



FIELD CORRECTIVE ACTION, FCA#3512
Slit lamp SL 220, Exchange of power supply and mirror

Dear Customer,

High quality and innovation is our most important target as well as your safety and your satisfaction. With this letter we would like to inform you about a field corrective action (FCA) which is initiated by Carl Zeiss Meditec AG for certain slit lamps SL 220. In order to ensure a continuous and reliable usage of our equipment which meets your quality requirements, we plan to exchange the power supply and mirror of the SL 220.

Problem description:

Based on post market surveillance activities, there is information that in certain devices there is an increased probability of 1) failure of the power supply ON/OFF switch, and 2) surface corrosion of the mirror. Therefore the power supply ON/OFF switch and the coating of the mirror has been modified to improve their reliability. All new manufactured units are delivered with an updated design. We have decided to extend the updated design to units in the field by replacing old power supplies and mirrors for purposes of ensuring customer satisfaction.

Hazard involved:

There is no potential health hazard and the probability of injury is extremely unlikely. In worst case, a burning smell may result from a thermal event at the power supply ON/OFF switch. In the event of any burning smell the device function is halted. The operator as well as the patient can move away from the instrument.

Issues associated with the surface corrosion of the mirror may lead in worst case to the slit projection being slightly darker and more diffused.

Affected products:

All manufactured slit lamps SL 220 with hardware status "12" and "14" are affected by the FCA except for those where the power supply or mirror had been replaced with new hardware in the past. Slit lamps with old hardware status can be identified with the help of the serial number:

- 970712XXXX and 970714XXXX are affected.
- 970716XXXX, 970718XXXX and 970720XXXX are not affected.



Actions to be taken:

Your Slit Lamp SL 220, serial no. 970712XXXX falls in the affected category.

Our Customer Care Department will contact you to arrange an appointment for our Service Engineer to replace the power supply and mirror of your Slit Lamp SL 220.

We thank you very much for your attention, feedback and continuous support. We apologize for any inconveniences this situation might cause. If you have any questions, please do not hesitate to contact us.

Regards