HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Alaris™/Asena™ GS, GH, CC, TIVA, PK, Syringe Pumps
Manufactured before September 2008

Priority 2 – Warning

HPRA Safety Notice: SN2017(37) **Issue Date: 9th November 2017**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
BD/CareFusion, Switzerland	V33494

ISSUE
BD/Carefusion has identified a risk whereby an internal malfunction can result in the syringe pump stopping and alerting the user to an internal failure. Customers are advised to immediately remove from clinical use pumps displaying any internal malfunction error code, such as the PL3 error message, and send them for servicing by qualified service personnel. A Field Safety Notice (FSN) has been issued advising customers of the appropriate actions to take. Please refer to the accompanying FSN for further details.

ACTION OR RECOMMENDATIONS
The HPRA advises that users: 1. Refer to the accompanying FSN and follow the instructions provided by the manufacturer.

2. Forward a copy of this Safety Notice and the accompanying FSN to all those that need to be aware within your organisation and to any organisation/person to which/whom these devices have been transferred.
3. Acknowledge receipt of the FSN if you have not already done so.
4. Report any adverse incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS

All wards
Clinical Directors
Clinical Engineers
Fertility clinics
Healthcare professionals who use these devices
Hospices
Hospital Managers / CEOs
Hospital Pharmacists
Nursing Homes
Nursing Managers
Nursing Staff
Oncology Nurse Specialists
Paediatric wards
Palliative Care Staff
Private Hospitals
Purchasing Managers
Risk Managers
Supplies Managers

BACKGROUND

BD Carefusion has identified that pumps manufactured prior to September 2008 could exhibit an internal malfunction such as a PL3 error code. Internal malfunction error codes are identified by the pump stopping, issuing an error message along with a red illuminated beacon, and a high pitched constant alarm tone that cannot be silenced. A list of impacted Stock Keeping Units (SKUs) can be found in the FSN. Please refer to the accompanying FSN for further details.

The HPRA is issuing this safety notice to raise awareness of this issue.

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **distributor** should be addressed to:

Aquilant Services
Aquilant House
21 Fonthill Business Park
Clondalkin
Dublin 22

Telephone: +353-1-4048330
E-mail: Damien.Deehan@aquilantservices.com

Enquiries to the **manufacturer** should be addressed to:

CareFusion Switzerland 317 Sárl
A-One Business Centre
Z.A. Vers-la-Piece No 10
Rolle, CH-1180
Switzerland

Telephone: +41-21-5563041
E-mail: Ralph.HILBERATH@bd.com

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie