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URGENT FIELD SAFETY NOTICE

Product Name:	**Alaris® GP, GP Guardrails®, GP Plus & GP Plus Guardrails® Infusion Pumps**
Product Reference:	**80263UN01, 80263UN01-G, 9002MED01, 9002MED01-G**
Serial Numbers:	**Pumps manufactured between Dec 2009 and Jan 2012**
FSCA Identifier:	**RA-2013-04-01**
Date:	**May 2013**
Type of Action:	**Device Modification (Preventative Motor Replacement)**

ATTENTION: Clinical Personnel, Risk Managers, Biomedical Personnel

Details on Affected Devices

The Alaris® GP, GP Guardrails®, GP Plus & GP Plus Guardrails® infusion pumps are general purpose volumetric infusion pumps intended for acute and sub-acute applications. They use a stepper motor to operate its pumping mechanism.

Note: All other Alaris® Syringe pumps including GP, GP Guardrails, GP Plus and GP Plus Guardrails® Pumps manufactured outside the period between Dec 2009 and Jan 2012 are not affected.

Description of the Problem

Through CareFusion's Post Market Surveillance system, we have identified an increased occurrence of stepper motor stalls in a proportion of the Alaris® GP, GP Guardrails®, GP Plus & GP Plus Guardrails® infusion pump population. Our analysis has determined that these stalls are due to the stepper motor's front and rear bearings which may not perform as designed after a period of use. The population of affected Alaris® GP, GP Guardrails®, GP Plus & GP Plus Guardrails® infusion pumps were manufactured between December 2009 and January 2012.

The motor stall condition may occur during:

- start up (immediately after the Start key is pressed)

or

- during an infusion which may result in the early termination of an infusion. Early termination of an infusion could require intervention especially if critical drugs are being administered.

In either case the pump is designed to **fail safe** giving an audible alarm, a visual alarm displayed on the infusion pump display - "DRV1" or "DRV2" and the red beacon light on the infusion pump will flash, prompting the infusion pump user to intervene.

CareFusion is aware of several reports where motor stalls have occurred during an infusion but **none** have resulted in an undesirable clinical outcome. However, in line with our commitment to patient safety, CareFusion has taken the decision to proactively replace all the motors in the pumps affected to mitigate the very remote but potential clinical risk.

Products Affected

Our traceability analysis determined that your hospital/facility has received products that were manufactured between December 2009 and January 2012 (Serial Numbers detailed on Appendix 1).

Action Required by Hospital / Facility

Step	Action
1	Inspect GP, GP Guardrails®, GP Plus & GP Plus Guardrails® pump inventory for products 80263UN01, 80263UN01-G, 9002MED01 and 9002MED01-G and record the status as follows against each serial number listed on Appendix 1. • Located • Not located • No Longer Used (i.e. pump is no longer used in clinical practice). • Disposed
2	Return completed verification form (Appendix 1) to your CareFusion representative no later than 31 October 2013

Action Required by CareFusion

On receipt of the completed verification form Appendix 1, CareFusion will contact the hospital / facility to plan for the replacement of the motors.

Recommended Interim Use of Potentially Affected Pumps

CareFusion has issued this notice as quickly as possible to advise users of the potential issue with the Motor. However, due to the availability of new motors, the replacement of the motors will not commence until **September 2013**.

Until the motors can be replaced, users can continue to use potentially affected pumps in accordance with the Directions for Use. In the unlikely event that you experience a "DRV1" or a "DRV2" error then take the pump out of service immediately and contact your local CareFusion Representative.

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

CareFusion

Appendix 1

URGENT FIELD SAFETY NOTICE – Verification Form

Product Name:	**Alaris® GP, GP Guardrails®, GP Plus & GP Plus Guardrails Infusion Pumps**
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☐ I have read and understood the contents of this Field Action and confirm that our pump inventory has been checked and have recorded the status of each pump in the attached table :

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

Example:

Serial Number	Status	Serial Number	Status
XXXXXX	Located		
YYYYYY	Not Located		
ZZZZZZ	No longer Used		
AAAAAAA	Disposed		

Please return by **31 October 2013** to:

Local CareFusion Representative

Appendix 1 continued

Pump Serial Number	Status	Pump Serial Number	Status