



Carl Zeiss Meditec AG 07740 Jena

TO WHOM IT MAY CONCERN

Carl Zeiss Meditec AG
Goeschwitzer Strasse 51-52
07745 Jena
Germany

Phone:

Fax:

e-mail: [REDACTED]

Division/Dept.: Quality Management

Your contact: [REDACTED]

Our ref.:

Date: 2020-07-29

FIELD SAFETY CORRECTIVE ACTION

Exchange of communication board of VISULENS 550 digital lensmeter and VISUREF 150 Autorefractor

Dear valued Customer,

you are using our ZEISS VISULENS 550 digital lensmeter and/or a VISUREF 150 Autorefractor. Thank you for being a valued customer of ZEISS. High quality and innovation are our main goals, but safety and customer satisfaction are our priority. This letter is to inform you about a Field Safety Corrective Action (FSCA) for the VISULENS 550 and VISUREF 150 with the aim to exchange the communication board.

Problem description:

Based on post market surveillance activities, we found that the communication board is not performing as expected and need to be exchanged as a precaution measure. In rare cases the RS232 communication port can fail on the communication board. Both products use the same technology.

Hazard involved:

The effectiveness of the communication board cannot be guaranteed. In the worst-case situation, the safety function of the communication board is insufficient when a connected third-party device is causing an electrical overload at the RS232 interface. This could result in an increased leakage current and electrical shock for the user / patient. If there is no device connected to the RS232 interface there is no risk for an electrical shock. If the communication board fails without connecting a third-party device, in rare cases a burning smell can occur as a result from a thermal event. Please note that the outer

Address of Record:
Goeschwitzer Strasse 51 - 52
07745 Jena, Germany

Address for Delivery:
Carl Zeiss Meditec AG
Carl-Zeiss-Promenade 10
07745 Jena, Germany

Banks:
Deutsche Bank Jena
Account: 624536900 (BLZ 820 700 00)
IBAN: DE90 8207 0000 0624 5369 00
BIC/ SWIFT: DEUT DE 8EXXX

Commerzbank Jena
Account: 258072800 (BLZ 820 400 00)
IBAN: DE31 8204 0000 0258 0728 00
BIC/ SWIFT: COBADEFFXXX

Commercial Register:
Local Court Jena HRB 205623

VAT-ID No.: DE 811 922 737
WEEE-Reg.-No.: DE55298748

Chairman of the Supervisory Board:
Dr. Michael Kaschke

Board of Management:
Dr. Ludwin Monz (CEO)
Justus Felix Wehmer
Jan Willem de Cler



housing materials of the VISULENS 550 and VISUREF 150 fulfill the normative requirement concerning flammability.

Affected products:

Serial number[s] of your VISULENS 500 that [are/is] affected: [serial number(s)]:

Serial number[s] of your VISUREF 150 that [are/is] affected: [serial number(s)]:

Actions to be taken by the Customer / User:

We kindly ask you to disconnect all non-medical grade devices from the VISULENS 550 and VISUREF 150 RS232 interface. If your VISULENS 550 and VISUREF 150 is connected to a VISUPHOR 500 digital phoropter a disconnection is not needed.

Further we kindly ask you to switch off the VISULENS 550 and VISUREF 150 when you cannot supervise the device, especially when you close your location after the working hours.

You will receive additional information about the handling of this FSCA from our local ZEISS service organization. We are planning to replace the affected component at the next opportunity. Our service staff will contact you to arrange an appointment for the exchange. Our goal is to avoid any disturbance of your running business. Please note that the repair of your unit is mandatory.

Please return the attached "Acknowledgement and Receipt Form" to the contact mentioned on the form.

We thank you very much for your careful attention to this matter and for putting your trust in ZEISS. We apologize for any inconvenience this situation might cause. We will do our best to address your individual needs and concerns.

Best regards

Carl Zeiss Meditec AG



i.V.

Head of Routine Diagnostics



i.V.

Head of Quality
Management Side Jena