

Medical Device Alert

Action

Ref: MDA/2009/078 Issued: 07 December 2009 at 14:00

Device

Intra-aortic balloon pump harness safety system supplied for use with the CS300 balloon pump.

Supplied by Datascope, now Maquet.

Problem	Action
<p>The harness was not designed to be used with the CS300 balloon pump and therefore does not adequately secure it during ambulance transportation.</p>	<ul style="list-style-type: none"> Identify harnesses. Do not use them with the CS300 intra-aortic balloon pump. Return harnesses supplied with the CS300 intra-aortic balloon pump to the manufacturer for a refund and information on alternatives.
Action by	
<p>All ambulance, medical, nursing and technical staff associated with the transportation of CS300 balloon pumps.</p>	
CAS deadlines	Contact
<p>Action underway: 21 December 2009 Action complete: 04 January 2010</p>	<p>Manufacturer Mr Colin Moralee Maquet Ltd Tel: 0191 519 6200 Fax: 0191 519 6201 E-mail: cmoralee@maquet.co.uk</p>

Device

The harness secures the intra-aortic balloon pump during ambulance transportation.

Problem

The harness was originally designed for the CS100 model intra-aortic balloon pump. However, it was incorrectly supplied with the new CS300 model, which has different dimensions to the older CS100 model balloon pump.

Maquet Ltd issued a customer notification letter ([Field Safety Notice](#)) about this problem. However, the MHRA has supported Maquet's action with this Medical Device Alert as it is not certain that the Field Safety Notice has reached all relevant customers.

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters)
- 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 all who need to know or be aware of it. This may include distribution by:

Trusts to:

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

- Adult intensive care units
- Ambulance services directors
- Ambulance staff
- Cardiology departments
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgery directors
- Clinical governance leads
- Clinical perfusion scientists
- Coronary care departments
- Intensive care units
- Intensive care, directors of
- Paediatric intensive care units
- Paramedics
- Patient transport managers
- Theatre managers
- Theatres

Care Quality Commission (CQC) (England only) to:

The MHRA considers this information to be important to:

- Hospitals in the independent sector
- Independent treatment centres

Contacts

Manufacturer

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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2009/078** or **2009/009/001/291/021**

Technical aspects

Claire Dunne or Douglas McIvor
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Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3162 / 3193

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Clinical aspects

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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 (NIAIC)

Health Estates

Estate Policy Directorate

Stoney Road

Dundonald

Belfast

BT16 1US

Tel: 02890 523 704

Fax: 02890 523 900

E-mail: 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

E-mail: 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 Jane Ludlow
Senior Medical Officer
Medical Device Alerts
Welsh Assembly Government
Cathays Park
Cardiff
CF10 3NQ

Tel: 029 2082 3505 / 3922

E-mail: Haz-Aic@wales.gsi.gov.uk