

Medical Device Alert

Ref: MDA/2011/078 Issued: 07/07/2011 at 15:30

Device

28% air entrainment (white Venturi) jet adapter for use with oxygen facemasks.

Manufactured by Meditech Systems Ltd.

Supplied by various distributors.

Specific lot numbers are affected.



Problem

Risk of inadequate oxygen supply.

All devices manufactured from July 2009 to April 2010 inclusive are being recalled due to an intermittent fault in the moulding process which may result in occlusion of the jet.

Action by

Healthcare professionals using these devices.

CAS deadlines

Action underway: 21 July 2011

Action complete: 04 August 2011

Action

- Do not use affected devices, as advised in the [Field Safety Notice](#) dated 08 April 2011.
- Return the 'Recall Questionnaire for end users' to your distributor.
- Return any affected devices to your distributor.

Contact

Manufacturer

Roland Merry
Meditech Systems Ltd.

Tel: 01258 471 770

Fax: 01258 471 772

Email: roland@electrosurgery.co.uk

Device

The affected 28% air entrainment (Venturi) jets are supplied with adult facemasks or as stand alone units. Affected lot numbers are given below:

Adult Mask + 28% Venturi jet, REF number 1083/28.

2908086-1	2909039-4	2910014-1	2901004-5	2910076-5	2911031-1
3010055-5	3020026-1	3020140-4	30202734	3020338-1	3020414-4
3020449-2	3020496-1	3020495-3	3020534-1	3020566-4	30206992
3020718-2	30207633	30209981	3080010-6	3080093-3	3090053-3
3090150-5	3100030-2	3100142-3	310019-2	3120076-1	3120124-2
3120270-4					

Adult Oxygen Mask + 28% venturi jet + tubing, Ref number 1083/28T

2906064	2910151-2	2911015-2	2912055-2	3002026-7	3020372-3
3100030-6	3100041-2	31001003	3100134-3	3120124-7	

28% Venturi Jet (White), REF number 1003MMU

Product code	Pack size	Qty	Product lot
1003MMU	50	260	2904051
1003MMU	50	93	2908137-1
1003MMU	50	27	2909132
1003MMU	50	158	3010045-2
1003MMU	50	42	3010091-1
1003MMU	50	60	3120183-4

Problem

As the manufacturer/distributors have received few responses to the Field Safety Notices, the MHRA has decided to issue this alert to raise awareness of the recall of affected devices.

The FSN requested that affected devices were returned for credit by the 8th May 2011, this date has been extended.

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)
- Local authorities 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:

- A&E departments
- Adult intensive care units
- All clinical departments
- All wards
- Ambulance staff
- Anaesthetists
- Day surgery units
- Intensive care units
- Medical directors
- Nursing executive directors
- Resuscitation officers and trainers
- Theatres

Primary care trusts

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

- Community hospitals
- Community pharmacists
- Minor injury units
- NHS walk-in centres
- Walk-in centres

Independent distribution

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

This alert should be read by:

- Hospices
- Hospitals in the independent sector
- Independent treatment centres

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

Roland Merry
Meditech Systems Ltd
Unit 3 Richmar
Butts Pond Industrial Estate
Sturminster Newton
Dorset
DT10 1AZ

Tel: 01258 471 770

Fax: 01258 471 772

Email: roland@electrosurgery.co.uk

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/0078** or **2011/002/025/401/002**

Technical aspects

Douglas McIvor or Andy Marsden
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7193 / 7205

Fax: 020 8754 3965

Email: douglas.mcivor@mhra.gsi.gov.uk
andy.marsden@mhra.gsi.gov.uk

Clinical aspects

Jonathan Plumb
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7128

Fax: 020 8754 3965

Email: jonathan.plumb@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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