B BRAUN
SHARING EXPERTISE

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Вих. № 2034
від 18.11.2021

Всім кого це стосується

Термінове ПОВІДОМЛЕННЯ ПРО ТЕХНІКУ БЕЗПЕКИ(FSN) - INFUSOMAT®PLUS LINES

Компанія **ТОВ «Б. Браун Медікал Україна»,** яка є Уповноваженим представником в Україні виробника **Б.Браун Медікал АГ, Німеччина**, з розпорядження виробника розпочала проактивно інформувати наших клієнтів про появу невиправданих повітряних тривог у пристроях Infusomat® compactplus у поєднанні з Infusomat®plus Lines PUR або особливо Cyto-Set® Infusomatplus Lines згідно з Коригувальними діями з безпеки на місцях(FSCA).

Причина для Коригувальної дії з безпеки на місцях

Виробником було звернено увагу, що під час використання Infusomat®plus Lines PUR, особливо Cyto-Set® Infusomatplus Lines, у поєднанні з пристроями Infusomat® compactplus виникають невиправдані повітряні тривоги. Невиправдані сповіщення про повітря можуть призвести до затримки терапії чи неможливість розпочати терапію, додаткові маніпуляції можуть спричинити ризик контакту з несумісними речовинами у вигляді цитостатичних препаратів. Потенційний ефект можна спостерігати для всіх партій, вироблених з травня 2021 року.
До цього часу в B. Braun Melsungen AG не повідомлялося про жодну шкоду або будь-які інші несприятливі наслідки для пацієнтів пов'язані з вищеописаною невідповідністю.

Посилений контроль якості та впровадження коригуючих дій у виробництві гарантують, що лінії, виготовлені з жовтня (21L11) і далі, не показують описаних збоїв.

Дії, які вжитваються

• Користувачі вищезгаданих продуктів та інші зацікавлені особи поінформовані згідно повідомлення про безпеку від виробника.
• Клієнтам, які закупляють вищевказані лінії надіслано прохання оновити свої насоси до останньої версії програмного забезпечення I0003A0006 та завантажтити додатковий список одноразового використання з рядками PUR (так званий InfusomatCompactPlus_DisposableList_v1.12.2.upd) за допомогою ServiceTool compactplus (версія 1.3.0). ServiceTool compactplus доступний для кваліфікованих спеціалістів на сервісному порталі B. Braun.

Проміжний звіт виробника з Коригувальними діями безпеки на місцях додаємо.

З повагою,

Директор ТОВ «Б.Браун Медікал Україна» Шаповалов А.Б.

Товариство з обмеженою відповідальністю «Б. БРАУН МЕДІКАЛ УКРАЇНА» м. Київ Ідентифікаційний код 36798085

Уповноважена особа з якості, ризиків та управління скаргами ТОВ «Б.Браун Медікал Україна» Денис А.В.

B BRAUN

B. Braun Melsungen AG
Division Hospital Care
Safety Officer Medical Devices
34209 Melsungen
Germany

Your reference:
Our reference: FSCA 2021-11-17

Contact: Dr. Stephan Krause

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Date: November 17th, 2021

TO WHOM IT MAY CONCERN

Urgent FIELD SAFETY NOTICE - INFUSOMAT®PLUS LINES PUR

Dear Sir or Madam,

We, the B. Braun Melsungen AG, have decided to proactively inform our customers on the occurrence of not justified air alarms in Infusomat® compact^{plus} devices in combination with Infusomat®^{plus} Lines PUR or especially Cyto-Set® Infusomat^{plus} Lines in the course of a Field Safety Corrective Action.
Our distribution data indicate that you received one or more of the affected batches as referenced in the Appendix.

Reason for the Field Safety Corrective Action

It has been brought to our attention that unjustified air alarms are occurring while using Infusomat®^{plus} Lines PUR, especially Cyto-Set® Infusomat^{plus} Lines, in combination with Infusomat® compact^{plus} devices. The unjustified air alerts might lead to a delay of therapy or in case a start of the therapy is not possible, the additional handling might harbour the risk of contact to incompatible substances in form of Cytostatic drugs.
The effect can potentially be observed for all batches produced since May 2021.
Up to now, no harm or any other adverse patient outcome, which could be associated to the above described failure, has been reported to the B. Braun Melsungen AG.

