IRISH MEDICINES BOARD

MEDICAL DEVICE

SAFETY NOTICE

H-1200 Fast Fluid Warmer with integrated Air Detector / Clamp and H-31B and H-30 Air Detector / Clamp Accessory

IMB Safety Notice: SN2008(02)

SAFETY NOTICE

MANUFACTURER / SUPPLIER

Smiths Medical, United Kingdom.

TARGET GROUPS

Accident & Emergency Departments
Intensive Care Units
Cardio Thoracic Units
All Wards
Clinical Perfusionists
IV Nurse Specialists
Maternity Units
Theatre Managers
Theatre Nurse
Risk Managers
Clinical Engineering

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.

BACKGROUND

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.

ACTION OR RECOMMENDATIONS

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

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:	vigilance@imb.ie
Website:	www.imb.ie

SAFETY NOTICE

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5th July 2007

IMPORTANT: Safety Alert

Level 1® QUICK REFERENCE GUIDE With Additional Warning for the H-1200 Fast Flow fluid Warmer equipped with the H31B and the Level 1® H-31B Air Detector/Clamp accessory

To: **Level 1®** H-1200 H31-B Fast flow fluid Warmer Users
Level 1® H31-B Air Detector/ Clamp Users

As a result of customer input and our ongoing effort to continually improve ease of use and the correct clinical applications of our devices, Smiths Medical ASD, Inc (Smiths Medical) has created a Quick Reference Guide for our Fast Fluid Warming devices equipped with Air Detection. These instructions have been printed on laminated cards in a format designed to be attached directly to the device.

The Quick Reference Guides include an additional Warning that the Air detector/Clamp is deactivated when the unit is turned off when power is otherwise lost to the device. Allowing the Air Detector/ Clamp to stay open during power loss permits fluid therapy to continue.

The additional Warning:

> *Do not turn OFF the Fluid Warmer when the Air Detector alarm is active. If the Fluid Warmer is powered OFF in an active alarm state, the Air Detector/Clamp will open and the Air Detector will become disabled. This could allow any air within the patient line to be delivered to the patient resulting in serious injury or death.*

This new warning is also included in updated Operator's Manual(s) for all of the Fast Flow Fluid warming devices and will be available with all new devices. Manuals will be made available to all existing customers per request. All new H-1200 and H-31B devices will be equipped with the Quick Reference Guide.

With this letter, we have included Quick Reference Guides to be installed on your devices. Ordering information for acquiring additional Quick Reference Guides and/or an electronic copy of the updated Operator's Manual is included in the response sheet on the last page of this notice.

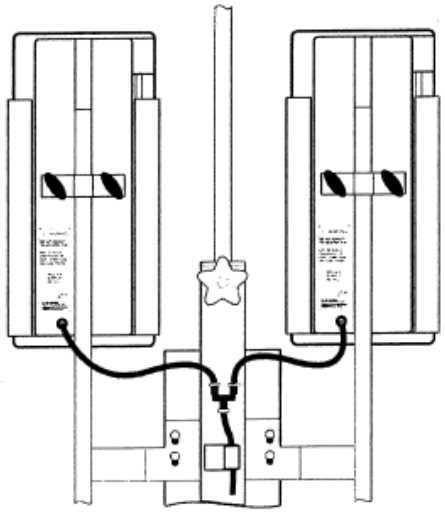
Required actions

1. Provide copies of this Advisory Notice to all users of the Level 1® H-1200 Fast Flow Fluid Warmer Users with an H31-B integrated Air Detector accessory in your facility including the training staff

2. Install the enclosed Quick Reference Guide on all of the affected Level 1® devices in your facility
3. Indicate on the enclosed Acknowledgment the serial numbers of those devices on which the Quick Reference Guides have been installed.
4. Order additional sets of the Quick Reference Guide and/or electronic copy of the updated Operator's Manual. As necessary, by completing the appropriate section of the Acknowledgement.
5. Please complete and fax the attached "Safety Alert Notice Acknowledgement" to **+44(0) 1923 237576**. This will confirm that you have received, understood and acted upon this Safety Alert.

Installing the Quick Reference Guide

1. Face the back of the fluid warmer unit.
2. Loosen the knob on the top of the Fluid Warmer tower and raise the I.V. pole.
3. Loosen the thumbscrews of the left pressure chamber
4. Slide the pressure chamber off the flanking pole
5. Place the quick reference guide snap ring over the flanking pole.
6. Replace the pressure chamber by sliding it onto the flanking pole
7. Tighten the pressure chamber thumbscrew.
8. Lower the I.V. pole and tighten the knob



Smiths Medical has informed the relevant regulatory authorities of this notice. We regret any inconvenience as a result of this action. If you have any questions please contact Smiths Medical International Ltd (Watford) QA Department on **+44 (0) 1923 475809**

Yours sincerely

For and on behalf of Smiths Medical International Ltd, Watford

Jon Charters
Quality Assurance Manager

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bringing technology to life

Smiths Medical Safety Alert Acknowledgement

I acknowledge receipt of this Safety Alert, Dated 2nd April 2007 which serves as confirmation that I have installed the Quick Reference Guide on all of the H-1200 or H-31B Air Detector Clamps at my facility and I have noted below if I require any additional Quick Reference Guides or updated Operators Manuals (electronic copy) sent to me ** **Please complete and fax to +44 (0) 1923 237576.**

Facility Name:

_____

Address: _____

_____

Phone Contact No:

_____

Signed: _____ Date: _____

Print Name: _____

Title: _____

If your facility no longer has any H-1200s, or H-31Bs please indicate by checking here: [ ]

Device type (H-1200w/H-31B, H-1200 H-31B)	Device Serial Number	Quick Reference Guide Installed

Does your facility want additional Quick reference Guides (H-31B part number 45-33-710)? Yes or No

If yes, how many? _____ If yes, which version? _____

Does your facility want an electronic copy of the updated Operators manual (H-31B part number 45-337-08GB)? Yes or No

If Yes which version? _____

If yes, please provide the e-mail address that the manual should be sent to _____

Please fax this page to **+44 (0) 1923 237576**

If you have any questions please contact Smiths Medical International ltd (Watford) QA Department on **+44 (0) 1923 475809**