

# Safety Notice

## Medical Devices



IRISH MEDICINES BOARD

## BBraun Perfusor Space Infusion Pump



### Priority 2 – Warning

IMB Safety Notice: SN2014(17)

Issue Date: 08 April 2014

MANUFACTURER / SUPPLIER	IMB CASE REFERENCE
B. Braun Melsungen AG	V19335

#### ISSUE

The Irish Medicines Board (IMB) wishes to remind users of a field safety notice (FSN) issued by B. Braun in December 2013. B. Braun has identified a risk that when the Perfusor Space pump is used with an aged battery, that the pump may not have sufficient current to perform a syringe change, despite the battery indicator on the pump showing full charge.

The issue can only occur when the pump is not connected to the mains and presents a risk when the pump is used on battery only.

#### ACTION OR RECOMMENDATIONS

The IMB would like to remind users to:

- (1) Follow the instructions outlined by the manufacturer in the FSN attached.
- (2) Identify any batteries (or battery packs) of four years or older.
- (3) Contact your Biomedical Engineering Department to arrange for replacement or testing of the battery (battery pack), as outlined in the device service manual.
- (4) Always have an additional pump available for infusion of critical medications and during transport of patients.
- (5) Forward this IMB Safety Notice to all those within your organisation that need to be aware of this information.

## TARGET GROUPS

A&E Departments	Midwifery Departments
Ambulance Service	Neonatology Departments
Anaesthetic medical/nursing staff	Nursing Managers
Biomedical Engineering staff	Nursing staff
Cardiology Departments	Obstetrics and Gynaecology Departments
Cardiothoracic Departments	Oncology Nurse Specialists
Chief Executive Officers	Orthopaedic Departments
Clinical Directors	Paediatric Departments
Day Surgery Units	Paramedics
Emergency Medical Technicians	Peritoneal Dialysis Units
Gastroenterology Departments	Purchasing Managers
Haemodialysis Units	Renal Medicines Departments
High Dependency Units	Resuscitation Officers
Hospital Managers	Risk Managers
Hospital Pharmacists	Special Care Baby Units
Intensive Care Units	Supplies Managers
IV Nurse Specialists	Theatre Managers and nurses
Maternity Units	Urology Departments

## BACKGROUND

The issue identified with the Perfusor Space infusion pump battery (or battery pack) may occur because a syringe change requires a large current which may not be available if the battery has been significantly aged.



## MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

B.Braun Melsungen AG  
Carl-Braun-Str. 1  
Melsungen  
34212  
Germany

Telephone: +49 5661 712 769  
Fax: +49 5661 752 769  
E-mail: [ludwig.schuetz@bbraun.com](mailto:ludwig.schuetz@bbraun.com)  
Website:

Enquiries to the **distributor** should be addressed to:

B.Braun Medical  
3 Naas Road Industrial Park  
Dublin 12

Telephone: +353 1 709 1800  
Fax: +353 1 709 1889  
E-mail: [roberta.egan@bbraun.com](mailto:roberta.egan@bbraun.com)  
Website:

## IMB CONTACT INFORMATION

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

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

Telephone: +353-1-6764971  
Fax: +353-1-6344033  
E-mail: [vigilance@imb.ie](mailto:vigilance@imb.ie)  
Website: [www.imb.ie](http://www.imb.ie)