Urgent Field Safety Notice

Commercial name/Model: *Dryline II Water Trap*
FSCA-identifier: *CP16-JH0072*
Type of action: *Device exchange*

August 2016

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 matter associated with the Dryline II Water Trap used in the AG/CO2 Module of the Beneview T Series Patient Monitors and A series Anaesthesia machine.This letter is intended to provide you with information as following:

Details on affected devices:

The affected products are the Dryline II Water Traps used in the AG/CO2 Modules of the Beneview T Series Patient Monitor and A series Anaesthesia machine. The affected Lot numbers and how to identify the Lot numbers are listed in appendix 1 ***List of Affected devices***.

Description of the problem:

Mindray has identified a potential leakage issue with the AG/CO2 Module's Dryline II Water Trap used with the Beneview T Series Patient Monitor and A series Anaesthesia machine. The initial failure mode and clinical assessment indicated that the problem may result in inaccurate CO2 and/or anesthetic gas monitoring, which might cause or contribute to an incorrect treatment.

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 Dryline II Water Traps in your facility according to the affected list. Your local Mindray Service Representative will contact you as soon as possible to replace the affected water traps.

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 Dryline II Water Trap is distributed as individual component or with an equipment(Beneview T Series Patient Monitor,A series Anaesthesia machine, individual AG module and CO2 Module), if any Dryline II Water Trap 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 water traps.

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:

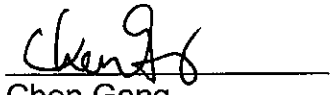
We apologize for the inconvenience caused by this situation. If you have any questions, please contact with your local Mindray Customer Service Engineer or designated Technical Support Engineer – Harry He

Organization: Shenzhen Mindray Bio-Medical Electronics Co., LTD
Tel: 0086-755-81885021
Fax: 0086-755-26582680
Email: hewenlong@mindray.com

This Notice has been notified the appropriate Regulatory Agency.

(Closing paragraph)

Signature:



Chen Gang
General Manager, 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 8188 5688
Fax : 0086 755 26582680
Email : mr@mindray.com

Acknowledgement Form

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Confirmation of Receipt of Field Safety Notice

Affected Products : *Dryline II Water Trap*
FSCA : *CP16-JH0072*
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: hewenlong@mindray.com

Name: _____

Tel. No.: _____

E-mail address: _____

Date and Signature: _____

Address of the Organization:

_____

_____

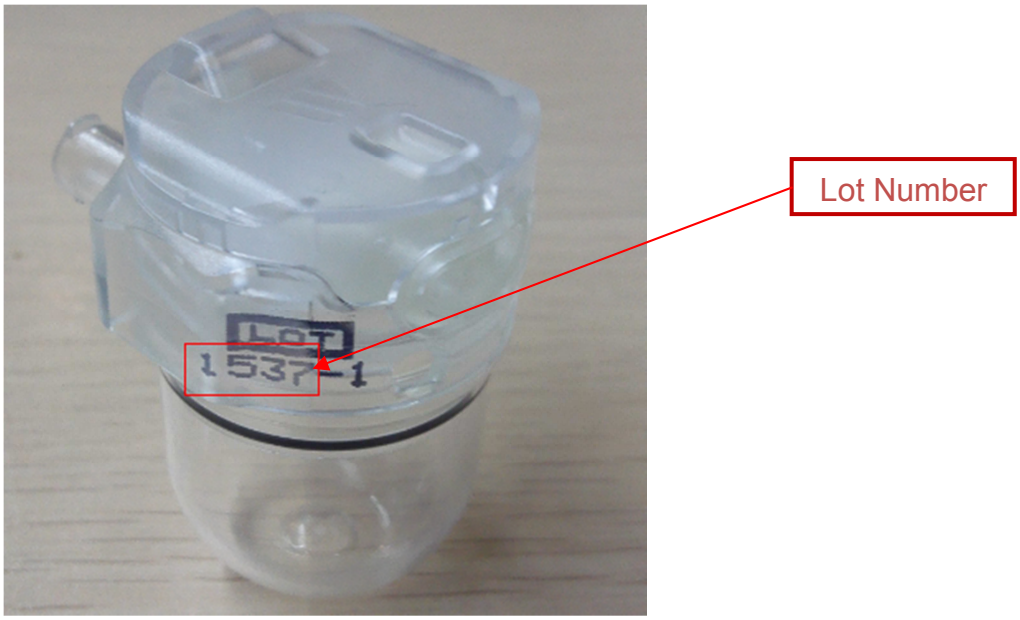
Appendix 1 List of Affected Devices.

We have identified that the issue is associated with a specific Lot #1537, 1538, 1541, 1545, 1547,1548,1602,1606.

The commercial name and Lot number are on the label which is on the side of the package，the Lot number could also be identified from the single unit. If you do not know how to identify the machine serial number, please refer to below picture:

Figure 1 Side of the package

Figure 2 Single Unit



1. List of water traps which distributed with equipments

Country	Equipment S/N	Commercial name/Model	Water trap quantity	Distributor/Hospital	Contact person	Address	Telephone	Email

2. List of individual distributed water traps

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