

Reference: 2018-002M

1st June 2018

FIELD SAFETY NOTICE

VISERA ELITE II VIDEO SYSTEM CENTER OTV-S200 / OTV-S300 – POWER SUPPLY SHUTDOWN

Dear Sir/Madam,

OLYMPUS is implementing a Field Safety Corrective Action for the VISERA ELITE II Video System Center. The affected models and serial numbers are listed below.

Model Number	Serial Number
OTV-S200	All serial number prior to S/N starting with 781xxxx
OTV-S300	All serial number prior to S/N starting with 781xxxx

The video system center is intended to be used with Olympus camera heads, endoscopes, monitors, EndoTherapy accessories and other ancillary equipment for endoscopic diagnosis, treatment and video observation. It is a compact system that allows 2D and 3D observation.

OLYMPUS has received information of power supply unit shut down in user facilities and during inspection process at factory. Manufacturer's investigation found out that the electrical component in the power supply unit was deteriorated. It was found that this deterioration was caused by electrical stress as there was insufficient temperature margin of specification of the component against actual use due to power supply design.

There is no patient injury reported. If the power supply fails when the video system center is turned on at the start of patient procedure, it may cause delay while replacing with an alternative device. If it fails during the procedure, the affected product should be replaced with an alternative device as described in the instruction manual. Since the product is used under the supervision of medical professional, it is considered that appropriate treatment would be undertaken and it is unlikely that it will lead to severe health hazard.

OLYMPUS is implementing corrective action to rework the video system center by replacing the power supply unit with countermeasured ones.

Actions to be taken by end user

Our records indicate your facility has purchased one or more of the affected VISERA ELITE II Video System Center OTV-S200 and OTV-S300 from OLYMPUS.

OLYMPUS requests you to take the following actions:

1. Inspect your inventory and identify all affected OTV-S200 and OTV-S300 models.
2. Your local Olympus representative will contact your facility to arrange for return of all affected models for rework process.
3. Please acknowledge on the enclosed "Response Form" that you have received this Field Safety Notice ("FSN") and include the quantity of affected devices you have identified in your inventory and intend to return for rework activities.
4. Email the completed "Response Form" to the Regulatory Affairs Department at mes-ra.osp@olympus-ap.com, or you may return the completed form to your local Olympus representative.

OLYMPUS regrets any inconvenience and fully appreciates your prompt cooperation in addressing this situation. If you have any questions or concerns, please do not hesitate to contact us for additional information.

Contact information

Olympus Singapore Pte. Ltd.

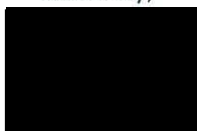
Regulatory Affairs Department

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Sincerely,



Loh E Thei
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Olympus Singapore Pte. Ltd.

cc: Chairman Medical Board and relevant Head of Departments