



Carl Zeiss Meditec AG 07740 Jena
To whom it may concern

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Your ref.:
Yours of:
Our ref.: FCA # 3512
Date: 25.08.2017

FIELD CORRECTIVE ACTION

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 equipments 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 which changes the direction of the light projection. 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.

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**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 inadequate mirror function. The slit projection may be 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:

With this letter we provide you the latest hardware status of the power supply and mirror. We kindly ask you to update the power supply and the mirror of your slit lamp SL 220. Therefore, please

- 1) Exchange the power supply of the SL 220 according to the exchange instruction "Exchange of power supply unit".
- 2) The exchanged defective power supply can be scrapped according to national regulations.
- 3) Exchange the mirror of the SL 220 according to the instruction "Exchange of mirror".
- 4) The exchanged defective mirror can be scrapped according to national regulations.

We thank you very much for your careful attention, your consequent feedback and your continuous support. We apologize for any inconveniences this situation might cause. If you have any questions please contact us.

Best regards

Carl Zeiss Meditec AG