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Name
Address

URGENT FIELD SAFETY NOTICE

Product Name:	**Alaris™ Syringe Pump – (CC, GH, GS, PK and TIVA)**
FSCA Identifier:	**RA-2015-07-01**
Date:	**July 2015**
Type of Action:	**Advisory Notice**
	(Device Compatibility Issue with Nipro Syringe)

ATTENTION: Clinical Personnel, Risk Managers, Biomedical Personnel

Details on Affected Devices

Applicable only to users who use the following Alaris™ CC, GH, GS, PK and TIVA Syringe pumps with Nipro Syringes.

Note: This Advisory notice is **not** stating that the Nipro Syringes do not meet the required industry standards or that there is a fault with the Alaris Syringe Pumps but to advise that the Nipro Syringes is no longer compatible with the Alaris Syringe Pumps.

Description	SKU
Alaris™ CC, Universal	80033UNN0
Alaris™ CC, Universal, RS232	80033UNN1
Alaris™ CC, Universal, Dedicated	80033UND0
Alaris™ CC, Universal, Dedicated, RS232	80033UND1
Alaris™ CC Syringe Pump with Plus Software	8003MED01
Alaris™ CC with Guardrails™ Safety Software, Universal, Dedicated	80033UND0-G
Alaris™ CC with Guardrails™ Safety Software, Universal, Dedicated, RS232	80033UND1-G
Alaris™ CC Guardrails Syringe Pump with Plus Software	8003MED01-G
Alaris™ CC Syringe Pump with Plus Software	8003TIG01
Alaris™ CC Guardrails Syringe Pump with Plus Software	8003TIG01-G
Alaris™ GH, Universal	80023UN00
Alaris™ GH, Universal, RS232	80023UN01
Alaris™ GH Syringe Pump with Plus Software	8002MED01
Alaris™ GH with Guardrails™ Safety Software, Universal	80023UN00-G
Alaris™ GH with Guardrails™ Safety Software, Universal, RS232	80023UN01-G
Alaris™ GH Guardrails Syringe Pump with Plus Software	8002MED01-G
Alaris™ GH Syringe Pump with Plus Software	8002TIG01
Alaris™ GH Guardrails Syringe Pump with Plus Software	8002TIG01-G
Alaris™ GS, Universal	80013UN00
Alaris™ GS, Universal, RS232	80013UN01
Alaris™ PK Syringe Pump, Universal	80053UN01
Alaris™ TIVA, Universal, RS232	80043UN01

Description of the Problem

CareFusion has identified that the Alaris Syringe Pump & the Nipro Syringe are no longer compatible and Nipro be removed from the list of recognised syringes. The system effect when using an Alaris Syringe Pump with a Nipro Syringe could result in the following:

1. **Inability to program and commence an infusion** if the user is unable to confirm the syringe brand/size would result in a delayed start of an infusion.

2. **Delay in the start of the next infusion** if the pump does not alarm for a NEOI to give the clinician sufficient time to obtain/prepare a new syringe. The Near End of Infusion (NEOI) Warning sets the Near End of Infusion warning time, as time left to End Of Infusion. This warning is used to alert the user that the pump is nearing the end of the infusion. It can be configured from 1min to 15min to end of infusion, or 10% of syringe volume, whichever is smaller.

3. **Air-in-line** resulting in an unintended interruption of an infusion to remove the air. The End of Infusion (EOI) Point sets the End of Infusion point. This alarm alerts the user that the pump has reached the end of the infusion. A pre-set volume will remain in the syringe to minimize the risk of the infusion of air bubbles into the set. The EOI Alarm can be set between 0.1% and 5% of syringe volume. In the reported instance there will not be any fluid remaining in the syringe therefore small amounts of air may get into the administration set. Although this is very unlikely to result in any air reaching the patient it may necessitate re-priming or replacement of the administration set.

4. **Under-infusion**. The worst case results for Long Term Rate Accuracy were -14% at 0.1ml/h and -12% at rates >5ml/h, this would result in an under infusion. As stated in the *Directions for Use* for System Accuracy the Volumetric Mean is ±2% for rates ≥ 1ml/h (nominal). N.B. Short Term Rate Accuracy was within specification.

