



Your Vision, Our Future

Reference: 2017-001W

Cc: Chairman Medical Board and Relevant Heat of Departments

February 24, 2017

**IMPORTANT SAFETY NOTICE**

**TEMPERATURE ISSUE OF OLYMPUS ENDOEYE HD II VIDEO TELESCOPE (MODEL: WA50040A and WA50042A)**

Dear Sir/Mdm,

Olympus has initiated to implement a Field Safety Corrective Action ("FSCA") on OLYMPUS ENDOEYE HD II Video Telescopes ("ENDOEYE"). This FSCA affects model numbers WA50040A and WA50042A only. 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 after discovering that the ENDOEYE distal end might 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 perform on-site modification of the affected models.

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 that 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.

Our records indicate that your facility has purchased one or more of the affected ENDOEYE models. Hence, we are writing to inform you that our Service personnel will be contacting you to arrange for an appointment to modify the affected ENDOEYE models at your facility.

Please complete "Response Form" to indicate that you have received this safety notice. In addition, kindly ensure that information in this notice is made available to all relevant personnel within your facility.

Olympus regrets any inconvenience from this action and fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact us for any additional information on this matter.

**OLYMPUS SINGAPORE PTE. LTD.**

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Thank you for your patience and support.

Sincerely,



Loh E Thel  
General Manager  
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Olympus Singapore Pte. Ltd.

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