



For Attention and Action by:
Chief Executive of each HSS Trust
General Manager/Chief Executive of each HSS Board
Chief Executive of each Agency

**NORTHERN
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CENTRE**

TITLE:

ARTIFICIAL AIRWAYS (ENDOTRACHEAL AND TRACHEOSTOMY TUBES) AND PRESSURISED BREATHING SYSTEMS: RISK OF SERIOUS INJURY DUE TO INCORRECT ASSEMBLY

MANUFACTURER/SUPPLIER

Various

PROBLEM

Reports of incidents involving the inappropriate connection of breathing system devices continue to be received by the Medical Devices Agency (MDA). These incidents report of barotrauma to patients caused by incorrectly assembled respiratory therapy devices, where an expiratory pathway was not provided.

DISTRIBUTION

This notice should be brought to the attention of all who need to know or be aware of it, including those listed below, in accordance with local procedures. This will include:

- Liaison Officers
- Risk Managers
- Clinical and Social Care Governance Lead
- Health & Safety Officers/Advisors
- Device Managers
- Medical Directors
- Clinical Directors
- Nurse Directors
- Medical, Nursing and Care Staff
- Directors of Anaesthetics
- Consultant Anaesthetists
- Operating Theatre Staff
- Resuscitation Officers
- Ambulance Staff and Paramedics
- General Medical Practitioners
- Practice Managers
- District Nurses
- Health Visitors
- Private Clinics
- Residential and Nursing Homes
- Hospices
- Accident & Emergency Departments
- Theatre Managers
- Adult & Paediatric Intensive Care Units
- Special Care Baby Units
- Trust Pharmacy Managers

Boards/Trusts should ensure that if appropriate, this information is passed to all persons having the responsibility for the premises registered under "THE REGISTERED HOMES (NI) ORDER 1992.

IMMEDIATE ACTION

- Staff with responsibility for prescribing, assembling and maintaining breathing systems to be used in association with endotracheal or tracheostomy tubes should ensure that appropriate procedures are followed to minimise the risk of the patient's airway being occluded or obstructed. Risk is heightened when cuffed tubes are used but airway occlusion may also occur with uncuffed tubes and with tight-fitting face masks.
- Staff should be adequately trained and retain sufficient regular exposure to maintain their skills in utilising such devices. The skills required include correct assembly of breathing systems and recognition and prompt correction of system/tube/mask problems which may arise during therapy. It is desirable that, in the event of an emergency, such staff should have ready access to medical and nursing personnel who specialise in breathing systems but the presence of appropriately skilled staff

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- should reduce the incidence of such emergency calls.
- Ensure that the manufacturer's instructions for use are followed
- Trusts should review their patient care management arrangements to consider whether patients who require respiratory support with positive pressure breathing systems should be managed in an area where they can be closely observed by adequately trained staff.

BACKGROUND

NIAIC Safety Notices SN(NI)2000/43 Continuous Positive Airway Pressure (CPAP) Circuits: Risk of misassembly, and SN(NI)2002/25 Artificial Airways(endotracheal and tracheostomy tubes) and pressurized breathing systems, were published in November 2000, and June 2002 respectively. These notices are available from the NIAIC website www.dhsspsni.gov.uk/niaic and highlight the risks of misassembly and misconnection associated with particular respiratory therapy devices. Further reports have been received highlighting the need for vigilance in the assembly and connection of any respiratory therapy device/component or breathing circuit that can be connected to patients with endotracheal and tracheostomy tubes.

NIAIC has been informed that the Medical Devices Agency (MDA) has received two recent reports of the inappropriate assembly of respiratory therapy devices. In one incident a disposable nebuliser chamber was connected directly onto a patient's tracheal tube. The second incident involved an oxygen therapy connector being connected to a breathing system filter, which was directly attached to a patient's endotracheal tube. Both cases had serious consequences as a gas supply was attached with no expiratory gas pathway, allowing the build up of excessive pressures, causing lung damage. There is the possibility that incorrectly assembled respiratory therapy devices connected to uncuffed tubes could also be a hazard.

Respiratory therapy devices are designed with standard-sized connectors to ensure compatibility between devices. This is to minimize any interruption in respiratory therapy when additional parts such as nebulisers, humidifiers or filters are added, removed, or replaced if faulty. Staff must be adequately trained in the use of these devices and be made fully aware of the possibility of incorrect assembly and potential hazards.

All staff should be provided with training in the safe use of equipment as outlined in Device Bulletin DB9904 (NI), "Medical Device and Equipment Management for Hospital and Community Based Organisations"

Further guidance is provided in 'Devices in Practice - a guide for health and social care professionals'. This publication is available on the NIAIC website at www.dhsspsni.gov.uk/niaic. This states that "health and social care professionals are personally accountable for the use of the device and therefore must ensure that they have appropriate training" (section 4, p8).

ENQUIRIES

Enquires to the NIAIC should quote the reference number HN(NI) 2002/09 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC), Health Estates, Estate Policy Directorate, Stoney Road, Dundonald, Belfast BT16 1US, Tel: 02890 523714 Fax: 02890 523900, Email: brian.godfrey@dhsspsni.gov.uk

Brian Godfrey, NIAIC Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in Safety Notice SN (NI) 2002/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety
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