Urgent Field Safety Notice

Commercial name/Model: BeneHeart D1 Automated External Defibrillator
FSCA-identifier: CP2602-JH05958
Type of action: Update the Operator's Manual

May 18,2026

Attention:

Dear Sir or Madam,

Through continuous monitoring of distributed products, Mindray has identified that the Operator's manual for the BeneHeart D1 Automated External Defibrillator (AED) needs further revision. This letter serves to provide you with the following information:

Details on affected devices:

The serial numbers (SN.) of the affected BeneHeart D1 Automated External Defibrillator can be identified from the labels. The serial numbers of the affected devices are listed in Appendix 1.

Description of the problem:

To help users better understand the procedure for switching patient types on the Mindray BeneHeart D1 Automated External Defibrillator (AED), Mindray has updated the BeneHeart D1 AED user manual with refined operational guidance. The details of the update are as follows:

1. Section 5.4 "AED Procedure" of the Operator's Manual is supplemented with the following content " Check the patient type on the defibrillator. If the patient type is inconsistent with the current patient, select to set the patient type correctly."
2. Section 5.4 "The NOTE " of the Operator's Manual is supplemented with the following content: "After MR60 or MR61 electrode pads are connected to the defibrillator and the patient, the defibrillator switches to Adult mode. If the displayed patient type does not match the actual patient, manually adjust the patient type."

This Operator's Manual revision only adds supplementary prompt information. No changes have been made to the product itself or its operational procedures, and therefore no new clinical risks will be introduced.

Nature of the corrective safety action

Mindray's service team or authorized service personnel will contact you and deliver the updated operator's manual.

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 can continue to use the BeneHeart D1 Automated External Defibrillator.

3. The Mindray's service team or authorized service personnel will contact you as soon as possible and send you the updated Operator's Manual.

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 BeneHeart D1 Automated External Defibrillator.

2. If any BeneHeart D1 Automated External Defibrillators in your facility is on the affected list, please sell these devices to customers with the updated manual. Mindray's service team or authorized service personnel will contact you to provide the updated Operator's Manual of the affected units.

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 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:

Alice Xia

Representative of PMS Quality Center

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Nanshan, Shenzhen 518057, P.R. China
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Acknowledgement Form

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Confirmation of Receipt of Field Safety Notice

Commercial name/Model: BeneHeart D1 Automated External Defibrillator
FSCA-identifier: CP2602-JH05958
Type of action: Update the manual

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

Email: *service.nl@mindray.com*

Name: _____

Tel. No.: _____

E-mail address: _____

Date and Signature: _____

Address of the Organization:

_____

_____

Appendix 1 List of Affected Devices

No	Commercial Name	Serial Number of products
1	BeneHeart D1	FQ-7A011882
2	BeneHeart D1	FQ-7A011883