

**URGENT: MEDICAL DEVICE REMOVAL**  
ESG-410 Electrosurgical Generator

**Product Name:** ESG-410 Electrosurgical Generator

**Model/Catalog Number:** WA91307C (US Version)

**Serial Number/UDI-DI:** See attachment

Date: June 21, 2024

Attention: *Operating Room Director, Biomedical Engineers*

Dear Healthcare Professional:

Olympus is writing to inform you of a removal action for the repair of specific ESG-410 Electrosurgical Generator units. This product, in conjunction with electrosurgical accessories and ancillary equipment, is intended for cutting and coagulation of tissue in open surgery, laparoscopic surgery, and endoscopic surgery.

**Reason for Action:**

Olympus is conducting this action after identifying an increase in complaints related to the ESG-410 generator not powering on. Olympus' investigation has determined that this phenomenon is caused by a failure of electrical components on the generator's power supply. However, if the device has successfully powered on, it will work within specification. To address this issue, Olympus will be replacing the current power supply with a new power supply part that is not susceptible to this issue.

Olympus has identified forty-seven (47) complaints for the ESG-410 generator not powering on that may have resulted from this issue. No serious injuries or reportable malfunctions have been reported in relation to this issue.

**Risk to Health:**

The device not powering on may result in delays in initiating treatment or prolonged surgery.

**Actions Required:**

Our records indicate that your facility has received one or more affected ESG-410 units. A list of affected serial numbers is attached to this letter. The serial number is on a label affixed to the backside of the generator.

An Olympus representative will reach out to you to coordinate a repair to replace the power supply on your affected ESG-410 unit(s). Technical analysis of this issue performed by Olympus has determined that when the device is successfully powered on, it will work within specification. Therefore, you may continue to use your ESG-410 generator until the power supply is replaced. To minimize procedural delays, power on the generator prior to starting the procedure and, whenever possible, have a replacement device available.

Additionally, Olympus requires you to take the following actions:

1. Carefully read the content of this notification.
2. If you have further distributed this product, identify your customers, and forward them this notification.
3. Acknowledge receipt of this letter through the Olympus web portal:
  - a. Go to <https://olympusamerica.com/recall>

- b. Enter the recall number "0447"
  - c. Complete the form as instructed and include your account ID number
4. Please forward this notice to other users who may have the affected products if you have further distributed it.

Olympus requests that you report any complaints, including the ESG-410 generator not powering on, to the Technical Assistance Center (TAC) at 1- 800-848-9024 (option 1), and the FDA. Adverse events experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me by phone at (647) 999-3203 from Monday through Friday, 9 am to 5 pm EDT, or by e-mail at [Cynthia.Ow@olympus.com](mailto:Cynthia.Ow@olympus.com).

Sincerely,

*Cynthia Ow*

Cynthia Ow  
Field Corrective Actions Lead, Americas

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Attachment – Affected Serial Numbers for Repair

100641	102410	102441	102523
101001	102411	102442	102802
101377	102412	102443	102807
101754	102413	102444	102808
101966	102414	102445	102809
102363	102415	102497	102810
102364	102416	102498	102814
102366	102417	102499	102818
102369	102418	102500	102819
102371	102419	102501	102820
102372	102420	102502	102821
102373	102421	102503	102822
102391	102422	102504	102823
102392	102423	102505	102828
102393	102424	102506	102829
102394	102425	102507	102830
102395	102426	102508	102831
102396	102428	102509	102832
102397	102429	102510	102834
102399	102430	102511	102836
102400	102431	102512	102912
102401	102432	102513	102913
102402	102433	102515	102914
102403	102434	102516	102916
102404	102435	102517	102917
102405	102436	102518	102919
102406	102437	102519	102921
102407	102438	102520	102923
102408	102439	102521	102925
102409	102440	102522	