

MEDICAL DEVICE ALERT

Issued: **03 April 2006** at 11:00

Ref: **MDA/2006/023**

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

Device: X-ray system: GE Healthcare, Precision 500D undercouch radiography/fluoroscopy system.	
Problem: The tabletop intermittently fails to retract when being tilted in a downward direction. This may result in a collision of the tabletop with the floor and subsequent patient injury.	▶ Page 2
Action by: Radiology Service Managers, Directors of Radiology, Superintendent Radiographers, In-house X-ray maintenance staff.	
Action: Users of this system should contact GE Healthcare to obtain an upgrade and to determine the necessary precautions to be taken in the meantime.	
Distributed to: NHS trusts in England Healthcare Commission (CHAI) <ul style="list-style-type: none"> – Chief Executives* – Headquarters <p style="text-align: right;">* via CE Bulletin</p>	▶ Page 2
Contacts: Details of manufacturer/supplier and MHRA contacts for technical and clinical aspects. Change of address or removal from address list for Healthcare Commission.	▶ Page 2

Action deadlines for the Safety Alert Broadcast System (SABS)

Deadline (action underway) : 10 April 2006

Deadline (action complete): 18 April 2006

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

Problem:

Under some conditions, the tabletop does not retract as the software incorrectly interprets the tilt direction of the table to be the opposite of the actual motion, the table moves into the collision zone instead of out of it.

It is possible that the tabletop will collide with the floor.

GE Healthcare is aware of this failure.

A solution to this problem has been developed and will be provided to all affected systems.

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:

- Directors of Radiology
- Health & safety managers
- In-house Maintenance Staff
- Radiology Service Managers
- Risk managers
- Safety officers
- Superintendent Radiographers.

Healthcare Commission (CHAI) to:

Headquarters for onward distribution to:

- Hospitals in the independent sector providing radiology services.
- Private hospitals providing radiology services

MHRA to:

- Armed forces providing radiology services

Contacts:

Enquiries to the manufacturer/supplier should be addressed to:

Bob Murton
Quality & EHS Leader - Northern Europe
GE Healthcare Technologies
352 Buckingham Avenue
Slough
SL1 4ER

Tel: 01753 874 516

Fax: 01753 874 508

E-mail: bob.murton@med.ge.com

Enquiries to the MHRA should quote reference number **2006/001/005/061/003** and be addressed to:

Technical aspects:

David Grainger or Richard Glover
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3199 / 3209

Fax: 020 7084 3209

E-mail: david.grainger@mhra.gsi.gov.uk
richard.glover@mhra.gsi.gov.uk

Clinical aspects:

Dr Susanne Ludgate
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3123

Fax: 020 7084 3111

E-mail: susanne.ludgate@mhra.gsi.gov.uk

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

Contacts (continued):

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/sar/cmopatie.nsf

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