



Date: July XX, 2021
Olympus reference: QIL 154-006

URGENT FIELD SAFETY NOTICE

RE: SOFTWARE UPGRADE AND UPDATED INSTRUCTIONS FOR USE FOR OLYMPUS SOLTIVE™
SUPERPULSED LASER SYSTEM PRO EGTFL-SLS AND PREMIUM EGTFL-PLS

Attention: Operating Room Director

	Model Name	Serial number
OLYMPUS Soltive™ SuperPulsed Laser System	Pro EGTFL-SLS	All
OLYMPUS Soltive™ SuperPulsed Laser System	Premium EGTFL-PLS	All

Dear HealthCare Professional,

Olympus America Inc. ("Olympus") has recently received complaints of patient injury associated with the OLYMPUS Soltive Laser System ("Soltive Laser"), models Pro (EG)TFL-SLS and Premium (EG)TFL-PLS, when used in dusting and fragmentation of ureteral stones. The Soltive Laser is intended for incision, excision, resection, ablation, coagulation, hemostasis, and vaporization of soft tissue, with or without an endoscope, in urology, lithotripsy, gastroenterological surgery and gynecological surgery.

The complaint investigations revealed a user likely exceeded the 20W standard presets for stone dusting and fragmentation when treating impacted stones in the ureter and ureteropelvic junction. A combination of using laser power settings exceeding the cooling power of irrigation fluid, with ureters and kidneys that were already under stress due to stone impaction, were likely contributing factors to ureteral thermal injury in three patients. It is also possible that the ureteral thermal injury contributed to the kidney failure observed at post-operative follow-up in two of these three patients.

To mitigate the risk for thermal injury events, users should exercise the same level of caution and lower power settings for ureter and ureteropelvic junction procedures with Soltive laser applications as they do when using other laser units, such as Holmium YAG lasers. This may be especially important for patients presenting with impacted ureteral stones. Additionally, irrigation flow is important even at lower power settings to cool the tissue site during laser emission.

To mitigate and prevent thermal injury events, Olympus is issuing a software upgrade for the Soltive Laser to version 2.1. Software version 2.1 includes a new Ureteral Stone Preset of 8W under the Lithotripsy treatment mode. Olympus is currently updating the Soltive Laser Instructions for Use ("IFU") to reflect these software changes which also includes a pop-up alert reminding user to consider the potential clinical consequences of selecting settings greater than 20W in sensitive anatomy like the ureter. Enclosed with this Field Safety Notice you can find an Addendum to the IFU containing a summary of the new updated IFU sections.




Olympus will contact your facility as soon as possible to schedule a software upgrade for your Soltive Laser.

Action steps to be taken by the end user:

Our records indicate that your facility has purchased one or more of the affected Soltive™ SuperPulsed Laser Systems. Therefore, Olympus requires you to take the following actions:

1. Carefully read the content of this Field Safety Notice as well as the attached Addendum “PN0024336_AA Soltive Laser Software Revisions”. This Addendum contains the summary of the new updated IFU sections.
2. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this FSN and the referenced Addendum and attach the Addendum to the existing IFU of the mentioned devices.
3. An Olympus representative will reach out to you within the next 9 months (maximum) to arrange a mutually convenient time to have your Soltive Laser(s) updated.
4. Please note on the enclosed FSN Reply Form the serial number available in your facility and that you have received, understood, and followed this information. Kindly also indicate the quantity of required IFU hard copies per Model on the Reply Form.

Note: Please note that Olympus is currently still adopting the affected IFUs and will update the local translations afterwards. Once the IFUs have been updated the most current language version will be available on the following Olympus webpage:
www.olympus-europa.com.

When opening the webpage select ‘Medical Systems’, select ‘Contact & Support’, click on the magnifying symbol (), select ‘Instruction Manual’ and search for the relevant model (e.g. ‘TFL’).

5. Send the completed Reply Form back to your Olympus representative ([xxx]) latest by [XXXX] regardless of whether you have any affected inventory at your facility.
6. If you have further distributed the products listed, identify your customers, forward them this Field Safety Notice including the Addendum “PN0024336_AA Soltive Laser Software Revisions”, appropriately document your notification process and let us know the end-customer feedbacks accordingly.

Your National Competent Authority has been informed of this Field Safety Notice.

Olympus regrets any inconveniences caused by this Field safety Corrective Action fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact me directly at [phone number] or at [e-mail address] for any additional information concerning this matter.

Sincerely,



REPLY FORM – QIL 154-006

URGENT FIELD SAFETY NOTICE			
RE: SOFTWARE UPGRADE AND UPDATED INSTRUCTIONS FOR USE FOR OLYMPUS SOLTIVE™ SUPERPULSED LASER SYSTEM PRO EGTFE-SLS AND PREMIUM EGTFE-PLS			
[Name & Address of Hospital/Medical Facility]			
[Dept/Attn]			
[Date]			
Model name	Quantity of replacement IFUs required	Serial numbers available in your facility	
OLYMPUS Soltive™ SuperPulsed Laser System Pro EGTFE-SLS			
OLYMPUS Soltive™ SuperPulsed Laser System Premium EGTFE-PLS			

Dear Sirs or Madams,

I herewith confirm the receipt of your Field Safety Notice.

