



B. Braun Melsungen AG  
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Our reference: FSCA-2026-03-04

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**URGENT Field Safety Corrective Action**  
**Space®<sup>plus</sup> Perfusor® - Take Over Mode Software D05**  
**FSCA-2026-03-04**  
**Software-Update**

**Attention: Clinical Personnel, Intensive Care Personnel, Anaesthesia Personnel, Emergency Department Personnel, Operating Room Personnel, General Nursing Personnel, Risk Managers, Patient Safety Officers, Biomedical/Medical Technical Personnel, Clinical Engineers, Device Maintenance Technicians, Hospital Administration, Purchasing Managers, Training and Education Coordinators**

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®<sup>plus</sup> Perfusor® pumps with software version D05.

**Reason for the FSCA**

As part of our regular market surveillance and product quality control activities, we have observed a sporadic disruption in the communication processes between pumps within the station. This will be indicated by both pumps with a respective audible and visual alarm. The communication interruption leads to a loss of TOM-setup and a not automatic start of the second pump.

However, the therapy-setup remains available on the second pump, which can be started immediately.

This effect is limited to software versions D05 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.

**Clinical Risk**

Chairwoman of the Supervisory Board:  
Anna Maria Braun, LL.M.

Executive Board:  
Markus Strotmann  
(Chairman)  
Priv.-Doz. Dr. Stefan Ruppert  
Jürgen Stihl

Corporate Office: Melsungen  
Register Court:  
Local Court Fritzlär  
HRB 11 000  
WEEE-Reg.-No. DE 42690900

Address:  
B. Braun Melsungen AG  
Carl-Braun-Straße 1  
34212 Melsungen  
Germany

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<sup>®plus</sup> Station and the TOM feature is actively enabled on the pump configuration.

Due to a sporadic disruption in the communication processes between pumps within the station the TOM setup may not complete as intended, potentially causing an interruption in delivery. The communication loss is indicated on both devices by:

- 1<sup>st</sup> pump: activation of a high priority *operational alarm*
- 2<sup>nd</sup> pump: triggering of a *caution alarm* during the takeover sequence.

After acknowledging (muting) the caution alarm on the second device, the infusion can be started manually on the same device. The therapy-setup remains available on the second pump.

Due to the sporadic communication loss, the take-over process may be interrupted, requiring the second pump to be started manually.

In rare cases, a brief delay may lead to a temporary undersupply. Depending on the medication and the patient's condition, the potential health effects may vary, ranging from no clinically relevant impact to serious patient harm 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<sup>®plus</sup> Perfusor<sup>®</sup> for customers with the TOM function enabled. 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 version D05 remain unaffected, do not use Take Over Mode (TOM) until a software update to D06 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 to D06 has been installed.
- Confirm receipt of this information by completing the attached confirmation sheet and return this to B. Braun by 2026-03-XX using the contact details provided.

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If more information is needed, please contact

Local contact 1

Name

Title

Email

telephone

Local contact 2

We believe in improving people's health through everything we do. Patient and user safety is our highest priority. As a true partner we develop smart solutions and set standards to improve health care. Kindly accept our apologies for any inconveniences caused and thank you in advance for your cooperation to resolve this matter quickly.

The undersign confirms that this notice has been notified the appropriate Regulatory Agency.

Yours sincerely,