

Urgent Field Safety Notice

Commercial name/Model: DA8K-10-14453 British standard power cord

FSCA-identifier: CP1905-JH00686

Type of action: Device exchange

June 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 a batch of British standard power cord used on some of Mindray's products. This letter is intended to provide you with information as following:

Details on affected devices:

The affected batch No. of the British standard power cord is 42/18 which can be identified from the label. How to identify the batch number is listed in **appendix 1**

Description of the problem:

The affected British standard power cord may cause the earth leakage protection system of the hospital to trip.

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 stop using the affected power cord according to the affected list. Your local Mindray Service Representative will contact you as soon as possible to replace the affected British standard power cord.

Advise on action to be taken by the distributor:

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 delivered.
2. If any products in your facility are on the affected list, please do not sell or install these devices to customers. Mindray Service Representative will contact you to replace the affected British standard power cord.

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.

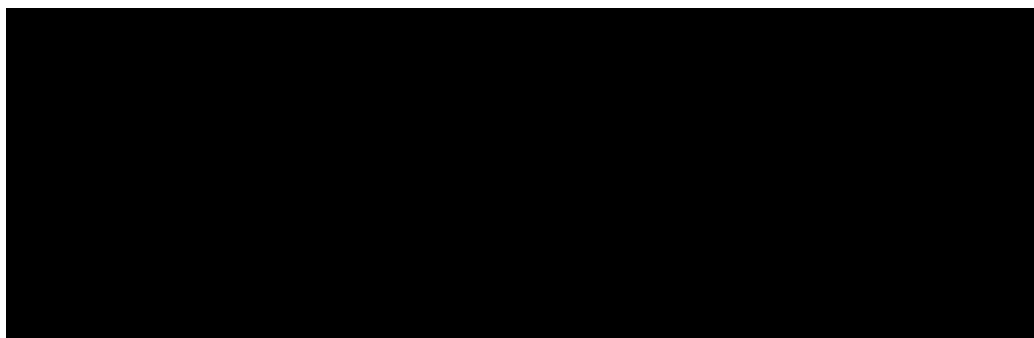
We would be grateful if you could confirm receipt of this letter. Please fill in below Acknowledgement Form and return via E-mail or Fax.

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 – Liu Angju

Organization: Shenzhen Mindray Bio-Medical Electronics Co., LTD
Tel: 0086-755-81886680
Fax: 0086-755-26582680
Email: unicorn.ajiliu@mindray.com

This Notice has been notified the appropriate Regulatory Agency.



SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD
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Shenzhen 518057, P.R.China
Tel: 0086 755 8188 5479
Fax : 0086 755 26582680
Email : mr@mindray.com

Acknowledgement Form

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Confirmation of Receipt of Field Safety Notice
Affected Products : *DA8K-10-14453 British standard power cord*
FSCA : *CP1905-JH00686*
Type of FSCA : *Device exchange*
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Please fill in this form and return this confirmation by E-mail or Fax immediately.

Fax: 0086-755-26582680
Email: unicorn.ajiliu @mindray.com

Name: _____

Tel. No.: _____

E-mail address: _____

Date and Signature: _____

Address of the Organization:

Appendix 1 List of Affected Devices

The label attached to the power cord contains the supplier name , model number and the batch number. Please refer to below pictures:

Figure 1 The information on the label



1. List of British standard power cord which distributed with equipments

Country	Equipment S/N	Commercial name/Model	British standard power cord quantity	Distributor/Hospital	Contact person	Address	Telephone	Email