

February 10, 2017

URGENT: MEDICAL DEVICE CORRECTIVE ACTION

Attention: Operating Room Manager

Regarding: **OLYMPUS ENDOEYE HD II Video Telescope - temperature issue**

| Model Number | Serial Number(s) |
|--------------|--------------------|
| WA50040A | All serial numbers |
| WA50042A | All serial numbers |

Dear Healthcare Practitioner:

OLYMPUS is implementing a Corrective Action of the OLYMPUS ENDOEYE HD II video telescopes ("ENDOYE") 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.

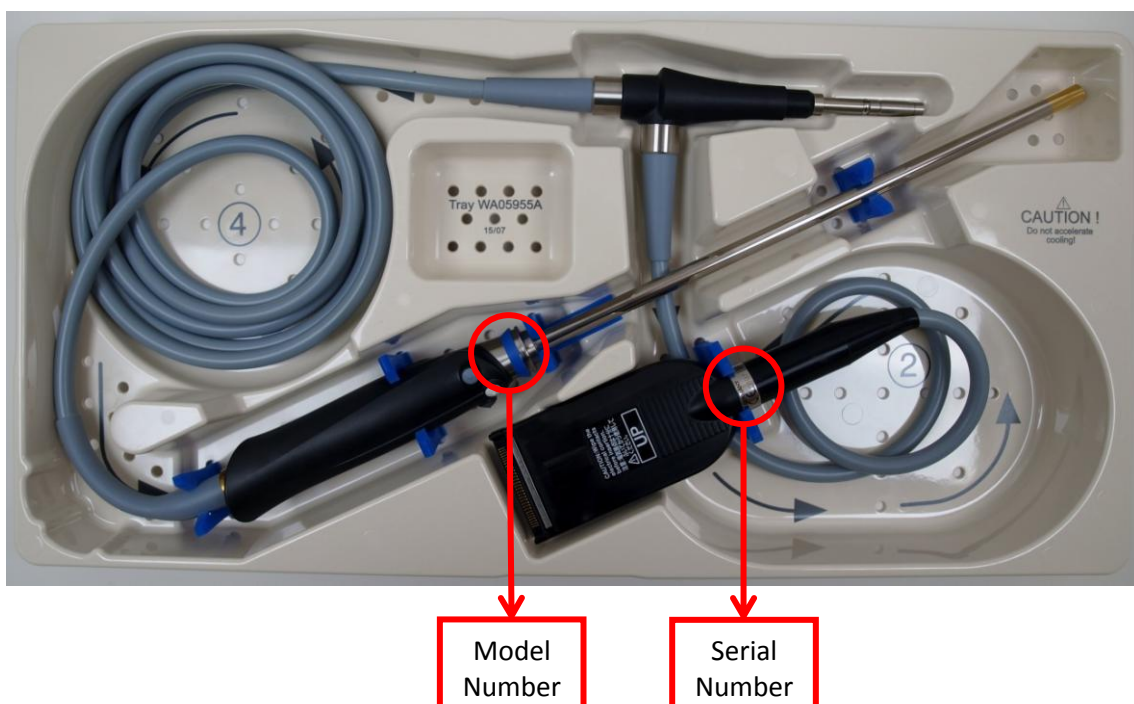
OLYMPUS has initiated this corrective action after discovering that the ENDOEYE distal end can become abnormally hot if the temperature sensor at the device's tip is damaged. Although no customer complaints have been received referring to this issue and thus we are not aware of any patient or user injury, excessive heating of the ENDOEYE distal end could result in patient or user injury. To prevent a potential risk to patient or user health, OLYMPUS is undertaking this action to repair the devices by disabling a specific feature on the video telescopes ("fog-free function") to prevent excessive heating of the ENDOEYE distal end in case of certain faults. An addendum to the instructions for use with your modified devices is enclosed with this letter.

OLYMPUS is currently evaluating possible technical solutions to enable the reactivation of this feature in the future. OLYMPUS will provide further information once an appropriate solution is available.

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.





Model
Number



Serial
Number

2. Discontinue use of any affected device identified in your inventory.
3. Please note on the enclosed Reply Form that you have received this notification. Olympus requires that you indicate on the attached Reply Form the contact information for your facility so we can schedule a mutually convenient time for an Olympus Field Service Representative to visit your facility to repair the telescope or for return of the telescope to our National Service Center for the repair. Service personnel will repair the devices by disabling a specific feature on the video telescopes ("fog-free function") to prevent excessive heating of the ENDOEYE distal end in case of certain faults.
4. Fax the completed Reply Form to 484-896-7128.

The U.S. Food and Drug Administration is aware of this action.

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 484-896-5688 or at laura.storms@olympus.com if you have any questions on this matter.

Regards,

Laura Storms
V.P., Regulatory Affairs & Quality Assurance