IRISH MEDICINES BOARD
SAFETY NOTICE

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Ondal Acrobat 2000 (AC2000)

IMB Safety Notice: SN2011(07)
Circulation Date: 12 May 2011

MANUFACTURER/SUPPLIER
Various manufacturers

TARGET GROUPS
General Surgeons
Theatre and Nursing Staff
Procurement Managers
Nursing Managers
Consultant General Surgeons
Hospital Managers / CEOs
Clinical Directors
Risk Managers
Medical Device Distributors
Clinical / Biomedical Engineers

ISSUE
Ondal has become aware that there is the risk that a welded seam at the pivot of the Acrobat 2000 spring-loaded arms could break. The Acrobat 2000 spring arm has been used by a number of different manufacturers to support operating lights and monitors which have been placed on the market in Ireland.

BACKGROUND
Ondal has confirmed that the affected spring arms were manufactured from January 2000 to June 2006. The affected serial numbers may be identified by the following convention:

0111 **010** XXXXX to 0111 **066** XXXXX

010 to **066** = month **01** / year 200**0** to month **06** / year 200**6**
XXXXX = 5-digit serial number

As outlined above, the Acrobat 2000 spring arm is used to support operating lights and monitors which have been placed on the market by various manufacturers. A number of manufacturers have initiated / completed field safety corrective actions in Ireland to address this issue. A listing of these manufacturers is provided below (please note that this is not an exhaustive list):

Trumpf Medizin Systeme –Manfred Fehn Ph: +49 3671 586 41211
Brandon Medical – Graeme Hall Ph: +44 113 277 7393
Maquet – Gerry O'Brien Ph: + 353 1 426 0032

SAFETY NOTICE

Drager – Doug Sims Ph: +44 1442 213542
Gebrüder MARTIN – Sven Zehnder Ph: + 49 7461 706 453

The Irish Medicines Board (IMB) wishes to highlight these actions and requests that users remain vigilant for potentially affected devices in their facility.

ACTION OR RECOMMENDATIONS
The IMB advises that users:

- Identify the affected spring arms in your facility and contact the appropriate manufacturer for further guidance.
- Follow the manufacturer's recommendations as outlined in the associated field safety notices.
- Users are advised to exercise caution when moving or repositioning devices connected to these spring arms pending upgrade / inspection by the manufacturer.

ENQUIRIES
All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

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Fax: +353-1-6344033
E-mail: vigilance@imb.ie
Website: www.imb.ie