

## **Urgent Field Safety Notice**

---

**Commercial name/Model:** *BeneHeart D1 Automated External Defibrillator*

**FSCA-identifier:** *CP2404-JH04699*

**Type of action:** *Manual upgrade*

---

30<sup>th</sup> May. 2024

### **Attention:**

Dear Sir or Madam,

Through the continuous monitoring of the products distributed by Mindray, we have become aware of a potential issue may be associated with BeneHeart D1 Automated External Defibrillator. This letter is intended to provide you with information as following:

### **Details on affected devices:**

The affected serial numbers (SN) of the BeneHeart D1 can be identified from the label. The serial numbers of affected devices are listed in ***appendix 1***

### **Description of the problem:**

Mindray has identified a potential issue associated with BeneHeart D1 Automated External Defibrillator. It was found that, BeneHeart D1 can support MR60, MR61, MR62, MR63 electrode pads and some customers may purchase more than one model of electrode pads. When there are different models of electrode pads connected to the D1, different prompts for the connection of pads appear on the device. However, those different connection prompts might be confusing for the customers.

To date, Mindray has not received any report of serious incidents such as death or serious injury due to the above issue. A new version of BeneHeart D1 product manual has been released, which adds electrode pad connection differences and a more detailed AED procedure to optimise the potential issue mentioned above.

### **Advice on action to be taken by the Hospital administrator:**

1. Please pass the FSN to anyone in your organization who needs to know this information, and to organizations or individuals to whom the affected products may have been sold or transferred
2. You can continue to use the device when you receive this field safety notice (FSN) and the updated user manual.
3. Our local Mindray Service Representatives or cooperative distributors will contact you as soon as possible to provide the new version of the product manuals of the affected units.

### **Advice on action to be taken by the distributor:**

1. Please pass the FSN to anyone in your facility who needs to know this information, and to organizations or individuals to whom the affected products may have been distributed.
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 Representatives will contact you to provide the new version of the product manual of

the affected units.

**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.

**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](mailto:marco.pugliese@mindray.com)

This Notice has been notified the appropriate Regulatory Agency.

**Signature:**



Matthew Ding

---

Representative of Post-market Surveillance of 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 5638  
Email : mr@mindray.com

Acknowledgement Form

=====

**Confirmation of Receipt of Field Safety Notice**

**Commercial name/Model:** *BeneHeart D1 Automated External Defibrillator*  
**FSCA-identifier:** *CP2404-JH04699*  
**Type of FSCA :** *Manual upgrade*

=====

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

**Cont.:** Marco Pugliese  
**Email:** [marco.pugliese@mindray.com](mailto: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	24	BeneHeart D1	FQ-36064383
2	BeneHeart D1	FQ-15058526	25	BeneHeart D1	FQ-36064384
3	BeneHeart D1	FQ-15058527	26	BeneHeart D1	FQ-36064385
4	BeneHeart D1	FQ-15058528	27	BeneHeart D1	FQ-36064386
5	BeneHeart D1	FQ-15058529	28	BeneHeart D1	FQ-36064387
6	BeneHeart D1	FQ-15058530	29	BeneHeart D1	FQ-36064388
7	BeneHeart D1	FQ-15058531	30	BeneHeart D1	FQ-36064389
8	BeneHeart D1	FQ-15058532	31	BeneHeart D1	FQ-36064390
9	BeneHeart D1	FQ-15058533	32	BeneHeart D1	FQ-36064391
10	BeneHeart D1	FQ-15058534	33	BeneHeart D1	FQ-36064392
11	BeneHeart D1	FQ-36064370	34	BeneHeart D1	FQ-36064393
12	BeneHeart D1	FQ-36064371	35	BeneHeart D1	FQ-36064394
13	BeneHeart D1	FQ-36064372	36	BeneHeart D1	FQ-3A064592
14	BeneHeart D1	FQ-36064373	37	BeneHeart D1	FQ-3A064593
15	BeneHeart D1	FQ-36064374	38	BeneHeart D1	FQ-3C000243
16	BeneHeart D1	FQ-36064375	39	BeneHeart D1	FQ-41064973
17	BeneHeart D1	FQ-36064376	40	BeneHeart D1	FQ-41064974
18	BeneHeart D1	FQ-36064377	41	BeneHeart D1	FQ-41064975
19	BeneHeart D1	FQ-36064378	42	BeneHeart D1	FQ-41064976
20	BeneHeart D1	FQ-36064379	43	BeneHeart D1	FQ-41064977
21	BeneHeart D1	FQ-36064380	44	BeneHeart D1	FQ-41064978
22	BeneHeart D1	FQ-36064381	45	BeneHeart D1	FQ-41064979
23	BeneHeart D1	FQ-36064382	46	BeneHeart D1	FQ-41064980
Total: 46					