

Date: 21.06.2024

Olympus reference: QIL FY25-EMEA-07-FY25-005-F – ESG-410 Unstable Power Supply

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.

[If applicable:] [competent authority] is aware of the actions described in this letter.

Olympus requests that you report any complaints, including the ESG-410 generator not powering on, to *[local facility complaint reporting contact]*. *[If applicable:]* Adverse events experienced with the use of this product may also be reported *[local competent authority]* by *[method]*.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact *[me directly at XXXX@olympus.com/ Olympus directly at (XXX) XXX-XXXX from Monday through Friday or by e-mail at XXX]*.

Sincerely,

Name

Olympus title

URGENT: FIELD CORRECTIVE ACTION

ESG-410 Electrosurgical Generator
Attachment – Affected Serial Numbers

102382	102657	102855	102525	102849	102540
102383	102727	102859	102535	102854	102952
102385	102730	102860	102536	102856	102953
102458	102731	102452	102537	102857	102954
102460	102732	102455	102538	102858	102852
102462	102734	102466	102541	102871	102850
102464	102735	102603	102542	102872	102386
102470	102736	102771	102543	102874	102387
102472	102739	102528	102606	102875	102607
102475	102741	102768	102609	102876	102494
102476	102742	102384	102610	102878	102611
102477	102743	102495	102613	102452	102614
102478	102744	102649	102616	102455	102615
102479	102746	102388	102617	102466	102620
102480	102749	102389	102618	102526	102622
102481	102756	102390	102621	102539	102623
102482	102757	102447	102628	102604	102624
102483	102760	102453	102632	102605	102625
102484	102762	102454	102633	102608	102627
102487	102764	102457	102634	102640	102629
102488	102765	102459	102635	102643	102630
102490	102769	102465	102636	102648	102631
102491	102842	102467	102639	102655	102638
102492	102843	102468	102641	102747	102646
102493	102844	102474	102642	102748	102647
102496	102846	102485	102644	102751	102851
102524	102848	102527	102645	102758	102770
102654	102761	102752	102653	102759	102766
102656	102763	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.
Name	Signature	Date (YYYY-MM-DD)

Please send the completed form to XXX by XX.XX.XXXX