Further I confirm that I have transferred the content of the attached FSN and Addendum to all affected departments on which this action has an impact and attached the referenced Addendum to the existing IFUs. I understand the necessity of following the updated IFU carefully.

Name (Signature) _____

Name (Print) _____

Position _____

Please scan / email your completed paper form response to XXXX latest by XXXX.

SOLTIVE Laser Software Revisions

June 16, 2021

PN0015551_AF SOLTIVE Laser Instructions for Use

Your Soltive™ laser software and Instructions for Use have been updated.

Below is a summary of the changes. To obtain a hard copy of the updated IFU (PN0015551_AF) please contact your local Olympus representative. All updated IFUs will be published on our website (www.Olympus-Europa.com) once the translated IFUs are available.

What has changed:

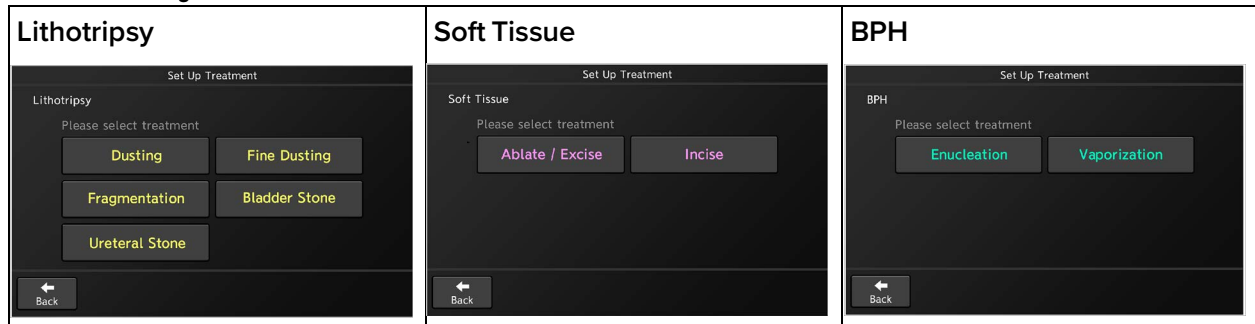
- On page 50 of the IFU, the laser will deliver up to 40W and 4J per pulse through a 150 µm core fiber. This was previously 25W and 3J per pulse. The following default settings have been increased up from 25W and 3J when a 150um fiber is being used:
 - Bladder Stone: 4J x 8Hz (Pro) 4J x 10Hz (Premium)
 - Enucleation: 1J x 34Hz (Pro) 1J x 40Hz (Premium)
 - Vaporization: 2J x 16Hz (Pro) 2J x 20Hz (Premium)

Table 1 Lithotripsy and BPH Preset Treatment Parameters

Lithotripsy			BPH	
Bladder Stone	Ureteral Stone		Enucleation	Vaporization
Left Pedal Name: Bladder Stone	Left Pedal Name: Soft Stone		Left Pedal Name: Enucleation	Left Pedal Name: Vaporization
Energy: 4 J;	Energy: 0.2 J		Energy: 1 J	Energy: 2 J
Frequency: Pro: 8 Hz; Premium: 14 Hz 150 µm fiber: 10 Hz	Frequency: 40 Hz;		Frequency: Pro: 34 Hz; Premium: 60 Hz 150 µm fiber: 40 Hz	Frequency: Pro: 16 Hz; Premium: 30 Hz 150 µm fiber: 20 Hz
Pulse Width: 1	Pulse Width: 1		Pulse Width: 3	Pulse Width: 3
Right Pedal Name: Hemostasis	Right Pedal Name: Hard Stone		Right Pedal Name: Hemostasis	Right Pedal Name: Hemostasis
Energy: 1 J	Energy: 0.6 J		Energy: 1 J	Energy: 1 J
Frequency: 20 Hz	Frequency: 14 Hz		Frequency: 20 Hz	Frequency: 20 Hz
Pulse Width: 3	Pulse Width: 1		Pulse Width: 3	Pulse Width: 3

