
Urgent Field Safety Notice

Commercial name/Model: WATO EX-65, WATO EX-55, A5 and A7 anesthesia machines

FSCA-identifier: CP17-MZ0036

Type of action: Safety Notice and Device modification

June, 2017

Attention: [Hospital/Distributor Name]

Dear Sir or Madam,

Through the continuous monitoring of the products distributed by Mindray, we have become aware an issue with the WATO-Series and A-Series anesthesia machines. This letter is intended to provide you with information as following:

Details on affected devices:

The affected products are WATO-Series (WATO EX-65/WATO EX-55) and A-Series (A5/A7) anesthesia machines. The affected devices and how to identify the serial numbers are listed in appendix 1 **List of Affected devices**.

Description of the problem:

Mindray WATO-Series and A-Series anesthesia machines may not be able to enter Standby mode at the end of a case or would automatically skip over the startup leak test when powering on.

The issue will not occur during a case. There are no adverse effects on the patient.

There have been no reports of injuries associated with this 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. If this issue has already occurred in your facility, please stop using the WATO EX-65, WATO EX-55, A5 or A7 anesthesia machines and contact your local Mindray Service Representative right away to schedule the upgrade. If this issue hasn't occurred in your facility, you may continue to use your anesthesia machines while awaiting the software upgrade. Your local Mindray Service Representative will contact you as soon as possible to fix this problem.

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 transferred.
2. If any WATO EX-65, WATO EX-55, A5 or A7 anesthesia machines 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 arrange software upgrade.

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:

[Redacted Signature]

SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD
Mindray building, Keji 12th Road South, High-tech Industrial Park, Nanshan,
Shenzhen 518057, P.R.China

[Redacted Address]

Acknowledgement Form

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Confirmation of Receipt of Field Safety Notice
Affected Products : *WATO EX-65, WATO EX-55, A5 and A7 anesthesia machines*
FSCA : *CP17-MZ0036*
Type of FSCA : *Device modification*
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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.

Country	Commercial name/Model	Serial Number	Distributor/End User	Contact person	Address	Telephone	Email

The commercial name is on the front housing, the serial number is on the main unit label which is on the back of the device. If you do not know how to identify the machine serial number, please refer to below picture:

Figure 1 Front housing (WATO-Series)



Figure 2 Main Unit Label (WATO-Series)



Serial Number: XX-XXXXXXXX

Figure 3 Front housing (WATO-Series)



Commercial Name

Figure 4 Main Unit Label (A-Series)



Serial Number: XX-XXXXXXX