



Carl Zeiss Pte. Ltd., Singapore

17 February 2017

<< Name of Customer >>

<< Hospital/Clinic Name >>

<< Address >>

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FIELD SAFETY CORRECTIVE ACTION

#3485 - VisuMax, errors in the battery test circuit components of the UPS Modules

Dear << Customer >>,

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

Problem description:

Based on complaints in the past we have indication, that in certain devices there is an increased probability of failure of the battery test circuit components of the UPS-module. Therefore the battery circuit for the UPS has been modified by our supplier to make the UPS more robust. All new manufactured units are delivered with an updated design. As a preventive measure, we will take action to replace all old power supplies for purposes of customer satisfaction, to ensure the best reliability and to prevent damages to our customers' VisuMax units.

Hazard involved:

There is no potential health hazard and the probability of injury is extremely unlikely. Issues associated with the combustion of device components resulting in smoke and burning smell could lead in worst case to smoke intoxication. But serious injuries like burns with a permanent impairment are not possible because of a fire enclosure and other risk control measures.

Affected products:

All manufactured VisuMax starting with S/N 963599 up to S/N 1157772 are affected by the field corrective action, except for those where UPS has been replaced in the past.

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Actions to be taken:

Our service staff will contact you to arrange for an appointment to check whether the UPS in the power supply of your VisuMax is affected by this FSCA.

If the UPS in your unit is affected, we will plan the power supply replacement as part of the next scheduled service activities on your VisuMax.

We thank you very much for your continuous support. We apologize for any inconveniences this situation might cause. If you have any questions, please contact our Service Department.

We would appreciate it very much if you can acknowledge receipt of this letter by signing on the attached 'Acknowledgement of FSCA #3485 - VisuMax, errors in the battery test circuit components of the UPS Modules' and return to us by either fax at +65-6842 7117 or email to our Regional Regulatory Affairs Manager at waileng.yuen@zeiss.com.

Thank you.

Best regards



Subramanian Raghuraman
Regional Director, Customer Care
Southeast Asia