Urgent Field Safety Notice

Commercial name/Model: *BeneHeart D1*
FSCA-identifier: *CP1812-JH00380*
Type of action: *Device correction*

July 5, 2019

Attention: [Hospital/Distributor Name]

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 the internal wire to defibrillator socket used on the Mindray's BeneHeart D1. This letter is intended to provide you with information as following:

Details on affected devices:

Ten (10) units have been affected by the potential issue, and the product information of the BeneHeart D1 affected and how to identify the affected products are listed in ***appendix 1.***

Description of the problem:

The potential issue may be associated with the internal wire to defibrillator socket used on the Mindray's BeneHeart D1, which may cause the defibrillation discharge failure to patient in extreme condition.

To date, there are no reports of patient injuries associated with this potential issue.

Advise on action to be taken by the Hospital administrator:

1. Please pass this Notice to all those who need to be aware within your organization or to any organization where the potentially affected device(s) have been transferred.

2. Please take the affected BeneHeart D1 out of service according to the affected list. Your local Mindray Service Representative will contact you as soon as possible to correct the affected devices.

Advise on action to be taken by the distributor:

Please pass this Notice to all those who need to be aware within your organization or to any organization where the potentially affected device(s) have been delivered. Mindray Service Representative will contact you to correct the affected devices.

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 representative –Kees van den Heuvel.

Organization: Mindray Medical Netherlands BV
Tel.: +31-33-2544911
Fax: +31-33-2572974
E-mail: k.vandenheuvel@mindray.com

This Notice has been notified the appropriate Regulatory Agency.

(Closing paragraph)

Signature:

_____
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……..
……..

Acknowledgement Form

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Confirmation of Receipt of Field Safety Notice

Commercial name/Model: BeneHeart D1
FSCA-identifier: CP1812-JH00380
Type of action: Device correction

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

Fax: +31-33-2572974
E-mail: k.vandenheuvel@mindray.com

Name: _____

Tel. No.: _____

E-mail address: _____

Date and Signature: _____

Address of the Organization:

_____

_____

Appendix 1 List of Affected Devices

We have identified that the issue may be associated with the internal wire to defibrillator socket used on the Mindray's BeneHeart D1 which is supplied by Shenzhen Taijia Electronics co., Ltd.

The label attached to the BeneHeart D1 contains the supplier name, model name and the serial number. The serial number will be the identification of the affected products. Please refer to below pictures:

Figure 1 BeneHeart D1 with label attached

1. List of distributed BeneHeart D1

Country	Equipment S/N	Commercial name/Model	Quantity	Distributor/Hospital	Contact person	Address	Telephone	Email