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Your ref.:
Yours of:
Our ref.: C # 3485
Date: 23.01.2017

FIELD CORRECTIVE ACTION

VisuMax, errors in the battery test circuit components of the UPS - Module

Dear Colleagues and Sales Partners,

This letter is to inform you about a field corrective service action (FCA) for the Uninterruptible 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.
Nevertheless, we will take action to replace all "old" power supplies for purposes of customer satisfaction, to ensure the best reliability and to prevent damages on 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. Our Refractive Support Team will send a separate letter to inform which VisuMax in your country has to be updated.

Actions to be taken

Our Refractive Support Team will be responsible for implementation of this FCA. You will receive additional information about the handeling of this FCA from our Refractive Support Team shortly.

We have reported this preventive service action to our local authority BfArM (Federal Institute for Drugs and Medical Devices). Please check regulations in your country and decide, whether it is obligatory to be reported in your country. Please inform us about your assessment using the attached feedback sheet, which we expect back latest by March 30, 2017. Please send the completed form to: fca-jen.med.de@zeiss.com.

We thank you very much for your careful attention, your consequent verifications 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

i.V.

Renate Westermann
Director Quality Site Jena

i.V.

Dirk Traber
Director of Technical Service – Refractive Laser

Attachment: Feedback Sheet "Reportability of Field Corrective Action"