

Medical Device Alert

Action update

Ref: MDA/2010/001 Issued: 04 January 2010 at 11:00

Device

Medical devices in general and non-medical products.

| Problem | Action |
|---|---|
| <ul style="list-style-type: none"> Off-label use of medical devices. User modifications of devices other than directed by the device manufacturer. Use of products, other than those that are CE-marked as medical devices, for clinical purposes. | <p>Ensure users are aware of the risks associated with and, where possible, avoid:</p> <ul style="list-style-type: none"> the off-label use of medical devices the modification of medical devices (unless such modifications are sanctioned in the manufacturer's instructions for use) the use of products other than those CE-marked as medical devices in clinical settings, particularly when CE-marked medical devices that are specifically designed and manufactured to be used for that clinical purpose are available. |
| <h3 data-bbox="124 1238 304 1283">Action by</h3> <p>All staff involved in the use of medical devices.</p> | |
| CAS deadlines | Contact |
| <p>Action underway: 05 March 2010 Action complete: 05 May 2010</p> | <p>Adverse Incident Centre Medicines & Healthcare products Regulatory Agency Tel: 020 7084 3080 E-mail: aic@mhra.gsi.gov.uk</p> |

Problem

The Medical Devices Regulations (that implement the relative Directive) stipulate that the manufacturer of a device is responsible for establishing that the device is safe and that it is suitable for its intended purpose. To establish this, manufacturers implement appropriate controls on the device design and manufacture, and evaluate the safety and performance of the device in its intended application. This involves an analysis of risks that could arise during use, an assessment of relevant pre-clinical and clinical data, the preparation of appropriate instructions for use and, if necessary, specific training schemes. From such activities, manufacturers are able to verify that risks have been eliminated or minimised and are judged acceptable when weighed against the anticipated benefits to patients.

Therefore devices that are:

- used off-label ([e.g. foley catheters as enteral feeding tubes](#))
- modified by the user (e.g. loading of an anaesthetic workstation beyond its specified capacity leading to the device overbalancing, or, reconfiguration of a Bain's breathing system, resulting in the wrong size oxygen connector being used and thus ventilation hindered)
- not intended for medical use (e.g. pillows or blankets used to position patients during MRI, leading to patient burns, or non-medical LED torches used for patient neurological observations, when the packaging warns against shining the torch into a person's eyes)

will not have undergone this level of scrutiny. The consequent lack of verification of device performance means that it cannot be assured to be safe, suitable or effective. The use of a device in these circumstances exposes users and patients to unknown and therefore unacceptable risks and may have legal and ethical implications.

Examples of potential dangers include:

- adverse reactions
- inadequate sterilisation
- insufficient mechanical strength and/or structural integrity
- insufficient durability
- misuse due to lack of adequate training for device.

As well as the risks to the patient and user, liability for the performance and safety of products that have been modified, adapted or used off-label, could be transferred to the user. Healthcare professionals should also be aware that following modification of a CE-marked medical device, the healthcare organisation and/or professional could be deemed to be the manufacturer of a new device and may therefore be subject to the requirements of the Medical Devices Regulations.

The consequences of using even simple medical devices outside their intended purpose can be serious. For example [use of tongue depressors \(Class I medical devices\) in a neonatal ITU](#) as limb splints led to two deaths and one amputation because of fungal infection. The MHRA has also issued [advice on the risk of entrapment and asphyxiation of people in beds used with incompatible side rails](#).

Action

- Ensure that you are familiar with the instructions for use including the intended purposes for all the devices you use.
- Only use devices for their intended purpose; do not modify or alter the function or structure of medical devices unless specifically sanctioned by the instructions for use.
- Do not use modified medical devices or non-medical products for clinical purposes unless there is no suitable CE-marked alternative.
- Where the healthcare organisation or healthcare professional judges that there is no alternative but to use a medical device off-label or modify an existing medical or non CE-marked medical device:
 - carry out and document a risk assessment
 - consider the ethical and legal implications
 - implement suitable precautions to minimize the risk

- review the risk assessment at suitable periods.
- Where a healthcare professional judges there is no alternative to off-label device use, the patient must be fully informed during the consent procedure and a note made in the patient's records.

This notice updates and replaces MDA/2004/006.

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters)
- Health Protection Agency (HPA) (Directors)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)
- OFSTED
- Primary care trusts in England (Chief Executives)
- Social services in England (Directors)

Onward distribution

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

Trusts to:

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- All departments
- All clinical staff
- All wards
- Clinical governance leads
- EBME departments
- Health and safety managers
- In-house maintenance staff
- Medical directors
- Medical physics departments
- Nursing executive directors
- Occupational health departments
- Occupational therapists
- Paramedics
- Pharmacists
- Point of care testing co-ordinators
- Purchasing managers
- Risk managers
- Supplies managers
- Theatre managers

Care Quality Commission (CQC) (England only) to:

The MHRA considers this information to be important to:

- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Domiciliary care providers
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Health Protection Agency to:

Directors for onward distribution to:

- Consultants in communicable disease control
- Divisional directors
- Heads of department
- Heads of health, safety and quality
- Health protection nurses

- HPA laboratories
- Laboratory managers
- Regional business managers
- Regional directors
- Regional epidemiologists
- Regional leads
- Regional microbiologists
- Risk manager
- Safety officers

OFSTED to:

The MHRA considers this to be important to:

- Children's services
- Educational establishments with beds for children
- Residential special schools

Primary care trusts to:

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

- All clinical staff
- Clinical governance leads
- Community hospitals
- Community pharmacists
- Directors of public health
- District nurses
- General dental practitioners
- General practices
- Health visitors
- NHS walk-in centres
- Occupational therapists
- Optometrists
- Physiotherapists
- Walk-in centres

Social services to:

Liaison officers for onward distribution to all relevant staff including:

- Back care/manual handling advisors
- Care management team managers
- 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
- Environmental health officers
- Equipment stores
- 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
- Schools with hoists
- Transport managers
- Wheelchair and seating service managers

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/001** or **2009/011/026/291/002**.

Technical aspects

Adverse Incident Centre
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3080

Fax: 020 7084 3109

E-mail: aic@mhra.gsi.gov.uk

Clinical aspects

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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 (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US
Tel: 02890 523 704
Fax: 02890 523 900
E-mail: 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
E-mail: 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 Jane Ludlow
Senior Medical Officer
Medical Device Alerts
Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3505 / 3922

E-mail: Haz-Aic@wales.gsi.gov.uk

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