

URGENT FIELD SAFETY NOTICE

RE: ENDOEYE HD II

Attention: Endoscopy Lab Manager, Risk Management Department

Product Name	Model/Catalog Number	Serial Numbers	UDI DI
ENDOEYE HD II	WA50040A	All	04042761074964
ENDOEYE HD II	WA50042A	All	04042761074971

Dear Healthcare Professional:

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 Corrective Action 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.

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.

Action steps to be taken by the end user:

Olympus requests you to take the following actions:

1. Carefully read the content of this Field Safety Notice (FSN).
2. Please make sure that all medical personnel are completely knowledgeable and thoroughly trained in the ENDOEYE HD II Instructions For Use (IFU). The purpose of this Field Corrective Action 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. Indicate on the Reply Form that you have received and understood this Field Safety Notice by filling out and returning the completed enclosed Reply Form back to your local Olympus representative latest by 30.11.2023.
4. If you have distributed these devices outside your facility, please notify your customers of this matter immediately by forwarding them this Field Safety Notice. Please appropriately document your notification process and let us know the end-customer feedback accordingly.

Olympus requests that you report any complaints to ra@olympus.co.uk.

Olympus regrets any inconvenience caused and fully appreciates your cooperation in this matter. Please do not hesitate to contact me directly at 01 4260100 or at info@olympus.ie for any additional information or support concerning this matter.

Sincerely,

Niamh Billings

NIAMH BILLINGS
Senior Technical Services Administrator



REPLY FORM – QIL FY24-EMEA-24-FY24-EMEA-08-Green Image

OLYMPUS URGENT FIELD SAFETY NOTICE ENDOYE HD II
[Name & Address of Hospital/Medical Facility]
[Dept/Attn]
[Date]

I herewith acknowledge the receipt of your Field Safety Notice.
Further I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact. I understand the necessity of following the instructions carefully.

Name (Signature) _____

Name (Print) _____

Position _____

Please send your completed paper form response to OlympusFY24-24@sedgwick.com latest by 30 November 2023.