Cournon d'Auvergne, the 24/07/2019

FIELD SAFETY NOTICE 002

DEVICE CONCERNED	EASYRET
FSCA NUMBER	002
DATE	24/07/2019
FSCA ACTION	Corrective action notification

Dear Sir / Madam,

During Easyret use, a software issue has been identified with the spot sensor of the device.

When the single spot mode and 50 µm spot size are selected, the power level delivered can be higher than the power level displayed on the laser screen.

A new software version: 1.06 version fixing the issue has just been released.

Consequently, a software update will be performed on all EASYRET lasers in use.

Our after sales service will contact you in order to arrange a visit for device software upgrading.

All necessary requests actions will be found bellow.

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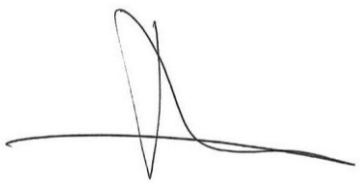

Cournon d'Auvergne the 24/07/2019

Concerned device	EASYRET – All software version
Issue description	A tolerance issue has been identified with the spot size measurement sensor of the Easyret. In the operating mode hereinafter and when the difference between spot size set and real value is too important, the software is not able to compensate correctly this value difference. ***The operating mode concerned is the single spot mode with a 50µm spot size*** (case of focal laser treatment for diabetic macular edema). The power level delivered can be higher than the power level displayed on the laser screen. Two cases of adverse event has been reported by one of our distributors. However, clinical severity is negligible.
Potential risk	Treat a patient with a higher power than desired. Use of too high settings for power and exposure time may cause accidental retinal burns.
What have you to do	- Do not to use the laser with a spot size inferior to 100 µm in single spot mode until the software upgrade is performed by our distributor's technician. - The present notification will be compulsory communicated to all person which is susceptible to use EASYRET.
Corrective action done by QUANTEL MEDICAL	- Informed users and competent authorities about situation - Updating all device with the new 1.06 version software version by one of our distributor's technician
For more information	materiovigilance@quantel-medical.fr

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