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Urgent Field Safety Notice

Commercial name/Model: *BeneVision N22 and N19 patient monitors*
FSCA-identifier: *CP16-JH0171*
Type of action: *Device modification*

June 2016

Attention: [Distributor Name]

Dear Sir or Madam,

As part of Mindray's continuous focus on reliability and safety we continuously monitor the performance of our products. During recent evaluations of BeneVision N22 and N19 patient monitors, we have identified a potential issue that may affect the performance of the equipment under certain conditions. This letter is intended to provide you with information as following:

Details on affected devices:

The affected products are BeneVision N22 and N19 patient monitors. The serial numbers and how to identify the serial numbers are listed in appendix 1 ***List of Affected devices***.

Description of the problem:

Mindray has identified an issue with the BeneVision N22 and N19 patient monitors that would cause the monitor screen frozen. This issue may occur after 49 days of continuous operation. When the monitor screen frozen, the related parameters and waveforms could not be refreshed, and alarms could not be triggered, which could lead to a delay in treatment. However, if the monitor was connected to the Central Monitoring System, the Central Monitoring System will display a disconnection alarm.

The screen frozen failure of the BeneVision N22 and N19 patient monitors was caused by a software anomaly.

Advise on action to be taken by the distributor:

1. Please pass this Notice to all those who need to be aware within your organization or to any organization where the potentially affected device(s) have been transferred.

2. If any BeneVision N22 or N19 patient monitors in your facility is on the affected list, please do not sell or install these devices to customers. Mindray Service Representative will contact you to fix this problem.

3.

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 device(s) 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 or Fax.

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Contact reference person:

We apologize for the inconvenience caused by this situation. If you have any questions, please contact with your Mindray Customer Service Engineer or designated Technical Support Engineer –Harry He
Organization: Shenzhen Mindray Bio-Medical Electronics Co., LTD
Tel: 0086-755-81885021 Fax: 0086-755-26582680
Email: hewenlong@mindray.com

This Notice has been notified the appropriate Regulatory Agency.

(Closing paragraph)

Signature:

Chen Gang
General Manager, 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 8188 5688
Fax : 0086 755 26582680
Email : mr@mindray.com

Acknowledgement Form

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Confirmation of Receipt of Field Safety Notice

Affected Products : *BeneVision N22 and N19 patient monitors*
FSCA : *CP16-JH0171*
Type of FSCA : *Device modification*

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

Fax: 0086-755-26582680
Email: hewenlong@mindray.com

Name: _____

Tel. No.: _____

E-mail address: _____

Date and Signature: _____

Address of the Organization:

_____

_____

Appendix 1 List of Affected Devices.

Country	Commercial name/Model	Serial Number	Distributor/End User	Contact person	Address	Telephone	Email

The commercial name is on the front housing，the serial number is on the main unit label which is on the back of the device. If you do not know how to identify the machine serial number, please refer to below picture:

Figure 1 Front housing (N22)

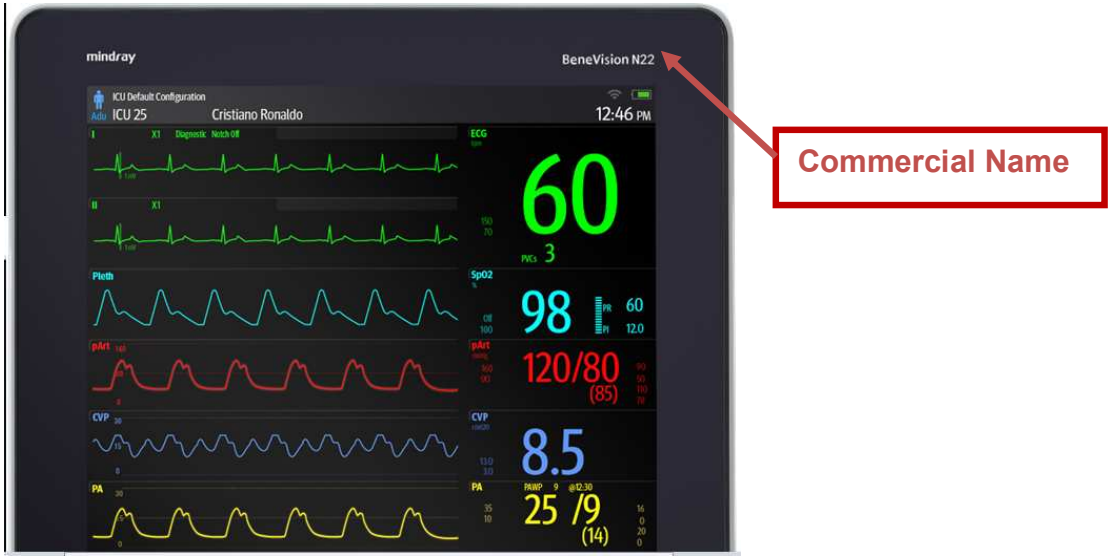

Figure 2 Front housing(N19)

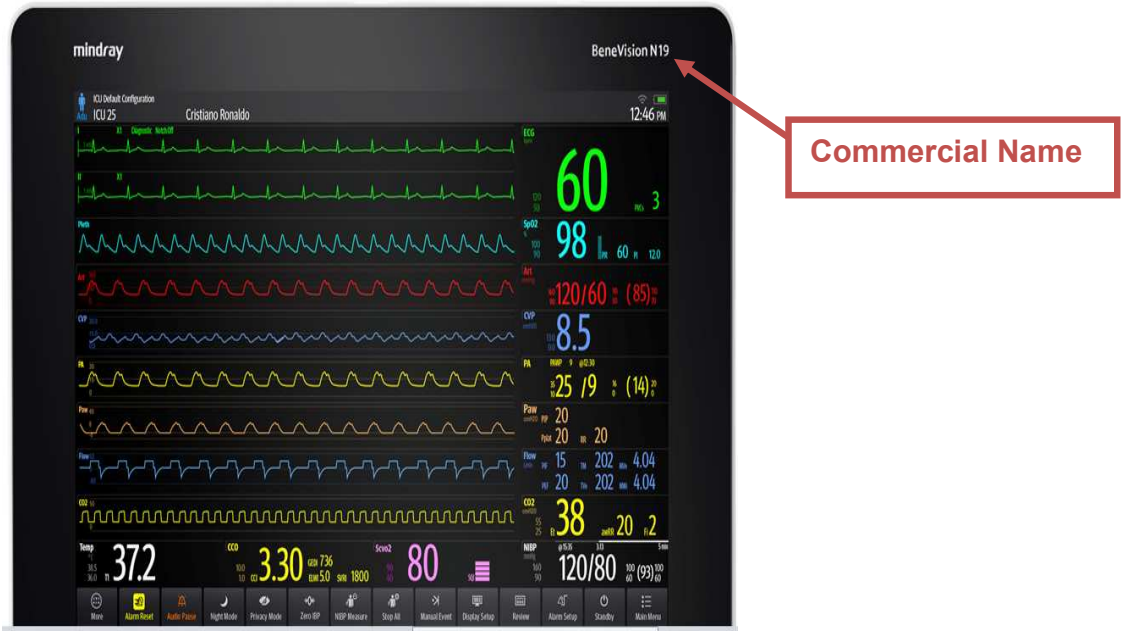

Figure 3 Main Unit Label