IRISH MEDICINES BOARD

Notice Information: - Warning
08 April 2014

Part 1. Product Information

a)	Title:	BBraun Perfusor Space Infusion Pump. Priority 2 - Warning
b)	Product Name/Type:	BBraun Perfusor Space Infusion Pump. Priority 2 - Warning
c)	Reference:	SN2014(17)
d)	Manufacturer/Supplier:	B. Braun Melsungen AG

Part 2. Target Audience

a) Target Audience:

A&E Departments

Ambulance Service

Anaesthetic medical/nursing staff

Biomedical Engineering staff

Cardiology Departments

Cardiothoracic Departments

Chief Executive Officers

Clinical Directors

Day Surgery Units

Emergency Medical Technicians

Gastroenterology Departments

Haemodialysis Units

High Dependency Units

Hospital Managers

Hospital Pharmacists

Intensive Care Units

IV Nurse Specialists

Maternity Units

Midwifery Departments

Neonatology Departments

Nursing Managers

Nursing staff

Obstetrics and Gynaecology Departments

Oncology Nurse Specialists

Orthopaedic Departments

Paediatric Departments Paramedics Peritoneal Dialysis Units Purchasing Mana

Paediatric Departments

Paramedics

Peritoneal Dialysis Units

Purchasing Managers

Renal Medicines Departments

Resuscitation Officers

Risk Managers

Special Care Baby Units

Supplies Managers

Theatre Managers and nurses

Urology Departments

Part 3. Problem/Issue

a) Problem/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.

Part 4. Background Information

a) Background Information:

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.

See PDF version for copy of image.

Part 5. Action to be taken

a) Action to be taken:

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

Part 6. Enquiries

a) All enquiries should be made to:

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

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

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:

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Telephone: +353-1-6764971

Fax: +353-1-6344033

E-mail: vigilance@imb.ie

Website: www.imb.ie

Please click here to view a PDF version of this safety notice

Please click here to view a copy of the field safety notice

Please click here to view a copy of the Service manual