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URGENT Field Safety Corrective Action Space®^{plus} Perfusor® - Take Over Mode Software C02, C03, C04

Dear Valued Customer,

We would like to inform you about a Field Safety Corrective Action (FSCA) for the use of Take Over Mode (TOM) in Space®^{plus} Perfusor® pumps with software versions C02, C03 or C04.

Reason for the FSCA

With software C02, the Take Over Mode (TOM), was introduced for the Space®^{plus} Perfusor®. As part of our regular market surveillance and product quality control activities, we have observed that the use of TOM may result in over or under infusion under some circumstances. This effect is limited to software versions C02, C03 or C04 in combination with the use of TOM.

The hardware of the device or any other software versions are not affected. Safety or performance features other than TOM are not affected.

Potential Risks to Health

Take Over Mode is a feature to support the user during syringe changes by automatically starting a second syringe pump when the first has run empty. The second pump automatically takes over the infusion rate from the first pump. This feature is only supported when pumps are inserted in the same Space®^{plus} Station and the TOM feature is enabled on the pump configuration.

When starting the Take Over Mode, user interface related issues may lead to a parallel infusion of both pumps doubling the infusion rate.

During a forced handover, the Take Over Mode may fail if the predefined infusion rate limits were violated during therapy setup.

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(Chairman)
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In rare cases, this may be associated with potential patient risks ranging from no clinical relevance to serious injury or death.

In view of the identified risks, a decision was made to execute the below described actions in the market.

Nature of the FSCA

B. Braun provides a software update for Space^{®plus} Perfusor[®] with the TOM function enabled to facilitate the use of TOM. After receipt of your completed acknowledgement form, your local B. Braun representative will provide you with the updated software package.

While all other functions of software versions C02, C03 and C04 remain unaffected, please do not use Take Over Mode (TOM) until a software update \geq C05 has been performed.

Actions to be taken

We kindly ask you to initiate the following activities with priority:

- Please review this Field Safety Corrective Action Notice in its entirety and ensure that all TOM users of the above mentioned product in your organization and other concerned persons are informed.
- If you are a distributor, please forward this correction notification to your customers.
- Identify affected care areas of TOM application and discontinue the use of TOM until a software update \geq C05 has been installed.
- Confirm receipt of this information by completing the attached confirmation slip and return this to B. Braun using the contact details provided.

If more information is needed, please contact

Local contact 1

Name

Title

Email

telephone

Local contact 2

Patient and user satisfaction is our highest priority. We are sorry for any inconvenience. Thank you in advance for your cooperation to resolve this matter quickly.