

MEDICAL DEVICE ALERT

Issued: **21 March 2007 at 15:30**

Ref: **MDA/2007/027**

<input checked="" type="checkbox"/>	Immediate action
<input type="checkbox"/>	Action
<input type="checkbox"/>	Update
<input checked="" type="checkbox"/>	Information request

Device: Haemodialysis machine: Integra manufactured by Gambro.	
Problem: Events of insufficient fluid removal have been recorded during ultrafiltration.	► Page 2
Action by: All renal unit staff and renal technicians.	
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 MHRA (Adverse Incident Centre).	
Distributed to: NHS trusts in England Healthcare Commission (CHAI) – Chief Executives* – Headquarters * via CE Bulletin	► Page 2
Contacts: Details of manufacturer contacts and MHRA contacts for technical and clinical aspects. Change of address or removal from address list for Healthcare Commission.	► Pages 2-3

Action deadlines for the Safety Alert Broadcast System (SABS)

Deadline (action underway): 11 April 2007

Deadline (action complete): 02 May 2007

This notice is also on our website: <http://www.mhra.gov.uk>

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.

Distribution:

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

Trusts to:

SABS liaison officers for onward distribution to all relevant staff including:

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

Healthcare Commission (CHAI) to:

Headquarters for onward distribution to:

- Independent dialysis centres

Contacts:

Enquiries 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

Contacts continued:

Enquiries to the MHRA should quote reference number **2005/007/029/061/006** and be addressed to:

Technical aspects:

Miss Roopa Prabhakar or Mrs Catriona Blake
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3293 / 3219

Fax: 020 7084 3209

E-mail: roopa.prabhakar@mhra.gsi.gov.uk
catriona.blake@mhra.gsi.gov.uk

Clinical aspects:

Mr Jonathan Plumb
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3128

Fax: 020 7084 3111

E-mail: jonathan.plumb@mhra.gsi.gov.uk

Change of address or removal from address list for Healthcare Commission:

Healthcare Commission
Finsbury Tower
103-105 Bunhill Row
London
EC1Y 8TG

Tel: 020 7448 0842

E-mail: contacts@healthcarecommission.org.uk

How to report adverse incidents

Incidents relating to medical devices must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) as soon as possible.

Further information about reporting incidents; on-line incident reporting facilities; and downloadable report forms are available from MHRA's website (<http://www.mhra.gov.uk>).

Alternatively, further information and printed incident report forms are available from:
MHRA Adverse Incident Centre

Medicines and Healthcare products Regulatory Agency
Market Towers, 1 Nine Elms Lane, London SW8 5NQ
Telephone 020 7084 3080 or Fax 020 7084 3109
or e-mail: aic@mhra.gsi.gov.uk

(An answerphone service operates outside normal office hours)

Medical Device Alerts are available in full text on the MHRA website: <http://www.mhra.gov.uk>

Further information about **SABS** can be found at www.info.doh.gov.uk/sar2/cmopatie.nsf

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