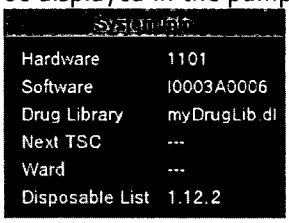
Actions to be taken

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

- Review this Field Safety Notice in its entirety and ensure that all users of the above mentioned products in your organization and other concerned persons are informed about this Field Safety Notice.
- If you are a distributor, please forward this correction notification to your customer.
- Confirm receipt of this information by completing the attached confirmation slip and return this to B. Braun using the contact details provided.
- Please update your pumps to the latest software version I0003A0006 and upload the additional disposable list with PUR lines (called InfusomatCompactPlus_DisposableList_v1.12.2.upd) by using the

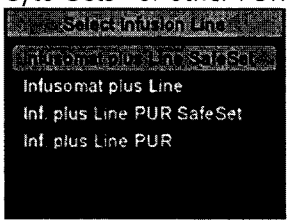
ServiceTool compact^{plus} (Version 1.3.0). The ServiceTool compact^{plus} is available for trained technicians in the B. Braun Service Portal.

For checking the current status of your infusion pump, please press the MENU-Key on the pump, select "Settings...", enter the service code and open the "System Info" of the device. The following screen will be displayed in the pump:



If the software version I0003A0006 and disposable list 1.12.2 is displayed, the device has been updated to the latest software version and the additional disposable list has been uploaded correctly.

After the software update and disposable list upload have been performed, the Infusomat® compact^{plus} will show the following infusion lines on the pump screen, when the disposable was inserted. Ensure that the healthcare professionals are trained to select "Inf. plus Line PUR (SafeSet)" lines in case that Cyto-Sets® or other PUR lines shall be used:



Note: the displayed infusion lines may depend on the customized settings.

- Kindly implement all actions mentioned above, independent from the availability of the referenced batches on your stock.

Kindly accept our apologies for any inconveniences.

...

Appendix - Affected Articles

Art.No.	Art.Name	Batch
8700300	INF.PLUS LINE SAFESET STERIFIX 0.2M, PUR	21E27FBZ02
8700300	INF.PLUS LINE SAFESET STERIFIX 0.2M, PUR	21G15FBZ01
8700300	INF.PLUS LINE SAFESET STERIFIX 0.2M, PUR	21F01FBZ05
8700300	INF.PLUS LINE SAFESET STERIFIX 0.2M, PUR	21F23FBZ02
8700300	INF.PLUS LINE SAFESET STERIFIX 0.2M, PUR	21H02FBZ01
8700300	INF.PLUS LINE SAFESET STERIFIX 0.2M, PUR	21H05FBZ03
8700300	INF.PLUS LINE SAFESET STERIFIX 0.2M, PUR	21H09FBZ01
8700300	INF.PLUS LINE SAFESET STERIFIX 0.2M, PUR	21K13FBZ01
8700300	INF.PLUS LINE SAFESET STERIFIX 0.2M, PUR	21K30FBZ03
8700300	INF.PLUS LINE SAFESET STERIFIX 0.2M, PUR	21L04FBZ02
8700420	CYTO-SET INF. PLUS LINE W.3 NF VALVES AS	21E07FBZ01
8700420	CYTO-SET INF. PLUS LINE W.3 NF VALVES AS	21F08FBZ01
8700420	CYTO-SET INF. PLUS LINE W.3 NF VALVES AS	21F18FBZ02
8700420	CYTO-SET INF. PLUS LINE W.3 NF VALVES AS	21F24FBZ06
8700420	CYTO-SET INF. PLUS LINE W.3 NF VALVES AS	21G05FBZ02
8700420	CYTO-SET INF. PLUS LINE W.3 NF VALVES AS	21G30FBZ01
8700420	CYTO-SET INF. PLUS LINE W.3 NF VALVES AS	21H06FBZ02
8700420	CYTO-SET INF. PLUS LINE W.3 NF VALVES AS	21K08FBZ03
8700420	CYTO-SET INF. PLUS LINE W.3 NF VALVES AS	21F01FBZ01
8700420	CYTO-SET INF. PLUS LINE W.3 NF VALVES AS	21H31FBZ07
8700430	CYTO-SET INF. PLUS LINE W.5 NF VALVES AS	21E07FBZ02
8700430	CYTO-SET INF. PLUS LINE W.5 NF VALVES AS	21E21FBZ01
8700430	CYTO-SET INF. PLUS LINE W.5 NF VALVES AS	21F01FBZ02
8700430	CYTO-SET INF. PLUS LINE W.5 NF VALVES AS	21F18FBZ03
8700430	CYTO-SET INF. PLUS LINE W.5 NF VALVES AS	21F24FBZ08
8700430	CYTO-SET INF. PLUS LINE W.5 NF VALVES AS	21F29FBZ05
8700430	CYTO-SET INF. PLUS LINE W.5 NF VALVES AS	21H06FBZ03
8700430	CYTO-SET INF. PLUS LINE W.5 NF VALVES AS	21H31FBZ08
8700430	CYTO-SET INF. PLUS LINE W.5 NF VALVES AS	21K06FBZ03

