

Important Product Information

Use of aged batteries with Perfusor® Space

Date
December 10, 2013

Product	Reference Code
Perfusor® Space	8713030
Battery Pack	8713180, 34520856, 34520856A

Dear Customer,

As a medical device manufacturer, B. Braun takes patient safety and product quality very seriously.

Although there have been no reports of adverse patient incidents, there is a risk 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. This is because a syringe change requires a large current which may not be available if the battery has been significantly aged. This does not affect running infusions.

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 (for example during patient transfer) and is particularly relevant for patients on life sustaining or other critical medications.

Over time, batteries in any medical device will degrade and therefore batteries should be replaced at appropriate intervals. It has been the practice of B. Braun Medical Ltd. Ireland to advise customers to replace batteries at least every 4 years.

On receipt of this information, we request the following actions:

Clinical Users:

1. For infusions of critical medications, always have an additional pump available. This is described in the Perfusor® Space Instructions for Use (section: Patient Safety).
2. If a Perfusor® Space pump used on battery only and showing full battery charge stops during syringe change and alarms, it should be removed from use. Users should then return the pumps with aged batteries (or the aged battery pack) to the Medical Engineering Department for replacement.

Engineering / Technical Personnel:

1. Identify any Perfusor® Space pumps with batteries that are 4 years old or over.
2. If you have experienced such battery issues in your hospital, we recommend to test or replace the batteries of affected pumps as soon as possible. An updated service document which includes details of how to identify the age of the battery, the battery replacement recommendations and test procedure is enclosed.
3. If you have not experienced battery issues so far, we recommend replacing/testing batteries during the next maintenance cycle for the identified Perfusor® Space pumps in accordance with the instructions in the service documentation.
4. If switching of batteries between pumps is standard practice, ensure both the serial number of the battery and the pump are recorded.

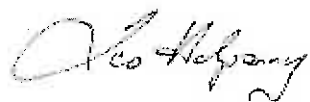
This information should be passed to all appropriate staff within your hospital who need to be aware of this information, including all clinical departments, those who use the pumps during the transfer of patients and those involved in technical, equipment support.

If you have any questions or require further information please contact either of the following:

Ciarán McGuinness
Sales & Product Manager
Telephone: 086 2588019
Email: ciaran.mcguinness@bbraun.com

Eamonn Dargan
Technical Service Manager
Telephone: 086 2214686
Email: eamonn.dargan@bbraun.com

Yours sincerely,



Leo Halpenny
Director Sales & Marketing



Roberta Egan
Regulatory Affairs Manager