC unit by pressing the SYSTEM ON key, indicated by a red, flashing arrow. 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 immediately. Return the PC unit to your Biomedical Engineering department for troubleshooting and log retrieval.

If you are Biomedical Engineering, please contact CareFusion Customer Advocacy. See *General Contact Information* on page iii.

Description of Known System Errors

Here are examples of five known scenarios that may lead to System Error 255-16-275 in the patient care environment. The table below outlines the scenarios, steps that may result in the System Error, and tips on how to avoid the System Error. A System Error may occur for each scenario if all of the steps occur in the order they are written.

Table 1: Description of Known Scenarios that May Result in System Error 255-16-275

#	Scenario	Steps	How to avoid
1	**Closing door and in rapid succession, pressing START**	1. The clinician programs an infusion on the Alaris Pump module, but does not press START. 2. Prior to pressing START, the Pump module door is opened slightly until Safety Clamp Open – Close Door alarms occurs. 3. The clinician quickly closes the door and presses START in rapid succession (less than 1 second apart). 4. Although the Pump module is now infusing, the PC unit screen does not show an active infusion. If channel marker on the PC unit display does not indicate a running infusion, CHANNEL OFF and reprogram the infusion. If this is not done, any change to the infusion may trigger the System Error.	Address safety clamp alarm first and wait one second before starting infusion.
2	**Priming and starting system in delay pause**	1. Load and CONFIRM Syringe Manufacturer and Syringe Size. 2. Choose infusion type then use the Prime Set with Syringe feature on the Syringe Module, and press EXIT; do not press START. 3. Select PAUSE on the PC unit (either through DELAY OPTIONS or by using the PAUSE soft key) and CONFIRM. 4. Disengage the syringe Gripper Control/Drive Head, reselect and CONFIRM Syringe Manufacturer and Syringe Size.	If an infusion remains in the PAUSE state, select CHANNEL OFF prior to removing a syringe.

#	Scenario	Steps	How to avoid
3	**Delayed options and programming multiple modules**	1. Start Infusion on a Pump module or Syringe infusion module. 2. Press CHANNEL SELECT on the running channel and setup any delay using the DELAY OPTIONS feature. 3. CONFIRM the Delay while simultaneously pressing CHANNEL SELECT on another Pump/Syringe module (timing is important). 4. PC unit displays the Infusion Setup page for new channel selected. 5. Continue programing the infusion and press START, or CANCEL and exit the page. 6. System Error occurs	Complete programming on one module and wait one second before programming or interacting with another module.
4	**PCA Close and Lock door interrupted by other device message**	1. Set up or Modify a PCA module program while the Security Lock (PCA key) is in PROGRAM position. 2. CONFIRM the PCA programming/PCA BOLUS DOSE page. 3. PC unit displays "Close and lock the door" popup page. 4. The popup is interrupted by another popup from another source other than the PCA module. 5. Lock PCA module door. 6. System Error occurs.	Confirm any pop-up messages that occur during PCA programming before turning the Security Lock to the Locked position.
5	**Channeling off two Syringe modules that have completed infusions at the same time.**	1. Start infusions on two Syringe modules. 2. Run the infusions until Infusion Complete or Syringe Empty message displays on both modules. 3. Simultaneously press and hold CHANNEL OFF keys of both Syringe modules, until a beep is heard, approximately 1.5 seconds. 4. System Error occurs.	CHANNEL OFF one module at a time, or use the OPTIONS feature to Power Down All Channels

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User Manual Addendum

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:

Scenario	Brief Description	Probability
Scenario 1 – PCU and LVP	Closing pump module door and in rapid succession (less than 1 second apart) pressing START	0.005%
Scenario 2 – PCU and SYR	Priming and starting system in PAUSE state and then attempting to remove the syringe	0.001%
Scenario 3 – PCU and LVP or SYR	Starting an infusion using the DELAY OPTIONS. Then confirming the delay entry and pressing CHANNEL SELECT on another module at the same time	0.001%
Scenario 4 – PCU and PCA	Locking PCA door simultaneously when an on screen popup occurs on another module	No reported issues but can be reproduced
Scenario 5 – Two SYR Modules	Pressing CHANNEL OFF on two syringe modules after completion of infusions at the same time	0.001%

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.

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).

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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.

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.

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.

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:

BD 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@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