

Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/056

Issued: 21st July 2008

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section								
<p>Medical Device/Equipment: Puma and Beatle battery powered wheelchairs manufactured by Movingpeople.net or Handicare.</p>	▶ ①								
<p>Problem: Some variants of the Puma and Beatle are too heavy for standard four point webbing tie-down systems for use in a vehicle.</p>	▶ ②								
<p>Action by: All those involved in the provision, prescription, use and transport of wheelchairs. In particular: wheelchair service managers, rehabilitation engineers, occupational therapists and patient transport service managers.</p>	▶ ③								
<p>Action:</p> <ul style="list-style-type: none"> Trace all Puma and Beatle battery powered wheelchairs manufactured by Movingpeople.net or Handicare. Advise users of these wheelchairs not to use the wheelchair as a seat in transport when secured using standard four point webbing tie-downs until such time as they can verify that it weighs less than 140kg. 	▶ ④								
<p>Distributed by NIAIC to:</p> <table border="0"> <tr> <td>Chief Executive of each HSS Board</td> <td>Education and Library Boards (for onward distribution to educational establishments that have facilities for wheelchair users)</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td></td> </tr> <tr> <td>Chief Executive of each Agency</td> <td></td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td></td> </tr> </table>	Chief Executive of each HSS Board	Education and Library Boards (for onward distribution to educational establishments that have facilities for wheelchair users)	Chief Executive of each HSS Trust		Chief Executive of each Agency		NIAIC Liaison Officers		▶ ⑤
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<p>Contacts Details of manufacturer and NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥								
<p>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</p>									
<table border="1"> <tr> <td>Acknowledge Receipt of Alert: 23rd July 2008</td> <td>Action Under Way: 21st August 2008</td> <td>Action Complete: 21st October 2008</td> </tr> </table>	Acknowledge Receipt of Alert: 23 rd July 2008	Action Under Way: 21 st August 2008	Action Complete: 21 st October 2008	▶ ⑦					
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This Alert is on our web site: <http://sabs.dhsspsni.gov.uk>

1. DEVICE/EQUIPMENT:

All Puma and Beatle battery powered wheelchairs manufactured by Movingpeople.net, now known as Handicare.

2. PROBLEM:

A basic Puma or Beatle battery powered wheelchair can be transported using a four point webbing tie-down rated for a 140 kg wheelchair. However, some wheelchairs have additional features such as seat risers, tilt-in-space functions and powered elevating leg rests etc. Therefore, some variants of the Puma and Beatle battery powered wheelchairs weigh in excess of 140kg and are too heavy for the standard four point webbing tie-down system available for use in a vehicle. Guidance on how to verify the weight of the unoccupied wheelchair can also be found in the Field Safety Notice (see appendix). If a vehicle is involved in an impact there is a risk that the tie-down will fail, potentially leading to injury of the wheelchair user and others.

The manufacturer has been unable to recommend a tie-down system for wheelchairs weighing over 140 kg and has issued a Field Safety Notice (see appendix) recommending that they are not used as a seat in transport.

3. ACTION BY:

All those involved in the provision, prescription, use and transport of wheelchairs. In particular: wheelchair service managers, rehabilitation engineers, occupational therapists and patient transport service managers.

4. ACTION:

- Trace all Puma and Beatle battery powered wheelchairs manufactured by Movingpeople.net or Handicare.
- Advise users of these wheelchairs not to use the wheelchair as a seat in transport when secured using standard four point webbing tie-downs until such time as they can verify that it weighs less than 140kg.

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Ambulance services directors
- Equipment stores
- Health and safety managers
- Occupational therapists
- Patient transport managers
- Physiotherapists
- Rehabilitation engineers
- Risk managers
- Wheelchair service managers
- Independent Health and Social Care Providers – Private Hospitals and Clinics, through RQIA

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Customer Services Dept
Handicare Ltd
68 High street
Weybridge
Surrey KT13 8BL

Tel: 01932 827 222

Fax: 01932 855 599

E-mail: info@handicare.co.uk

Enquiries to NIAIC should quote reference number MDEA(NI)2008/056 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

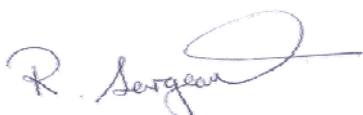
7. FEEDBACK:

Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

Acknowledge Receipt of Alert:
23rd July 2008

Action Under Way:
21st August 2008

Action Complete:
21st October 2008



Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2007/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety

APPENDIX to MDEA(NI)2008/056



Field Safety Notice

Beatle/Puma – Restraint system for transportation

Date: June 12th 2008

Type of action: Advise of manufacturer

Attention: All Beatle/Puma power wheelchair dealers and users

Handicare B.V.
Vossenbeemd 104
5705 CL Helmond
The Netherlands

T +31 (0)492 593 888
F +31 (0)492 537 931
info@handicare.com
www.handicare.com

Details of the affected devices:

Beatle/Puma power wheelchairs weighing over 140 kgs / 308 Lbs.

Description of the problem:

Handicare has been notified that the restraint systems for transportation that are in use, are not suitable for wheelchairs over 140 kgs / 308 Lbs.

The wheelchair needs to be secured by using a tie down system with a maximum weight suitable for your wheelchair. This means that the Beatle/Puma wheelchairs in some configurations (see table) cannot be restrained in a safe way with the usual four point webbing tie down systems (restraint systems).

Handicare is looking for a suitable system. In the meantime, we strongly recommend to NOT transport the Puma/Beatle wheelchairs, if you have not verified the actual weight. The user manual is currently being revised and will be available shortly. A further FSN will be issued once the revised user manual is available.

The potential risk of using the usual tie down system with these heavy wheelchairs is that the chair could break loose from the restraint system, which could lead to injury to the user or other vehicle occupants.

	Beatle	Puma
Total weight		
Basic configuration without batteries	73kg (160.9Lbs)	74,4kg (164Lbs)
Batteries (per two)		
40Ah	+29,2kg (64.4l.)	
56Ah		+43,6kg (96.1l.)
73Ah		+47,2kg (104.1l.)
Wheels (per two)		
Puncture proof drive	+2,4kg (5.3l.)	+3,8kg (8.38l.)
Puncture proof castors	+0,8kg (1.76l.)	+2,8kg (6.17l.)
Suspended castor forks		+2,5kg (5.5l.)
Electrical options		
Elec. High/Low		+23kg (50.7l.)
Elec. Tilt in space		+24kg (52.9l.)
Elec. Legrests (per two)		+4kg (8.8l.)
Worktop		+2,6kg (5.7l.)

Advice on action to be taken by the user:

Verify the total weight of your wheelchair. This can be done by weighing the chair (without the user) or using the weights in the table to calculate it from your wheelchair configuration. If the total weight of your wheelchair exceeds the safe weight of 140 kgs / 308 Lbs, do not transport it with the usual four point webbing tie down system.

Advice on action to be taken by the dealer:

- Please provide this information to your Beatle/Puma power wheelchair users.

This Field Safety Notice will be posted on our company website and sent to the Competent Authorities of all countries affected.

If you have any queries, please contact Handicare's Customer Service department on telephone number 01932 827 222 or via e-mail info@handicare.co.uk.

Kind regards,
Handicare

Alex van Veen
Customer Service Manager

