

URGENT FIELD SAFETY NOTICE**RE: ESG-410 Electrosurgical Generator****Attention:** *Operating Room Director, Biomedical Engineers*

| Material ID | Model Number | Material Description | Serial Numbers | UDI-DI |
|-------------|--------------|----------------------|----------------|---------------|
| WA91307W | ESG-410 | HF units ESG-410 | See attachment | 4042761086332 |

Dear Healthcare Professional:

Olympus is writing to inform you of a Field Corrective Action pertaining to the ESG-410 Electrosurgical Generator. 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 field correction 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 the service 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. Olympus's record of the completed power supply replacement for your ESG-410 generator(s) will serve as the acknowledgment of this field corrective action for your facility.
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 concerns@olympus.co.uk.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact our office on 01 4260100 or email info@olympus.ie.

Sincerely,

Niamh Billings

Niamh Billings

Olympus Ireland



URGENT: FIELD CORRECTIVE ACTION
ESG-410 Electrosurgical Generator
Attachment – Affected Serial Numbers

| | | | | | | | | |
|--------|--------|--------|--------|--------|--------|--------|--------|--------|
| 102374 | 102603 | 102761 | 102389 | 102618 | 102846 | 102493 | 102734 | 102962 |
| 102375 | 102604 | 102762 | 102390 | 102619 | 102847 | 102494 | 102735 | 102963 |
| 102376 | 102605 | 102763 | 102446 | 102620 | 102848 | 102495 | 102736 | 102964 |
| 102377 | 102606 | 102764 | 102447 | 102621 | 102849 | 102496 | 102737 | 102965 |
| 102378 | 102607 | 102765 | 102448 | 102622 | 102850 | 102524 | 102738 | 102966 |
| 102379 | 102608 | 102766 | 102449 | 102623 | 102851 | 102525 | 102739 | 102967 |
| 102380 | 102609 | 102767 | 102450 | 102624 | 102852 | 102526 | 102740 | 102968 |
| 102381 | 102610 | 102768 | 102451 | 102625 | 102853 | 102527 | 102741 | 102969 |
| 102382 | 102611 | 102769 | 102452 | 102626 | 102854 | 102528 | 102742 | 102970 |
| 102383 | 102612 | 102770 | 102453 | 102627 | 102855 | 102529 | 102743 | 102971 |
| 102384 | 102613 | 102771 | 102454 | 102628 | 102856 | 102530 | 102744 | 102972 |
| 102385 | 102614 | 102842 | 102455 | 102629 | 102857 | 102531 | 102745 | 102973 |
| 102386 | 102615 | 102843 | 102456 | 102630 | 102858 | 102532 | 102746 | 102974 |
| 102387 | 102616 | 102844 | 102457 | 102631 | 102859 | 102533 | 102747 | 102975 |
| 102388 | 102617 | 102845 | 102458 | 102632 | 102860 | 102534 | 102748 | 102976 |
| 102472 | 102646 | 102874 | 102459 | 102633 | 102861 | 102535 | 102749 | 102977 |
| 102473 | 102647 | 102875 | 102460 | 102634 | 102862 | 102536 | 102750 | 102978 |
| 102474 | 102648 | 102876 | 102461 | 102635 | 102863 | 102537 | 102751 | 102979 |
| 102475 | 102649 | 102877 | 102462 | 102636 | 102864 | 102538 | 102752 | 102980 |
| 102476 | 102650 | 102878 | 102463 | 102637 | 102865 | 102539 | 102753 | 102981 |
| 102477 | 102651 | 102879 | 102464 | 102638 | 102866 | 102540 | 102754 | 102982 |
| 102478 | 102652 | 102880 | 102465 | 102639 | 102867 | 102541 | 102755 | 102983 |
| 102479 | 102653 | 102881 | 102466 | 102640 | 102868 | 102542 | 102756 | 102984 |
| 102480 | 102654 | 102949 | 102467 | 102641 | 102869 | 102543 | 102757 | 102985 |
| 102481 | 102655 | 102950 | 102468 | 102642 | 102870 | 102600 | 102758 | 102986 |
| 102482 | 102656 | 102951 | 102469 | 102643 | 102871 | 102601 | 102759 | 102987 |
| 102483 | 102657 | 102952 | 102470 | 102644 | 102872 | 102602 | 102760 | 102988 |
| 102484 | 102658 | 102953 | 102471 | 102645 | 102873 | 102491 | 102732 | 102851 |
| 102485 | 102726 | 102954 | 102488 | 102729 | 102957 | 102492 | 102733 | 102770 |
| 102486 | 102727 | 102955 | 102489 | 102730 | 102958 | 102960 | 102989 | 102766 |
| 102487 | 102728 | 102956 | 102490 | 102731 | 102959 | 102961 | 102990 | 102752 |
| 102619 | 102456 | | | | | | | |



REPLY FORM: QIL FY25-EMEA-07-FY25-005-F – ESG-410 Unstable Power Supply

| | |
|--|--|
| Facility Name | |
| Facility Address | |
| Contact Name | |
| Additional Customer Requests (Indicate if you have any additional requests to support this action) | |

I acknowledge receipt of this notification. I confirm that I have communicated further to any affected departments.

| Completed By: | | |
|----------------------|------------------|-------------------------------|
| | | Click or tap to enter a date. |
| <i>Name</i> | <i>Signature</i> | <i>Date (YYYY-MM-DD)</i> |

Please send the completed form to info@olympus.ie by 20th July 2024.