
Urgent Field Safety Notice

Commercial name/Model: BeneVision N1

FSCA-identifier: CP2507-JH05611

Type of action: Software upgrade

2025-08-11.

Attention:

Dear Sir or Madam,

Through the continuous monitoring of products distributed by Mindray, we have identified an issue relating to the alarm pause on the BeneVision N1. The purpose of this letter is to provide you with the following information:

Details on affected devices:

The affected serial numbers (SN) of the BeneVision N1 can be identified from the label. The serial numbers of the affected devices are listed in appendix.

Description of the problem:

Mindray has identified that when the BeneVision N1 patient monitor is used as a module with other Mindray monitors, there is low probability that, upon setting an alarm pause, the device may remain in the alarm pause state without displaying the remaining alarm pause time. In this situation, a prompt indicating the alarm pause state will remain visible on the interface, and all other monitoring functions and technical alarm functions will continue to operate normally. Users can cancel the alarm pause at any time. This issue only affects BeneVision N1 software versions V02.20 and earlier.

Therefore, BeneVision N1 devices with software versions later than V02.20 are not affected by this issue.

Nature of the corrective safety action

Mindray service team or authorized service personnel will contact you as soon as possible to solve this issue.

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

1. Please ensure that this Field Safety Notice (FSN) is communicated to all relevant personnel within your organization.
2. After receiving this Field Safety Notice, you may continue to use the BeneVision N1 as a module with other Mindray monitors. If the "Alarm Pause" quick key is pressed on the BeneVision N1 or the associated monitor, please follow the instructions in the manual to confirm that the remaining alarm pause time is displayed in the physiological alarm information area on the main interface of the monitor where the "Alarm Pause" was activated. If only "Alarm Pause" is displayed, press the "Alarm Pause" quick key again to exit the alarm pause state.

3. The Mindray service team or authorized service personnel will contact you as soon as possible to arrange a software upgrade.
4. Please return the Field Safety Notice Acknowledgement Form to Mindray to confirm that this notice has been read and understood.

Advise on action to be taken by the distributor:

1. Please ensure that this Field Safety Notice (FSN) is communicated to all relevant personnel within your organization, as well as to any organization that has received the affected BeneVision N1 devices.
2. If your organization has any BeneVision N1 devices on the affected list, please contact the Mindray service team or authorized service personnel as soon as possible to arrange a software upgrade.
3. Kindly assist the Mindray service team or authorized service personnel in completing this FSCA action.
4. Please return the Field Safety Notice Acknowledgement Form to Mindray to confirm that this notice has been read and understood.

Transmission of this Field Safety Notice:

Please ensure this Notice is communicated to all relevant personnel within your organization, as well as to any organization to which the potentially affected device(s) have been transferred.

Please ensure ongoing awareness of this Notice and any resulting actions for an appropriate period to support the effectiveness of the corrective measures.

We kindly request that you confirm receipt of this letter by completing the Acknowledgement Form below and returning it via email.

Contact reference person:

We apologize for any inconvenience this situation may have caused. If you have any questions, please contact your local Mindray Customer Service Engineer or designated Technical Support Engineer [Marco Pugliese](#)
Email: Marco.Pugliese@mindray.com

This Notice has been notified the appropriate Regulatory Agency.

Signature:

Yang xuexin

Representative of PMS Quality Center

SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
Mindray Building, Keji 12th Road South, High-tech Industrial Park,
Nanshan, Shenzhen 518057, P.R. China
Tel: 0086 755 81885898
Email : mr@mindray.com

Acknowledgement Form

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Confirmation of Receipt of Field Safety Notice

Commercial name/Model: BeneVision N1

FSCA-identifier: CP2507-JH05611

Type of action: Software upgrade

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

Name: *Marco Pugliese*

Email: *Marco.Pugliese@mindray.com*

Name: _____

Tel. No.: _____

E-mail address: _____

Date and Signature: _____

Address of the Organization:

