

# Medical Device Alert

Ref: MDA/2011/103 Issued: 03 November 2011 at 11:00

## Device

Wheeled walking aid:  
Nimbo paediatric walkers.

Entire product range.

Manufactured by Drive Medical Ltd.



Problem	Action	
<p>The manufacturer has clarified that these devices are for <b>indoor</b> use only.</p> <p>The manufacturer issued a <a href="#">Field Safety Notice (FSN) for this device</a> (dated 06 September 2011), but has not had sufficient confirmation from users that they have received and acted on this information.</p> <p>A copy of the FSN is in the appendix of this alert, and it is also available on the MHRA website.</p> <p>This alert has been issued in support of the manufacturer's actions.</p>	<ul style="list-style-type: none"> <li>• Ensure that relevant members of staff are aware of the problem.</li> <li>• Carry out the actions described in the manufacturer's FSN, including sending any confirmation requests.</li> </ul>	
Action by		
<p>Persons responsible for purchase and maintenance of paediatric walking aids.</p> <p>Carers overseeing the use of these walking aids.</p>	<th data-bbox="799 1823 1477 1877">Contact</th>	Contact
CAS deadlines	<p><b>Manufacturer</b> Paul Kendall Drive Medical Ltd Tel: 01422 314488 Email: <a href="mailto:kendallp@drivemedical.co.uk">kendallp@drivemedical.co.uk</a></p>	
<p>Action underway: 05 December 2011</p> <p>Action complete: 03 January 2012</p>		

## 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)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- OFSTED (Directors of Children's Services) for information
- Primary care 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:

- Equipment stores
- Health and safety managers
- Occupational therapists
- Physiotherapists
- Purchasing managers
- Supplies managers

### Primary care trusts

CAS liaison officers for onward distribution to all relevant staff including:

- Equipment libraries and stores
- Maintenance staff
- Occupational health departments
- Occupational therapists
- Physiotherapists

### Social services

Liaison officers for onward distribution to all relevant staff including:

- Children's disability services
- Day centres (learning disabilities, mental health, physical disabilities, respite care, autistic services)
- Disability equipment stores
- Education departments for equipment held in schools
- Equipment stores
- Equipment supplies managers
- Loan store managers
- Loaned equipment store managers
- Occupational health departments
- Occupational therapists
- Schools

### Independent distribution

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

This alert should be read by:

- Further education colleges registered as care homes
- Hospices with beds for children
- Hospitals with beds for children in the independent sector

#### Establishments registered with OFSTED

This alert should be read by:

- Children's services
- Educational establishments with beds for children
- Residential special schools

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**

Paul Kendall  
Drive Medical Ltd  
Ainley's Industrial Estate  
Elland HX5 9JP

Tel: 01422 314488

Fax: 01422 314481

Email: [technical@drivemedical.co.uk](mailto:technical@drivemedical.co.uk)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/103** or **2010/010/023/401/001**

### **Technical aspects**

Sara Vincent or Emma Rooke  
Medicines & Healthcare products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ

Tel: 020 3080 7169 or 6609

Fax: 020 8754 3965

Email: [sara.vincent@mhra.gsi.gov.uk](mailto:sara.vincent@mhra.gsi.gov.uk)  
[emma.rooke@mhra.gsi.gov.uk](mailto:emma.rooke@mhra.gsi.gov.uk)

### **Clinical aspects**

Dr Nicola Lennard  
Medicines & Healthcare products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ

Tel: 020 3080 7126

Fax: 020 8754 3965

Email: [nicola.lennard@mhra.gsi.gov.uk](mailto:nicola.lennard@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

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](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:

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](mailto:Haz-Aic@wales.gsi.gov.uk)

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Addressees may take copies for distribution within their own organisations

Appendix

**Urgent Field Safety Notice**

Drive Medical Nimbo  
 FSCA 004  
 Type of action : Revised Pre-Sales Information



Date: 06 Sep 2011  
 Attention: Drive Medical Stockists and Issuers

**Details on affected devices:**  
 Nimbo Paediatric Walkers

**Description of the problem:**  
 Users are operating the Nimbo walkers over unsuitable outdoor environments which is reducing the lifespan of the wheels and fasteners. This may be the result of incorrect pre-sales information being issued to users stating that the Nimbo was suitable for Indoor and Outdoor Use.

**Advise on action to be taken by the user:**  
 Users and Issuers should use the Nimbo walkers for indoor use only. Please acknowledge this notice by completing and returning this form to Drive Medical. The stockist who supplied the Nimbo walker should forward this information to the Nimbo end user for them to complete.

For solutions requiring outdoor use, users should contact Drive Medical.

**Transmission of this Field Safety Notice:** (if appropriate)  
 Distributed to Drive Medical Stockists who have purchased the walkers.

**Contact reference person:**  
 Paul Kendall  
 Drive Medical Ltd,  
 Ainley's Industrial Estate,  
 Elland, West Yorkshire HX5 9JP.

The undersign confirms that this notice has been notified the appropriate Regulatory Agency

*P Kendall*

Please fill in the information below and return immediately to Drive Medical by:  
 Post: DRIVE MEDICAL LTD, Ainley's Industrial Estate, Elland, West Yorkshire HX5 9JP  
 Fax: 01422 314481  
 Email: [technical@drivemedical.co.uk](mailto:technical@drivemedical.co.uk)

We acknowledge receipt of the field safety notice

Name			
Address			
Town		Postcode	
Telephone			
Email			