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Dear Customer,

Urgent FIELD SAFETY NOTICE – Stellaris PC - Software Fault Related to Laser Status Identified

As a Bausch & Lomb customer using a Stellaris PC we wanted to notify of a software fault that, under specific circumstances, could lead to the integrated laser system changing treatment status without being commanded to by the Surgeon or Scrub Nurse.

Description of laser treatment status

The Stellaris PC has a multi-level protection system that secures against accidental firing of the integrated laser system. This is made up of:

Laser Key – This is a **hardware** switch that prevents any activation of the laser system

Standby Mode – The **software** will not allow the foot pedal to activate the laser whilst it is in *Standby* status

Treat Mode – The Surgeon or Scrub Nurse have to command the system to move from Standby to *Treat* to allow the foot pedal to fire the laser

Foot Pedal – The **Laser foot pedal button** is required to be depressed to deliver laser energy. This involves raising a protective cover on the Stellaris PC Wireless Foot Pedal.

Description of circumstances where fault can occur

Whilst in a Posterior or Posterior/Combined case, when entering the Laser Phase of a Surgeon's programmed settings, a sub-mode drop-down is presented that allows for the changing of treatment modalities from Endo Laser (Repeating bursts of laser energy with defined power, duration and frequency) to Continuous Laser treatment (Constant laser delivery at a fixed power level). The drop-down defaults to Endo Laser as the most frequently used modality.

If the Surgeon requests that Continuous Laser is deployed, and this is selected on this modality drop-down menu during the Laser Phase of surgery, it has been witnessed that the software switches the laser treatment status from *Standby* to *Ready* without any input from the Surgeon or Nursing Staff.

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Impact of fault

If the system moves to *Ready* from *Standby*, and this has not been specifically commanded by the Surgeon or the Nurse, it raises the possibility that this change may not have been noticed and that the foot pedal *could* be depressed and the laser fired unexpectedly. This however is highly unlikely as the surgeon must still raise the protective cover on the laser firing button, and depress the button with the intent of firing the laser. This action, whilst possible, would be extremely rare whilst changing modality during a case.

Mitigation to be employed in the short term

Following the discovery of this fault, the following amendments to a Surgeon's settings file have been devised in order to minimise the potential of inadvertent firing of the laser.

- **Separate Laser Phases are created for each modality** – Endo Laser will now occupy one phase of a Surgeon's settings and Continuous Laser the next phase. This means each phase commences with the laser in *Standby* mode as expected, thus eliminating the risk of accidentally entering *Treat* mode. Changing modality is therefore achieved by changing phase of surgery, and not utilising the modality drop-down.
- **Modality Drop-down settings are amended** – To eliminate the risk of the modality drop-down menu being used by accident, or in ignorance of this fault, the settings will be changed for the Continuous Laser modality on the modality drop-down for every Laser Phase menu such that it requests that an Auxiliary Foot Pedal is plugged in and used, rather than the main Wireless Foot Pedal. Anyone entering Continuous Laser via this method will receive an error stating that the Auxiliary Foot Pedal is not present, and therefore Laser Delivery cannot be achieved. This will also happen in the Laser continuous phase if you were to select the endo from the drop down modality.

Until these amendments have been implemented on your system, you may continue to use your Stellaris PC laser system. Please pay special attention while changing the laser mode using the drop down sub-mode menu to avoid the unintentional change in laser status from Standby to Ready. You will still be required to raise the safety cover on the laser firing button to fire the laser.

Next steps

Please pass this field safety notice on to all those within your organisation who need to be aware of it.

In order that we ensure these software changes are implemented as soon as possible, we will be making arrangements to send an Equipment Specialist to your account to have all affected Surgeon settings amended.

Additionally, our software engineers have developed a software correction for the fault. As soon as this system software correction is available we will contact you to make arrangements to install this on your system. Should you have any questions, please feel free to contact me on +33 562 24 60 05, or your local Bausch + Lomb representative.

In closing, I would like to apologise for the inconvenience that this matter may cause you and thank you for your continued patronage of Bausch & Lomb products.

Yours sincerely

Alexandre Pizon
EMEA Quality Head Medical Devices