

## **Urgent Field Safety Notice**

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**Commercial name/Model:** BeneFusion nSP (Configured PCA )

**FSCA-identifier:** CP2411-SK05153

**Type of action:** Software upgrade

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2024-12-15.

**Attention:**

Dear Sir or Madam,

Through the continued monitoring of products distributed by Mindray, we have been aware of a potential issue related to the BeneFusion nSP syringe pumps (Configured PCA) using software version V01.25 , V01.26, V01.27 . This letter is intended to provide you with information as follows:

**Details on affected devices:**

The serial numbers (SN) of the affected BeneFusion nSP syringe pumps (Configured PCA) can be identified from the label. The serial numbers of the affected devices are listed **in appendix 1**

**Description of the problem:**

Mindray has identified that the lock screen of BeneFusion nSP syringe pump (Configured PCA) may be invalid in some specific scenarios. This effect is limited to software version V01.25, V01.26, V01.27 in conjunction with PCA mode.

Therefore,

- If you are using V01.25, V01.26, V01.27 software version, safety or performance features other than PCA mode are not affected.
- The device installed with any other software version is not affected.

**Nature of the corrective safety action**

Mindray will provide a software update for the affected devices. Upon receipt of your completed Field Safety Notice Acknowledgement, we will contact you to schedule the software update.

**Advise on action to be taken by the CUSTOMER / USER:**

1. Please pass this Urgent Field Safety Notice (FSN) to all those who need to be aware within your organization or to any organization where the potentially affected device(s) has(have) been transferred to.
2. After you have received this notice, the BeneFusion nSP syringe pumps can continue to be used, but you will need to discontinue using BeneFusion nSP syringe pump with PCA mode until the software is updated to 01.28 or above.
3. Return the Field Safety Notice Acknowledgement Form to Mindray confirming that the Field Safety Notice has been read and understood.

**Advise on action to be taken by the distributor:**

1. Please pass this Urgent Field Safety Notice to all those who need to be aware within your organization or to any organization where the potentially affected device(s) has(have) been delivered.
2. If any BeneFusion nSP syringe pump (Configured PCA) in your facility in the affected list, please don't sell units to customers or to install. Mindray's Service Representatives will contact you to schedule the software update.
3. Return the Field Safety Notice Acknowledgement Form to Mindray to confirm that the Field Safety Notice has been read and understood.

**Transmission of this Field Safety Notice:**

This Notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

We would be grateful if you could confirm receipt of this letter. Please fill in below Acknowledgement Form and return via E-mail.

**Contact reference person:**

We apologize for the inconvenience caused by this situation. If you have any questions, please contact with your local Mindray Customer Service Engineer or designated Technical Support Engineer – Jeffrey.tang

Tel: [+86 185 8821 6354](tel:+8618588216354)

Email: [jeffrey.tang@mindray.com](mailto:jeffrey.tang@mindray.com)

This Notice has been notified the appropriate Regulatory Agency.

**Signature:**

Emily Zhao

Representative of PMS Quality Center

Shenzhen Mindray Scientific Co., Ltd.

6/F, Bldg2, 1203 Nanhuan Avenue, Yutang Block Guangming District

518106 Shenzhen

PEOPLE'S REPUBLIC OF CHINA

Tel: 0086 755 81887277

Email : [mr@mindray.com](mailto:mr@mindray.com)

Acknowledgement Form

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**Confirmation of Receipt of Field Safety Notice**

**Commercial name/Model:** BeneFusion nSP( Configured PCA )

**FSCA-identifier:** CP2411-SK05153

**Type of action:** Software upgrade

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**Please fill in this form and return this confirmation by E-mail immediately.**

**Name:** *Erik Wang*

**Email:** *Erik.yxwang@mindray.com*

Name: \_\_\_\_\_

Tel. No.: \_\_\_\_\_

E-mail address: \_\_\_\_\_

Date and Signature: \_\_\_\_\_

Address of the Organization:

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**Appendix 1 List of Affected Devices**

No	Commercial Name	Serial Number of products
1	BeneFusion nSP	SG1-3C019233