

Medical Device Alert

Ref: MDA/2013/020 Issued: 27 March 2013 at 15:30

Device

Acrobat Swing (AC Swing) arm. Manufactured by Ondal.

Supplied by various companies to support operating lights and monitors.

Delivered from 1999 to 2008 inclusive.

Problem	Action
<p>Risk of injury from detachment of the swing arm.</p> <p>After approximately seven years of use, the plastic spigot joint of the swing arm can fail through fatigue.</p> <p>Ondal issued a Field Safety Notice in December 2012 to the suppliers that use these swing arms. Users should have been informed of this by their respective equipment supplier.</p>	<p>Identify all Ondal swing arms fitted with a plastic spigot.</p> <p>Contact the supplier of the equipment to arrange for them to replace affected swing arms.</p> <p>Users are advised to move lights and monitors carefully until affected swing arms are replaced.</p>
<h3 data-bbox="113 1444 794 1507">Action by</h3> <p>Those responsible for the service and maintenance of these devices.</p>	
CAS deadlines	Contact
<p>Action underway: 12 April 2013</p> <p>Action complete: 08 May 2013</p> <p>Note: These deadlines are for systems to be in place to identify and arrange for replacement of affected swing arms.</p>	<p>Contact the company that supplied you with the swing arm.</p>

Device

Identifying affected devices

The Ondal AC Swing arm may be curved or straight.

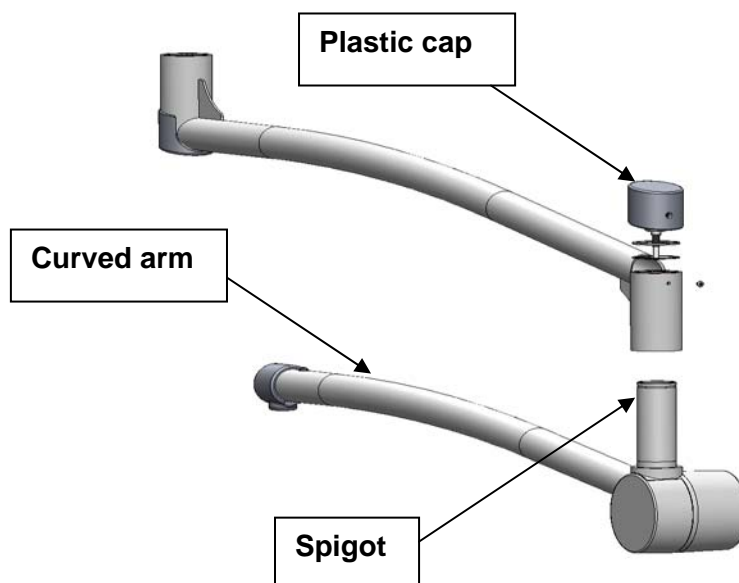
Curved arms will usually have a plastic spigot joint, which needs to be changed. Some may have a metal spigot joint, which is not affected.

Straight arms usually have a metal spigot joint, which is not affected. However, all straight arms should be checked to confirm that this is the case.

Suppliers may have added their name to the product and issued their own Field Safety Notices (FSN) on this issue. Advice includes removing the plastic cap on top of the spigot joint, held in place by a cross-head screw. If the spigot is plastic, contact the supplier of the equipment to arrange for them to replace the affected swing arm.

The affected Ondal AC Swing spring arms are widely used in the UK. Suppliers include (but are not limited to) the following:

Trumpf
Brandon
Draeger
Martin
Merivaara



Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- 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
- Cardiac care units
- Cardiac catheterisation suites
- Day surgery units
- Dentists
- EBME departments
- Endoscopy suites
- Estates departments
- Health and safety managers
- High dependency units
- In-house maintenance staff
- Maintenance staff
- Maternity theatres
- Medical directors
- Medical physics departments
- Nursing executive directors
- Paediatric intensive care units
- Risk managers
- Special care baby units
- Theatre managers
- Theatre nurses
- Theatres
- X-ray departments

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

The MHRA considers this information to be important to:

- Hospitals in the independent sector

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

Known suppliers are:

Trumpf Name: Alasdair Owen Telephone number: 01582 399 201
Brandon Name: Mandy Pearson Telephone number: 0113 272 8844
Draeger Name: Doug Sims Telephone number: 01442 292 868
Martin Name: Dr Ingo Haas Telephone number: 00 49 7463 838 185
Merivaara Name: Esko Hyvarinen Telephone number: 00 358 333 94 6186

Note: this is not an exhaustive list of suppliers.

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/020** or **2013/002/025/291/010**

Technical aspects

Andy Marsden or Ian Patterson-Waterston
Medicines & Healthcare products Regulatory Agency
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London SW1W 9SZ

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Clinical aspects

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London SW1W 9SZ

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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
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:

Improving Patient Safety Team
Medical Directorate
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

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

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