

[XX.] November 2015

Ref.: QIL-148P-01

URGENT: FIELD SAFETY NOTICE / RECALL – MEDICAL DEVICE REMOVAL

Attention: Operating Room Manager

Re: OLYMPUS ENDOEYE HD II Video Telescope

Model Number	Serial Number(s)
WA50040A	[to be populated]
WA50042A	[to be populated]

[Dear Customer:]

[Dear Healthcare Provider:]

[Dear Healthcare Practitioner:]

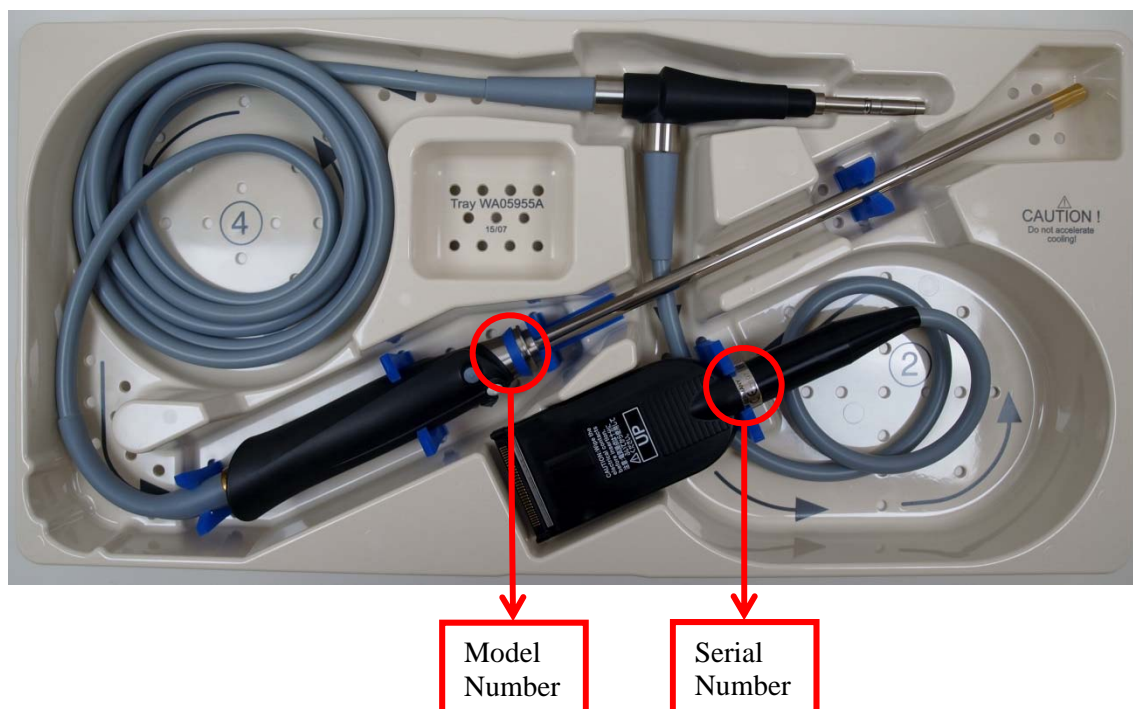
OLYMPUS is implementing a removal action of the OLYMPUS ENDOEYE HD II video telescopes (“ENDOEYE”) referenced above. The ENDOEYE video telescopes are used with other supporting equipment for endoscopy and endoscopic surgery within the thoracic and abdominal cavities including the female reproductive organs.

OLYMPUS has initiated this removal action following a complaint of a damaged temperature sensor at the ENDOEYE tip which caused the distal end to become abnormally hot. Although no patient or user injury occurred as a result of this reported complaint, excessive heating of the ENDOEYE distal end could result in patient or user injury. In an effort to prevent a potential risk to patient or user health, OLYMPUS is undertaking this action to remove the model and serial numbers identified above and to repair and return the devices.

Action Steps:

Our records indicate that your facility has purchased one or more ENDOEYE with the serial numbers listed above. **OLYMPUS requires you to take the following actions:**

1. Inspect your inventory for the referenced devices and identify any of the specified OLYMPUS models and serial numbers identified above. The model and serial number can be found on the device as illustrated in the following pictures.





Model
Number



Serial
Number

2. Discontinue use of any affected device identified in your inventory.
3. Contact [the OLYMPUS Customer Care Center / the OLYMPUS Service Center / your local OLYMPUS representative] at [telephone number]. You will be provided instructions on returning the ENDOEYE for repair and service.
4. Please note on the enclosed reply form that you have received this important safety information and include the quantity of any affected device that you have identified.
5. Fax the completed reply form to [telefax number].

The [local/national Competent Authority] is aware of this action.

Please indicate on the enclosed reply form that you have received this important safety information. OLYMPUS regrets any inconvenience from this action and fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact me directly at [telephone number] or at [e-mail address] if you have any questions on this matter.

Regards,

[Name]

[Position]

[Department]

[S-BC / Distributor]



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Affected Models: WA50040A and WA50042A – Video Telescopes "ENDOEYE HD II", 10 mm

Serial Number(s): [to be populated]

I have received the important safety information on the OLYMPUS ENDOEYE HD II video telescopes referenced above. I understand that I need to inspect my inventory and quarantine any affected device I have identified.

OLYMPUS will repair and service the video telescopes and return to your facility. Contact [the OLYMPUS Customer Care Center / the OLYMPUS Service Center / your local OLYMPUS representative] at [telephone number]. You will be provided instructions on returning the ENDOEYE for repair and service.

Choose either A or B:

A) _____ I checked my inventory and do NOT have this device.

B) _____ I checked my inventory and I will return the following number of video telescopes:
_____.

Facility (please do not abbreviate):

Address:

City:

Postal Code: _____ Country: _____

Your Name: _____

Your Phone Number: _____

Please fax this completed reply form to OLYMPUS at [telefax number]