oertli®
SWITZERLAND

Berneck, 7th February 2017

Urgent: Field Safety Notice

Commercial name of affected product:	OS4 SURGERY SYSTEM WITH ENDOLASER
Article number.:	VC860300
Type of action:	Notification and Corrective Action

Dear customer,

This letter is to advise you of a malfunction that has been identified with the **OS4 SURGERY SYSTEM WITH ENDOLASER**. This action only applies to OS4 systems with endo laser unit (VC860300).

This notice provides a description of the problem, the actions you can take to avoid the problem, and the steps Oertli Instrumente AG is taking to address the issue.

Description of the problem:
Our investigation has confirmed a failure to meet laser performance specifications when the user chooses the following values at selected LASER function:

- **"Laser Power" 50mW** (at all values for "Laser Duration" and "Laser Interval")
- **"Laser Power" 60mW** (at all values for "Laser Duration" and "Laser Interval")
- **"Laser Duration" 10ms** (at all values for "Laser Power")
- **"Laser Interval" 10ms** (at all values for "Laser Power")

A software failure causes that it is possible that the device emits higher laser power than expected. The malfunction occurs with software V1.3.0 and earlier software versions.

If your device is already updated to software V1.4.0 the issue is resolved.

Because the unexpected high laser emission can result in an injury we decided to initiate a Field Safety Corrective Action to resolve the issue as quick as possible.

Oertli Instrumente AG
Medizinaltechnik, Hafnerwisenstrasse 4, CH-9442 Berneck
Telefon +41 (0)71 747 42 00, Fax +41 (0)71 747 42 90, www.oertli-instruments.com

oertli®
SWITZERLAND

Action to be taken by the customer:

1. Do not use the following settings of your OS4 device:

   - **"Laser Power" 50mW** (at all values for "Laser Duration" and "Laser Interval")
   - **"Laser Power" 60mW** (at all values for "Laser Duration" and "Laser Interval")
   - **"Laser Duration" 10ms** (at all values for "Laser Power")
   - **"Laser Interval" 10ms** (at all values for "Laser Power")

2. Advise the appropriate personnel of the content of this letter.

3. Please sign and return the attached **Acknowledgement Form** for confirmation that you have read this Field Safety Notice, understand the problem and actions to be taken (until **17.02.2017**).

4. A Technical Service Representative will contact your site to schedule the software update of your OS4 device.

Please immediately forward this information to professionals within your organization who may be using the OS4 endo laser. Additionally, please ensure that a copy of this notification is provided to any other organizations to which the affected device has been transferred.

This notice has been reported to the appropriate Regulatory Agencies.

We sincerely apologize for any inconvenience and thank you in advance for your cooperation. If you require further clarification, please feel free to contact your local Oertli distributor.

Yours sincerely,

Oertli Instrumente AG

[redacted]

N. Brill
Quality Management
Representative

Oertli Instrumente AG
Medizinaltechnik, Hafnerwisenstrasse 4, CH-9442 Berneck
Telefon +41 (0)71 747 42 00, Fax +41 (0)71 747 42 90, www.oertli-instruments.com

oertli®
SWITZERLAND

Acknowledgement Form

Please return the completed form until **17.02.2017** via fax or email to:

Oertli Instrumente AG
Quality Management
Hafnerwisenstrasse 9
9442 Berneck
Schweiz

Email: quality@oertli-instruments.com
Fax: +41 (0)71 747 42 90

Notification and Corrective Action

Our Ref: Field Safety Notice OS4 surgery system with endolaser, February 1, 2017

Hospital Facility / Company: _____

Post Code / City: _____

Country: _____

I acknowledge receipt of the Customer Safety Notification for the issue referenced above. The information has been brought to the attention of all users.

Printed Name: _____

Signature of Facility Representative: _____

Date: _____