

Urgent Field Safety Notice

Commercial name/Model: BeneHeart C Series

FSCA-identifier: CP2403-JH04564

Type of action: Software upgrade

2024-06-24.

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 organization 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 –[Alexandre Noel](#)

Contact: [Alexandre Noel National Service Manager- Switzerland](#)
Email: vigilance.fr@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

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

Contact: *Alexandre Noel National Service Manager- Switzerland*

Email: *vigilance.fr@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 C1A	AF1-26044826	10	BeneHeart C1A	AF1-1C026719
2	BeneHeart C1A	AF1-34066637	11	BeneHeart C1A	AF1-1C026779
3	BeneHeart C2	AE7-1B033698	12	BeneHeart C1A	AF1-22030235
4	BeneHeart C2	AE7-1B033703	13	BeneHeart C1A	AF1-28057616
5	BeneHeart C2	AE7-26052202	14	BeneHeart C1A	AF1-28057814
6	BeneHeart C2	AE7-34076266	15	BeneHeart C1A	AF1-28057835
7	BeneHeart C1A	AF1-18016468	16	BeneHeart C1A	AF1-34066922
8	BeneHeart C1A	AF1-19018365	17	BeneHeart C1A	AF1-36068958
9	BeneHeart C1A	AF1-1C026716	/	/	/