Report Form
Field Safety Corrective Action
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

new case, keep base data

Version 2.7en
2012-12-03

1 Administrative Information

To which NCA(s) is this report being sent?
Type of report (•) Initial report ( ) Follow-up report ( ) Final report
Date of this report 2021-11-16
Reference number assigned by the manufacturer FSCA 2021-11-17
FSCA reference number assigned by NCA
Incidence reference number assigned by NCA
Name of the co-ordinating NCACompetent Authority (if applicable)

2 Information on submitter of the report

Status of submitter ( ) Manufacturer ( ) Authorised Representative within EEA and Switzerland (•) Others: (identify the role) Distributor

3 Manufacturer information new

Name B.Braun Melsungen AG	
Contact Name Dr. Stephan Krause	
Address Carl-Braun-Strasse 1	
Postcode 34212	**City** Melsungen
Phone +49 5661-71-1339	**Fax**
E-mail md-vigilance_hc-opm@bbraun.com	**Country** DE - Germany

4 Authorised Representative Information

new

Name	
Contact Name	
Address	
Postcode	**City**
Phone	**Fax**
E-mail	**Country** DE - Germany

5 National contact point information

new

National contact point name	
Name of the contact person	
Address	
Postcode	**City**
Phone	**Fax**
E-mail	**Country** US - USA

6 Medical device information

new

Class

- ○ AIMD Active implants
- ○ MDD Class III
- ○ MDD Class IIb
- ◉ MDD Class IIa
- ○ MDD Class I
- ○ IVD Annex II List A
- ○ IVD Annex II List B
- ○ IVD Devices for self-testing
- ○ IVD General

Nomenclature system (preferable GMDN)	**Nomenclature code**
GMDN	35833

Nomenclature text

Electric infusion pump administration set

Commercial name/ brand name / make

INFUSOMAT®PLUS LINES PUR (see section 8)

Model number	**Catalogue number**
	See section 8
Serial number(s)	**Lot/batch number(s)**
	See Section 8
Device Mfr Date	**Expiry date**

Notified Body (NB) ID-number

0123

Accessories / associated devices (if applicable)

Software version number (if applicable)

7 Description of the FSCA

Background information and reason for the FSCA

We, the B. Braun Melsungen AG, havedecided to proactively inform our customers on the occurrence of not justified air alarms in Infusomat® compactplus devices in combination with Infusomat®plus Lines PUR or especially Cyto-Set® Infusomatplus Lines in the course of a Field Safety Corrective Action.

The unjustified air alerts might lead to a delay of therapy or in case a start of the therapy is not possible, the additional handling might harbour the risk of contact to incompatible substances in form of Cytostatic drugs.
The effect can be potentially be observed for all batches produced since May 2021.
Up to now, no harm or any other adverse patient outcome, which could be associated to the above described failure, has been reported to the B. Braun Melsungen AG.

Based on the identified risk profile we decided to proactively inform our customers and implement measures in the course of a Field Safety Corrective Action.

Description and justification of the action (corrective / preventive)

The users are instructed to update the pumps to the latest software version and upload the additonal disposable list with PUR lines.
Implemention of the software and disposable list reduces the risk for the occurence of a false air alert. After implementation of the corrective actions the risk is within the acceptable limits.

Advice on actions to be taken by the distributor and the user

Follow the instructions in the FSN

Progress of FSCA , together with reconciliation data (Mandatory for a Final FSCA)

Time schedule for the implementation of the different actions

The FSN will be rolled out in CW46

A CAPA adressing the qualitiy of the PUR tubes has been inititated and is in the status of action implementation.

Attached please find

- ☐ Field Safety Notice (FSN) in English
- ☐ FSN in national language
- ☐ Others (please specify)

FSN Status

- ○ Draft FSN
- ◉ Final FSN

8 Comments

Art.No.	Art.Name	Batch
8700300	INF.PLUS LINE SAFESET STERIFIX 0.2M, PUR	21E27FBZ02
8700300	INF.PLUS LINE SAFESET STERIFIX 0.2M, PUR	21G15FBZ01
8700300	INF.PLUS LINE SAFESET STERIFIX 0.2M, PUR	21F01FBZ05
8700300	INF.PLUS LINE SAFESET STERIFIX 0.2M, PUR	21F23FBZ02
8700300	INF.PLUS LINE SAFESET STERIFIX 0.2M, PUR	21H02FBZ01
8700300	INF.PLUS LINE SAFESET STERIFIX 0.2M, PUR	21H05FBZ03
8700300	INF.PLUS LINE SAFESET STERIFIX 0.2M, PUR	21H09FBZ01
8700300	INF.PLUS LINE SAFESET STERIFIX 0.2M, PUR	21K13FBZ01
8700300	INF.PLUS LINE SAFESET STERIFIX 0.2M, PUR	21K30FBZ03
8700300	INF.PLUS LINE SAFESET STERIFIX 0.2M, PUR	21L04FBZ02
8700420	CYTO-SET INF. PLUS LINE W.3 NF VALVES AS	21E07FBZ01
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8700420	CYTO-SET INF. PLUS LINE W.3 NF VALVES AS	21F18FBZ02
8700420	CYTO-SET INF. PLUS LINE W.3 NF VALVES AS	21F24FBZ06
8700420	CYTO-SET INF. PLUS LINE W.3 NF VALVES AS	21G05FBZ02
8700420	CYTO-SET INF. PLUS LINE W.3 NF VALVES AS	21G30FBZ01
8700420	CYTO-SET INF. PLUS LINE W.3 NF VALVES AS	21H06FBZ02
8700420	CYTO-SET INF. PLUS LINE W.3 NF VALVES AS	21K08FBZ03
8700420	CYTO-SET INF. PLUS LINE W.3 NF VALVES AS	21F01FBZ01
8700420	CYTO-SET INF. PLUS LINE W.3 NF VALVES AS	21H31FBZ07
8700430	CYTO-SET INF. PLUS LINE W.5 NF VALVES AS	21E07FBZ02
8700430	CYTO-SET INF. PLUS LINE W.5 NF VALVES AS	21E21FBZ01
8700430	CYTO-SET INF. PLUS LINE W.5 NF VALVES AS	21F01FBZ02
8700430	CYTO-SET INF. PLUS LINE W.5 NF VALVES AS	21F18FBZ03
8700430	CYTO-SET INF. PLUS LINE W.5 NF VALVES AS	21F24FBZ08
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8700430	CYTO-SET INF. PLUS LINE W.5 NF VALVES AS	21H31FBZ08
8700430	CYTO-SET INF. PLUS LINE W.5 NF VALVES AS	21K06FBZ03

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail

The medical device has been distributed to the following countries:

within the EEA and Switzerland

☒ AT	☐ BE	☐ BG	☒ CH	☐ CY	☒ CZ	☒ DE	☐ DK
☐ EE	☐ ES	☐ FI	☐ FR	☐ GB	☐ GR	☐ HU	☐ IE
☐ IS	☒ IT	☐ LI	☐ LT	☒ LU	☐ LV	☐ MT	☐ NL
☐ NO	☒ PL	☐ PT	☒ RO	☐ SE	☐ SI	☐ SK	☐ TR

Candidate Countries

☐ HR

☐ All EEA, candidate countries and Switzerland

Others:

AR, CL, GP, KZ, MX, SA, UA