IRISH MEDICINES BOARD
SAFETY NOTICE

SAFETY NOTICE

Omnifuse and Omnifuse PCA Syringe Pumps

IMB Safety Notice: SN2012(01)
Circulation Date: 07 February 2012

MANUFACTURER/SUPPLIER
Smiths Medical International

TARGET GROUPS
Hospital
Hospital CEOs
Hospital Risk Managers
Medical Nursing Staff
Paramedics
Palliative Care Units
Intensive Care Units
Anaesthetic Officers
General Practitioners
Practice Nurses
Clinical Engineers
General Public
Hospices
Nursing Homes
Community Care Managers
Community Therapists
Carers

ISSUE
The Omnifuse and Omnifuse PCA Pumps may alarm and stop delivery of infusion due to significant vibration when transporting the pumps.

BACKGROUND
In July 2011, Smiths Medical initiated a field safety corrective action to highlight the possible impact of significant vibration or jarring to Omnifuse and Omnifuse PCA Pumps in inducing a System Fault Code, causing the Pump to alarm and stop delivery of the infusion. This is due to the sensitivities of the precision accuracy detection mechanisms within the Omnifuse Pumps.

An example of the type of vibration or jarring that may induce a System Fault Code would be transporting a pump across an uneven surface (e.g., block paving). Smiths Medical has outlined recommendations for users of these devices to avoid this system error from occurring. The field safety notice associated with this issue is attached with this safety notice.

SAFETY NOTICE

The manufacturer has notified the Irish Medicines Board (IMB) that despite their best efforts they have not managed to receive 100% reconciliation for acknowledgements of receipt of the field safety notice from customers in the Irish market. The IMB is issuing this safety notice to ensure all users of these devices are aware of this issue and to request that customers, upon receipt of the field safety notice, will confirm with the manufacturer that they are aware of the issue.

ACTION OR RECOMMENDATIONS

1. Ensure that the relevant personnel in your organisation are made aware of this issue.

2. Follow the recommendations as outlined by the manufacturer in the field safety notice attached and confirm acknowledgement of receipt of the field safety notice to the manufacturer.

3. If you have any concerns or queries relating to this issue please contact the manufacturer using the contact details below.

ENQUIRIES

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: vigilance@imb.ie
Website: www.imb.ie

Enquiries to the manufacturer should be addressed to:

Manufacturer:

Smiths Medical International Ltd.
Bramingham Business Park,
Enterprise Way,
Luton,
LU3 4BU,
United Kingdom.

Telephone: +44 (0)1582 430307 ext. 4770307
E-mail: Mick.Boydon@smiths-medical.com