IRISH MEDICINES BOARD

Notice Information: Medical Devices - Advisory 12 December 2005

Part 1. Product Information

a)	Title:	Cardio Respiratory Monitors
b)	Product Name/Type:	Cardio Respiratory Monitors
c)	Reference:	SN2005(05)
d)	Manufacturer/Supplier:	Various

Part 2. Target Audience

a)	Target Audience:	Risk Managers; Clinical Engineering Departments; Purchasing Managers; Nursing Managers; ICU; Theatre; Anaesthetics

Part 3. Problem/Issue

a)	Problem/Issue:	Alarm dysfunction on cardio-respiratory monitoring systems.

Part 4. Background Information

a)	Background Information:	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.

Part 5. Action to be taken

a)	Action to be taken:	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. 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.

Part 6. Enquiries

a)	All enquiries should be made to:	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 SN2005(05): Cardio Respiratory Monitors

Part 7. Keywords

a)	Keywords:	Cardio Respiratory Monitors