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Medical Device / Equipment ALERT

Date Issued : 5th May 2008 **Ref:MDB/A/2008/002**

IMMEDIATE ACTION	
ACTION	√
UPDATE	
INFORMATION REQUEST	

PRODUCT	**H-1200 Fast Fluid Warmer with integrated Air Detector / Clamp and H-31B and H-30 Air Detector / Clamp Accessory**
CLASS	n/a
USE	Fast Fluid Warmer with Air Detector
SOURCE OF MEDICAL DEVICE RECALL / ALERT	Irish Medicines Board website, date issued: 31st January 2008
ALERTING / RECALLING FIRM	**In Ireland (as reported through the IMB website):-** **Smiths Medical, United Kingdom**
REASON	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. 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. **<u>Incident Reported in other country.</u>** 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.
SCENARIO IN MALAYSIA	**No details available at this moment.** Please check whether the device is available and contact the distributor.
ACTION	***Action or Recommendations For Healthcare Professionals*** • Ensure that all relevant staff in your institution are informed of this safety alert/warning • Determine if you have the affected products • Locate and monitor the usage of the affected products • Determine how much of this product has been used • Follow the distributor / manufacturers recommendations for quarantine and disposal of product • Follow up patients as required.
RECOMMENDATION	Users of the abovementioned device should contact the distributors/supplier of this device (if available) and **inform the Medical Devices Bureau, Ministry of Health** providing the following information:- a. Name of healthcare centre/hospital/clinic b. Contact person and contact number c. Numbers of units available
CONTACT/ENQUIRIES IN MALAYSIA	Currently No Information Available
REFERENCES	http://www.imb.ie/EN/Safety--Quality/Advisory-Warning--Recall-Notices/Medical-Devices/H1200-Fast-Fluid-Warmer-with-integrated-Air-Detector--Clamp-and-H31B-and-H30-Air-Detector--Clam.aspx?page=1&noticetypeid=-1&year=-1