1.0 Executive Summary

Summary of FCA:	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 internal investigation by Olympus identified that this issue is caused by a previous change to an electronic component found on the generator's Contact Quality Monitor (CQM). This component change impacted the electrical continuity of the device, which could then result in the error message being displayed, and an automatic system reboot. None of the forty-three complaints resulted in an adverse event. Olympus is issuing a Customer Letter to customers with impacted serial numbers requesting that users contact Olympus for a device upgrade which resolves the cause of the issue. Loaner units will be provided for use during the upgrade.
HHA #:	FY25-088-A
CAPA/SCAR Number:	CAPA-202731
Ship Hold Number, if issued:	ID 432

2.0 Scope of the Field Corrective Action

2.1 Product Description

Product Description and Intended Use	**Product Description** The ESG-410 Electrosurgical Generator (ESG-410) is an electrosurgical generator that is designed to be used for the following electrosurgical applications: · Bipolar electrosurgical cutting and coagulation, and · Monopolar electrosurgical cutting and coagulation, which requires a neutral electrode. · Supports Ultrasonic instruments (only WA91327U) The cutting and coagulation modes, using high frequency current, are designed for procedures in open, laparoscopic, and endoscopic surgery. All settings of the device are selected via the LCD-touchscreen on the front panel. The device is non-sterile, reusable, and is a non-contacting patient device. The only patient contact components of the system are compatible medical devices such as applicators and/or hand instruments connected to the device. **Intended use and indications ESG-410 Legacy (WA91307C, WA91307W, WA91317J)** The electrosurgical generator, 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 - Endoscopic surgery Only for use by a qualified physician in an adequate medical environment. **Intended use and indications ESG-410 SEP (WA91327U)** The electrosurgical generator, in conjunction with compatible devices and electrosurgical accessories, is intended for cutting and coagulation of soft tissue and for ligation of vessels. The electrosurgical generator utilizes monopolar and bipolar high frequency current and supports ultrasonic instruments. The electrosurgical generator is intended to be used in the following medical fields: - Open surgery - Laparoscopic surgery, including single-site surgery - Endoscopic surgery Only for use by a qualified physician in an adequate medical environment.

2.2 Manufacturing Sites

Manufacturing Site(s) Responsible	**Legal Manufacturer** Olympus Winter & Ibe GmbH Kuehnstr. 61 22045 Hamburg, Germany **Manufacturing Site** Olympus Winter & Ibe GmbH Rheinstr. 8 14513 Teltow, Germany

2.3 Summary of Products Affected

Model Number	Item Code/ Material Number/ Reference Number	Serial/Lot Number	Catalog Numbers / Product Code	UDI	Affected Date Range	Quantity Affected in (units)
WA91307C	WA91307C	See Attachment	WA91307C	04042761086349	07/12/2022 – 02/19/2024	436
WA91307W	WA91307W	See Attachment	WA91307W	04042761086332	11/05/2020 – 02/23/2024	757
WA91317J	WA91317J	See Attachment	WA91317J	Not Applicable	07/18/2022 – 02/29/2024	377
WA91327U	WA91327U	See Attachment	WA91327U	04042761087698	05/15/2023 – 01/29/2024	161

Model Number	Item Code/ Material Number/ Reference Number	Serial/Lot Number	Catalog Numbers / Product Code	UDI	Affected Date Range	Quantity Affected in (units)
Total						1731

Table 1 Summary of Product Manufactured as of date:2025-07-14. The affected product table also accounts for spare part mobine boards that were serviced in ESG-410 that will need to be serviced.

Model Number	Americas	EMEA	Japan	China	APAC	Total (units)
WA91307C	436	0	0	0	0	436
WA91307W	0	591	13	0	153	757
WA91317J	0	0	377	0	0	377
WA91327U	161	0	0	0	0	161
Totals	597	591	390	0	153	1731

Table 2 Summary of Products Distributed Affected Globally as of date:2025-07-14

Define the criteria and process to determine the consignee lists	Consignee list is created from the shipment records of affected products from OSTE as of 2025-07-14. Consignee list should be generated based off the serial specific shipments including all inventory pools (i.e. loaners, demos, assets, & finished goods) to customers.

