

Date: 28th October 2013

FIELD SAFETY NOTICE (FSN)

Product	Reference code
Perfusor® Space	8713030
Battery pack	8713180

FSN identifier: TECH/PER/28102013

Dear Customer,

As a medical device manufacturer B. Braun Medical Ltd 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. This results in an increased internal impedance and so batteries should be replaced at appropriate intervals. Updated service documents which include details of how to identify the age of the battery, the battery replacement recommendations and test procedure are available on the service website for trained technicians and are attached to this FSN.

The following actions are required:

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.
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.

5. Clinical staff have been instructed via a FSN that if a Perfusor® Space pump used on battery only, showing full battery charge stops during syringe change and alarms, users should remove the pump from use and return the pumps with aged batteries (or the aged battery pack) to the Medical Engineering Department for replacement.

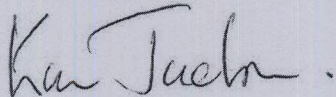
6. Please complete the attached reply form to confirm that you have received this FSN and have taken/will take the appropriate action described above. Return the form by fax to 0114 2259136.

7. This FSN should be passed to all technical, equipment support staff and others as appropriate who need to be aware of this information in your organisation.

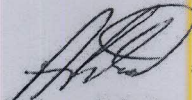
A second FSN with the same subject has been issued targeting the clinical staff (FSN no: CLIN/PER/28102013). The MHRA has been advised of the above FSN.

If you have any questions about this FSN or require further information please contact the Quality Management team at B. Braun, Catherine Clulow (email catherine.clulow@bbraun.com, Tel: 0114 225 9155).

Yours sincerely



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