Date: <Month Day, Year>

New Field Safety Notice
Medical Device Correction – E-100 Generator (PN 374848-09) Preventative Maintenance Issue
(ISIFA2022-04-C)

1- Introduction and Reason for Field Action	Dear Intuitive Customer, The purpose of this letter is to inform you that Intuitive recently became aware, through internal review, that certain testing requirements were not performed during the annual preventative maintenance (PM) process for certain E-100 Generators. Specifically, output power calibration, to confirm adherence to specifications for energy delivery to compatible devices, and electrical safety testing, to ensure electrical isolation and ground connection, were not performed. The E-100 Generator is compatible only with the Vessel Sealer Extend instrument and the SynchroSeal instrument.
2 - Risk to Health	All E-100 Generators are tested during manufacturing to ensure conformance to the output power and basic electrical safety requirements. As part of annual preventative maintenance, E-100 generators undergo electrical tests to ensure the generator is functioning within its electrical safety and performance specifications. E-100 Generators that have undergone incomplete annual preventative maintenance cannot be confirmed to function within the electrical safety and performance specifications The output power calibration test is required to verify that E-100 Generator energy delivered to compatible devices is within specification. Either insufficient energy delivery or additional energy delivery may result if the power delivery from the E-100 Generator is out of specification. Insufficient energy delivery to the compatible devices may lead to decreased vessel seal integrity that could result in bleeding. Additional energy delivery to the compatible devices may lead to increased thermal spread during device activation. The likelihood of the power output drifting out of specification is low. Incompletely performed electrical safety tests may fail to detect compromised electrical isolation barriers and missing earth ground connections. Electrical shock may occur to either the patient or user if the electrical isolation barriers of the E-100 Generator are compromised or the earth ground connection is missing. The risk of electrical shock is low as all E-100 Generators are tested at the time of installation in the field to verify they meet the leakage current and ground bond electrical safety requirements. To date, there have been no reported Complaints or Serious Incidents that have resulted from incomplete annual preventative maintenance of the E-100 Generator.

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<table>
<tr><td>3- Affected Products</td><td>
<table>
<tr><th>Part Number</th><th>Product Name</th><th>Unique Device Identifier</th><th>Affected Serial Number</th></tr>
<tr><td>374848-09</td><td>E-100 Generator</td><td>00886874116982</td><td>SK0614, SK1178, SK1227, SK1521, SK1918, SK4061, SK4098, SK4114, SK4129, SK4152, SK4215, SK4217, SK4301, SK4353, SK4380, SL0066, SL0615, SL0625, SL0719, SL0724, SL0744</td></tr>
</table>
</td></tr>
<tr><td>4- Actions to be taken by the Customer/User</td><td><u>Please take the following Actions:</u>
1. Notify all affected hospital personnel about this Field Safety Notice.
2. Complete the attached Acknowledgement Form immediately and return it via fax or email to Intuitive as instructed on the form.
3. Please retain a copy of this letter and the acknowledgement form for your files.
4. Please inform Intuitive of any Serious Incidents or quality problems concerning the use of the subject devices via the standard complaint process.
5. Additionally, if Serious Incidents or quality problems are experienced, please follow your standard reporting process to your health authority, if applicable.
6. Notify affected personnel when the affected product has been replaced by the Intuitive representative.

You may continue to use the E-100-Generator.</td></tr>
<tr><td>5- Actions to be taken by Intuitive</td><td>An Intuitive representative will schedule a site visit to replace the E-100 Generator from the affected system once available.</td></tr>
<tr><td>6- Further Information & Support</td><td>If you need further information or support concerning this Field Safety Notice, please contact your Clinical Sales Representative or contact Intuitive Customer Service at the numbers listed below:
• Europe, Middle East, Asia, South America and Africa: +800 0821 2020 or +41 21 821 2020 (8 AM to 6 PM CET) or EUCS@intusurg.com</td></tr>
</table>

Please be informed that the appropriate Regulatory Authority for your region has been notified as per local regulation requirement of this Field Safety Corrective Action.

Sincerely,

Intuitive Surgical SAS
11 avenue de Canteranne
33600 Pessac, France
+800 0821 20 20

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ACKNOWLEDGMENT FORM
New Field Safety Notice
Medical Device Correction E-100 Generator (PN 374848-09)
Preventative Maintenance Issue
(ISIFA2022-04-C)

Ship-to:
Hospital Name: <mail merge>
Address: <mail merge>
City, State, Zip: <mail merge>
SFID: <mail merge>
ATTENTION: <mail merge>

PLEASE COMPLETE ALL REQUESTED INFORMATION AND RETURN IMMEDIATELY

1. I have received and read this notice.
2. I have ensured all appropriate personnel are fully informed of the contents of this notice.
3. I will contact Intuitive if I have any questions.

Hospital name: _____

Name (print): _____

Signature: _____

Phone Number: _____

Email: _____

Date: _____

Position:

- ☐ **Robotics Coordinator**
- ☐ **Operating Room Director**
- ☐ **Risk Manager**
- ☐ **Surgeon**
- ☐ **Other:** _____

PLEASE FAX OR EMAIL THIS ACKNOWLEDGEMENT FORM TO Intuitive
ATTN: REGULATORY COMPLIANCE FIELD ACTIONS
Subject line for email: E-100 Generator
Scan and Email: EU.FSCA@intusurg.com or Fax: +800 0821 2021 / +41 21 821 2021

Customer Service:

- Europe, Middle East, Asia, South America and Africa: +800 0821 2020 or +41 21 821 2020 (8 AM to 6 PM CET)