

Medical Device Alert

Immediate action

Ref: MDA/2011/032 Issued: 05 April 2011 at 14:00

Device

Airtraq single-use optical laryngoscope manufactured by DragonHeart Medical Co Ltd. Supplied by Fannin UK.

Specific models and lot numbers affected.



Problem

Due to battery failure the laryngoscope's optical display may fail to work.

The manufacturer is conducting a recall of specific lots.

The MHRA is issuing this alert as there has been a poor response from users to recall notifications.

Action

- Identify affected devices and lot numbers indicated on the [Field Safety Notice \(click here\)](#) issued by Prodol, the manufacturer's European representative.
- Quarantine all affected devices and arrange for their return to the supplier – Fannin.
- Ensure that the acknowledgment fax-back form is returned to Fannin.

Action by

All healthcare workers who use these devices. Personnel involved in the purchase, supply and distribution of these devices.

CAS deadlines

Action underway: 12 April 2011

Action complete: 19 April 2011

Contact

Supplier:
 Fannin UK (excl Northern Ireland)
 Tel: 0118 9305333
 Email: enquiries@fanninuk.com
 Fannin Northern Ireland
 Tel: +48 90 735588
 Email: ni.orders@fanninni.com

Device

This device is designed to provide a view of the vocal cords to assist with laryngeal intubation in difficult airway cases. It is intended for use with adult and paediatric patients.

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 (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)

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:

- Accident and emergency departments
- Anaesthetists
- Clinical governance leads
- Health and safety managers
- Intensive care units
- Operating department practitioners
- Paediatric intensive care units
- Paramedics
- Purchasing managers
- Resuscitation officers and trainers
- Risk managers
- Special care baby units
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

Independent distribution

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

This alert should be read by:

- Hospitals in the independent sector

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

Supplier

Fannin UK (excl Northern Ireland)
Customer Services Department
Fannin (UK) Limited
42-46 Booth Drive
Park Farm South
Wellingborough
Northamptonshire NN8 6GT

Freephone: 0800 212827
Tel: 0118 9305333
Fax: 0118 9305111
Email: enquiries@fanninuk.com

Fannin Northern Ireland
FAO Stephen Mc Daniel
Fannin (NI) Limited
Unit 2 Heron View
Airport Road West
Belfast BT3 9LN
Northern Ireland

Tel.: +48 90 735588
Fax: +48 90 735599
Email: ni.orders@fanninni.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/032** or **2010/005/013/401/007**

Technical aspects

Douglas McIvor and Louise Mulroy
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7193 or 7344
Fax: 020 8754 3965
Email: douglas.mcivor@mhra.gsi.gov.uk
louise.mulroy@mhra.gsi.gov.uk

Clinical aspects

Tom Clutton-Brock
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7056
Fax: 020 8754 3965
Email: tom.clutton-brock@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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