

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 – [Marco Pugliese](#)

Email: marco.pugliese@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
Tel: 0086 755 81887277
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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: marco.pugliese@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	No	Commercial Name	Serial Number of products
1	BeneHeart D1	FQ-15058525	31	BeneHeart D1	FQ-36064390
2	BeneHeart D1	FQ-15058526	32	BeneHeart D1	FQ-36064391
3	BeneHeart D1	FQ-15058527	33	BeneHeart D1	FQ-36064392
4	BeneHeart D1	FQ-15058528	34	BeneHeart D1	FQ-36064393
5	BeneHeart D1	FQ-15058529	35	BeneHeart D1	FQ-36064394
6	BeneHeart D1	FQ-15058530	36	BeneHeart D1	FQ-3A064592
7	BeneHeart D1	FQ-15058531	37	BeneHeart D1	FQ-3A064593
8	BeneHeart D1	FQ-15058532	38	BeneHeart D1	FQ-3C000243
9	BeneHeart D1	FQ-15058533	39	BeneHeart D1	FQ-41064973
10	BeneHeart D1	FQ-15058534	40	BeneHeart D1	FQ-41064974
11	BeneHeart D1	FQ-36064370	41	BeneHeart D1	FQ-41064975
12	BeneHeart D1	FQ-36064371	42	BeneHeart D1	FQ-41064976
13	BeneHeart D1	FQ-36064372	43	BeneHeart D1	FQ-41064977
14	BeneHeart D1	FQ-36064373	44	BeneHeart D1	FQ-41064978
15	BeneHeart D1	FQ-36064374	45	BeneHeart D1	FQ-41064979
16	BeneHeart D1	FQ-36064375	46	BeneHeart D1	FQ-41064980
17	BeneHeart D1	FQ-36064376	47	BeneHeart D1	FQ-52067545
18	BeneHeart D1	FQ-36064377	48	BeneHeart D1	FQ-52067546
19	BeneHeart D1	FQ-36064378	49	BeneHeart D1	FQ-52067547
20	BeneHeart D1	FQ-36064379	50	BeneHeart D1	FQ-52067548
21	BeneHeart D1	FQ-36064380	51	BeneHeart D1	FQ-52067549
22	BeneHeart D1	FQ-36064381	52	BeneHeart D1	FQ-59068682
23	BeneHeart D1	FQ-36064382	53	BeneHeart D1	FQ-59068683
24	BeneHeart D1	FQ-36064383	54	BeneHeart D1	FQ-59068684
25	BeneHeart D1	FQ-36064384	55	BeneHeart D1	FQ-63069081
26	BeneHeart D1	FQ-36064385			
27	BeneHeart D1	FQ-36064386			
28	BeneHeart D1	FQ-36064387			
29	BeneHeart D1	FQ-36064388			
30	BeneHeart D1	FQ-36064389			