

Date: 23 February 2017

MEDICAL DEVICE FIELD ACTION NOTICE

Action Identification Number: **226**

Type of Action: **Medical Device Field Action**

Affected Product:

SPL-G – SHOCKPULSE GENERATOR

Affected serial numbers:

All serial numbers prior to CG0196

Serial numbers CG0201 - CG0204

All serial numbers starting DG

Dear Customer

Olympus has become aware of an issue with the above ShockPulse generators, which are part of the Olympus ShockPulse-SE Lithotripsy System. The System is intended to be used for fragmentation of urinary tract calculi in the kidney, ureter, and bladder. Our records indicate that you have purchased an affected generator.

The manufacturer of the ShockPulse generator, Cybersonics Inc, produced the product in accordance with IEC60601-1 standard, with an independent laboratory successfully certifying the system. However, more recent testing has identified that under certain conditions one of the test criteria (Touch Current under single fault condition) has the potential to exceed the standard.

Olympus conducted a risk assessment of this condition and determined the seriousness was *insignificant*, and the likelihood of this condition occurring to be *insubstantial*. This condition does not affect the safety of patients, users or others. As a result, the generators can continue to be used without any risk and restrictions.

Olympus has not received any complaints of injury associated with this condition. Nevertheless, due to the possibility that the standard's criterion could be exceeded, Olympus will be conducting this action on units with serial numbers listed above. Please note that internal modifications to the electronics incorporated on all units other than the serial numbers listed above resolve this issue.

Our records indicate that you may have received one of the affected units. An Olympus representative will contact you shortly to have your system returned to our service centre for a free electronics upgrade.

Actions to be taken by the user

1. Pass this Notice to all those within your facility who need to be made aware of its contents;
2. Confirm you have received this Notice by completing the attached Reply Form.
Please return this form to your locally appointed Olympus distributor **Salehiya Trading Establishment**;
3. Liaise with Salehiya Trading Establishment to arrange the return of your generator for a free electronics upgrade.

We appreciate your cooperation and apologise for any inconvenience this may cause. If you have any questions or would like further information, please do not hesitate to contact your locally appointed Olympus distributor Salehiya Trading Establishment.

