

October 1, 2024

URGENT: MEDICAL DEVICE CORRECTIVE ACTION
ESG-410 Electrosurgical Generator

Product Name: ESG-410 Electrosurgical Generator

Model/Catalog Number: WA91327U

Serial Number/UDI-DI: All, 04042761087698

Attention: Operating Room Director, Biomedical Engineers

Dear Healthcare Professional:

Olympus is writing to inform you of a Field Corrective Action pertaining to the ESG-410 Surgical Energy Platform (“ESG-410 (SEP)”) 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 indicating an occurrence of system error E1226 “Could not write to Audio Buffer” during procedures using the ESG-410 (SEP). This error is a high priority alarm which triggers an automatic reboot of the device, which may lead to a delayed or interrupted procedure until the reboot is completed. Rebooting is a safety measure to put the generator back into safe operation. After the reboot, the procedure can be continued. Olympus has developed a software update that prevents this system error E1226 from unnecessarily occurring.

Olympus has received six (6) complaints for the ESG-410 (SEP) generator with the occurrence of system error E1226. No serious injuries or reportable malfunctions have been reported in relation to this issue.

Risk to Health:

The potential immediate harms related to an occurrence of system error, E1226, include prolonged surgery while the device reboot occurs and the generator restarts, causing a minimal interruption of less than one minute. Reboot may occur more than once during the procedure. There is a potential for bleeding to occur if the device reboot occurs, during cutting and/or coagulation.

Actions Required:

Our records indicate that your facility has received one or more affected ESG-410 (SEP) units.

An Olympus representative will reach out to you to coordinate a mutually convenient time to complete a software update on your affected ESG-410 (SEP) unit(s). You may continue to use your ESG-410 (SEP) generator until the software update is completed. Additionally, Olympus requires you to take the following actions:

1. Carefully read the content of this notification.
2. Olympus requests that you acknowledge receipt of this letter. Access the Olympus recall portal to indicate that you have received this notification.
 - Go to <https://olympusamerica.com/recall>

- Enter the recall number "0457"
 - Complete the form as instructed.
3. Olympus's record of the completed software upgrade to your ESG-410 (SEP) generator(s) will serve as the acknowledgment of this field corrective action for your facility
 4. If you have further distributed this product, identify your customers, and forward them this notification.

Olympus requests that you report any complaints, including the ESG-410 generator system error E1226 "Could not write to Audio Buffer", or any associated injuries 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 directly by phone at (647) 999-3203 or by e-mail at Cynthia.Ow@Olympus.com.

Sincerely,

Cynthia Ow

Cynthia Ow
FCA Regional Lead, Americas

URGENT: MEDICAL DEVICE CORRECTIVE ACTION**ESG-410 Electrosurgical Generator
Attachment – Affected Serial Numbers**

101698	102191	102706	103016	103068	103112	103161	103199
101702	102195	102707	103018	103069	103114	103162	103200
101920	102197	102709	103019	103072	103115	103163	103201
101923	102266	102710	103020	103073	103116	103165	103203
101925	102427	102711	103025	103074	103117	103166	103206
101929	102660	102712	103026	103075	103119	103167	103207
101932	102661	102713	103029	103076	103120	103168	103208
101933	102664	102714	103030	103077	103121	103169	103209
101934	102665	102715	103031	103078	103122	103170	103210
101937	102668	102716	103033	103080	103123	103172	103211
101945	102672	102717	103034	103081	103124	103173	103212
101947	102673	102718	103035	103082	103125	103174	103214
102149	102674	102719	103037	103083	103126	103176	103215
102150	102678	102721	103041	103084	103127	103177	103216
102153	102679	102722	103042	103085	103132	103178	103217
102154	102681	102723	103043	103087	103133	103179	103218
102155	102682	102724	103044	103088	103134	103180	103219
102156	102683	102993	103045	103089	103135	103181	103220
102159	102684	102994	103046	103091	103136	103182	103221
102161	102685	102995	103047	103092	103137	103183	103222
102162	102686	102996	103048	103094	103139	103184	103223
102163	102687	102997	103049	103095	103140	103185	103224
102164	102688	102998	103050	103096	103141	103186	103225
102167	102689	102999	103051	103097	103142	103187	103228
102168	102691	103000	103052	103098	103143	103188	103583
102172	102692	103001	103053	103099	103144	103189	103584
102173	102693	103002	103056	103100	103149	103190	103585
102176	102694	103003	103059	103101	103150	103191	103587
102178	102695	103004	103060	103102	103152	103192	103791
102183	102697	103006	103061	103103	103153	103193	103796
102184	102698	103007	103062	103104	103155	103194	103802
102185	102699	103008	103063	103108	103156	103195	103812
102187	102700	103012	103064	103109	103158	103196	103832
102189	102702	103013	103066	103110	103159	103197	103833
102190	102705	103014	103067	103111	103160	103198	