CareFusion has only received 2 reports where end users experienced performance issues when attempting to use Alaris Syringe Pump with Nipro Syringes which gives a defect error rate of 0.0007% of the Alaris Syringe Pump Field base. Neither occurrence resulted in an undesirable clinical outcome. However, in line with our commitment to patient safety, CareFusion has taken the decision to proactively remove the Nipro Syringes from the list of recognised syringes on Alaris Syringe Pump range to mitigate the very remote but potential clinical risk.

Products Affected

Our traceability analysis determined that your hospital/facility may be affected by this FSN if you use Nipro Syringes with any of the Alaris Syringe Pump range.

Action Required by Hospital / Facility

If you **do not** use Nipro Syringes with any of the Alaris Syringe Pump range you **are not** affected by this FSN. Please complete Appendix 1 - sections A & C and return the form to your CareFusion representative.

If you **do** use Nipro Syringes with any of the Alaris Syringe Pump range you **are** affected by this FSN. Please follow the instructions below:

Step	Action
1	Immediately stop using the Nipro Syringe with any of the Alaris Syringe Pump range.
2	Follow instruction in Appendix 2 to permanently remove the Nipro Syringe from the choice of recognised syringes.
3	Complete sections Appendix 1 - sections B & C and return the form to your CareFusion representative.

Action Required by CareFusion

Market indications show that less than 0.1% of users' use of Nipro syringe and Alaris Syringe Pumps combination and that over 99.9% of users are not affected by this FSN. CareFusion will be removing the Nipro Syringe from the list of recognised syringes in the DFU, Editor and pump software as part of our commitment to patient safety.

CareFusion is updating the Directions for Use, Editor and pump software on current manufactured pumps to remove the Nipro Syringe from the list of recognised syringes.

Your Competent Authority has already been notified of this Field Safety Corrective Action by CareFusion's Authorised EU Representative.

Should you have any questions or require assistance relating to this Field Safety Corrective Action, please contact your Local CareFusion representative.

Transmission of this Field Safety Notice

Please distribute this notice to all those who need to be aware of this action within your organisation.

Sincerely,

CareFusion Representative

Appendix 1 – To be completed and returned by End User

URGENT FIELD SAFETY NOTICE

Product Name:	**Alaris™ Syringe Pump – (CC, GH, GS, PK and TIVA)**
FSCA Identifier:	**RA-2015-07-01**
Date:	**July 2015**
Type of Action:	**Advisory Notice**
	(Device Compatibility Issue with Nipro Syringe)

Section A

☐ I have read and understood the contents of this Advisory Notice and confirm that our facility does not use the Alaris Syringe Pump and Nipro Syringe combination:

Section B

☐ I have read and understood the contents of this Advisory Notice and confirm that our Facility will follow the instructions in Appendix 2 to disable the Nipro Syringe from the list of recognised syringes:

Section C

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name	
Signature	
Date	

Please return by **30 November 2015** to:

CareFusion Representative

Address:

Via Fax:

Via Email:

Appendix 2 – Disable Nipro Syringes on CareFusion Pumps

Alaris CC / GH / GS / TIVA Syringe Pumps

Description	SKU
Alaris™ CC, Universal	80033UNN0
Alaris™ CC, Universal, RS232	80033UNN1
Alaris™ CC, Universal, Dedicated	80033UND0
Alaris™ CC, Universal, Dedicated, RS232	80033UND1
Alaris™ GH, Universal	80023UN00
Alaris™ GH, Universal, RS232	80023UN01
Alaris™ GS, Universal	80013UN00
Alaris™ GS, Universal, RS232	80013UN01
Alaris™ TIVA, Universal, RS232	80043UN01

1. Hold down ⏻ and turn the pump on.
2. Enter the access code **251** using the ⏶⏷ keys and the **NEXT** softkey.
3. When the required code shows on screen, press **OK** to confirm.
4. Select **ENABLE SYRINGES** from the Configured Options menu using the ⏶⏷ keys and press the **OK** softkey.
5. Use the ⏶⏷ keys to scroll through the list of syringe brands, select **Nipro** and press **MODIFY** to disable the syringe brand and individual syringe sizes within the brand.
6. When complete press the **QUIT** softkey to return to the Configured Options menu.

