Date: 25.07.2025

Olympus reference: QIL FY26-EMEA-03-FY25-005-F

URGENT FIELD SAFETY NOTICE/Medical Device Correction

RE: ESG-410 Electrosurgical Generator

Attention: *Endoscopy Department, Operating Room, Risk Management*

Material ID	Model Number	Material Description	UDI-DI	Serial Number(s)
WA91307W	ESG-410	HF units ESG-410	4042761086332	101113, 101126, 101170 ,101172, 101184, 101306, 101317, 101327, 101429, 101485, 101510, 101677, 101734, 102033, 102087, 102137, 102452, 102455, 102466, 102539, 102604, 102640, 102643, 102655, 102759, 102761, 102849, 102855, 102859, 102860, 102861, 100698

Table 1: Affected Product Information

Dear Healthcare Professional:

Olympus is writing to inform you of a Field Corrective Action for the ESG-410 Electrosurgical Generators detailed in the table above. The ESG-410 electrosurgical generator WA91307W in conjunction with electrosurgical accessories and ancillary equipment, is intended for cutting and coagulation of tissue in the following medical fields: open surgery, laparoscopic surgery and endoscopic surgery. The electrosurgical generator utilizes monopolar and bipolar high frequency current.

Reason for Action:

Olympus received forty-three (43) complaints between 01-July-2022 to 20-March-2025 from users where the ESG-410 Electrosurgical Generator displayed error message: “E0662 System Error”, followed by either automatic single reboots of the device, or continuous reboot ‘loops’. Users reported that these reboots occurred both during and prior to clinical use. An investigation by Olympus identified that this issue is caused by a previous change to an electronic component. This component change impacted an internal performance check parameter, which could then result in the error message being displayed, and an automatic system reboot. In some cases, the system will be in a continuous reboot. None of the forty-three complaints resulted in an adverse event.

An Olympus representative will reach out to you to arrange for a device update which resolves the cause of this issue.

Risk to Health:

The potential harm that could result from the generator rebooting or going into a reboot loop is a delay in initiating scheduled surgical treatment or prolonged surgery due to the need to troubleshoot and/or replace the generator. If a reboot occurs during the procedure there is potential risk of bleeding, which may require the

clinician to utilize alternative surgical instrumentation (i.e., clamps, sutures, etc.) to maintain hemostasis while the device reboots or while obtaining a replacement generator if the device is in a continuous reboot.

As a reminder, the IFU indicates to prepare a spare electrosurgical generator or an alternative procedure to avoid interruption due to an unexpected electrosurgical generator failure during the procedure.

Actions Required:

Our records indicate that your facility has received one or more of the affected units. Olympus requests you to take the following actions:

1. Examine your inventory for affected serial numbers (refer to Table 1 for affected serial number information).
2. Customers may continue to use the device whilst they are waiting for the update, ensuring all users follow the product Instructions for Use (IFU). This includes the instruction to prepare a spare electrosurgical generator, or an alternative procedure, to avoid interruption due to an unexpected electrosurgical generator failure during the procedure. If any problems are encountered with the device, including error messages and automatic reboots, please contact Olympus.
3. Olympus representative will reach out to you to arrange a mutually convenient time to update the affected device at no charge.
4. Olympus requests that you acknowledge receipt of this letter. Indicate on the Reply that you have received and understood this notification by filling out and returning the completed enclosed Reply Form back to your local Olympus representative ra@olympus.co.uk by 16.08.2025.
5. Please forward this notice to other users who may have the affected products if you have further distributed it.

Health Products Regulatory Authority (HPRA) is aware of the actions described in this letter.

Olympus requests that you report any complaints, including instances of error messages and automatic reboot, to concerns@olympus.co.uk . Adverse events experienced with the use of this product may also be reported *to the* Health Products Regulatory Authority (HPRA) online.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact charlotte.bell@olympus.com/ Olympus directly at 01702 616333 from Monday through Friday or by ra@olympus.co.uk.

Sincerely,

Charlotte Bell

Charlotte Bell
Field Safety Corrective Actions & Quality Assurance Projects Manager

REPLY FORM: QIL FY26-EMEA-03-FY25-005-F – ESG-410 Error E0662

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 ra@olympus.co.uk *by* 16.08.2025.