Reference: 2023-013M

7 November 2023

URGENT - FIELD SAFETY NOTICE

To all users of Olympus ENDOEYE HD II **WA50040A & WA50042A (All serial numbers)**

Re: Reminding to inspect the ENDOEYE HD II image & have spare as described in the Instructions For Use (IFU).

Attention: **Endoscopy Department, Risk Management**

Dear Health Care Practitioner,

This customer notification pertains to the Olympus ENDOEYE HD II and is intended to remind you to inspect the image prior to a clinical procedure and to have spare equipment available as described in the instructions for use. ENDOEYE HD II is a rigid video laparoscope for general surgery in the abdomen and thorax and is intended to visualize a clear image of the surgical environment on a screen during procedures.

ENDOEYE HD II

Reason for this Field Corrective Action:

Olympus has identified a total of 1003 complaints, including 372 adverse events (since September 2020 to August 2023) related to pink or green coloration of the image, including cases with reported delays of treatments and/or prolonged surgery. Olympus investigated the complaints and identified that the CCD chip that produces the image became damaged. The CCD chip is sensitive to heat and mechanical shocks. Olympus's risk management is taking this into account, and the instructions for use mention necessary steps to prepare the video telescope prior to usage.

This Field Safety Notice reminds customers to follow the steps in the instructions for use, especially to inspect the image prior to a clinical procedure, and always have a spare laparoscope available.

Olympus is currently investigating technical solutions to address this issue.

OLYMPUS (MALAYSIA) SDN. BHD. (200101010901)
Unit T2-L05-1, PJ33, No. 3, Jalan Professor Khoo Kay Kim, Section 13, 46200 Petaling Jaya, Selangor, Malaysia
Tel: (603) 7650 8990 Fax: (603) 7650 8999

Risk to Health:

The imaging color is an important factor affecting visualization in laparoscopic procedures to recognize relevant tissue areas for treatment. When an image discoloration is detected prior to a procedure, it is expected that the device will require replacement, thereby leading to a delay in patient treatment. If the issue is encountered during a procedure, device exchange could potentially result in prolonged surgery, and due to potential visual impacts mucosal injury or bleeding may occur. In the event that no alternate devices are available, the surgeon may elect to convert to an open surgery.

Actions to be taken by the end user:

Our records indicate that your facility has purchased one or more of the affected ENDOEYE HD II.
Olympus **requests you to take the following actions:**

1. Carefully read the content of this notification.
2. Ensure all personnel are completely knowledgeable and thoroughly **trained in the ENDOEYE HD II Instructions For Use (IFU). The purpose of this Field Safety Notice is to reinforce the requirement in the IFU that users inspect the image prior to a clinical procedure (as described in** Section 7.4 Testing), **always have a spare laparoscope available (as described in** Section 2.5 General Dangers, Warnings and Cautions) **and to check the image for the spare equipment.**
3. Olympus requests that you acknowledge receipt of this letter return the 'Response Form' to us.
4. If you have further distributed this product, identify your customers, forward them this notification, and appropriately document your notification process.

Olympus requests that you report complaints, including any injuries associated with procedures and adverse events experienced with the use of this product, to Olympus.

Olympus regrets any inconvenience caused and fully appreciates your cooperation in this matter. Please do not hesitate to contact us for any additional information or support concerning this matter.

Contact for enquiries.
Regulatory Affairs and Quality Assurance Department
Email : mes-ra.oml@olympus.com
Tel : (603) 7650 8990
Fax : (603) 7650 8999

The **Medical Device Authority** has been informed of this notice.

Yours sincerely,

Hideki Nagai
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Hideki Nagai
Managing Director
Olympus (Malaysia) Sdn. Bhd.

OLYMPUS (MALAYSIA) SDN. BHD. (200101010901)
Unit T2-L05-1, PJ33, No. 3, Jalan Professor Khoo Kay Kim, Section 13, 46200 Petaling Jaya, Selangor, Malaysia
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Response Form

Please send the complete and signed Response Form to Regulatory Affairs and Quality Assurance Department at:

To : Olympus (Malaysia) Sdn. Bhd, Regulatory Affairs & Quality Assurance
Fax/Email : (603) 7650 8999 / mes-ra.oml@olympus.com
From : _____ [Facility Name] Contact no.:_____
Date : _____
Ref : 2023-013M

URGENT - FIELD SAFETY NOTICE

Re: Reminding to inspect the ENDOEYE HD II image & have spare as described in the Instructions For Use (IFU).

I acknowledge receipt of the Field Safety Notice ("FSN") referenced above. I understand that I need to undertake the action(s) listed in the FSN.

Check the applicable boxes below:

☐ I DO NOT have affected devices remaining. All have been condemned or discarded.

☐ I DO have the affected devices, which I will adhere to the FSN.

Name: _____

Designation: _____

....
Signature & Company Stamp Date

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2023-013M FSN - Customer Letter

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