



June XX, 2018
Olympus reference: QIL 151-003

**URGENT FIELD SAFETY NOTICE
FOR THE VISERA ELITE II VIDEO SYSTEM CENTER**

ATTENTION: Endoscopy Department, Risk Management and Reprocessing Units

Model	Serial Number(s)
VISERA ELITE II VIDEO SYSTEM CENTER OLYMPUS OTV-S200	[to be completed]
VISERA ELITE II VIDEO SYSTEM CENTER OLYMPUS OTV-S300	[to be completed]

Dear Health Care Professional,

Here at Olympus, we are permanently striving towards providing the highest quality and best service to our customers.

Our records indicate that your facility has purchased at least one of the above -mentioned medical devices.

As a result of our investigation, it was found that there is a possibility that the power supply of the affected products may shut down. This failure may occur because of an electrical component that did not comply with the required specifications, due to the design used in the power supply.

Olympus has therefore decided to replace the power supply of the affected products with a countermeasured one.

If the power supply of an OTV-S200 / OTV-S300 fails the start of the patient procedure may be delayed or the duration of the patient procedure may be extended while switching to the back up device as stated in the respective instructions for use. However, since the product is used under the supervision of medical professionals, Olympus has deemed that appropriate treatment may be undertaken and that it is unlikely that this will lead to a health risk.

Olympus reviewed the complaint history for the OTV-S200/ OTV-S300 and did not find any cases where a patient injury was reported.

Action Steps:

As our records indicate that your facility has purchased an affected OTV-S200/ OTV-S300, Olympus requires you to take the following immediate action:

1. Inspect your inventory and identify any OTV-S200/ OTV-S300 models.
2. **Olympus XX will contact your facility in time to make arrangements for a rework of your OTV-S200/ OTV-S300.** You do not need to proactively contact Olympus and you may continue using your existing OTV-S200/ OTV-S300. In order to replace all affected devices in the market we calculate up to 6 month. However if the power supply of your OTV-S200 /OTV-S300 fails before it has been replaced by Olympus, please contact your local Olympus representative and we will find a workable solution for you.
3. If you have further distributed the OTV-S200/ OTV-S300, please identify your client(s). Notify them at once of this URGENT FIELD SAFETY NOTICE and duly document your notification process.
4. Please indicate on the enclosed questionnaire that you have received this notification. Please include the quantity of products you have identified in your inventory, including their Serial Numbers, on the enclosed questionnaire and fax the completed form to XXX-XXX-XXXX by XX.XX.XXXX at the latest.

Your National Competent Authority has been informed of this Field Safety Notice.

Olympus fully appreciates your cooperation in addressing this situation and apologises for any inconvenience caused.

If you have any questions on this matter, please do not hesitate to contact us directly at [Olympus contact details] or by e-mail at [Olympus contact details].

Yours sincerely,

REPLY FORM - QIL 151-003

OLYMPUS URGENT FIELD SAFETY NOTICE VISERA ELITE II VIDEO SYSTEM CENTER OTV-S200 OTV-S300	
[Name & Address of Hospital/Medical Facility]	
[Dept/Attn]:	
[Date]:	
By submitting this reply form, I acknowledge that I have received the Urgent Field Safety Notice.	
Model	Serial Number

Name (Signature):

Name (Printed):

Position:

Please fax this completed reply form to Olympus at [contact number]