Urgent Field Safety Notice

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

30th 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 Mindray UK Service.

Email: *UK Service@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

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Confirmation of Receipt of Field Safety Notice

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

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

Email: *UK Service@mindray.com*

Name: _____

Tel. No.: _____

E-mail address: _____

Date and Signature: _____

Address of the Organization:

_____

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Appendix 1 List of Affected Devices

No.	Commercial Name	Serial Number of products	No.	Commercial Name	Serial Number of products
1	BeneHeart D1	FQ-85017167	35	BeneHeart D1	FQ-97034666
2	BeneHeart D1	FQ-95031889	36	BeneHeart D1	FQ-97034667
3	BeneHeart D1	FQ-95031890	37	BeneHeart D1	FQ-97034668
4	BeneHeart D1	FQ-95031891	38	BeneHeart D1	FQ-97034885
5	BeneHeart D1	FQ-95031892	39	BeneHeart D1	FQ-97034886
6	BeneHeart D1	FQ-95031893	40	BeneHeart D1	FQ-97034887
7	BeneHeart D1	FQ-95031894	41	BeneHeart D1	FQ-97034888
8	BeneHeart D1	FQ-95031895	42	BeneHeart D1	FQ-97034889
9	BeneHeart D1	FQ-95031896	43	BeneHeart D1	FQ-97034890
10	BeneHeart D1	FQ-95031897	44	BeneHeart D1	FQ-97034891
11	BeneHeart D1	FQ-95031898	45	BeneHeart D1	FQ-97034892
12	BeneHeart D1	FQ-95031899	46	BeneHeart D1	FQ-97034893
13	BeneHeart D1	FQ-95031900	47	BeneHeart D1	FQ-97034894
14	BeneHeart D1	FQ-95031901	48	BeneHeart D1	FQ-97034895
15	BeneHeart D1	FQ-95031902	49	BeneHeart D1	FQ-97034896
16	BeneHeart D1	FQ-95031903	50	BeneHeart D1	FQ-97034897
17	BeneHeart D1	FQ-95031904	51	BeneHeart D1	FQ-97034898
18	BeneHeart D1	FQ-97034649	52	BeneHeart D1	FQ-97034899
19	BeneHeart D1	FQ-97034650	53	BeneHeart D1	FQ-97034900
20	BeneHeart D1	FQ-97034651	54	BeneHeart D1	FQ-97034901
21	BeneHeart D1	FQ-97034652	55	BeneHeart D1	FQ-97034902
22	BeneHeart D1	FQ-97034653	56	BeneHeart D1	FQ-97034903
23	BeneHeart D1	FQ-97034654	57	BeneHeart D1	FQ-97034904
24	BeneHeart D1	FQ-97034655	58	BeneHeart D1	FQ-97034905
25	BeneHeart D1	FQ-97034656	59	BeneHeart D1	FQ-97034906
26	BeneHeart D1	FQ-97034657	60	BeneHeart D1	FQ-97034907
27	BeneHeart D1	FQ-97034658	61	BeneHeart D1	FQ-97034908
28	BeneHeart D1	FQ-97034659	62	BeneHeart D1	FQ-97034909
29	BeneHeart D1	FQ-97034660	63	BeneHeart D1	FQ-97034910
30	BeneHeart D1	FQ-97034661	64	BeneHeart D1	FQ-97034911
31	BeneHeart D1	FQ-97034662	65	BeneHeart D1	FQ-97034912
32	BeneHeart D1	FQ-97034663	66	BeneHeart D1	FQ-97034913
33	BeneHeart D1	FQ-97034664	67	BeneHeart D1	FQ-97034914
34	BeneHeart D1	FQ-97034665	Total: 67		