Alaris PK Syringe Pump

Description	SKU
Alaris™ PK Syringe Pump, Universal	80053UN01

The syringe brands are only configurable via the PK Editor Software (PC based), see PK Editor Directions For Use for full details.

1. Start the PK Editor on the PC.
2. Select **Import Data Set** or Open Data Set to load the Data Set required to be updated.
3. Select **Master Lists** tab and click **Syringe Library** in list.
4. Clear check boxes for **Nipro** syringes to disable.
5. Review, Approve and Release Data Set.
6. Upload Data Set to all Pumps required.
7. Verify Data Set Upload.
8. Switch the Pump off.
9. Switch the Pump on and verify that the data set details screen displays the correct data set name and version. The Pump is now ready to use.

Note: When creating any new Data Sets ensure that Nipro syringes are disabled.

Alaris CC and GH Guardrails Syringe Pumps

Description	SKU
Alaris™ CC with Guardrails™ Safety Software, Universal, Dedicated	80033UND0-G
Alaris™ CC with Guardrails™ Safety Software, Universal, Dedicated, RS232	80033UND1-G
Alaris™ GH with Guardrails™ Safety Software, Universal	80023UN00-G
Alaris™ GH with Guardrails™ Safety Software, Universal, RS232	80023UN01-G

The syringe brands are only configurable via the Guardrails Editor Software (PC based), see Guardrails Editor Directions For Use for full details.

1. Start the Guardrails Editor on the PC.
2. Select **Import Data Set** to import the Data Set required to be updated.
3. Click **Syringe Library** in tree list.
4. To start editing click on **Edit** in bottom right hand corner, double click in right pane, right click in right pane and select **edit** or through the menu bar dropdown **Syringe Library**.
5. **Edit Syringe Library** dialog box appears.
6. Clear check boxes for **Nipro** syringes to disable.
7. Click **OK** when all syringes have been set to the required state to confirm.
8. Review, Approve and Release Data Set.
9. Upload Data Set to all Pumps required.
10. Verify Data Set Upload.
11. Switch the Pump off.
12. Switch the Pump on and verify that the data set details screen displays the correct data set name and version. The Pump is now ready to use.

Note: When creating any new Data Sets ensure that Nipro syringes are disabled.

Alaris CC and GH (Guardrails) Plus Syringe Pumps

Description	SKU
Alaris™ CC Syringe Pump with Plus Software	8003MED01
Alaris™ CC Guardrails Syringe Pump with Plus Software	8003MED01-G
Alaris™ CC Syringe Pump with Plus Software	8003TIG01
Alaris™ CC Guardrails Syringe Pump with Plus Software	8003TIG01-G
Alaris™ GH Syringe Pump with Plus Software	8002MED01
Alaris™ GH Guardrails Syringe Pump with Plus Software	8002MED01-G
Alaris™ GH Syringe Pump with Plus Software	8002TIG01
Alaris™ GH Guardrails Syringe Pump with Plus Software	8002TIG01-G

The syringe brands are only configurable via the Alaris Plus Editor Software (PC based), see Alaris Plus Editor Directions For Use for full details.

1. Start the Alaris Plus Editor on the PC.
2. Select **Data Set Open** to open the Data Set required to be updated.
3. Click **Profiles** in the **Data Set Navigation** pane.
4. Select **Profile Syringe Library** from the **Profile Views.**
5. Clear check boxes for **Nipro** syringes to disable.

Note: Nipro syringes will need to be disabled on all Profiles separately.

6. Review, Approve and Export Data Set.
7. Upload Data Set to all Pumps required.
8. Prior to clinical use, check that the Data Set ID on the approved data set report matches the Data Set ID shown on the Pump.
9. Switch the Pump off.
10. Switch the Pump on and verify that the data set details screen displays the correct data set name and version. The Pump is now ready to use.

Note: When creating any new Data Sets ensure that Nipro syringes are disabled.