[XX] January [XX] 2017 [Reference: QIL-149P-04]

[URGENT: FIELD SAFETY NOTICE / FIELD SAFETY CORRECTIVE ACTION]
[URGENT: RECALL - MEDICAL DEVICE REMOVAL]

Attention: Operating Room Manager

Regarding: OLYMPUS ENDOEYE HD II Video Telescope - temperature issue

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

[Dear Customer,/:]
[Dear Healthcare Provider,/:]
[Dear Healthcare Practitioner,/:]

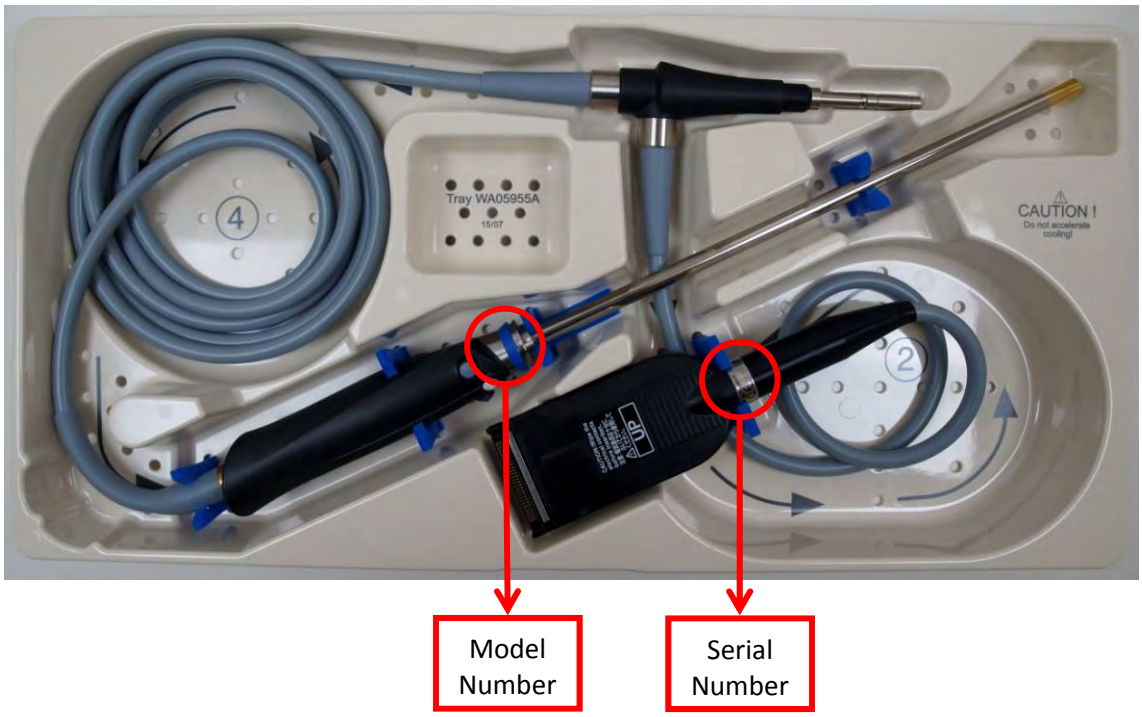
OLYMPUS is implementing a [Field Safety Corrective Action ("FSCA") / removal action] of the OLYMPUS ENDOEYE HD II video telescopes ("ENDOEYE") referenced above. The ENDOEYE video telescopes are used with other supporting equipment for endoscopy and endoscopic surgery within the thoracic and abdominal cavities including the female reproductive organs.

OLYMPUS has initiated this [FSCA / removal action] after discovering that the ENDOEYE distal end can become abnormally hot if the temperature sensor at the device's tip is damaged. Although no [customer] complaints have been received referring to this issue and thus no patient or user injury has occurred, 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 [recall / remove] the model and serial numbers identified above and to modify and return the devices.

Disabling a specific feature on the video telescopes ("fog-free function") will prevent excessive heating of the ENDOEYE distal end in case of certain faults. You will be provided with an Addendum to the instructions for use with your modified devices. OLYMPUS strives to find a technical solution which will enable the reactivation of this feature in the near future. You will be duly informed as soon as OLYMPUS has concluded the technical investigation and has assessed possible solutions.

Action steps to be taken by the end user:
Our records indicate that your facility has purchased one or more of the affected ENDOEYE models 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 model and serial numbers identified above. The model and serial number can be found on the device as illustrated in the following pictures.



2. Discontinue use of any affected device identified in your inventory.

3. Contact [the OLYMPUS Customer Care Center / the OLYMPUS Helpdesk / the OLYMPUS Service Center / your local OLYMPUS representative] at [telephone number]. You will be provided with instructions on how to return the ENDOEYE for modification [as well as arranging temporary loan equipment].

4. Please note on the enclosed reply form that you have received this [Field Safety Notice ("FSN") / product removal notice]. Please include the quantity of any affected ENDOEYE you have identified in your inventory and intend to return.

5. Fax or e-mail the completed reply form to [Department] at [telefax number] or [e-mail address].

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

OLYMPUS regrets any inconvenience resulting from this action and fully appreciates your prompt cooperation in addressing this situation. If you have any questions or concerns, please do not hesitate to contact me directly at [telephone number] or at [e-mail address].

Sincerely,

[Name]
[Position]
[Department]
[S-BC / Distributor]

[URGENT: FIELD SAFETY NOTICE / FIELD SAFETY CORRECTIVE ACTION]
[URGENT: RECALL - MEDICAL DEVICE REMOVAL]

Regarding: OLYMPUS ENDOEYE HD II Video Telescope - temperature issue

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

I have received the [important safety information / product removal notice] 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.

Contact [the OLYMPUS Customer Care Center / the OLYMPUS Helpdesk / the OLYMPUS Service Center / your local OLYMPUS representative] at [telephone number]. You will be provided with instructions on how to return the ENDOEYE for modification [as well as arranging temporary loan equipment].

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 devices:

_____.

Facility / Hospital Name (please do not abbreviate):

_____

Address:

_____

Postal Code / City: Country:

_____

Name: Title:

_____

Date: Signature:

_____

Please send the completed and signed reply form to [Department] at

[telefax number] or [e-mail address].