


# Medical Device Alert

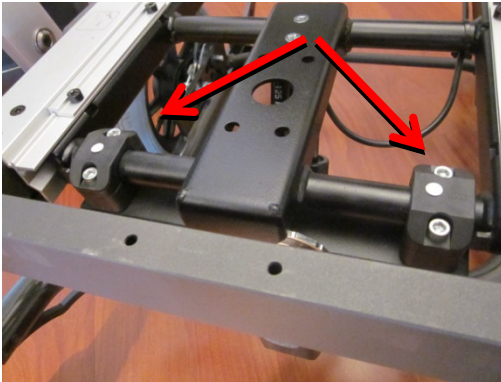
Ref: MDA/2013/049 Issued: 04 July 2013 at 12:00

Device
<p>Ibis Comfort wheelchair.</p> <p>Manufactured by Handicare B.V.</p> <p>Specific serial numbers of chairs manufactured from 29 January to 12 April 2013 inclusive.</p> 

Problem	Action
<p>Handicare has identified a quality issue with the tilt adjustment on Ibis Comfort wheelchairs.</p> <p>The upper hinge block component used in the tilt mechanism may break. This could cause the seat unit to tip backwards unexpectedly.</p> <p>There is a <a href="#">Field Safety Notice</a> for UK Customers.</p>	<ul style="list-style-type: none"> <li>• Identify all affected Ibis Comfort wheelchairs.</li> <li>• Contact Handicare or your dealership to arrange exchange of the tilt adjustment component (upper hinge blocks).</li> <li>• Dealers should contact Handicare for the instructions for changing the hinge blocks.</li> <li>• Dealers should inform Handicare when the component has been replaced.</li> </ul>
Action by	
<p>All those involved in the supply and maintenance of these wheelchairs. In particular: wheelchair service managers, rehabilitation engineers and maintenance staff.</p>	
CAS deadlines	Contact
<p>Action underway: 18 July 2013</p> <p>Action complete: 01 August 2013</p> <p><b>Note: These deadlines are for contacting the dealer to arrange replacement of the affected parts.</b></p>	<p><b>Supplier</b> Darren Legg Mobility Handicare Ltd Tel: 0845 0745 945 Fax: 0845 0745 946 Mobile: 07852 589 933 Email: <a href="mailto:Darren.legg@handicare.co.uk">Darren.legg@handicare.co.uk</a></p>

## Device

Photograph showing location of affected hinge block



Photograph showing old and new style hinge blocks.



## Distribution

This MDA has been sent to:

- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams for information
- NHS trusts in England (chief executives)
- Social services in England (directors)

### 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:

- Directors of nursing
- Equipment stores
- Maintenance staff
- Occupational therapists
- Physiotherapists
- Rehabilitation engineers
- Wheelchair service managers

### **Social services**

Liaison officers for onward distribution to all relevant staff including:

- Disability equipment stores
- Equipment stores
- Loan store managers
- Loaned equipment store managers
- Occupational therapists
- Wheelchair and seating service managers

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](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## **Contacts**

### **Manufacturer**

Handicare B.V.  
Vossenbeemd 104  
5705 CL Helmond  
The Netherlands  
Tel +31 (0) 492 593 888  
Fax +31 (0) 492 537 931  
Email: [Alex.vanVeen@handicare.com](mailto:Alex.vanVeen@handicare.com)

### **Supplier**

Darren Legg, National Sales Manager  
Handicare Ltd  
Mobility  
82 First Avenue  
Pensnett Estate  
Kingswinford  
West Midlands  
DY6 7FJ  
Tel: 0845 0745 945  
Fax: 0845 0745 946  
Mobile: 07852 589 933  
Email: [Darren.legg@handicare.co.uk](mailto:Darren.legg@handicare.co.uk)

## **England**

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/049** or **2013/004/019/291/005**

### **Technical aspects**

Elke Kerwick and Claire Dunne  
Medicines & Healthcare products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ  
Tel: 020 3080 6826 / 7162  
Fax: 020 8754 3965  
Email: [elke.kerwick@mhra.gsi.gov.uk](mailto:elke.kerwick@mhra.gsi.gov.uk)  
[claire.dunne@mhra.gsi.gov.uk](mailto:claire.dunne@mhra.gsi.gov.uk)

**Clinical aspects**

Jonathan Plumb  
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London SW1W 9SZ  
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Fax: 020 8754 3965  
Email: [jonathan.plumb@mhra.gsi.gov.uk](mailto: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](mailto: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  
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](mailto: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](mailto:Haz-Aic@wales.gsi.gov.uk)