IRISH MEDICINES BOARD

Notice Information: Medical Devices - Advisory 20 September 2004

Part 1. Product Information

a)	Title:	Invasive Blood Pressure Monitoring Devices with Transducers
b)	Product Name/Type:	Invasive Blood Pressure Monitoring Devices with Transducers
c)	Reference:	SN2004(08)
d)	Manufacturer/Supplier:	Various

Part 2. Target Audience

a)	Target Audience:	ICU Staff; Ward Staff; Risk Managers; Purchasing Managers

Part 3. Problem/Issue

a)	Problem/Issue:	Possible “off label” use of the device.

Part 4. Background Information

a)	Background Information:	It has come to the attention of the Irish Medicines Board (IMB) that some of the above devices are being used in Irish hospitals for a configuration / application that may not have been validated by the manufacturer. The CE certification of many of these devices covers fluid delivery using an integrated flush system with a giving set for the administration of fluid at a specific rate of flow e.g. 3ml/h under pressure. Therefore, users of these devices should review the instructions for use (IFU) provided with the device before use and ensure that the device is only being used at the flow rates, pressures and configurations that are recommended by the manufacturer in the instructions for use. Please note that, as outlined in the IMB Safety Notice SN2004(04), the user of a medical device should be aware that the consequence of using medical devices outside the intended purpose defined by the manufacturer can be serious. Continued use of the device outside the intended purpose requires careful consideration as the user of the device assumes the responsibilities of the manufacturer under the legislation.

Part 5. Action to be taken

a)	Action to be taken:	Examine the instructions for use (IFU) that are provided with the device and determine the recommended flow rate. Assess the manner in which these devices are being used in your hospital. Report any problems that you experience with these devices to the Medical Devices Department in the Irish Medicines Board.

Part 6. Enquiries

a)	All enquiries should be made to:	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: vigilance@imb.ie Website: www.imb.ie SN2004(08): Invasive Blood Pressure Monitoring Devices with Transducers

Part 7. Keywords

a)	Keywords:	Invasive Blood Pressure Monitoring Devices with Transducers