

Medical Device Alert

Immediate action

Ref: MDA(NI)2009-014 Issued: 23 January 2009 at 17:00

Device

UNISTAT L floor stand for diagnostic X-ray and superficial X-ray therapy systems.

Manufactured by MECALL Srl.

Problem

The MHRA has received a report of the X-ray tube head falling onto the table after the support cable and the backup 'safety device' failed simultaneously.

The tube head weighs 40 kg and there is a risk of death or serious patient injury if this failure occurs during examination.

Action

- Identify any affected devices.
- Immediately remove from service.
- Contact the manufacturer.
- Ensure that the whole length of the support cable and the 'safety device' are inspected following the updated service instructions and are free from defect before returning into service.

Action by

All healthcare workers who use or maintain these devices.

SABS deadlines

Action underway: 02 March 2009
Action complete: 23 March 2009

Contact

Manufacturer

Luigi Besana
Safety and Regulatory Manager

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E-mail: lbesana@mecall.it

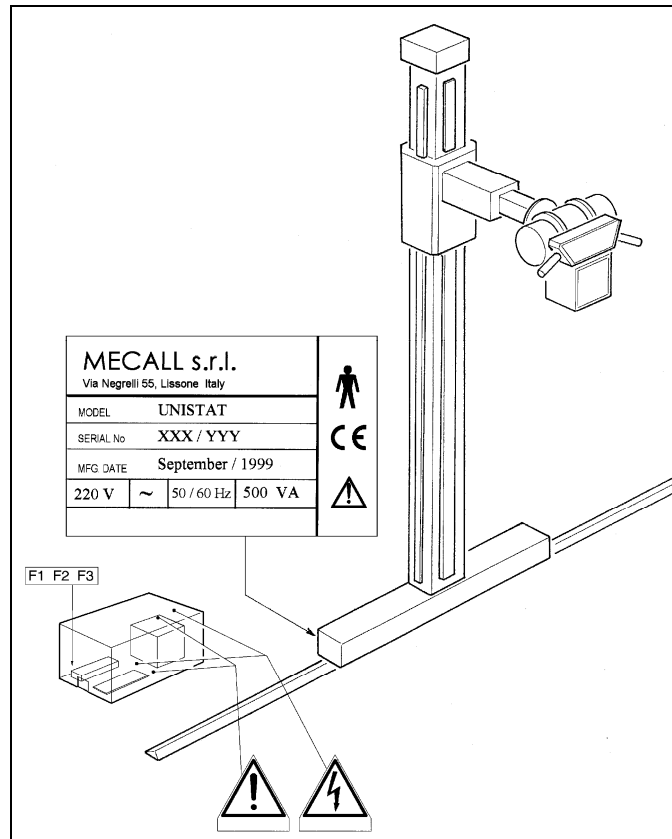
Device

These stands were manufactured between 1990 and 2000.

The table below lists the serial numbers of the affected systems by supplier.

Supplier	Serial numbers
Astrophysics	002/436, 003/437, 003/438, 003/439, 003/440
Forward	006/507, 006/508, 006/509
Pantak	004/465, 004/466, 004/467, 004/469, 004/470, 005/493, 006/497, 007/521, 007/525, 007/535, 008/537, 008/538, 008/543, 008/546, 009/571
Raytechnologies	005/480, 005/481, 005/482
Wolverson	005/492, 006/503, 006/506, 006/511, 006/514, 006/515, 007/519, 007/522, 007/527
Zenith	007/518, 008/539, 008/540

The location of the serial number label is shown in the following diagram:



Problem

The X-ray tube head is supported by a metal rope that winds over a pulley system behind the tube support covers. There is a safety device fitted, which should catch the rope if it breaks.

Wear on the cable may go undetected as the current service instructions for this device do not require that the whole length of the cable is inspected nor do they require that the 'safety device' is inspected.

The manufacturer has updated the service instructions and issued a Field Safety Notice, available to download from:

<http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/FieldSafetyNoticesformedicaldevices/CON038728> .

Distribution

The NIAIC has sent this MDA via SABS to:

- HSC Trust, HSS Board, and Agency's Chief Executive's
- HSC Trust, HSS Board, and Agency's SABS Liaison Officer
- Selected members of the DPSSPSNI
- Hospitals in the independent sector
- Hospices

Onward distribution

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

Trusts to:

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

- Directors of radiation oncology
- Directors of radiology
- Medical directors
- Radiation and medical oncology departments
- Radiographers
- Radiologists
- Radiology departments
- Risk managers
- Superintendent radiographers

The Regulation and Quality Improvement Authority (RQIA) to:

Headquarters for onward distribution to:

- Nursing agencies

Boards to:

SABS liaison officers for onward distribution to:

- Risk manager

Central Services Agency (CSA) to:

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

- Staff with responsibility for purchasing

Contacts

Manufacturer

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NIAIC

Enquiries in Northern Ireland, please send enquiries about this notice to the NAIC quoting reference number **MDA(NI)2009-014** and addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast
BT16 1US

Tel: 02890 523868
Fax: 02890 523900
E-mail: NIAIC@dhsspsni.gov.uk
<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

How to report adverse incidents

Incidents relating to medical devices in Northern Ireland must be reported to the Northern Ireland Adverse Incident Centre (NIAIC) as soon as possible.

Further information about reporting incidents can be found in DB(NI)2008-001; and downloadable report forms are available from the NIAIC's website (<http://www.dhsspsni.gov.uk/niaic>).

Alternatively, further information and printed incident report forms are available from: NIAIC at the address above.

(An answerphone service operates outside normal office hours)

Medical Device Alerts are available in full text on the NIAC website

Further information about SABS can be found at <http://sabs.dhsspsni.gov.uk>

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