
Urgent Field Safety Notice

Commercial name/Model: *Beneview T1 patient monitor*

FSCA-identifier: *CP17-JH0008*

Type of action: *Device exchange*

March 2017

Attention: [Hospital/Distributor Name]

Dear Sir or Madam,

Through the continuous monitoring of the products distributed by Mindray, we have become aware of one potential issue associated with the Rechargeable Lithium Ion battery used in the Beneview T1 Patient Monitor. This letter is intended to provide you with information as following:

Details on affected devices:

The affected products are the Rechargeable Lithium Ion batteries used in the Beneview T1 Patient Monitors. The affected devices and how to identify the serial numbers are listed in appendix 1 ***List of Affected devices***.

Description of the problem:

Mindray has identified a potential overheat issue with the Rechargeable Lithium Ion battery used in the Beneview T1 Patient Monitor. The initial failure mode and clinical assessment indicated that the problem may result in battery overheat, smoke which might lead to hot melting of the shell under extremely circumstance.

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 Rechargeable Lithium Ion battery of Beneview T1 Patient Monitor in your facility according to the affected list. Your local Mindray Service Representative will contact you as soon as possible to replace the affected batteries.
3. Please store the affected batteries properly as follows, your local Mindray Service Representative will visit your facility to dispose the batteries to eliminate the potential hazard.
 - Do not charge batteries in storage.
 - Take necessary measures to prevent short circuiting of the batteries. For example, you can cover the two ends of the connector with insulating tape.
 - Store the batteries at cool places($\leq 70^{\circ}\text{F}$) far away from combustibles.
 - Please store the batteries separately, do not mix, overlay or pile up them with other batteries.

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. The Rechargeable Lithium Ion battery is distributed as individual component or with an equipment(Beneview T1 Patient Monitor), if any Rechargeable Lithium Ion battery in your facility is on the affected list, please do not sell or install these devices to customers. Mindray Service Representative will contact you to replace the affected batteries.
3. Please remove and store the affected batteries properly as follows, Mindray Service Representative will provide guidance to your facility on how to dispose the batteries to eliminate the potential hazard.
 - Do not charge batteries in storage.
 - Take necessary measures to prevent short circuiting of the batteries. For example, you can cover the two ends of the connector with insulating tape.
 - Store the batteries at cool places($\leq 70^{\circ}\text{F}$) far away from combustibles.
 - Please store the batteries separately, do not mix, overlay or pile up them with other batteries.

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 – Shiling Yang

Organization: Shenzhen Mindray Bio-Medical Electronics Co., LTD
Tel: 0086-755-81886669
Fax: 0086-755-26582934-86669
Email: yangshiling@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: *Beneview T1 patient monitor*

FSCA-identifier: *CP17-JH0008*

Type of action: *Device exchange*

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

Fax: 0086-755-26582934-86669

Email: yangshiling@mindray.com

Name: _____

Tel. No.: _____

E-mail address: _____

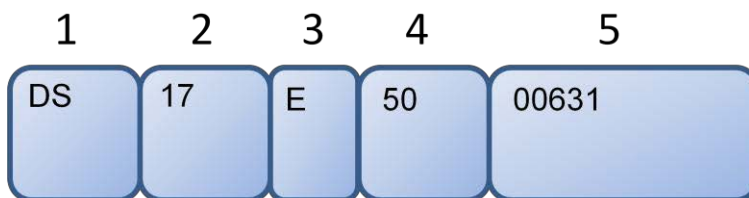
Date and Signature: _____

Address of the Organization:

Appendix 1 List of Affected Devices.

The affected T1 batteries could be identified by below instruction:

1. The Serial Number of a T1 battery could be divided into 5 parts, please refer to below illustration for details.



2. The T1 batteries with below SN characteristic are affected by the potential overheat problem.

- DS 10 X XX XXXXX
- DS 17 E XX XXXXX
- DS 17 F XX XXXXX
- DS 17 G 04 XXXXX
- DS 17 G 08 XXXXX X:

Stands for a character or number.

1. List of T1 batteries which distributed with equipments

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

2. List of T1 batteries which distributed as FRU parts

Country	Commercial name/Model	Affected quantity	Distributor/Hospital	Contact person	Address	Telephone	Email