

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/28

Issued: 22 March 2007

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	✓



HEALTH ESTATES

creating healing environments

	Section
Medical Device/Equipment: Haemodialysis machine: Integra manufactured by Gambro.	▶ ①
Problem: Events of insufficient fluid removal have been recorded during ultrafiltration.	▶ ②
Action by: All renal unit staff and renal technicians.	▶ ③
Action: 1. Ensure systems are in place for users to be aware that the Integra may not remove the correct amounts of fluid as programmed. 2. If inadequate fluid removal episodes are encountered, contact Gambro to arrange for initial maintenance of the devices (which includes flow meter replacement) as well as increased frequency of follow-up visits. 3. Check that all machines are operating on software version 2.19.4. If not, contact Gambro for the software upgrade. 4. If problems of insufficient fluid removal are experienced whilst using the Integra system, report to the NIAIC (Adverse Incident Centre).	▶ 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 and NIAIC contacts for technical aspects.	▶ ⑥
Feedback Requirements to NIAIC In accordance with PEL(06)17 acknowledgment of assurance should be given	▶ ⑦

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

1. DEVICE/EQUIPMENT:

Haemodialysis machine: Integra manufactured by Gambro.

2. PROBLEM:

Gambro has identified that the present flowmeter components and the use of high permeability dialysers may be contributory factors to the problem of inadequate fluid removal.

Gambro has identified and is evaluating a long-term solution for Integra systems that are not removing the correct amount of fluid.

In the interim period, Gambro is contacting all UK centres with Integra systems, to identify if any unreported events of insufficient fluid removal have occurred. Gambro will then:

- visit your centre and arrange initial maintenance of the devices including flow meter replacement and software upgrade where required
- schedule follow-up visits to ensure that any potential problems with insufficient fluid removal are closely monitored
- make any additional corrective action, where required.

Gambro will also undertake corrective measures through more frequent contact with all sites using Integra machines to check the status of the equipment.

- For sites unaffected by inadequate fluid removal, Gambro will carry out quarterly checks.
- For sites affected by inadequate fluid removal, preventive maintenance will be carried out on a quarterly basis, with additional monthly contact by Gambro.

Not all renal units have experienced inadequate fluid removal with the Integra machines. However in the event that such issues have been identified, please contact Gambro to increase the frequency of maintenance.

3. ACTION BY:

All renal unit staff and renal technicians.

4. ACTION:

1. Ensure systems are in place for users to be aware that the Integra may not remove the correct amounts of fluid as programmed.
2. If inadequate fluid removal episodes are encountered, contact Gambro to arrange for initial maintenance of the devices (which includes flow meter replacement) as well as increased frequency of follow-up visits.
3. Check that all machines are operating on software version 2.19.4. If not, contact Gambro for the software upgrade.
4. If problems of insufficient fluid removal are experienced whilst using the Integra system, report to the NIAIC (Adverse Incident Centre).

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:

- Clinical governance leads
- EBME staff
- In-house maintenance staff
- Medical directors
- Nursing executive directors
- Risk managers
- Supplies departments
- Haemodialysis units and satellites
- Renal medicine, directors of
- Renal nurses
- Renal physicians
- Renal technicians
- Renal units
- Staff supporting patients receiving haemodialysis at home

6. CONTACTS:

Enquires to the manufacturer should be addressed to:

Graham Little
Customer Services Manager
Gambro Hospital Ltd
Ermine Business Park
Huntingdon
PE29 6XX

Tel: 01480 444 000

E-mail: graham.little@gambro.com

Enquires to NIAIC should quote reference number MDEA(NI)2007/28 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

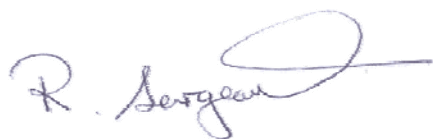
Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

Deadline (Email received) : 23rd March 2007

Deadline (action underway) : 13th April 2007

Deadline (action complete) : 4th May 2007



Robert Sergeant
NIAIC Operational 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 MDEA(NI)2006/01. 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