A.R.C. LASER

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Urgent Field Safety Notice

product: Wolf 445 nm
FSCA-identifier 29.03.2019
type of action : Device modification

29.03.2019

Attention: This notice is related to the surgical laser device Wolf (445 nm) and describes a Field Safety Corrective Action.

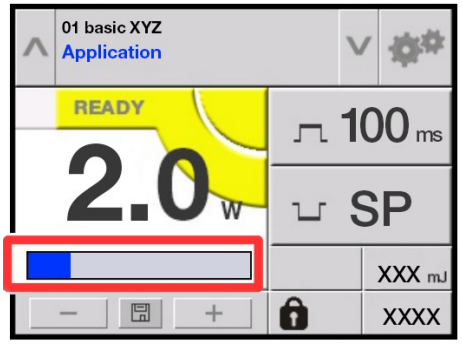
Details on affected devices:

manufacturer:	**A.R.C. Laser GmbH**
distributor:	**Soluvos Medical**
country:	**The Netherlands**
device:	**surgical laser (non-ophthalmic)**
product:	**Wolf**
wavelength:	**445 nm**
Serial Number:	**650115**

Description of the problem:
A software bug was detected by using the bar (pic01) to adjust the laser power of the device. That bug occur only in case four (all together) circumstances happen.

The surgical laser device Wolf (445 nm) is delivered with 16 pre-settings. However, the user may change the laser power (increase/ decrease) by using one of these two options

- the plus and minus button
- the bar (pic01)



pic01

If the following four (all together) circumstances happen respectively perform at the same time, the maximum allowed laser power of the basic mode is exceed :

- choose one of the seven special pre-setting (pulse duration: 100 ms or cw)
- choose the laser power instead the pulse duration to increase the energy
- choose the bar instead of the + button to increase the laser power
- increase to a much higher (100 % to 300 %) laser power than the preset in basic mode

The device software correctly reduce the display value back to the maximum allowed laser power of the basic mode.

The malfunction is, that the device software does not reduce the internal laser power as correctly shown in the display.

The potential hazard is that a patient may be treated with a higher laser power than shown in the display.

The associated risk to the patient could be a local tissue damage.

There is no risk to the user, other persons or to patients who are previously treated.

The malfunction of the software was detected in our lab. Up to now no case from the market has been reported, in particular no case is known to us where a patient was harmed.

Advise on action to be taken by the user:

1) DO NOT USE in any case the bar to change the laser power.
2) An employee of the manufacturer or the local agent will contact you within the next day's to arrange a meeting to be able to perform a modification of your device by a software update. Thereafter, the malfunction can no longer occur and the use is again unrestricted.
3) Within 48 hours after you got this Urgent Field Safety Notice send the signed FORM (annex) back to the local agent/ manufacturer.

At the latest four weeks after this notice the new software will be implemented

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organiza- tion where the potentially affected devices have been transferred.

If you are the dealer of the affected device, you are obliged to forward this Safety Notice to your customers immediately and to confirm this with the enclosed signed FORM from the customer.

Contact reference person:

name	Marcel Ernstberger Safety Manager
address	A.R.C. Laser GmbH, Bessemerstr. 14, 90411 Nuremberg, Germany
contact details	m.ernstberger@arclaser.de +49 (0) 911 217790

The undersign confirms that this notice will be communicated to the appropriate Regulatory Authority.

We thank you for your understanding and remain with best regards
A.R.C.Laser GmbH

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-CEO-

- Annex -

FORM, that has to be sent back to A.R.C. Laser GmbH

Attention: to the Medical Device Person in charge, complete and sign

Details on affected devices:

manufacturer:	**A.R.C. Laser GmbH**
distributor:	**Soluvos Medical**
country:	**The Netherlands**
device:	**surgical laser (non-ophthalmic)**
product:	**Wolf**
wavelength:	**445 nm**
Serial Number:	**650115**

O 1. User and Operator

I am the person in charge for the medical devices.

I hereby confirm that I have received the Urgent Field Safety Notice about the surgical laser device Wolf (445 nm).

We own the device with Serial Number: 650115

I understood the description of the problem.
I will pay attention to all of the described actions to be taken by the user.
I will implement all of the described transmission of this Field Safety Notice.

O 2. Distributor

For all from us distributed products I have informed my customers and end users about sending of the Urgent Field Safety Notice and

O from these received an acknowledgment of receipt

O asked to return the confirmation to the manufacturer

_____ _____ _____

date name signature