

Medical Device Alert

Ref: MDA/2013/057 Issued: 25 July 2013 at 15:00

Device
<p>Spectra series powered wheelchairs Manufactured by Invacare</p> <p>Fitted with the Pilot+ digital wheelchair control system supplied by PG Drives Technology</p>

Problem	Action
<p>Potential for wheelchair components to overheat in the event of a stall condition.</p> <p>This can occur when the control system is programmed with parameters different to those recommended by Invacare.</p> <p>The manufacturer issued a Field Safety Notice (FSN), dated 14 May 2013, but has not had confirmation from a significant number of customers that they have received and acted upon this information.</p>	<p>Ensure that those responsible for maintenance of these devices:</p> <ul style="list-style-type: none"> • identify affected devices • assess and verify that the foldback parameters of the control system are correct as instructed in the FSN • inform Invacare that the FSN has been received and the required action completed.
Action by	
<p>All those involved in the maintenance of these wheelchairs. In particular: wheelchair service managers, rehabilitation engineers and maintenance staff.</p>	
CAS deadlines	Contact
<p>Action underway: 27 August 2013</p> <p>Action complete: 25 October 2013</p> <p>Note: These deadlines are for arrangements to be made for checks to be carried out and parameters changed as required.</p>	<p>Manufacturer Invacare, Technical Services Department Tel: 0165 677 6333 Email: serviceuk@invacare.com</p> <p>PG Drives Technology (Curtis-Wright Controls Industry): John Hayward Tel: 0142 527 1444 Email: JHayward@curtisswright.com</p>

Problem

In a stall condition, where the user is powering the wheelchair forwards or backwards and the wheelchair is prevented from doing so by an obstacle or rough terrain, there is potential for the wheelchair to overheat. Where third parties have replaced (or amended the software parameters for) the joysticks or control modules and set the foldback parameters incorrectly, the chances of an overheat condition are increased.

Action

The foldback parameters can be verified and adjusted using the current issue of the Dealer Level PC Programmer software from PG Drives Technology (Software Version – 11.3.0). The latest version of the programmer software is available to download from <http://www.pgdt.com/Library/Manuals-Software.aspx>.

Contact Invacare for the correct original equipment manufacturer level programming file, and if required, for assistance obtaining the Programmer handheld device.

The PG Pilot+ digital wheelchair control system should be set with the following Invacare defined foldback parameters:

- Current foldback time (seconds) - 15 seconds
- Current foldback level (%) - 25%

PG Drives Technology have provided additional guidance for verifying and adjusting the foldback parameters:

1. Using the Dealer Level PC Programmer (Software Revision 11.3.0) extract the current programming file from the Pilot+ control system using 'Controller/read from controller' in the toolbar and save it against the client's name. This will preserve all the client specific changes that may have been made to speeds, accelerations or perhaps joystick-throw.
2. Using the same Dealer Level PC Programmer open the OEM level programming file required for the chair, as provided by Invacare. This will contain the recommended current fold-back parameters for the chair.
3. Click on the 'Program' shortcut on the programmer or select 'Controller/Write to controller' from the tool bar to update the programming file.
4. Still using the same Dealer Level PC Programmer, once the Invacare file has been successfully uploaded to the controller, reopen the saved client file from step 1 and reprogramme the controller with these settings. This will overwrite just the dealer level parameters to ensure the chair will behave in the same way for the client as prior to the corrective action whilst the current fold-back parameters will remain as per the Invacare corrective action.

Distribution

This MDA has been sent to

- Clinical commissioning groups (CCGs)
- Health and Safety Executive
- 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:

- Equipment libraries and stores
- Equipment stores
- Health and safety managers
- In-house maintenance staff
- Maintenance staff
- Occupational health departments
- Occupational therapists
- Physiotherapists
- Rehabilitation engineers
- Wheelchair service managers

Social services

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Children's disability services
- Community care staff
- Day centres (older people, 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
- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes
- Loan store managers
- Loaned equipment store managers
- Occupational health departments
- Occupational therapists
- Wheelchair and seating service managers

Independent distribution

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

This alert should be read by:

- Care homes providing personal care (adults)
- Further education colleges registered as care homes
- Hospices

Establishments registered with OFSTED

This alert should be read by:

- 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 and requesting this facility.

Contacts

Manufacturer

Invacare:

Technical Services Department, Invacare Ltd, Pencoed Technology Park, Pencoed, Bridgend, CF35 5AQ

Tel: 0165 677 6333

Fax: 0165 677 6330

Email: serviceuk@invacare.com

PG Drives Technology (Curtis-Wright Controls Industry):

John Hayward

Sales Manager - Mobility Products Europe, PG Drives Technology

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Fax: 0142 527 2655

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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/057** or **2012/009/004/401/015**

Technical aspects

Emma Rooke and Ian Sealey

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Clinical aspects

Jonathan Plumb

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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

<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

<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

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