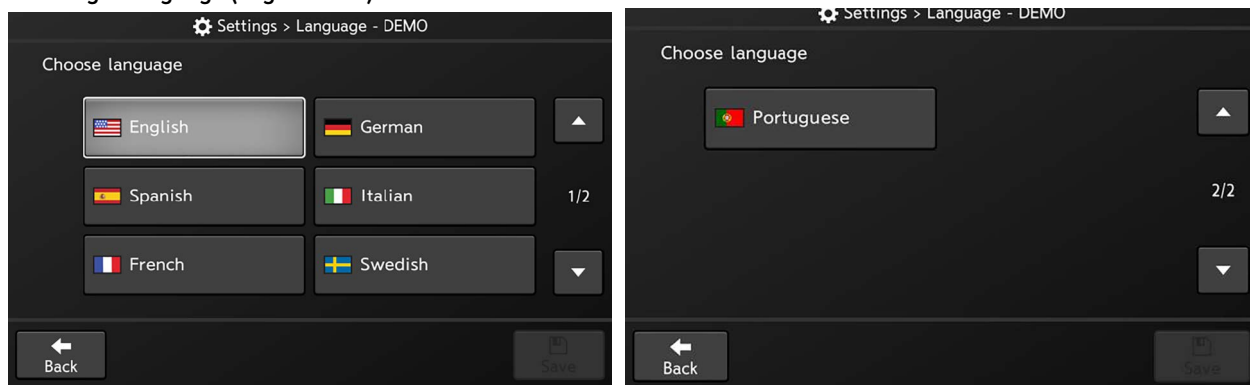
- The treatment settings, such as Lithotripsy, buttons, have been reduced in height to accommodate 6 buttons per screen instead of only 4 (page 36 of the Graphical Interface Section).

Treatment Settings



- There is a new **Ureteral Stone** Factory Preset under the Lithotripsy treatment mode.
- Additional language options have been provided (page 25).
The language list now includes:
 - English
 - German
 - Spanish
 - Italian
 - French
 - Swedish
 - Portuguese (on page 2)

Choosing a Language (Page 1 and 2)



- Additional information about the effects of laser temperature have been provided (page 17 of the Clinical Guide section of the IFU).
Users of the Soltive laser may experience low retropulsion effects that may support longer durations of continuous lithotripsy without repositioning the fiber. A laser delivers heat to the surrounding fluid while it is emitting. In general, the heating effect is directly proportional to the average power of the laser settings. If the average power of the laser exceeds the cooling power that results from the irrigation temperature and flow rate, and the patient's ability to dissipate the heat, then the fluid temperature will increase at the anatomical site until laser emission ceases. Inadequate cooling can also result from using higher irrigant temperatures or from using larger diameter fibers with insufficient irrigation pressure to compensate for the lower irrigation flow rate.
- Added configuration feature, enabled by default, to automatically save system logs during system startup if a USB drive is connected to the port at the rear of the system (page 28).

7. Revised positioning of wireless footpedals for pairing on page 33.

Footswitch Unpaired



To Start Pairing



8. Added to Step 6 on page 33: Then Click **Continue** within 4 seconds.

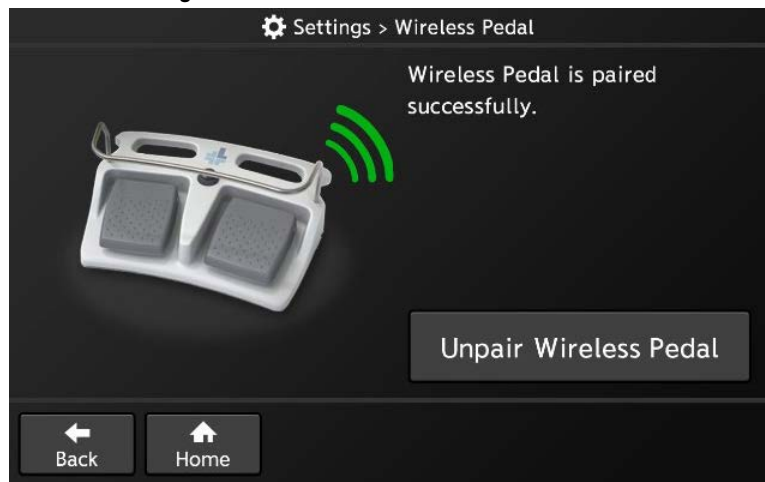
9. Pairing will begin.

Pairing in Process



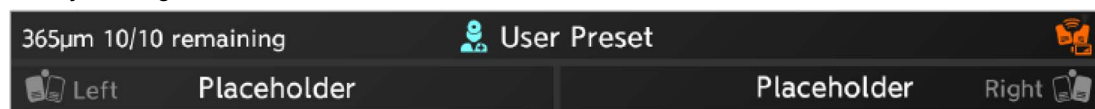
Successful pairing will be indicated in [Figure Successful Pairing](#).

Successful Pairing



10. Added Cleaning Solutions statement: The outer surfaces are compatible with the following cleaning solutions: Enzol enzymatic detergent, 70% Isopropyl alcohol, 5% bleach solution (page 54).
11. Added footswitch low battery indicator and popup window (page 56).

Battery Warning



12. Updated Olympus Korea company address in the list of Distributors to:
 Olympus Korea Co., Ltd.
 Seocho-dong, Majestar City One
 2F-3F, 12, Seocho-daero 38 gil, Seocho-gu
 Seoul, 06655, Korea
 T +82 1544-3200