

Medical Device Alert

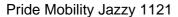
Action

Ref: MDA/2009/010 Issued: 16 February 2009 at 10:30

Device

All models of Jazzy, Quantum and LX battery powered wheelchairs manufactured by Pride Mobility Ltd.







Pride Quantum 600



Pride LX

Problem

On some models of Jazzy, Quantum and LX powered wheelchairs the manufacturer has fitted tiedown securement brackets (known as the Transit Securement Package – TSP) before delivery and has now issued updated instructions for use.

Action by

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

CAS deadlines

Action underway: 16 March 2009 Action complete: 14 May 2009

Action

- Trace all models of Jazzy, Quantum and LX powered wheelchairs manufactured by Pride Mobility.
- 2. Ascertain if the wheelchair has a Transit Securement Package (TSP) fitted (See Appendix I).
- 3. If the wheelchair has a TSP fitted, obtain new instructions for use from Pride Mobility at www.pridemobility.com and ensure that the user is aware of the revised content. Also, remove any labels from the wheelchairs which state that the user 'should not remain seated in the mobility device while travelling in a motor vehicle'.

Contact

Manufacturer

Mr Craig Sweetlove Pride Mobility Ltd

Tel: 01869 324 600 Fax: 01869 323 070

E-mail: craig@pride-mobility.co.uk

http://www.mhra.gov.uk

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Problem

The instructions for use (IFU) issued with all Pride Mobility powered wheelchairs state that they are not intended to be used as a seat in a motor vehicle, although some models were fitted with tiedown securement brackets. These brackets are known as the Transit Securement Package (TSP) (see Appendix I for examples of TSP) and are only available factory-fitted by Pride Mobility. With this package fitted, the wheelchair can be used as a seat in a motor vehicle, provided that an appropriate wheelchair tiedown and occupant restraint system (WTORS) is used. Pride Mobility did not make this clear in the IFU provided with wheelchairs fitted with a TSP. Also, Pride Mobility, following fitment of the TSP, have not always removed the labels which state that the user 'should not remain seated in the mobility device while travelling in a motor vehicle'.

Some Jazzy and Quantum models also have small metal loops fitted to the seat unit, which do not form part of a TSP and are not intended to be used for tying down an occupied wheelchair in a motor vehicle. These points are only intended for securing an unoccupied wheelchair.

Pride Mobility has issued several Field Safety Notices on these subjects, but they do not contain sufficient detail to cover all issues.

Pride Mobility has now produced revised IFU for all models with a TSP fitted, but has not been able to trace all users. In addition, Pride Mobility has now produced a powerchair transportation compatibility chart (see Appendix 2). This shows the models of wheelchair which, when fitted with a TSP by Pride Mobility and used in conjunction with an appropriate WTORS, are intended to be used as a seat in a motor vehicle and those that are not.

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- Commission for Social Care Inspection (CSCI) (Headquarters)
- Healthcare Commission (CHAI) (Headquarters)
- NHS Boards in Scotland (Chief Executives)
- OFSTED (Directors of Children's Services)
- Primary care trusts in England (Chief Executives)
- Social services in England (Directors)

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 liaison officers for onward distribution to all relevant staff including:

- Ambulance services directors
- Equipment store managers
- Health and safety managers
- · Maintenance staff and contractors
- Occupational therapists
- Patient transport managers
- Physiotherapists
- Rehabilitation engineers
- Risk managers
- Wheelchair service managers

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Distribution (continued)

Commission for Social Care Inspection (CSCI) to:

Headquarters for onward distribution to:

- Care homes providing nursing care (adults)
- · Care homes providing personal care (adults)
- · FECs registered as care homes

Healthcare Commission (CHAI) to:

Headquarters for onward distribution to:

- Hospices
- · Hospitals in the independent sector

OFSTED to:

Directors of children's services for onward distribution to:

- · Children's services
- · Residential special schools

Primary care trusts to:

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

- · Community hospitals
- Equipment stores managers
- Maintenance staff and contractors
- · Occupational therapists
- · Patient transport managers
- Physiotherapists
- · Rehabilitation engineers
- · Risk managers
- Wheelchair service managers

Social services to:

Liaison officers for onward distribution to all relevant staff including:

- · Day centres
- · Equipment store managers
- · Maintenance staff and contractors
- · Occupational therapists
- Risk managers
- Transport managers
- Wheelchair service managers

Change of address or removal from address list for CSCI and Healthcare Commission:

CSCI Customer Service Unit

St Nicholas Building

St Nicholas Street

Newcastle-upon-Tyne NE1 1NB

Tel: 0845 015 0120

E-mail: enquiries@csci.gsi.gov.uk

Healthcare Commission

Finsbury Tower

103-105 Bunhill Row

London EC1Y 8TG

Tel: 020 7448 0842

E-mail: contacts@healthcarecommission.org.uk

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Contacts

Manufacturer

Mr Craig Sweetlove Pride Mobility Products Ltd 32 Wedgewood Road Bicester OX26 4UL

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E-mail: craig@pride-mobility.co.uk

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number MDA/2009/010 or 2008/004/024/401/003.

