

## **Urgent Field Safety Notice**

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**Commercial name/Model:** BeneHeart C Series

**FSCA-identifier:** CP2403-JH04564

**Type of action:** Software upgrade

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2024-06-14.

**Attention:** [Hospital/Distributor Name]

Dear Sir or Madam,

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

**Details on affected devices:**

The affected serial numbers (SN) of the BeneHeart C Series Automated External Defibrillator can be identified from the label. The serial numbers of the affected devices are listed **in appendix 1**.

**Description of the problem:**

Mindray has identified the affected BeneHeart C Series Automated External Defibrillator might not provide required patient defibrillation therapy. The reason for this failure is due to incorrect function configurations.

To date, Mindray has not received any report of serious incidents such as death or serious injury due to the above issue.

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

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 BeneHeart C Series Automated External Defibrillators have been delivered.
2. After you receive this Field Safety Notice, please confirm that if you have any BeneHeart C Series Automated External Defibrillators on the affected list, please discontinue use of the device and contact us. Mindray service team will repair the problem as soon as possible.
3. Return the Field Safety Notice Acknowledgement Form to Mindray confirming that the Field Safety Notice has been read and understood.

**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 BeneHeart C Series Automated External Defibrillators have been delivered.
2. If your organisation has any BeneHeart C Series Automated External Defibrillators on the affected list, please do not sell or install these devices to your customers. Mindray's service team will contact you as soon as possible to provide software and upgrade instructions. If you have any questions regarding the software upgrade process, please contact our local Mindray service team.
3. Return the Field Safety Notice Acknowledgement Form to Mindray confirming 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 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 – [UK Service](#)

contact: [UK Service](#)  
Email: [UK\\_Service@mindray.com](mailto:UK_Service@mindray.com)

This Notice has been notified the appropriate Regulatory Agency.

**Signature:**

\_\_\_\_\_ Emily Zhao \_\_\_\_\_

Representative of PMS 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 81887277  
Email : mr@mindray.com

Acknowledgement Form

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**Confirmation of Receipt of Field Safety Notice**

**Commercial name/Model:** BeneHeart C Series

**FSCA-identifier:** CP2403-JH04564

**Type of action:** Software upgrade

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

contact: [UK Service](#)

Email: [UK\\_Service@mindray.com](mailto:UK_Service@mindray.com)

Name: \_\_\_\_\_

Tel. No.: \_\_\_\_\_

E-mail address: \_\_\_\_\_

Date and Signature: \_\_\_\_\_

Address of the Organization:

\_\_\_\_\_  
\_\_\_\_\_

**Appendix list**

No	Commercial Name	Serial Number of products	No	Commercial Name	Serial Number of products
1	BeneHeart C2	AE7-18021402	40	BeneHeart C1A	AF1-1A023673
2	BeneHeart C2	AE7-18021445	41	BeneHeart C1A	AF1-1B024289
3	BeneHeart C2	AE7-18021451	42	BeneHeart C1A	AF1-1B025334
4	BeneHeart C2	AE7-19023277	43	BeneHeart C1A	AF1-1B025369
5	BeneHeart C2	AE7-23040702	44	BeneHeart C1A	AF1-1B025556
6	BeneHeart C2	AE7-24048380	45	BeneHeart C1A	AF1-1B025562
7	BeneHeart C2	AE7-24048510	46	BeneHeart C1A	AF1-1B025563
8	BeneHeart C2	AE7-28066564	47	BeneHeart C1A	AF1-1C026731
9	BeneHeart C2	AE7-28066575	48	BeneHeart C1A	AF1-1C026736
10	BeneHeart C2	AE7-29069447	49	BeneHeart C1A	AF1-1C026763
11	BeneHeart C2	AE7-34076103	50	BeneHeart C1A	AF1-1C026808
12	BeneHeart C2	AE7-34076195	51	BeneHeart C1A	AF1-21026869
13	BeneHeart C2	AE7-34076288	52	BeneHeart C1A	AF1-21026908
14	BeneHeart C2	AE7-34076303	53	BeneHeart C1A	AF1-21027410
15	BeneHeart C1A	AF1-13012454	54	BeneHeart C1A	AF1-21027444
16	BeneHeart C1A	AF1-17014593	55	BeneHeart C1A	AF1-21027629
17	BeneHeart C1A	AF1-18016672	56	BeneHeart C1A	AF1-21027850
18	BeneHeart C1A	AF1-18016698	57	BeneHeart C1A	AF1-22028757
19	BeneHeart C1A	AF1-18016699	58	BeneHeart C1A	AF1-22028769
20	BeneHeart C1A	AF1-18016700	59	BeneHeart C1A	AF1-22028810
21	BeneHeart C1A	AF1-18016751	60	BeneHeart C1A	AF1-28056215
22	BeneHeart C1A	AF1-18016753	61	BeneHeart C1A	AF1-28056241
23	BeneHeart C1A	AF1-18016754	62	BeneHeart C1A	AF1-28056283
24	BeneHeart C1A	AF1-18016757	63	BeneHeart C1A	AF1-29059535
25	BeneHeart C1A	AF1-19018167	64	BeneHeart C1A	AF1-2C061001
26	BeneHeart C1A	AF1-19018182	65	BeneHeart C1A	AF1-2C061572
27	BeneHeart C1A	AF1-19018187	66	BeneHeart C1A	AF1-2C061585
28	BeneHeart C1A	AF1-19018194	67	BeneHeart C1A	AF1-2C061617
29	BeneHeart C1A	AF1-19018204	68	BeneHeart C1A	AF1-34066245
30	BeneHeart C1A	AF1-19018211	69	BeneHeart C1A	AF1-34066360
31	BeneHeart C1A	AF1-19018223	70	BeneHeart C1A	AF1-34066385
32	BeneHeart C1A	AF1-19018229	71	BeneHeart C1A	AF1-34066458
33	BeneHeart C1A	AF1-19018230	72	BeneHeart C1A	AF1-34066563
34	BeneHeart C1A	AF1-19018240	73	BeneHeart C1A	AF1-34066617
35	BeneHeart C1A	AF1-19018245	74	BeneHeart C1A	AF1-34066632
36	BeneHeart C1A	AF1-19022384	75	BeneHeart C1A	AF1-34066736
37	BeneHeart C1A	AF1-1A023545	76	BeneHeart C1A	AF1-36069202
38	BeneHeart C1A	AF1-1A023582	77	BeneHeart C1A	AF1-36069713
39	BeneHeart C1A	AF1-1A023672	78	BeneHeart C1A	AF1-36069722