
Field Safety Notice

Commercial name/Model: LED Surgical Light

FSCA-identifier: CP-2018-100

Type of action: Device repair

May 2019

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 sterilizable handle assembly used in LED Surgical Light. This letter is intended to provide you with information as following:

Details on affected devices:

The affected products are the sterilizable handles assembly used in LED Surgical Light. 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 issue with the sterilizable handle assembly used in LED Surgical Light. Some of the material fitting size of the sterilizable handles assembly may not meet the company's internal control standards, which affects product reliability. In order to eliminate potential safety risk, Mindray will recall all affected products voluntarily.

To date, there are no reports of death or injury 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. 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 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 LED surgical Light.

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.

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 –Thaddeus Yan

Organization: Nanjing Mindray Bio-Medical Electronics Co.,LTD
Tel: +86 025 66082834
Email: thaddeus.yan@mindray.com

This Notice has been notified the appropriate Regulatory Agency.

(Closing paragraph)

Signature:

Li Xiaoqiao
Quality Manager, Quality Management Department
Nanjing Mindray Bio-Medical Electronics Co.,LTD
666# Middle ZhengFang Road, Jiangning,211111 Nanjing, Jiangsu, P.R.China
Tel: 0086 025 66082629
Email : njmrq@mindray.com

Acknowledgement Form

=====
Confirmation of Receipt of Field Safety Notice
Commercial name/Model: *LED Surgical Light*
FSCA-identifier: *CP-2018-100*
Type of action: *Device repair*
=====

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

Email: thaddeus.yan@mindray.com

Name: _____

Tel. No.: _____

E-mail address: _____

Date and Signature: _____

Address of the Organization:

Appendix 1 List of Affected Devices.

1. List of LED surgical Light which distributed with equipments

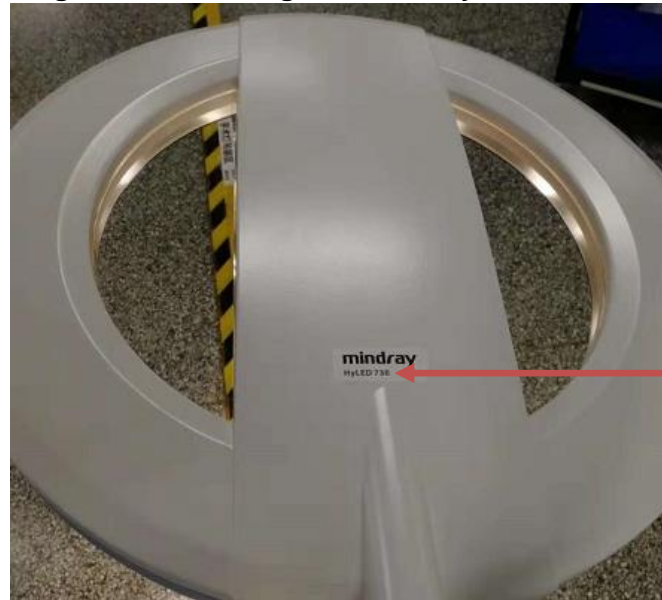
Country	Equipment S/N	Commercial name/Model	Distributor/Hospital	Contact person	Address	Telephone	Email

2. List of LED surgical Light which distributed as FRU parts

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

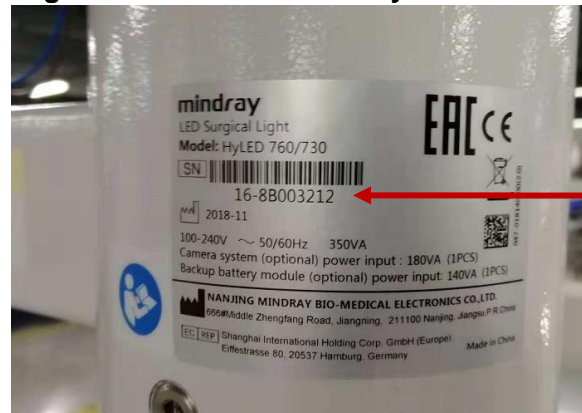
The commercial name is on the back of the light head; the serial number is on the main unit label which is on the back of the swivel arm assembly. Please refer to below picture:

Figure 1 Back of Light Head (HyLED-Series)



Commercial Name

Figure 2 Main Unit Label (HyLED-Series)



Serial Number: XX-XXXXXXXX