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Our reference: FSCA-2023-08-14 (1)

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URGENT Field Safety Corrective Action
Infusomat® Space - Upstream Occlusion Sensor

Dear Valued Customer,

We would like to inform you about a Field Safety Corrective Action (FSCA) for the following articles and serial numbers:

Article	Article Number	Serial Number
INFUSOMAT® SPACE	8713050	A list of all affected Serial Numbers is provided in ATTACHMENT 1
INFUSOMAT® SPACE - CN VERSION	8713050CN	
INFUSOMAT® SPACE US	8713050U	
INFUSOMAT® SPACE US+Wireless BATTERY PACK	8713051U	
INFUSOMAT® SPACE US+STANDARD BATTERY PACK	8713052U	
INFUSOMAT® SPACE - RECONDITIONED	8713050G	

Reason for the FSCA
In the course of Post Market Surveillance activities, we identified a sporadic occurrence of potentially false down- and upstream pressure alarms which are caused by the upstream occlusion pressure sensor of the Infusomat® Space Infusion Pump.

Our investigations have shown that an isolated batch of upstream occlusion sensors built in the mentioned serial numbers of pumps may deviate from their technical specification.

Electrostatic interactions are naturally generated during the peristaltic movement of the Infusion Pump. This electrostatic effect may influence the sensor and lead to degradation of the upstream sensor performance over time. The sensor may then stop working after extended periods of operation. The frequency of occurrence depends on the manner in which the devices are handled and the environment.

Therefore, not all devices within the identified serial number range exhibit this behavior in actual clinical use.

Potential Risks to Health
In clinical practice the following scenarios may occur and may lead to an interruption of the infusion that could result in potential patient risks ranging from no clinical relevance up to serious injury or patients' death:

- Increased number of downstream occlusion alarms with no actual obstruction of fluid flow which cannot be compensated by adjusting the device pressure settings to higher values;
- Higher frequency of upstream alarms, with no actual obstruction of fluid flow in the pump IV set;
- Pump IV-set not accepted when closing the pump door (e.g. when changing the set).

In view of the identified risks and in order to ensure performance and convenience in clinical use, a decision was reached to voluntarily execute the below described actions in the market.

Nature of the FSCA
B. Braun will be exchanging the Upstream Occlusion Sensor built in the mentioned serial numbers of Infusomat® Space Infusion Pumps. After receipt of your completed acknowledgement form, your local B. Braun representative will contact you to arrange for replacement of the sensor.

In the meantime, in order to optimize performance of the sensor, B. Braun is providing mitigation steps for the clinician:

- Please ensure that a 2nd pump is available when delivering high-risk medication (see IfU).
- Always ensure additional monitoring of the patient's physiological parameters when delivering high-risk medication (see IfU).
- Exhibit special care when starting high-risk infusions by checking that drops are falling in the drip chamber.
- In case you experience frequent false occlusion alarms, which cannot be resolved by other means, we recommend to use Softaskin®. Bring a drop of Softaskin® onto the surface of the peristaltic fingers after every change of an Infusomat® Space Line (see Appendix).
  It leads to a minimization of the electrostatic interaction and ensures performance of the upstream sensor.
- Softaskin® will be provided by your sales rep free of charge.

Actions to be taken
Our records have shown that your institution has received the affected articles.

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

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- Please review this Field Safety Corrective Action Notice in its entirety and ensure that all users of the above mentioned product in your organization and other concerned persons are informed about this Field Safety Corrective Action Notice.
- 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	Local contact 2
Name	
Title	
Email	
telephone	

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.

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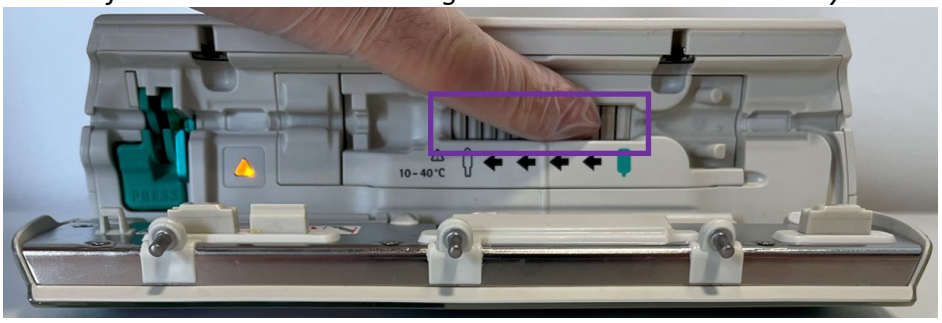
APPENDIX 1

1. *Open the pump door.*

2. *Take a drop of approx. 0.1 to 0.2 ml Softaskin® to your finger.*

3. *Bring the Softaskin® onto the peristalsis of the pump and distribute it evenly in the marked area. Softaskin® must not be brought onto air sensor above the yellow warning light.*



4. *Insert the Infusomat® Space Line and close the pump door.*