

November 3, 2016

URGENT: MEDICAL DEVICE REMOVAL

Attention: Urology Department

Re: ESG-400 Electrosurgical Generator - Instrument Recognition Issue Affected Product: HF Cable WA00014A - Designated LOT Numbers

Model Number	LOT Numbers		
	158W	161W	
	159W	162W	
	15XW	163W	
WA00014A	15YW	164W	
	15ZW	165W	
		166W	
		167W	

Dear Healthcare Practitioner:

Olympus America Inc. ("OAI") is implementing a removal action of the HF cable WA00014A which is used with the Olympus ESG-400 electrosurgical generator. The Olympus ESG-400 electrosurgical generator is intended for tissue cutting and coagulation in open, laparoscopic and endoscopic surgery.

OAI has initiated this removal action following complaints that the following error codes may be generated/displayed during a procedure under certain conditions even though the HF cable with instrument had been connected properly to the UNIVERSAL socket of the ESG-400 electrosurgical generator:

- E619 "Data transfer"
- E486 "No instrument connected" or a
- Pop-up message "Use default instrument settings?"

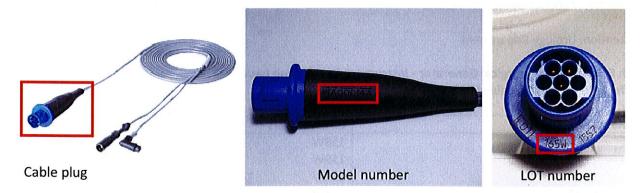
While error code E619 or E486 or the pop-up message is displayed, no high-frequency output is possible. These messages will disappear after 10 seconds or when the user presses the "OK button" in the error message screen. The high-frequency output of the ESG-400 electrosurgical generator will be available immediately afterwards and the procedure can be continued.

Please note that the error codes may also be displayed as per the conditions described in the ESG-400 instruction manual. The error codes will persist if the cause is other than the HF cable. See pages 61 to 62 for a description of the pop-up message "Use default instrument settings?" and page 108 for the possible causes and remedial actions for the error codes E619 "Data transfer" and E486 "No instrument connected".

Olympus has not received to date any report of a patient or user injury occurring as a result of this reported complaint.

Action Steps: Our records indicate that your facility has purchased one or more of the potentially affected HF cables WA00014A with the LOT numbers given above.

1. Inspect your inventory for the referenced cables and identify any of the specified model and LOT numbers. The model and LOT number can be found on the cable plug as illustrated in the following pictures.



- 2. Call Olympus Customer Service at 888-524-7266 to obtain a Returned Material Authorization (RMA) so you can return the product at no charge to you. Olympus will issue a credit or replacement to your facility for any returned product. Depending on the stock availability of the replacement cables, you might be asked to return your inventory gradually. You can continue to use the affected cables until replaced.
- 3. Please note on the enclosed Reply Form that you have received this product removal notice and include the quantity of any affected cables you have identified.
- 4. Fax the completed Reply Form to Olympus Regulatory Affairs at 484-896-7128 regardless of whether you have any affected inventory at your facility.

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

We regret any inconvenience this may cause you and your patients. If you have any questions or concerns, please do not hesitate to contact me directly at 484-896-5688 or at laura.storms@olympus.com.

Sincerely.

Laura Storms

V.P., Regulatory Affairs & Quality Assurance