3.0 FCA Strategy

3.1 Communications Strategy

Select and attach those methods being used	Communications Materials e.g., Service Bulletin	Audience	Distribution Method
☒	Customer Letter	Endoscopy Department, Operating Room, Risk Management	Mail, courier, e-mail or other methods per local procedures
☒	Customer Acknowledgement	Endoscopy Department, Operating Room, Risk Management	Mail, courier, e-mail or other methods per local procedures
☒	Q&A	Olympus Employees	E-mail
☒	Service Bulletin	Olympus Repair/Service Center Employees	E-mail/Other
☐	Website	N/A	N/A
☐	Press Release	N/A	N/A
☐	Other:	N/A	N/A

Table 3 Communications Materials

3.2 Field Action Activities

Required Activity	Category	Description of Action
☒	**Field Corrective Action Type**	Correction (return to Olympus required for upgrade, or in-field upgrade if possible, locally)
☐	**Customer Returned Product Disposition Instructions**	N/A – product is not being dispositioned
☒	**Service Requirements**	A Service Bulletin will be supplied to Repair Centers to conduct the correction work. Countries have the option to conduct the activities by Field Service personnel at the customer site if the Service Manual requirements are met.
☒	**On-hand Olympus Controlled Inventory**	On-hand inventory which is not get updated will be placed on shiphold until remediated.
☒	**Assets (Demonstration / loaner devices / non-clinical product)**	Demo and loaner products to be upgraded via Repair Centers, if not already. Only upgraded loaners are to be supplied to customers. Devices pending update will be placed on shiphold.
☐	*Other*	N/A

Table 4 Other Field Activities

3.3 Effectiveness Checks and Completion Criteria

Timing and Follow up Notifications	A minimum of three documented contact attempts (or more where local requirements dictate) will be made to customers that are unresponsive to Olympus' attempts at scheduling the device update. Olympus may use multiple methods to contact customers, where appropriate.
Effective Check Documentation Method	Effectiveness checks will be documented using the following methods: Customer response certificates, Customer Portal Responses, Courier delivery confirmations, repair records, product disposition records, and records of e-mails, phone or personal visits. Regional Leads or country resources provide status updates via dashboards.

Completion Criteria	All consignees must have effectiveness check documentation. Consignee response rate needs to be 85% or higher or supported with a rationale for FCA termination.
	All affected fielded products need to be corrected per this plan, except where minimum contact attempts have been exhausted (see Timing and Follow up Notifications).

4.0 Global FCA Team

Team Member	Name (enter N/A if not required)
FCA Project Lead	Kaye Glaysher
Regional FCA Lead – Americas	Cynthia Ow
Regional FCA Lead – EMEA	Angelika Hunsalz
Regional FCA Lead – China	N/A - not impacted

Team Member	Name (enter N/A if not required)
Regional FCA Lead – APAC	Masahiro Asakura, Zainab Mohammadi
Regional FCA Lead – Japan	Masahiro Asakura
HHA Owner	Felix Krogull
Global Marketing	Phil Roy
Medical Safety	Jill Burnett
Global FCA Process Owner	Pearley Bhambri, Carlos Alfonzo
Compliance	N/A
Service/Repair	Andre Schulze, Andreas Thoma, Cesar Pernia

Table 5 FCA Team Members

5.0 Regulatory Considerations

Impacted?	Country or Region	Reporting Required	Comments
☒	Notified Body (NB) Name: TÜV Rheinland	☒Yes ☐ No Justification:	To be managed by MBC (OSTE)
☒	United States	☒ Yes ☐ No Justification:	
☐	Brazil	☐ Yes ☒ No Justification: No distribution	
☒	Australia	☒ Yes ☐ No Justification:	
☒	Japan	☒ Yes ☐ No Justification	
☒	Canada	☒ Yes ☐ No Justification	

Table 6 Regulatory Reporting

Other regulatory bodies will be notified per local requirements.

6.0 List of Attachments

Attachment #	Description
1.	Global FCA Customer Letter
2.	Project Plan / Calendar
3.	Product Distribution List
4.	Q&A
5.	Service Bulletin

7.0 Approvals

Role/Function/Title	Name	Signature/Date
Global FCA Process Owner	Pearley Bhambri	Signed by: Pearley Bhambri Signer Name: Pearley Bhambri Signing Reason: I approve Signing Time: 15-Jul-2025 | 12:27:10 EDT 79DF91B411A0448EAB07656DC480F16D
Quality VP	Joe Hutson	Signed by: Joe Hutson Signer Name: Joe Hutson Signing Reason: I approve Signing Time: 15-Jul-2025 | 07:54:31 EDT 896B951F6ACA46CE980D57AC6650F86F
Global FCA Project Lead	Kaye Glaysher	Signed by: Kaye Glaysher Signer Name: Kaye Glaysher Signing Reason: I prepared Signing Time: 15-Jul-2025 | 03:10:21 PDT 0D6DBFB37DFA45F3B9C95FDEC4E48AC5

8.0 Revision History

Revision	Details of Change
AA	Initial release