Reference: 2024-003M

18 June 2024

URGENT - FIELD SAFETY NOTICE

To user of **Olympus ESG-410 Electrosurgical Generator (Model: WA91307W, Serial No: 102486.)**

Re: Olympus will be Replacing the Current Power Supply with a New Power Supply.

Attention: **Operating Room, Biomedical Engineers**

Dear Health Care Provider:

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 of the affected ESG-410 units. Affected serial number is ''102486''. 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. 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.

OLYMPUS (MALAYSIA) SDN. BHD. (200101010901)
Unit T2-L05-1, PJ33, No. 3, Jalan Professor Khoo Kay Kim, Section 13, 46200 Petaling Jaya, Selangor, Malaysia
Tel: (603) 7650 8990 Fax: (603) 7650 8999

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 and return the 'Response Form' to us.
3. If you have distributed this product, identify your customer's, and forward them this notification.
4. Olympus's record of the completed power supply replacement for the ESG-410 generator will serve as the completion of this field corrective action for your facility.
5. Please forward this notice to other users who may have the affected product if you have further distributed it.

Olympus requests that you report any complaints, including the ESG-410 generator not powering on and adverse events experienced with the use of this product to Olympus.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact us.

Contact for enquiries.
Regulatory Affairs and Quality Assurance Department
Email : mes-ra.oml@olympus.com
Tel : (603) 7650 8990
Fax : (603) 7650 8999

The **Medical Device Authority** has been informed of this notice.

Yours sincerely,

Hideki Nagai
……
Hideki Nagai
Managing Director
Olympus (Malaysia) Sdn. Bhd.

OLYMPUS (MALAYSIA) SDN. BHD. (200101010901)
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Tel: (603) 7650 8990 Fax: (603) 7650 8999

Response Form

Please send the complete and signed Response Form to Regulatory Affairs and Quality Assurance Department at:

To : Olympus (Malaysia) Sdn. Bhd, Regulatory Affairs & Quality Assurance
Fax/Email : (603) 7650 8999 / mes-ra.oml@olympus.com
From : _____ [Facility Name] Contact no.:_____
Date : _____
Ref : 2024-003M

URGENT - FIELD SAFETY NOTICE

Re: Olympus will be Replacing the Current Power Supply with a New Power Supply.

I acknowledge receipt of the Field Safety Notice ("FSN") referenced above. I confirm that I have further communicated to any affected departments.

Check the applicable boxes below:

☐ I DO NOT have affected product remaining. Product has been condemned or discarded.

☐ I DO have the affected product, **Serial No: _____**

Additional Customer Requests:

(Indicate if you have any additional requests to support this action)

Name: _____

Designation: _____

....
Signature & Company Stamp Date

OLYMPUS (MALAYSIA) SDN. BHD. (200101010901)
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2024-003M FSN - Customer Letter

Final Audit Report 2024-06-18

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