mindray 迈瑞

Urgent Field Safety Notice

Commercial name/Model: BeneVision WorkStation / ViewStation
FSCA-identifier: CP2610-JH06304
Type of action: Software Update

2026-11-18.

Attention:

Dear Sir or Madam,

Through the continuous monitoring of products distributed by Mindray, we have identified that certain versions of the BeneVision WorkStation and ViewStation may intermittently disconnect from the CentralStation. The purpose of this letter is to provide you with the following information:

Details on affected devices:

The affected serial number (SN.) of the BeneVision WorkStation and ViewStation can be identified from the label, and these serial numbers are listed in Appendix 1.

Description of the problem:

Mindray has identified that, when network jitter occurs between the CentralStation and the Master Server, there is a low probability that the WorkStation or ViewStation running certain affected software versions may intermittently lose connection with the CentralStation and clear the bed information received from it.

Model	Affected software versions
WorkStation ViewStation	v07.32.00.01, v07.33.00.01, v07.36.00.01, v07.37.00.01, v07.38.00.01 (2021.12 ~ 2023.07)

Impact to clinical use:

If this issue occurs, medical personnel can identify on the WorkStation or ViewStation that the patient's bed information has disappeared, and at this point, it is not possible to view the patient's clinical information via the WorkStation or ViewStation. However, **the patient monitoring devices continue to provide bedside monitoring and generate alarms.** Although monitoring continues, the loss of patient information at the affected WorkStation or ViewStation may delay clinical staff's awareness of a nonfatal change in a patient's physiological condition. This could delay intervention and result in the need for professional medical treatment.

If patient information disappears from a WorkStation or ViewStation, or patient monitoring devices appear offline, promptly verify patient status at the bedside, increase patient surveillance as clinically appropriate, and contact your Biomedical Engineering department or Mindray Technical Support to restore the connection.

To date, no reports of adverse events relating to this issue have been received.

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

1. You may continue to use the BeneVision WorkStation and ViewStation normally.

2. If the patient's bed information has disappeared from the affected WorkStation or ViewStation, please contact your biomedical engineering team or Mindray Technical Support to restore the connection if required.

3. The Mindray service team or authorized service personnel will contact you as soon as possible to arrange a software update on the affected devices to resolve this issue.

4. Please ensure this Notice is shared within any departments to which the affected devices at your facility have been deployed.

5. Please return the **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 is communicated to all relevant personnel within your organization, as well as to any organization that has received the affected devices.

2. If your organization has any device on the affected list, please contact the Mindray service team or authorized service personnel as soon as possible to arrange a software update.

3. Kindly assist the Mindray service team or authorized service personnel in completing this FSCA action.

4. Please return the **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 action may cause and appreciate your prompt attention and cooperation. If you have any questions regarding this notice, please contact with your local Mindray Customer Service Engineer or designated Technical Support Engineer – *Rick Beerens*
Email: *rick.beerens@mindray.com*

This Notice has been notified the appropriate Regulatory Agency.

Signature:

Vera Zhang

Representative of PMS Quality Center

SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO.,LTD
Mindray Building, Keji 12th Road South
Shenzhen 518057, P.R. China
Tel: 0086 755 8188 6776
Email : mr@mindray.com

mindray 迈瑞

Acknowledgement Form

==========

Confirmation of Receipt of Field Safety Notice

Commercial name/Model: BeneVision WorkStation / ViewStation
FSCA-identifier: CP2610-JH06304
Type of FSCA : Software Update

==========

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

Contact: *Rick Beerens*
Email: *rick.beerens@mindray.com*

Name: _____

Tel. No.: _____

E-mail address: _____

Date and Signature: _____

Address of the Organization:

_____

_____