
Urgent Field Safety Notice

Commercial name/Model: V90 electronic vaporizer (for used with A9 anesthesia system)

FSCA-identifier: CP2410-MZ05114

Type of action: Hardware replacement

October 13, 2025

Attention: [Hospital/Distributor Name]

Dear Sir or Madam,

Mindray has identified the following potential problems with the V90 electronic vaporizer used with the A9 anesthesia system. This letter is intended to provide you with information as following:

Details on affected devices:

The affected serial number (SN.) of the V90 electronic vaporizers can be identified from the label.

The serial numbers of the affected products are listed in **appendix**.

Description of the problem:

Mindray has identified that the V90 electronic vaporizer used with the A9 anesthesia system may have leakage issue:

During the process of filling the anesthetic agent into the vaporizer, frequently applying excessive downward pressure on the anesthetic agent bottle may damage the internal structure of the filling port. This damage may lead to improper sealing of the filling port after the removal of the anesthetic agent bottle and may result in anesthetic leakage.

While leakage occurs, medical staff will smell the odor of anesthetic and can address the leakage issue.

Impact to clinical use:

Leakage at the filling port area may cause medical personnel to feel discomfort or symptoms such as mild nausea or vomiting when smelling the anesthetic agent. During use, the output concentration of the vaporizer may be low, potentially causing fluctuations in the patient's blood pressure and heart rate.

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

Upon receipt of this notice, please confirm whether your organization has any devices in the affected list, and pay attention to the following matters when using the affected devices.

The V90 electronic vaporizer can still be used as usual; however, please note that when adding anesthetic agent to the V90 electronic vaporizer, you should press the bottle slowly downward and avoid using excessive force; if you smell a specific odor of anesthetic when using it, you can either replace it with another V90 electronic vaporizer or use intravenous anesthesia.

Mindray service team or authorized service technicians will contact you as soon as possible to replace the filling port for the affected V90 electronic vaporizer(s).

Advise on action to be taken by the distributor:

1. Please pass the Field Safety Notice (FSN) to all those who need to be aware within your organization or to any organization where the affected product, the V90 electronic vaporizer(s) have been delivered.
2. If any V90 electronic vaporizer(s) in your facility within the list, please don't sell units to customers or to install. Mindray's service representative will contact you to replace the filling port for the affected vaporizers.
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 within the list.

Please maintain awareness on this notice and the follow-up 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 Acknowledgement Form attached as below and return it via E-mail or Fax.

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 –Service NL
Email: service.nl@mindray.com

This Notice has been notified the appropriate Regulatory Agency.

Signature:

Jie Gao

Representative of PMS Quality Center

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Nanshan, Shenzhen 518057, P.R. China
Tel: 0086 755 8188 5716
Email : mr@mindray.com

Acknowledgement Form

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Confirmation of Receipt of Field Safety Notice

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FSCA-identifier: CP2410-MZ05114

Type of FSCA : Hardware replacement

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

Contact: Service NL

Email: service.nl@mindray.com

Name: _____

Tel. No.: _____

E-mail address: _____

Date and Signature: _____

Address of the Organization:
