

Medical Device Alert

Action

Ref: MDA/2011/009 Issued: 24 January 2011 at 15:30

Device

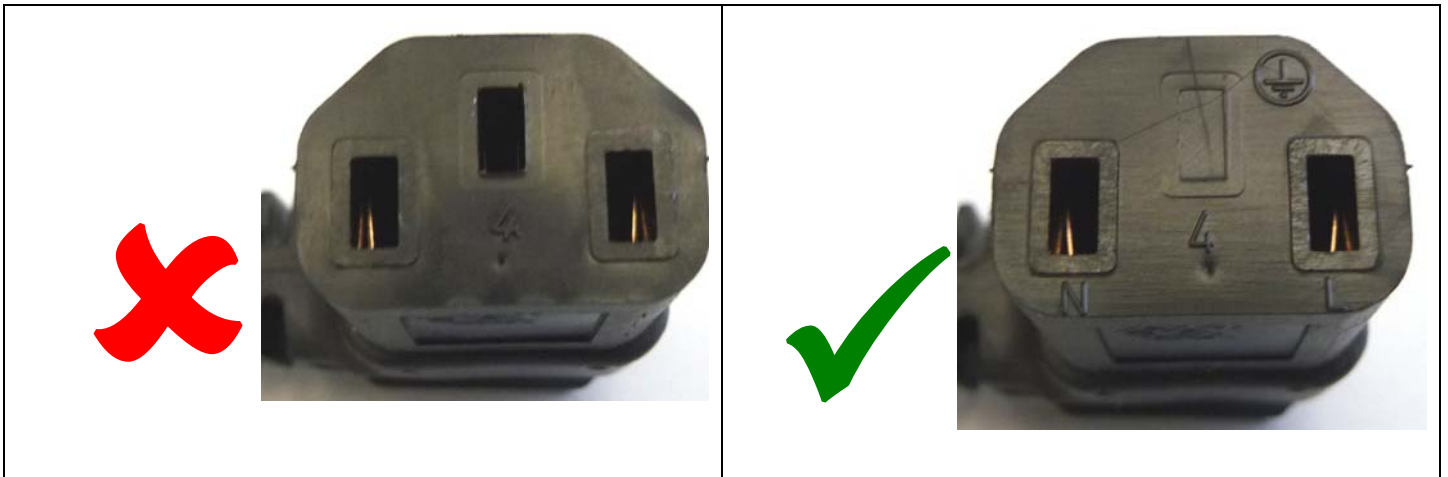
Mobile operating tables manufactured by Maquet – mains power lead.

Models Alphaclassic, Alphastar, Betastar and Alphamaxx series.



Problem	Action
<p>Some leads supplied with these tables have been incorrectly manufactured and have an opening for a protective earth pin, although there is no connection to the attached mains plug.</p> <p>Using the lead with another device or item of electrical equipment that requires a protective earth presents a risk of electric shock, should an electrical fault occur.</p>	<ul style="list-style-type: none"> Identify the power leads supplied with these operating tables. They have the Maquet logo on blue Velcro tape, a right-angled connector and a red mains plug. Check whether the lead has an earth opening (see photo on page 2). If so, remove the faulty lead from use. Do not discard faulty lead. Contact Maquet and return the faulty lead for a replacement.
Action by	
Operating theatre practitioners and technical staff responsible for maintenance.	
CAS deadlines	Contact
<p>Action underway: 07 February 2011</p> <p>Action complete: 24 March 2011</p>	<p>Manufacturer Maquet Ltd Tel: 0191 519 6200 Fax: 0191 519 6201 Email: cmoralee@maquet.co.uk</p>

Device



Problem

Using a faulty power lead with the Maquet Alphaclassic, Alphastar, Betastar and Alphamaxx series of operating tables is safe, as they have protective insulation (class II). However, using this lead with other electrical equipment that requires a protective earth rated lead (class I) is potentially unsafe, as the device would be operating without the required earth.

A small number of affected leads was supplied from November 2009 to September 2010 inclusive.

The manufacturer has issued a [Field Safety Notice](#). The MHRA has issued this MDA to ensure that all users are aware of the problem. After discussion with the manufacturer, they now advise that the faulty leads be returned to them, rather than being disposed of locally.

No related injuries or incidents have been reported to the MHRA or the manufacturer.

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Adult intensive care units
- Cardiac catheterisation suites
- Day surgery units
- EBME departments
- Endoscopy suites
- Health and safety managers
- High dependency units
- In-house maintenance staff
- Maintenance staff
- Maternity theatres
- Medical directors
- Medical physics departments
- Nursing executive directors
- Operating department practitioners
- Paediatric intensive care units
- Risk managers
- Special care baby units
- Theatre managers
- Theatre nurses
- Theatres
- X-ray departments

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Hospitals in the independent sector
- Independent treatment centres

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Contacts

Manufacturer

Colin Moralee
Maquet Ltd
14-15 Burford Way
Baldon Business Park
NE35 9PZ

Tel: 0191 519 6200

Fax: 0191 519 6201

Email: cmoralee@maquet.co.uk

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/009** or **2010/009/015/401/003**

Technical aspects

Andy Marsden or Ian Patterson-Waterston
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7205 / 7216

Fax: 020 8754 3965

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ian.patterson-waterston@mhra.gsi.gov.uk

Clinical aspects

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London SW1W 9SZ

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Email: jonathan.plumb@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>

Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate
Dundonald BT4 3SQ

Tel: 02890 523 704

Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk
<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>

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

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre

Health Facilities Scotland

NHS National Services Scotland

Gyle Square

1 South Gyle Crescent

Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: nss.irc@nhs.net

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes

Senior Medical Officer

Medical Device Alerts

Welsh Assembly Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk

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