

Medical Device Alert

Ref: MDA/2011/106 Issued: 09 November 2011 at 14:00

Device

Bathlift: Endres Riviera

Manufactured by Drive Medical Ltd.

All serial numbers are affected.



Problem

Risk of failure due to component fatigue.

The user instructions have been revised to include an estimated life expectancy for the device (page 20), improved guidance regarding frequency of required maintenance and a clarification of who is responsible for this (page 13).

The manufacturer issued a [Field Safety Notice \(FSN\)](#) – dated 09 August 2011 - for this device but has not had confirmation from a significant number of users that they have received and acted on this information.

A copy of the FSN is in the appendix of this alert, and it is also available on the MHRA website.

This alert has been issued in support of the manufacturer's actions.

Action

- Ensure that relevant members of staff are aware of the problem.
- Carry out the actions described in the manufacturer's FSN, including sending confirmation requests.

Action by

All those involved in the supply, maintenance, and use of these bath lifts. In particular: equipment store managers, nursing and care home managers, occupational therapists, care staff, maintenance staff and contractors.

CAS deadlines

Action underway: 09 December 2011

Action complete: 09 February 2012

Contact

Manufacturer

Paul Kendall
Drive Medical Ltd.

Tel: 0142 231 4488

Fax: 0142 231 4481

Email: technical@drivemedical.co.uk

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)
- 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 store managers
- In-house maintenance staff
- Maintenance staff and contractors
- Occupational health departments
- Occupational therapists
- Physiotherapists
- Purchasing managers
- Rehabilitation engineers
- Risk 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:

- Community care staff
- Disability equipment stores
- 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
- Moving and handling co-ordinators
- Occupational health departments
- Occupational therapists

Independent distribution

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

This alert should be read by:

- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Domiciliary care providers
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies

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

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

Tel: 0142 231 4488
Fax: 0142 231 4481
Email: technical@drivemedical.co.uk

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/106** or **2010/008/009/401/001**

Technical aspects

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

Tel: 020 3080 6609 / 7169
Fax: 020 8754 3965
Email: emma.rooke@mhra.gsi.gov.uk
sara.vincent@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

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
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

<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

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Addressees may take copies for distribution within their own organisations

Appendix

Urgent Field Safety Notice

Endres Riviera Bathlift
FSCA 09-08-2011
Type of action : Revised Instructions



Date: 09 Aug 2011

Attention: Drive Medical Stockists and Endres Community Supply

Details on affected devices:
Riviera Bathlift (all models)

Description of the problem:
The user instructions have been revised to include an estimated service life and improved servicing direction.

Advise on action to be taken by the user:
The user or stockist should download the revised IFU from www.drivemedical.co.uk/endres/riviera.pdf or contact Drive Medical for a paper copy. The details below should be completed and returned to Drive Medical. The stockist should forward this FSN to any end users who they have supplied with Riviera bathlifts.

Transmission of this Field Safety Notice: (if appropriate)

Distributed to Drive Medical Stockists and Issuers who have sold the bathlifts.

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

- We acknowledge receipt of the field safety notice and have downloaded the revised IFU
- We acknowledge receipt of the field safety notice and require a paper copy of the IFU sending

Name			
Address			
Town		Postcode	
Telephone			
Email			