



25 August 2017

FIELD CORRECTIVE ACTION #1079628
VisuMax, Exchange of BPC Board

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 VisuMax devices. In order to ensure a continuous and reliable usage of our equipments which meets your quality requirements, we plan to exchange the Beam Pointing Control Board (BPC Board) of the VisuMax.

Problem description:

Based on post market surveillance activities, there is information that in certain devices there is an increased probability of failure of the BPC Board. The function of this board is to control an electrically driven mirror which adjusts the laser beam position if necessary. This design allows a position compensation in case the laser beam should drift.

It had been determined that there was a deviation in the soldering process during the manufacture of two batches of the BPC Board which can affect the reliability of the VisuMax beam pointing control subsystem. Carl Zeiss Meditec AG Jena will take action to exchange affected BPC boards to ensure expected reliability of VisuMax units in possession of our customers.

Hazard involved:

There is no potential health hazard and the probability of injury is extremely unlikely. Any failure of the BPC Board like error 0x3172 is detected by the monitoring functions of the device either during startup or before start of a treatment. In case of a system error the system test is cancelled before any treatment. If an error occurs, the device goes in a safe mode.

Affected products:

All BPC Boards with batch number **118648** 08/16 000## and **120852** 01/17 000## are affected by the FCA.

Actions to be taken:

You will receive additional information about the handling of this FCA from our local Carl Zeiss Meditec service organisation. We are planning to replace the affected BPC Board at the next opportunity. Our service staff will contact you to arrange an appointment for the BPC Board exchange.



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

Thank you for your cooperation and support.

Sincerely,