

Medical Device/Equipment ALERT

Ref. MDEA(NI)2003/28

Issued: 2 October 2003

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION REQUEST	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
Medical Device/Equipment: Arcomed Syramed SP6000 syringe pump.	▶ ①
Problem: Risk of over infusion. If the "stop" key is pressed when the pump is loading during the automatic loading mode the syringe may be completely emptied.	▶ ②
Action by: Medical Device Co-ordinators, Medical Device Engineering Departments, all nursing and medical personnel using these devices.	▶ ③
Action: <ul style="list-style-type: none"> Users should be aware of this problem and ensure they have contacted or have been contacted by Arcomedical to have corrections undertaken; In the meantime, the pumps should be used in the controlled loading mode only. 	▶ ④
Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers For onward distribution see Section 5	▶ ⑤
Contacts Details of manufacturer contacts, NIAIC contacts for technical aspects.	▶ ⑥
Feedback Requirements to NIAIC None required.	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

Arcomedical Infusion Ltd. Syramed SP6000 syringe pumps.

2. PROBLEM:

The MHRA has been informed that in the automatic loading mode it is possible to press the “stop” key at a specific point during the loading process, which will produce a complete emptying of the syringe. The only means to prevent the emptying is to press the on/off key.

This is due to a software problem.

3. ACTION BY:

All nursing and medical personnel using these devices.

4. ACTION:

- Users should ensure they have been contacted by Arcomedical and have had their pumps’ software upgraded free of charge.
- If Arcomedical have not been in contact users should contact Arcomedical to arrange correction as soon as possible.
- In the meantime users are advised to use the pump in the controlled loading mode only.

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Estates Managers
- Medical Directors
- Nurse Directors
- Special Care Baby Units
- Maternity Wards
- Paediatric Units
- Accident & Emergency Departments
- Adult and Paediatric Intensive Care Units
- Oncology Departments
- Renal Units and Satellites
- All Wards
- Care Homes
- Independent Health and Social Care Providers – specifically Independent Clinics and Nursing Homes

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Mr C Young
Service Manager
Arcomedical Infusion Ltd
Medical Systems
5J West Horndon Industrial Estate
West Horndon
Essex CM13 3XL

Tel: 01277 810 432

Fax: 01277 811 967

E-mail: sales@arcomed.co.uk

Enquires to NIAIC should quote reference number MDEA(NI)2003/32 and be addressed to:
Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868
Fax: 028 9052 3900
Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

None required.



Brian Godfrey
NIAIC Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in Safety Notice SN (NI) 2003/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety