

Aug X, 2014

URGENT: Field Safety Corrective Action

Attention:

Urgent, Recall GIF-XP190N

Dear Customer,

Recently Olympus became aware that in the repair process the HF-test parameter for the S-Cord System were not within the range as defined by the manufacturer.

Olympus identified a few GIF-XP190N for which it cannot be assured that these endoscopes passed the HF-testing of the S-Cord System properly. Please find below the list of affected devices.

| No | Endoscope | S.N. |
|----|------------|---------|
| 1 | GIF-XP190N | 2200173 |
| 2 | GIF-XP190N | 2300333 |
| 3 | GIF-XP190N | 2300563 |
| 4 | GIF-XP190N | 2300424 |
| 5 | GIF-XP190N | 2200176 |

A risk may occur if the GIF-XP190N is connected to a PSD-10/20/30/60 during a HF surgery. Than device or patient leakage currents may beyond the manufacturer specifications. To avoid any risk for patients we decided to recall these devices.

OLYMPUS regrets if the implementation of these measures might cause inconveniences and fully appreciates your prompt cooperation in addressing this situation. In case of any questions, please do not hesitate to contact your local vendor/OLYMPUS partner who will be delighted to support you or make the necessary arrangements.

Please return the signed Reply Form and the Endoscope to your local vendor/OLYMPUS partner.

Yours sincerely,

<Name>

<Position>

<Address>

<Contact information>

REPLY FORM

| |
|----------------------------|
| [Dept/Attn] |
| [Street No.] |
| |
| [ZIP City] |
| |
| Date Ref No. EXT-xxx |
| |
| |
| |
| Recall GIF-XP190N |

Dear Sirs and Madams,

We herewith confirm the receipt of your customer letter. We will share this information with the relevant departments.

Name _____

Hospital _____

Department _____

Street _____

Postal Code/ City _____