

## **Urgent Field Safety Notice**

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**Commercial name/Model:** *Ultrasound Fusion Imaging Kit*

**FSCA-identifier:** *CP2008-CS01585*

**Type of action:** *Device modification*

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21<sup>st</sup> Sep.2020

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

To whom it may concern,

Mindray has recently received a notification from the supplier Northern Digital Inc.(NDI) that some of the Mid-Range Transmitters NDI supplied to Mindray had potential durability issues. These may affect the 3D medical navigation application on Ultrasound Fusion Imaging on Mindray ultrasound systems. This letter is intended to provide you with necessary information as following:

### **Description of the problem:**

The Mid-Range Transmitters is configured in some ultrasound products which provides navigation and positioning functions for the probes. This mentioned problem may lead to inaccurate positioning when ultrasound fusion imaging and needle navigation guiding are applied.

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

### **Details on affected devices:**

The serial numbers of all affected Mid-Range Transmitters supplied to Mindray are listed in Appendix 1.

### **Advise on actions to be taken by the Hospital administrator:**

1. Please pass this Urgent Field Safety Notice to all those who need to be aware within your organization or to any organization where the potentially affected device(s) has(have) been transferred to.
2. Please stop using the affected Mid-Range Transmitters according to the affected list. Your local Mindray Service Representative will contact you as soon as possible to replace the affected Mid-Range Transmitters.

### **Advise on actions to be taken by the distributor:**

1. Please pass this Urgent Field Safety Notice to all those who need to be aware within your organization or to any organization where the potentially affected device(s) has(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 Mid-Range Transmitters.

### **Transmission of this Field Safety Notice:**

This Notice needs to be passed to all those who need to be aware of the issue within your organization or to any organization where the potentially affected Mid-Range Transmitters

have been transferred.

Please maintain awareness of this notice and the resulting action for an appropriate period to ensure the effectiveness of the corrective actions.

We would be grateful if you could confirm receipt of this letter. Please fill in the Acknowledgement Form below 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 –Alan Xiao

Organization: Shenzhen Mindray Bio-Medical Electronics Co., LTD  
Tel: 0086-755-81886668  
Fax: 0086-755-26582680  
Email: Alan.Xiao@mindray.com

This Notice has been notified to the appropriate Regulatory Agency.

(Closing paragraph)

**Signature:**

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Phoebe Zhang  
Representative of PMS    Quality Center

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Fax : 0086 755 26582680  
Email : mr@mindray.com

Acknowledgement Form

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**Confirmation of Receipt of Field Safety Notice**

**Affected Products :** *Ultrasound Fusion Imaging Kit*

**FSCA :** *CP2008-CS01585*

**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:** Alan.Xiao @mindray.com

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

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

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

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

Address of the Organization:

\_\_\_\_\_

\_\_\_\_\_

**Appendix 1 List of Affected Mid-Range Transmitters.**

<b>Serial number</b>
023921
023923
023924
023925
023929
023931
023934
023936
023943
024020
024021
023778
023755
023772
023779
024031
024034
024045
024035
024388
024406
024410
024376
024379
024382
024389
024394
024546
024387

