IRISH MEDICINES BOARD

Notice Information: Medical Devices - Warning 31 January 2008

Part 1. Product Information

a)	Title:	H-1200 Fast Fluid Warmer with integrated Air Detector / Clamp and H-31B and H-30 Air Detector / Clamp Accessory
b)	Product Name/Type:	H-1200 Fast Fluid Warmer with integrated Air Detector / Clamp and H-31B and H-30 Air Detector / Clamp Accessory
c)	Reference:	SN2008(02)
d)	Manufacturer/Supplier:	Smiths Medical, United Kingdom

Part 2. Target Audience

a)	Target Audience:	Accident & Emergency Departments; Intensive Care Units; Cardio Thoracic Units; All Wards; Clinical Perfusionists; IV Nurse Specialists; Maternity Units; Theatre Managers; Theatre Nurses; Risk Managers; Clinical Engineering

Part 3. Problem/Issue

a)	Problem/Issue:	The risk of air embolism if the power of the fluid warmer unit is interrupted either manually or through power failure during an air detection event.

Part 4. Background Information

a)	Background Information:	Smiths Medical circulated an advisory notice to Irish hospitals in July 2007 advising of the potential risk of air embolism with the above device. They advised that this could occur when the power supply to the unit is interrupted during an air detection alarm e.g. by manually switching off the power during an air detection event, causing the air detector clamp to open and remain open. Smiths Medical provided Irish hospitals with a 'quick reference guide' warning them of this issue. Despite this action, an incident was reported in the USA, where during an air detection event the alarms were activated but the user turned the unit off despite the recommendations of the 'quick reference guide'. Air was delivered to the patient but no serious patient injury was reported.

Part 5. Action to be taken

a)	Action to be taken:	Further to this incident the Irish Medicines Board (IMB) advises users to discontinue the use of the device until further notice. Identify and quarantine affected devices until further notice. If no alternative fluid warmer is available, ensure users are aware of the advice provided in the manufacturer's customer letter (copy attached as appendix 1) and ensure that the quick reference guide is attached to all affected devices. Contact the manufacturer to request a copy of quick reference guide if not attached to all affected devices

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: vigilance@imb.ie Website: www.imb.ie SN2008(02): IMB Safety Notice - H-1200 Fast Fluid Warmer with integrated Air Detector / Clamp and H-31B and H-30 Air Detector / Clamp Accessory SN2008(02): Appendix 1 - Smiths Medical Safety Alert

Part 7. Keywords

a)	Keywords:	SN2008(02): H-1200 Fast Fluid Warmer with integrated Air Detector / Clamp and H-31B and H-30 Air Detector / Clamp Accessory