Brian Mather or Jonathan Smith Medicines & Healthcare products Regulatory Agency Centre for Assistive Technology 241 Bristol Avenue Bispham Blackpool FY2 0BR

Tel: 01253 596 000 Fax: 01253 596 177

E-mail: brian.mather@mhra.gsi.gov.uk jonathan.smith@mhra.gsi.gov.uk

Northern Ireland

Enquiries in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)

Health Estates

Estate Policy Directorate

Stoney Road Dundonald

Belfast BT16 1US

Tel: 02890 523 704 Fax: 02890 523 900

E-mail: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

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

E-mail: iric@shs.csa.scot.nhs.uk

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:

National Assembly for Wales HIMTE 3 Division NHS Directorate Cathays Park Cardiff CF10 3NQ

Tel: 029 2082 3373 Fax: 029 2082 5479

E-mail: Haz-Aic@wales.gsi.gov.uk

How to report adverse incidents

Please report via our website http://www.mhra.gov.uk

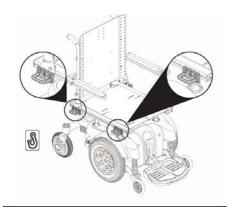
Further information about CAS can be found at https://www.cas.dh.gov.uk/Home.aspx

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Appendix to MDA/2009/010

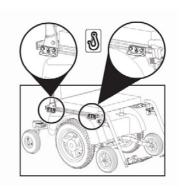
Appendix I – Examples of Transit Securement Packages (TSP)



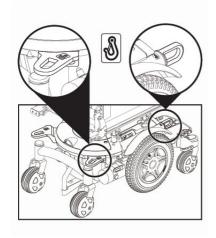
Jazzy 1121 with Synergy Seat



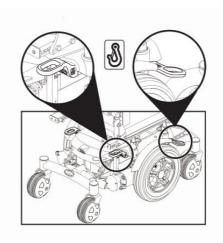
Jazzy 1121 with Modular Seat



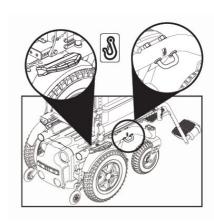
Quantum 1420 with Synergy Seat



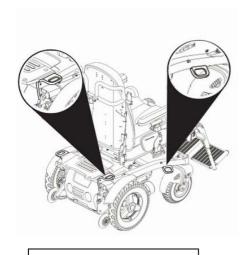
Quantum 600



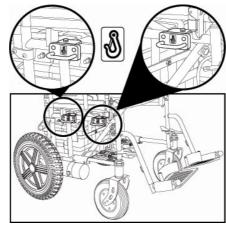
Quantum 6000 / 600 Sport



Quantum R4000



Quantum R400



LX

Appendix to MDA/2009/010

Appendix 2 - Powerchair transportation compatibility chart

COMPATIBILITY CHA		AIR TRANSPORTA	rion						
	Economy Seat	Euro Seat	Euro Power	Modular Seat	Synergy Seat	Tru Comfort	Synergy Power	Vogue Seating	Vogue Power
Jazzy Range	T .		Options		T T		Options	ı	Options
Jazzy Select									
Jazzy Select 6									
Jazzy 610									
Jazzy 1103 Ultra				When fitted with TSP	When fitted with TSP	When fitted with TSP			
Jazzy 1107									
Jazzy 1121		When fitted with TSP							
Quantum 6 Range									
Quantum 810				When fitted with TSP	When fitted with TSP	When fittled with TSP			
Quantum 800		When fitted with TSP							
Quantum 800 Sport		When fitted with TSP	When fitted with TSP		When fitted with TSP	When fitted with TSP			
Quantum 8000		When fitted with TSP							
Heavy Duty Range									
rivery way rivings									
Guantum 1420		When fitted with TSP							
Quantum 1860									
Rear Wheel Range									
LX	When fitted with TSP	•				•			
Quantum R400					When fitted with TSP	When fitted with TSP		When fitted with TSP	When fitted with TSP
Quantum R4000					When fitted with TSP	When fitted with TSP		When fitted with TSP	When fitted with TSP

Key:

When fitted with TSP	When a Transit Securement Package has been factory-fitted by Pride Mobility before delivery, the wheelchair can be used as a seat in a motor vehicle providing the instructions for use for the wheelchair tiedown and occupant restraint system (WTORS) are followed. Note 1: Without a TSP they are not intended to be used as a seat in a motor vehicle and these wheelchairs should be clearly labelled as such. Note 2: Small metal loops on Jazzy and Quantum seat units are not part of a TSP.				
Blank Space	Models not intended by Pride Mobility to be used as a seat in a motor vehicle as no TSP option is available. These wheelchairs should have a label which states that that the user 'should not remain seated in the mobility device while travelling in a motor vehicle'.				

If you are unsure of the suitability of your powerchair please contact Pride Mobility on 01869 324600.