

URGENT: FIELD SAFETY NOTICE

Action Identifier Number: **211**

Type of Action: **Field Safety Corrective Action**

Affected Product: **WA50040A - Video telescope "ENDOEYE HD II", 10mm, 0° Autoclavable**
Affected Serials: **622721, 623695 622802 & 1620987**

Affected Product: **WA50042A – Video telescope "ENDOEYE HD II", 10mm, 30° Autoclavable**
Affected Serials: **624183, 623758 & 623757**

Olympus is implementing a Field Safety Corrective 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 with the thoracic and abdominal cavities including the female reproductive organs.

Olympus has initiated this field 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 recall the model and serial numbers identified above and to repair and return the devices.

Action Steps to be taken by the end user:

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



Model
Number



Serial
Number

2. Discontinue use of any affected device identified in your inventory.
3. Contact our Olympus helpdesk on 01 426 0100. You will be provided with instructions on how to return the ENDOEYE for repair as well as arranging temporary loan equipment.
4. Please complete the enclosed reply form indicating that you have received this important safety information and specify the quantity of any affected device that you have identified in your inventory and intend to return.
5. Fax or Email the completed reply form to 01 426 0123 or info@olympus.ie

Olympus regrets any inconvenience from this action and fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact our helpdesk team on 01 426 0100 or email info@olympus.ie if you have any questions on this matter.