IRISH MEDICINES BOARD

MEDICAL DEVICE

SAFETY NOTICE

Switch Controlled (Electric) Height Adjustable Beds

IMB Safety Notice: SN2004(03)

SAFETY NOTICE

MANUFACTURER / SUPPLIER

Various

TARGET GROUPS

ICU Staff
Ward Staff
Physiotherapy Managers / Occupational Therapists
Risk Managers
Purchasing Managers

ISSUE

The risk of accidental entrapment under hospital beds and therapy tables.

BACKGROUND

The IMB has been advised, by several other European Regulatory agencies, of a number of patient deaths and patient injuries that have occurred as a result of patients becoming entrapped under height adjustable beds and therapy tables. Many of the incidents occurred when patients inadvertently pressed the control switch.

In one case a child's head became entrapped in the height mechanism of a therapy when he was left unsupervised.

A greater number of the reported incidents, to date, have related to foot switch operated control device.

As result of the incidents that occurred in France, the French Competent Authority for Medical Devices has advised French health services to inactivate foot switches. They have also requested that manufacturers of beds no longer supply foot switches to the French market. For further information (in French) http://afssaps.sante.fr/htm/alertes/indreco.htm.

No adverse incidents relating to this issue have been reported to the Competent Authority for Medical Devices in Ireland, the Irish Medicines Board (IMB).

ACTION OR RECOMMENDATIONS

- Ensure that all relevant staff is made aware of this potential risk with these devices.
- Ensure that the risk associated with foot operated controls and hand operated controls are closely examined before the use, prescription or purchase of these devices.
- Ensure that a risk assessment is conducted before using these devices with children, children / adults with learning disability and the elderly.
- Ensure that the electrical control switches for these devices are positioned /stored in a safe location after each use.
  - A position that cannot be accessed inadvertently
  - A position safe from the interference of children
- Ensure that patients / carers / staff using these devices have adequate training, and supervision where necessary.
- Report any problems that you experience with these devices to the Medical Devices Department in the Irish Medicines Board.

ENQUIRIES

All adverse incidents relating to a Medical Device should be reported to the:

Medical Devices Department
Irish Medicines Board
Earlsfort Centre
Earlsfort Terrace
Dublin 2

If you have any enquiries, you may contact the Medical Devices Department at:

Telephone: +353-1-6764971
Fax: +353-1-6767836
Email: medicaldevices@imb.ie
Website: www.imb.ie

SAFETY NOTICE