IRISH MEDICINES BOARD

MEDICAL DEVICE

SAFETY NOTICE

Cardio Respiratory Monitors
IMB Safety Notice: SN2005(05)

MANUFACTURER / SUPPLIER

Various

TARGET GROUPS

Risk Managers
Clinical Engineering Departments
Purchasing Managers
Nursing Managers
ICU
Theatre
Anaesthetics

ISSUE

Alarm dysfunction on cardio-respiratory monitoring systems.

BACKGROUND

Assessment of reported incidents and near incidents relating to alarm dysfunction on cardio-respiratory monitoring systems by our colleagues in other European member states have concluded that users have an important role to play in the configuration and management of alarms on such devices.

To date the IMB has had not been notified of any reported problems in Ireland.

ACTION OR RECOMMENDATIONS

- Ensure the users of these devices are made aware of this safety notice
- Ensure that:
  - Alarm configurations are set up in accordance with your needs.

SAFETY NOTICE

- Alarm configurations are checked after each preventative or corrective maintenance or software upgrade.

- Adequate and repeated training is provided to all staff using these devices.

The development of written procedure relating to alarm management has also proven to be a useful in ensuring the good use of cardio-respiratory monitoring systems.

Please ensure that any incidents that occur with these medical devices are reported to the IMB.

ENQUIRIES

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board
Medical Devices Department
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

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

Telephone: +353-1-6764971
Fax: +353-1-6344033
Email: medicaldevices@imb.ie
Website: www.imb.ie

SAFETY NOTICE