

Medical Device Alert

Ref: MDA/2012/037 Issued: 28 June 2012 at 14:00

Device

Reusable transoesophageal echocardiography, transvaginal and transrectal ultrasound probes (transducers).

All models.

All manufacturers.

Problem

The MHRA is aware of an incident where the death of a patient from hepatitis B infection may have been associated with a failure to appropriately decontaminate a transoesophageal echocardiography probe between each patient use.

The MHRA is issuing this alert to advise users to appropriately decontaminate all types of reusable ultrasound probes.

Action by

Trust decontamination leads.

Healthcare professionals using these devices and staff responsible for reprocessing medical devices.

CAS deadlines

Action underway: 11 July 2012

Action complete: 19 July 2012

Note: These deadlines are for systems to be in place to ensure the actions are undertaken.

Action

Review, and if necessary update, local procedures for all ultrasound probes that are used within body cavities to ensure that they are decontaminated appropriately between each patient use, in accordance with the manufacturer's instructions.

Ensure that staff who decontaminate medical devices are appropriately trained and fully aware of their responsibilities.

Be aware of the MHRA's guidance document 'Managing Medical Devices' (available from our website www.mhra.gov.uk).

Be aware of the Department of Health's publications (England only): Choice Framework for local Policy and Procedures 01-06 – Decontamination of flexible endoscopes: Operational management manual 13536:1.0. Available from Space for Health, sign-in required: <http://www.spaceforhealth.nhs.uk/England/topics/choice-framework-local-policy-and-protocols-01-06-%E2%80%93-decontamination-flexible-endoscopes>

Also be aware of similar advice as/when published by the devolved administrations.

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:

- Adult intensive care units
- All wards
- Anaesthetists
- Coronary care departments
- A&E departments
- A&E departments
- Cardiologists
- Clinical governance leads
- Colposcopy departments
- Day surgery units
- Decontamination leads
- Directors of infection prevention and control
- Endoscope reprocessing units
- Endoscopy units
- Gastroenterology departments
- General surgery
- Gynaecology departments
- Gynaecology nurses
- Health and safety managers
- Infection control departments
- Infection control nurses
- Infection prevention and control directors
- Intensive care nursing staff (adult)
- Intensive care units
- Microbiologists
- Outpatients
- Radiographers
- Radiologists
- Radiology departments
- Risk managers
- Sonographers
- Sterile services departments
- Theatres
- Ultrasound departments
- Urologists

Primary care trusts

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

- Community hospitals
- Infection control teams

Independent distribution

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

This alert should be read by:

- 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.

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2012/037** or **2011/007/026/081/015**

Technical aspects

John McManus or Sharon Knight
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7226 or 020 3080 7202

Fax: 020 8754 3965

Email: john.mcmanus@mhra.gsi.gov.uk
sharon.knight@mhra.gsi.gov.uk

Clinical aspects

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

Important note: For decontamination advice in Scotland, contact:

HFS Decontamination Team

Email: nss.hfsdeconteam@nhs.net

Tel: 0141 207 1857

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:

Improving Patient Safety Team

Medical Directorate

Welsh Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk

MHRA is an executive agency of the Department of Health

© Crown Copyright 2012

Addressees may take copies for distribution within their own organisations